Integrating primary eye care into child health policies and programmes: A case study from Tanzania

Aeesha NJ Malik

Thesis submitted in accordance with the requirements for the degree of Doctor of Philosophy of the University of London

MAY 2023

Department of Disease Control

Faculty of Infectious and Tropical Diseases

LONDON SCHOOL OF HYGIENE & TROPICAL MEDICINE

Supervisor: Prof Joanna Schellenberg

Secondary Supervisors: Prof Clare Gilbert and Dr Neil Spicer

Funded by The British Council of Prevention of Blindness (BCPB), Christian Blind Mission (CBM), and The Queen Elizabeth Diamond Jubilee Trust for project expenses and self-funding of PhD fees

Table of Contents

Declaration

I, Aeesha NJ Malik, 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.

Abstract

The lack of primary eye care services in low resource settings leads to children presenting late to health services, ultimately leading to avoidable sight loss. Integration of eye care into child health programmes and policies would be a sustainable solution to the delivery of primary eye care for children. This thesis aimed to present a model of how eye health could be integrated into child health programmes and policies, using Tanzania as a case study.

The first paper is a systematic review of the evidence on whether universal screening of the eye within eight weeks of birth improves vision and health outcomes. The review found that screening shortly after birth increases early identification, referral, and surgery for congenital cataracts.

The second paper is an evaluation of training primary healthcare workers using an additional module on eye care as part of the curriculum of the WHO/UNICEF Integrated Management of Newborn and Childhood Illness (IMNCI) training programme in Tanzania. The knowledge and skills of primary healthcare workers in childhood eye diseases improved after routine IMNCI training included the new eye care module.

The final paper is a qualitative health policy analysis exploring key factors which led to the policy change in Tanzania to include eye health in the national IMNCI strategy. Leveraging existing policy communities and networks, clear consensus on the framing of ideas, generating local evidence and a critical IMNCI policy window in Tanzania, together with the expansion of global child health policy all influenced the policy change.

The case study of Tanzania used in this thesis proposes a model of how eye health can be included in the child health strategy IMNCI at programme and policy levels. The lessons learned can be used in other countries to include eye health in IMNCI or other child health policies and programmes.

(299)

Acknowledgements

I am incredibly grateful to a wide group of people for their support, encouragement, and patience with me over the course of this PhD.

I would like to first thank my inspiring supervisors, Joanna Schellenberg and Clare Gilbert, without whom I would never have completed this PhD. I am incredibly grateful to Joanna for her sharp intellect which pushed me further academically, her immense patience and belief in me (when I felt like giving up!), and her remarkable calm and steadiness which did begin to rub off on me! Our meetings always left me with greater confidence and a sense everything would work out.

It is impossible for me to thank Clare enough, she has been a supervisor, mentor and more like a mother to me over the last decade. I would not be here working in global child eye health and completing this PhD without her. I have been so inspired by her dedication, hard work, attention to detail and continuing passion to this day. I am incredibly grateful for her belief in me, the continuous support for every funding grant and every paper written, and everything she has done for me. My aim is to continue with the same passion and dedication you have shown to child eye health and inspire others as you have inspired me.

I would also like to thank the amazing team of people who I have worked with who have supported me; Milka Mafwiri who has been the best colleague, collaborator and company over the last many years of travelling through Tanzania together to do this work which I hope will continue for many more; Neil Spicer for his patience and the long discussions to keep me inspired on policy research; and all the team in Tanzania and ICEH who have all provided support and guidance.

I want to especially thank Matthew Burton for his incredible belief in the work of this PhD and me, and continued support and encouragement to take this further.

I would also like to thank the funders, BPCB (sadly who have closed), CBM and QEDJT.

Finally, I would like to thank my family for their incredible support, especially my two girls, Samara and Ailah. I would like to dedicate this PhD to my father, who passed away last year, who always encouraged me in my education and work, to have ambition and always believed I could achieve more than I thought possible.

List of Figures

List of Tables

List of Abbreviations

COREQ The Consolidated Criteria for Reporting Qualitative Research

ECD Early Childhood Development

IMCI Integrated Management of Childhood Illness (IMCI)

IMNCI Integrated Management of Newborn and Childhood Illness (IMNCI)

LSHTM London School of Hygiene and Tropical Medicine

MCQ Multiple Choice Question

MDG Millennium Development Goal

MOH Ministry of Health

MUHAS Muhimbili University of Health and Allied Sciences

NES Newborn Eye Screening

NIMR National Institute for Medical Research

NGO Non-Governmental Organization

PEC Primary Eye Care

PHC Primary Health Care

PHW Primary Healthcare Worker

RRT Red (fundal) reflex testing

STD Sexually Transmitted Diseases

WHO World Health Organization

CHAPTER 1 Introduction to the Thesis

Vision is one of our most critical and valued senses and visual loss in childhood has lifelong consequences affecting the child's development and future potential. Early childhood visual impairment can negatively affect a child's motor, cognitive, psychological, and social development, as well as lower educational achievement, and lead to fewer opportunities for work, earning potential, marriage, social and recreation activities.[1 2] Blind children, in particular girls, can also face stigma, bullying and discrimination. Most children with visual loss, up to 80%, are living in low resource settings, which reflects both the higher estimated prevalence and the higher child populations.[3] Childhood blindness mostly occurs from birth or develops before the child is five years old, therefore children under 5 years old are a key target group to reduce avoidable visual loss.

WHO Prevention of Blindness group first published 'ten key activities' to promote healthy eyes in children in 2002, and recommended that the interventions be integrated into maternal and child health services.[4] These primary level eye care interventions have been shown to be efficacious but have not been widely implemented, and the effectiveness of a package of these interventions has not been evaluated.[5] There has been a lack of primary care services for children in low resource settings due to a lack of human resources, the perception that eye care is too specialised or difficult to put in place, and a lack of political priority in a climate where the emphasis has been on improving child survival.

The Integrated Management of Childhood Illness (IMCI) was started in 1995 jointly by WHO and UNICEF and which is now present in over 100 countries worldwide.[6] At a later date newborn care was added (IMNCI) as awareness of newborn mortality grew. IMNCI aims to reduce the avoidable causes of childhood death, illness, and disability. It also aims to promote healthy growth and development and so includes prevention as well as treatment. The training of primary healthcare workers (PHWs) in IMNCI follows a modular structure covering the management of conditions such as fever, cough, and diarrhoea, but does not include eye care. More recently WHO included eye screening in their postnatal care guidelines (2022) and in the joint WHO/UNICEF report "Survive and Thrive: transforming care for every small and sick newborn" (2019).

An pilot study (2014) based in Dar es Salaam, Tanzania found that PHWs knowledge of childhood eye conditions was low but that this improved after a brief training which included the WHO 'ten key activities' and was retained at one year.[7] Following this study formative research was conducted in a rural region in Tanzania (2016) leading to a theory of change for reducing avoidable blindness in children (unpublished). Subsequently another study in Tanzania (2021) trained PHWs in eye screening or 'red or fundal reflex testing' (RRT) using a number of devices and found a low cost device designed for low resource settings (the Arclight) to be easy to learn and use for PHWs .[7 8] These studies showed that PHWs in Tanzania could be trained in primary eye care and to screen eye conditions in children.

Summary of thesis

This thesis explores the theme of integrating eye health into child health policies and programmes and includes: a systematic review of newborn eye screening including RRT, a study which developed and evaluated an eye module for inclusion into the IMNCI strategy in Tanzania, and a health policy analysis of the factors influencing the inclusion of eye health into the national IMNCI strategy in Tanzania.

What this thesis adds

This thesis presents the evidence from a systematic review that universal newborn eye screening increases early identification, referral, and surgery for congenital cataracts (in high resource settings). It then goes on to demonstrate how a novel approach of including eye health in the IMNCI strategy in Tanzania improved the knowledge and skills of PHWs in eye care for children. The final part of the thesis explores the local and global factors to the policy change that in Tanzania of including eye health into the IMNCI strategy. Leveraging existing policy communities, clear framing, presenting local evidence as well as policy windows at both a local and global level influenced the inclusion of eye health into the IMNCI strategy in Tanzania.

Why is this thesis important and for whom

This thesis has shown how the gap in primary child eye care in low resource settings could be addressed. IMNCI is a global strategy which is being delivered in over 100 countries. Using Tanzania as a case study, this thesis shows how eye health could be included in IMNCI on a national scale, in the absence of global level policy. Critical health policy factors enabling the inclusion of eye health into the IMNCI strategy are discussed: these can be used by child eye health advocates and policy makers in other countries and has possible broader application for other child health policies.

Thesis Components

This is a research paper style thesis consisting of seven chapters (including this one), as summarised below.

Chapter 1 An introduction to the PhD thesis and what it adds to research knowledge and whom it is aimed at.

Chapter 2 A review of literature relevant to each of the three research papers. The first part of the chapter discusses the epidemiology of childhood visual impairment, primary eye care for children and key interventions in primary eye care including newborn eye screening. The second part of the chapter covers the joint WHO/UNICEF IMNCI strategy. The final part of the chapter encompasses agenda setting in health policy and the use of frameworks in health policy analysis, in particular the Shiffman and Smith framework.[9]

Chapter 3 Details all the methods for each of the three individual studies which form the thesis.

Chapter 4 Published paper. The paper shows the findings of a systematic literature review and guideline review on universal newborn eye screening. The review synthesised existing evidence on how universal screening of the eye within 8 weeks of birth improves newborn

and infant vision and health outcomes. This review was commissioned by the maternal and child health department of WHO as part of their review of the evidence to inform the development of the Postnatal Care Guidelines published in 2022.[10] In this review Randomized and observational studies of all newborns were included that compared universal newborn eye screening for any eye abnormality by eight weeks of age with no universal screening. Two authors independently selected studies, extracted data, and evaluated the risk of bias. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach was used to assess the certainty of evidence. The available guidelines and recommendations on newborn eye screening were also reviewed.

The review was commissioned by the maternal and child health department of WHO as part of their review of the evidence to inform the development of the Postnatal Care Guidelines which were subsequently published in 2022.[10] These guidelines included newborn eye screening for the first time as one of their recommendations. The review was published in the Journal of Global Health in 2022.

Chapter 5 Published paper. The paper shows the results of eye care training of PHWs who deliver the IMNCI programme in a semi-rural district of Tanzania. The study had a mixed methods, before and after design, and the purpose was to evaluate whether including eye care in the training curriculum of IMNCI improved PHWs knowledge and skills in eye care for children and was accessible and acceptable to PHWs. The study involved the development of an eye module for inclusion into the IMNCI strategy in Tanzania. The knowledge and skills of the PHWs was assessed before and immediately after training, and six months later. The attitudes of the PHWs towards the eye module including the ease of use, level of content, applicability and challenges in daily practice were assessed in semi-structured interviews six months after training in Swahili. The study was published in BMJ Paediatrics Open in May 2020.

Chapter 6 Paper submitted for publication. This paper presents the key enabling factors and barriers which influenced Tanzanian MOH to include eye health in the IMNCI national strategy. The study involved thirty-one semi structured interviews; with fourteen national actors based in Tanzania and seventeen international actors. The interviews were analysed

using an adapted Shiffman and Smith framework. This study has been submitted to the Journal of Globalization and Health.

Chapter 7 The final chapter synthesises the findings of all three research studies, discusses the research findings in more depth, reviews the limitations of the body of work, discusses the implications of the findings for policy, and proposes a future research agenda.

The appendices supplement the thesis, with relevant information related to each chapter.

References

1. Keil S, Fielder A, Sargent J. Management of children and young people with vision impairment: diagnosis, developmental challenges and outcomes. *Arch Dis Child* 2017;102(6):566-71. doi: 10.1136/archdischild-2016-311775 [published Online First: 20161116]
2. Solebo AL, Teoh L, Rahi J. Epidemiology of blindness in children. *Arch Dis Child* 2017;102(9):853-57. doi: 10.1136/archdischild-2016-310532 [published Online First: 20170502]
3. Burton MJ, Ramke J, Marques AP, et al. The Lancet Global Health Commission on Global Eye Health: vision beyond 2020. *Lancet Glob Health* 2021;9(4):e489-e551. doi: 10.1016/s2214-109x(20)30488-5 [published Online First: 2021/02/20]
4. World Health Organization. A five year project for the prevention of childhood blindness: Report of a WHO Consultation: World Health Organisation, 2002.
5. Malik ANJ, Mafwiri M, Gilbert C. Integrating primary eye care into global child health policies. *Arch Dis Child* 2018;103(2):176-80. doi: 10.1136/archdischild-2017-313536 [published Online First: 2017/10/11]
6. World Health Organization. Integrated Management of Childhood Illness. *http://wwwwhoint/maternal_child_adolescent/topics/child/imci/en/* 2017
7. Mafwiri MM, Kisenge R, Gilbert CE. A pilot study to evaluate incorporating eye care for children into reproductive and child health services in Dar-es-Salaam, Tanzania: a historical comparison study. *BMC nursing* 2014;13:15. doi: 10.1186/1472-6955-13-15 [published Online First: 2014/06/17]

8. Mndeme FG, Mmbaga BT, Kim MJ, et al. Red reflex examination in reproductive and child health clinics for early detection of paediatric cataract and ocular media disorders: cross-sectional diagnostic accuracy and feasibility studies from Kilimanjaro, Tanzania. *Eye (Lond)* 2021;35(5):1347-53. doi: 10.1038/s41433-020-1019-5 [published Online First: 20200616]
9. Shiffman J, Smith S. Generation of political priority for global health initiatives: a framework and case study of maternal mortality. *Lancet* 2007;370(9595):1370-9. doi: 10.1016/s0140-6736(07)61579-7 [published Online First: 2007/10/16]
10. Geneva WHO. WHO recommendations on maternal and newborn care for a positive postnatal experience. 2022;https://www.who.int/publications/i/item/9789240045989

CHAPTER 2 Background to the Thesis

In this chapter I will present a review of the literature relevant to all three research papers. First, the chapter introduces child eye health which includes epidemiology, visual development, and a summary of the most important eye conditions. The next part of the chapter examines newborn eye screening and its importance, primary eye care for children and the IMNCI strategy. The final part of the chapter describes health policy agenda setting, health policy frameworks and the Shiffman and Smith framework. The chapter then concludes with the aims and objectives of the thesis.

Epidemiology of visual impairment and blindness in children

Globally 70.2 million children are estimated to have sight loss, 1.4 million of whom are blind. [1] The majority of children with sight loss, up to 80%, are living in Africa, Asia and South America, reflecting the higher estimated prevalence and the large child populations. The available evidence suggests that in all regions most blindness in children is caused by congenital conditions where they are born blind or from acquired conditions which occur before the age of 5 years old. [23]

The major causes of blindness in children are congenital and developmental cataract, corneal scarring (from measles infection, vitamin A deficiency and conjunctivitis of the newborn), retinal or congenital eye abnormalities, glaucoma, and retinopathy of prematurity (ROP). Approximately 40-50% of these causes are avoidable, being preventable or treatable. Cataract, glaucoma, retinoblastoma can either be present from birth or develop during the first few months or early years of life.

Cataract and retinoblastoma are both important causes of leukocoria (“white pupil”) during infancy. Both can be present at birth or develop within months of birth (Table 1).

Table 1: Epidemiology of congenital cataract and glaucoma, and retinoblastoma

Condition	**Birth prevalence /100,000 live births**	**% with clinical signs present at birth**	**% of cases with a positive family history**
Congenital cataract (one or both eyes)	10-60	Not known	10–29% (autosomal dominant >> autosomal recessive) [4]
Retinoblastoma (one or both eyes) [5]	5 [6]	Not known: cases with a family history have an earlier age of onset[7]	4.7% all countries (range 3.1% in low-income countries to 8.4% in high income countries) [5]
Congenital glaucoma (one or both eyes) [8]	5 [9]	Not known	Very low; most cases are sporadic

EUROCAT, which provides data on the epidemiology of congenital anomalies in 21 European countries, covers a population of more than 1.7 million births per year. Cases are only registered once confirmed by a relevant clinician. The prevalence of eye anomalies amongst live births was 36.2 (34.6- 37.9)/100,000 between 2011 and 2017 (Table 2). [10]

Table 2: Prevalence of congenital eye anomalies per 100,000 live births registered with EUROCAT 2011-2017[10]

Congenital eye anomaly	**Birth prevalence (/100,000)**	**%**
Congenital cataract	12.2 (11.2-13.2)	33.7%
Anophthalmos/microphthalmos	6.5 (5.8-7.2)	18.0%
Congenital glaucoma	3.1 (2.6-3.6)	8.6%
Anophthalmos	1.2 (1.1-1.3)	3.3%
Proportion of all eye anomalies		**64%**

There is likely to be a higher birth prevalence of congenital anomalies in low resource settings due to the higher incidence of intrauterine infections, and consanguinity which both would increase the incidence of autosomal recessive conditions such as cataract, microphthalmos and glaucoma. [8 11 12]

Visual development

After birth there is a period of intensive anatomical and physiological change in the eyes and visual system as the eyes grow and change shape and complex physiological changes take place in the visual centres in the brain as the circuits in their brain develop. At one month of age a baby's visual acuity is about 1/30th that of a healthy adult increasing to 1/8th by 6 months, and then about 1/3rd at 12 months. Normal visual acuity (6/6) is not achieved until 8 or 9 years of age. [13] There is no objective method to assess visual function in newborns as all tests of vision require either the co-operation of the child, or observing eye movements, such as fixing on and then following an object as it is moved. However, the visual system is not developed enough in newborns for these assessments to be possible. [14] Therefore screening for defects in visual acuity is not possible in newborns.

Development and vision

Good vision from early in life is essential for normal development. Normal vision in early childhood is essential for a child's vision to reach the full potential of normal adult vision. Visual stimulation is an essential component of the anatomical and physiological changes which take place in the first few months and years of life. The earlier a child has vision problems and the more profound the reduced vision, the greater the negative impact on the development of their vision which is unlikely to ever reach normal adult vision. For example, if a child has reduced vision in one or both eyes from a condition which can be managed to restore vision, such as surgery for congenital cataract, if this is not undertaken within a few months of life, the higher visual centres do not develop normally which leads to permanent visual loss, called deprivation amblyopia. [15] This cannot be reversed - even if the child has

treatment as an adult or surgery later in childhood (e.g. at the age of 3-4 years). Therefore, timely intervention is extremely important in congenital/childhood eye conditions. Any treatment delays directly increase the effect on the long-term vision of the child.

Children also learn about their environment through vision and from observation of people and their facial expressions. Vision plays a vital role in coordinating all other sensory input, enabling a child to interpret the world around them. Any condition which deprives a child of vision from soon after birth can lead to developmental delay affecting motor, cognitive, social, and emotional development, which also impacts on their subsequent educational attainment. [16] Early identification and management of eye conditions are, therefore, essential if affected children are to reach their full potential in many areas of their lives.

Eye conditions which can be present at birth/during infancy

Early detection and management of treatable eye conditions present at birth or during early infancy which are potentially visually impairing, or life threatening (in the case of retinoblastoma) is essential. Eye conditions which are present at birth and where interventions are required can be divided depending on whether they are treatable or where they cannot be treated but rehabilitation is required:

1. Conditions which are potentially visually impairing and treatable;
    a. eyelid abnormalities where the pupil is covered such as ptosis (drooping of the eyelid), very narrow eye lids, and some skin lesions such as haemangiomas, which can require surgery.
    b. congenital cataract (opacity of the lens of the eye) which can require surgery
    c. congenital glaucoma which leads to an enlarged eye which requires surgery
    d. retinoblastoma (a malignant tumour) in one or both eyes which requires urgent treatment, which may include laser or radiation treatment, chemotherapy, or removal of the eye
    e. congenital squint (strabismus) which cab require surgery

f. some inflammatory/vascular conditions on the retina, which may require laser treatment
g. congenital anomalies, such as absent iris (aniridia), coloboma (uveal defects) abnormally small eyes (microphthalmos) where follow up is required to complications and a general examination due to the increased risk of abnormalities in other organs[17]

2. Eye abnormalities not treated clinically to restore vision but where the child requires early vision rehabilitation to support them to reach their full potential
    a. anophthalmos (absent eyes)
    b. corneal opacities
    c. most conditions of the optic nerve and retina

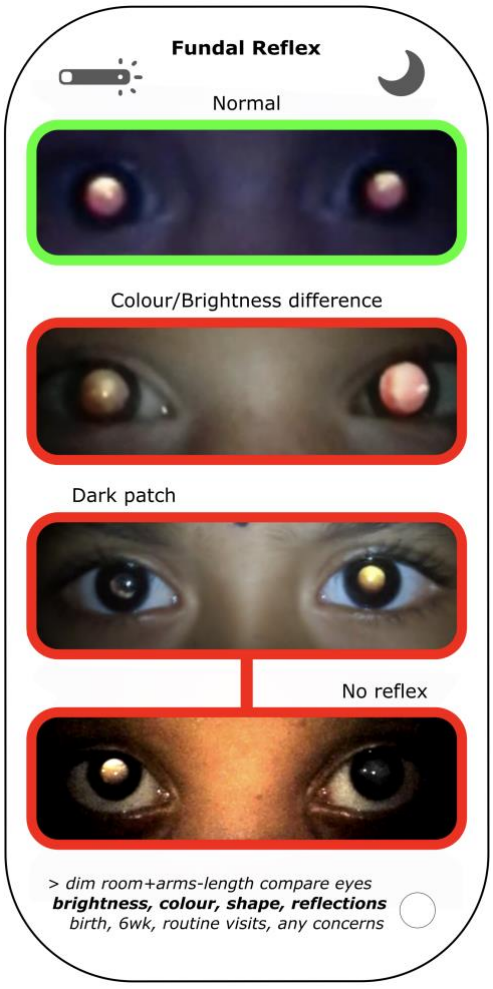
There are also eye conditions which have no long-term clinical significance but can be present, such as retinal haemorrhages which are common, particularly after vaginal delivery, and mostly resolve spontaneously. [18]

What is newborn eye screening?

Newborn eye screening (NES) involves examining the eyes to check for signs of any abnormality. The main method of examination is with fundal (red) reflex testing (RRT) to check for abnormalities of the cornea, lens, and alignment of the eyes. A simple torch examination is sometimes used but can only detect conditions of the external eye (eyelids, cornea, or alignment of the eyes) and not for important conditions such as cataracts (unless it is very dense and therefore obvious).

RRT refers to the light reflex seen within the pupil reflected from the retina. Traditionally the RRT requires a hand-held device, traditionally a direct ophthalmoscope, and can be performed by anyone trained to deliver the test, usually a nurse or doctor. [19] There is some evidence that the reflex is easier to detect in Caucasian than black eyes. [20] The test is performed at around arm's length, and light from the ophthalmoscope is shone into both

eyes at the same time. The reflex can be normal, partially obscured, or absent (no light reflected) or white instead of red as light is reflected back from something white inside the eye (e.g. retinoblastoma, a malignant tumour). [21] Figure 1 shows examples of normal and abnormal fundal (red) reflex signs. Retinoblastoma tumours can be small and located in the retinal periphery, which means that screening can miss these cases. [22] However, fundal (red) reflex testing has the potential to detect large and centrally located lesions. [23] The most common important condition detected is cataract.



No action required

Urgent referral

Urgent referral

Urgent referral

Figure 1: Normal and abnormal red reflex (from educational materials developed for Arclight)

Equipment which can be used to elicit the RRT includes a standard direct ophthalmoscope, a very low cost equivalent (Arclight ophthalmoscope) [24] (Figure 2). Other devices which have

been pilot tested for newborn screening include eliciting a reflex using infrared light, [20] which uses an illuminating light that does not cause pupil constriction, and imaging using the camera on a smartphone, however the Arclight performed better than both these devices in the field. [25] [26]

Figure 2a) photo of Arclight 2b) and c) healthcare workers using Arclight

Impact of early detection and management

Blindness can have a profound impact on the child, their family and society. Early onset blindness can lead to psychomotor and cognitive delay, lower educational achievement, and fewer opportunities later in life for work, recreation and in some cultures, marriage. [27] Blind children, particularly girls can also face bullying, stigma, and discrimination.

Congenital cataract and glaucoma have better functional outcomes if they are managed early. It is standard practice in high income countries to operate on dense bilateral congenital cataracts 6-7 weeks after birth as later surgery increases the risk of amblyopia and poor visual outcomes. [28] [29] [30] In retinoblastoma earlier detection can require less aggressive management which preserves sight and reduces mortality. [22] [31] [32] It is extremely rare for retinoblastoma to lead to death in high income countries, but this is relatively regular occurrence in low resource settings where children present late for management. [6]

Implementation of newborn eye screening

Newborn eye screening is standard practice or recommended in many high resource settings such as the UK and US. [33] [34] A European study where questionnaires were sent to 38

countries found that 35 countries (97.2% of those providing data) had screening in place (28 had a national programme, and 7 had only regional programmes). [35] This is summarised in Figures 2 below. Age at screening varied from 1-6 weeks, with 12 (33%) countries screening more than once.

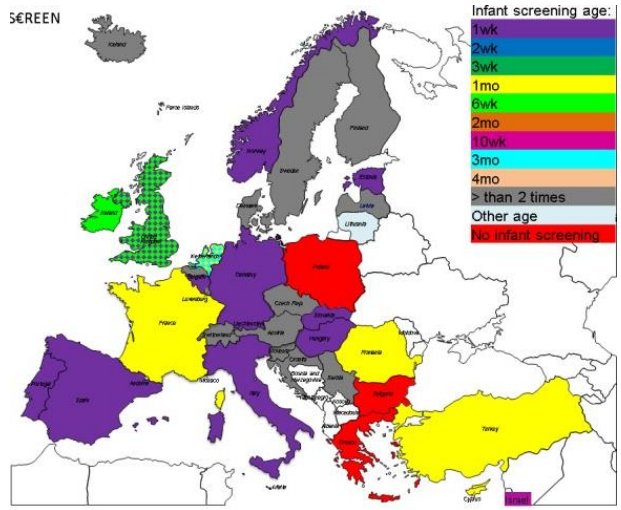


Figure 3: Timing of universal eye screening in Europe (2013-2014)

However, universal newborn eye screening in not standard practice in low resource settings, which means that newborns with clinically significant eye conditions are not being detected early compromising their vision and general development.

Primary Eye Care for Children

Newborn eye screening is important but is not enough alone. Primary eye care for children under 5 years old consists of a package of preventative, screening, and treatment interventions. The WHO blindness prevention team recommended in 2002 'ten key activities for healthy eyes in children' which outlines clearly what interventions need to be addressed at primary care level [36] [Table 3]. These interventions address health promotion (breast feeding; face washing), specific preventive measures (vitamin A supplementation, measles immunization) and the detection and referral of treatable eye conditions (RRT screening for cataract, glaucoma). The 'ten key activities' are a comprehensive package for primary eye care services for children under 5 years old and were recommended to be

included in all primary maternal and child health services. Some interventions such as breastfeeding, vitamin A supplementation and measles immunization, are a routine part of child health programmes and others require PHWS to acquire new skills, for example RRT, and are not included in child health programmes.

Table 3: Ten key activities to promote healthy eyes in children

Control of conditions which can be associated with visual loss	
Vitamin A deficiency	1. Give vitamin A supplements to children routinely
	2. Give vitamin A supplements to mothers after delivery
	3. Promote breast feeding and good nutrition
Measles	4. Give vitamin A supplements to children with measles or malnutrition
	5. Immunize children against measles
Control of ocular conditions	
Conjunctivitis of the newborn	6. Clean the eyes of babies at delivery and apply antibiotic drops
Trachoma	7. Keep children's faces clean
Cataract/ retinoblastoma/ ocular abnormalities	8. Refer children with poor vision, white pupils, or ocular abnormality to an eye worker
Traditional eye remedies	9. Avoid the use of traditional eye medicines
Trauma	10. Refer children with history of injury to an eye worker

Vitamin A supplementation, breastfeeding and good nutrition

Vitamin A (retinol) has multiple functions and retinol deficiency or Vitamin A Deficiency Disorders (VADD) therefore impacts multiple systems of a child's body, including susceptibility to infection, stunting and anaemia. Chronic deficiency of VADD can lead to ocular signs of night blindness or classically 'Bitot's spots'(foamy looking lesions made of keratin on the conjunctiva). Acute deficiency can cause corneal ulceration or keratomalacia which can lead to blindness. Strategies to prevent vitamin A deficiency include six monthly vitamin A supplementation from 6 to 59 months of age due to its impact on childhood morbidity and mortality, as well as nutrition education and breastfeeding. [37]

Measles immunization

Measles infection can cause corneal blindness through various route which includes; acute vitamin A deficiency (reduced intake and malabsorption coupled with increased demand), herpes simplex keratitis and/ or measles keratitis. High dose vitamin A during measles infection reduces mortality but will also reduce ocular complications. Approximately 1% of children who are in hospital for measles will eventually go blind, not including unilateral blindness. [38]

Ophthalmia neonatorum prophylaxis

Ophthalmia neonatorum is defined as conjunctivitis within the first 28 days of life. The underlying aetiology is due to the causes of untreated sexually transmitted diseases (STDs) during pregnancy. Ophthalmia neonatorum due to Neisseria gonococcus has the most severe effects and can rapidly lead to corneal perforation and visual loss. In low resource settings up to 16% of infants affected by gonococcal infection have corneal involvement at presentation. [39] In high resource settings ophthalmia neonatorum has become rare due to better treatment and lower rates of STDs in pregnant women as well as ocular prophylaxis (antibiotic cream applied to the eyes at birth). [40] [41] Transmission rates of gonococcal infection from mother to newborn can be up to 30%- 50% when there is no ocular prophylaxis.[42] Globally 91% of STDs are in lower resource settings. [43] Therefore universal ocular prophylaxis is important in low resource settings with high rates of untreated STDs. A recent systematic review did not find data on whether prophylaxis prevents serious outcomes such as blindness or poor visual outcomes, however this is mainly due to the difficulties of conducting such research with the necessary long follow-up, diagnostic confirmation challenges and assessing of visual acuity in infants. [44] [45] The Centers for Disease Control and Prevention, American Academy of Pediatrics, American College of Obstetricians and Gynaecologists, and WHO all recommend universal topical ocular prophylaxis to prevent ophthalmia neonatorum. [46-48]

Face washing

Trachoma is most common in Africa, Asia and the Middle East and estimated to cause visual impairment in 2.2 million people and irreversible blindness in 1.2 million people globally. [49]

The visual impairing complications of chronic infection present in adults, while the chronic infection (conjunctivitis) is more common in children. WHO have endorsed the SAFE strategy (Surgery, Antibiotics, Facial Cleanliness, Environmental improvement) for trachoma control. 'Surgery' is for adults with upper eyelid trichiasis, and community drug administration of azithromycin ('Antibiotics') to reduce active infection. [50] 'Facial cleanliness' and 'Environmental improvement' reduce transmission through improved access to water supplies and sanitation, with health education. Face washing is particularly important in children is important as they are the main reservoir of infection.

Fundal (red) reflex testing and external eye examination

Cataracts in children can be present at birth or develop during the first few months or years of life. Cataract is one of the main causes of treatable blindness in children in low resource setting with an estimated that 200,000 children blind due to cataracts (bilateral). [51] The reported prevalence of cataracts varies widely from 0.2-22.9/10,000 children globally. [52]

The standard management of bilateral congenital cataracts is surgery 6-7 weeks after birth. [53] Delays to treatment of even a few months can lead to permanent visual loss and blindness. It is far more common in low resource settings for cataracts to be detected late. A study in Tanzania found the mean delay from detection of the cataract to surgery was almost 3 years (median, 18 months). [54] In most low resource settings there is no screening for cataracts in children while in contrast universal newborn eye screening is recommended in the UK, US, and most European countries. [55] [56]

Retinoblastoma

Retinoblastoma is a childhood eye cancer which is rare but life-threatening. Low resource settings bear the burden of the highest number of affected children and the highest mortality rates. In Asia and Africa, 40%–70% of children with retinoblastoma die compared with 3%–5% in Europe and North America. [6] Early detection allows for management which preserves sight, saves the eye and reduces mortality. The most common sign is a abnormal RRT or white pupil noticed by parents or noted in photographs.

Avoiding use of Traditional Eye Remedies

Some traditional eye remedies are harmless, but others can be extremely toxic to the eye causing trauma or corneal infection, including hot oil, human urine (which may be infected), or any acidic or alkaline liquids. [57] These remedies not only delay children getting the appropriate care but can also cause serious eye problems leading to blindness. [58] Poor eye care services, cultural beliefs as well as greater accessibility for patients with lower costs, and low levels of education lead people to use these alternative treatments. [57] Education and working with caretakers and the community on the potential harm of traditional eye remedies is the first step but often this can be a complex issue to address.

Ocular Trauma

There is very limited data from low resource settings for ocular trauma for children, but it has been estimated that 3.3-5.7 million children sustain eye injuries annually. [59] [60] Early diagnosis, and treatment are vital for the best visual outcome but delays in seeking medical attention are common in low resource settings. Often there are misconceptions that there is little that can be done and therefore, educating PHWs and caretakers on the importance of seeking immediate medical attention is a first step.

Summary

A recent review confirms that many of the interventions described for child eye health in low resource settings are highly efficacious. [61] Some of these interventions are being implemented as part of essential child health services, but there is a need for evidence of the effectiveness of the package of these interventions or their integration into primary care services for children in different contexts.

The Integrated Management of Newborn and Childhood Illness (IMNCI)

The Integrated Management of Childhood Illness (IMCI) strategy is a global health strategy aimed at reducing mortality and morbidity in children under 5 years old which was launched in 1995 by UNICEF and WHO. [62] It was developed as a response to single disease programmes and the observation that more than two-thirds of childhood deaths in low resource settings were due to the five most common conditions in children; respiratory infections, malaria, diarrhoea, malnutrition and measles. Subsequently tuberculosis (TB) and HIV/AID were added, and more recently newborn health and early childhood development have been recognised as components, following which the name changed to the Integrated Management of Newborn and Childhood Illness (IMNCI). It is designed to be comprehensive and includes ear health but does not include eye health. This 'gap' in the strategy gives an opportunity for inclusion of eye health within an established child health strategy.

Initially, IMCI was developed as a case-management approach for sick children but it soon included interventions for the household, community, health facility, and referral levels, thus contributing to health system strengthening. The main three components are:

1. Improving case management skills of healthcare providers (training health workers in IMNCI case management skills including counselling on early childhood development, and mentorship)
2. Improving health systems to provide quality care (improving availability of drugs, supplies, equipment, regular supportive supervision of health workers, improving the referral system)
3. Improving family and community health practices for health, growth, and development (community IMNCI)

Over 100 countries implement the IMCI strategy, either in part or all three components. In most countries, the first component of improving case management skills of health care providers has been the focus. The central part of IMNCI involves the assessment of the sick

child by the PHW using a structured approach of assessment by first checking for any of the five general 'danger' signs, which include a child not able to drink or breastfeed or vomiting everything. Any child which the PHW classifies as having a general 'danger' sign indicates the child has severe disease and needs an urgent referral to hospital. The PHW is also taught to assess and treat children with a wide- range of conditions, including; cough/difficult breathing, diarrhoea, fever, ear problems, malnutrition and anaemia, HIV, serious bacterial infection, diarrhoea, HIV infection, feeding problems or low weight, and immunization status. Each of these conditions is assessed through a combination of signs and questions which lead to colour coded classifications of severe problem, problem, and normal/ no condition, rather than coming to a diagnosis. IMCI classifications is designed to allow the PHW to decide if a child needs urgent referral or can be treated at the primary level (e.g., with oral antibiotic, antimalarial), or safely managed at home. Once the classification has been made then specific treatment can be identified and counselling provided to the caretaker including on follow-up care and when the child should be brought back to the clinic (summarised in Figure 4).

Assessment

- **Assess** a child by checking first for general danger signs (or possible bacterial infection in a young infant), asking questions about common conditions, examining the child, and checking nutrition and immunization status. Assessment includes checking the child for other health problems.

Classification

- **Classify** a child's illnesses using a colour-coded classification system. Because many children have more than one condition, each illness is classified according to whether it requires:
    - urgent pre-referral treatment and referral (pink), or
    - specific medical treatment and advice (yellow), or
    - simple advice on home management (green).

Identify treatment and treat

- After classifying all conditions, **identify** specific treatments for the child. If a child requires urgent referral, give essential treatment before the patient is transferred. If

a child needs treatment at home, develop an integrated treatment plan for the child and give the first dose of drugs in the clinic. If a child should be immunized, give immunizations.

- Provide practical **treatment** instructions, including teaching the caregiver how to give oral drugs, how to feed and give fluids during illness, and how to treat local infections at home. Ask the caregiver to return for follow-up on a specific date and teach her how to recognise signs that indicate the child should return immediately to the health post.
- Assess feeding, including assessment of breastfeeding practices, and counsel to solve any feeding problems found. Then counsel the mother about her own health.

Follow-up care

- When a child is brought back to the health post as requested, give follow-up care and, if necessary, reassess the child for new problems.

Figure 4: The IMNCI case management process[63]

Impact of IMCI

A Cochrane review by Gera et al in 2016 found that IMCI was associated with a 15% reduction in infant and child mortality when implemented in health facilities and communities, although the certainty of evidence was low. [64] Little or no effects were seen on nutritional status or vaccine coverage but maternal care seeking behaviour for their child was more appropriate where IMNCI was being implemented.

Adaptation and scale up of IMNCI

A structured approach to diagnosis with evidence-based treatment and flexible guidelines which adapt to local epidemiology are some of the key features of IMCI. [65] After consensus is reached with key national stakeholders certain conditions, for example, malaria can be removed from guidelines where malaria is not prevalent and other conditions added instead. Neonatal care was added early on in implementation in many countries. [66] Antibiotic selection is also based on local sensitivity and availability. In countries where

HIV/AIDS is important cause of child morbidity and mortality it has also been included in IMCI guidelines. [67] To ensure guidelines are adapted in a consistent manner WHO has formulated an Adaptation Guide to describe the process of adaptation and facilitate continuous evolution of the programme. [68]

Financial challenges are common for scale up and continuation of IMCI, and in many places external international donors have been major funders of IMNCI training of PHWs. A global study conducted across 27 countries found high cost a major challenge to scaling up. [69] One method of reducing costs of IMCI has been to reduce the time of the PHW training. A randomized trial in Zambia compared PHWs performance who were trained in the standard 11-day course with those trained in a 6-day shortened course and did not find any significant difference in any of the indicators of performance. [70] The effectiveness of shortening IMCI guidelines training was systematically reviewed, and the standard in-service IMCI training course was found be slightly more effective than the shorter training, although the size of the difference was unclear (-3 to +18% points by a summary comparison measures). [71] However the review was limited by few studies of adequate study design to reach firm conclusions whether shortening the training did reduce effectiveness and to what degree.

The ability of IMNCI to be flexible both in the content and training approaches has made it a resilient strategy which is still being used almost 25 years after it was first developed.

Generating political priority for child eye health

The sustainable, holistic approach to delivering primary eye care for children is through the integration of eye health into child health programmes and policies. Despite this approach being proposed in 2002 by the WHO prevention of blindness program there has been little progress on achieving this integration into child health polices or any political priority for child eye health.

Agenda setting theoretical frameworks

Walt and Gilson (1994) developed a policy analysis framework specifically to analyse health policy research health. [72] Their policy triangle framework incorporates context, content, process, and actors as individuals or as members of groups and is the most used overarching framework. It has been used to analyse a wide range of health issues, from mental to reproductive health, in many different countries. [73]

Agenda setting is used to describe the process by which an issue is brought to the attention of policy makers and is an essential first step in the policy cycle. [74 75 76 77] There are several frameworks used to analyse agenda setting with Kingdon (1984) and Shiffman (2007) being the most common. [73 78 79] Kingdon's theory of agenda setting is used to help understand how opportunities to prioritise health issues arise. The theory uses three different and continuous 'streams' of activities or processes. The 'problem stream' refers to the features of the issue and whether and how the issue is seen as public matter which requires government attention. Data, policy reports and advocacy from groups and stakeholders influence what policy makers learn about issues. The 'policy stream' covers analysis and discussions of the issues and proposed solutions by experts, researchers, and NGOs. The 'politics stream' includes political events such as elections, changes of government and public campaigns. Kingdon proposed that the combination of these three largely independent (but simultaneous) streams can create 'policy windows' which are opportunities for new issues to gain political attention and lead to policy change. 'Policy entrepreneurs" are actors who advocate for policy solutions located inside or outside Government and can act publicly or behind the scenes. Kingdon's model has been applied to understanding the Safe Motherhood policy in Vietnam, sanitation and health promotion policy in Ethiopia and analysing power and agenda setting in Tanzanian health policy. [80-82]

Baumgartner and Jones (1991) described policy agendas as relatively stable unless factors, such as the way an issue is presented (the 'image') and the actors and institutions involved (the 'venue'), change significantly. [83] Stone (1989) claimed that issues gain priority only when they are seen as having clear actionable solutions. [84] They also argue that the

'precursor' or problem definition stage of an issue before it reaches the public agenda should not be neglected.

Walt and Gilson chose to study the Shiffman and Smith framework as they describe it as the more developed and comprehensive framework on agenda or priority setting. [85] They systematically reviewed a set of health policy papers on agenda setting and tested them using the framework. They found that the framework was useful in conducting cross-national as well as cross policy research and contributed to more thorough health policy analysis research. They suggested some enhancements to the framework such as adding contestability or conflict under the 'characteristics of the problem' being considered, separating 'guiding institutions or organizations' under 'actor power', and the formal and informal norms and rules under 'political context'.

The Shiffman and Smith framework focuses specifically on health developed using evidence from several case studies to form a generalized framework to assess what were the factors which lead to some issues being prioritised over others in the process of health policy agenda setting. [79] The four elements used to describe factors are: 1) the interaction between actors and their power, 2) ideas, 3) context of the political environment and 4) characteristics of the issues themselves (Table 4). Each of these four elements is described, and then characterized further by eleven factors, as shown in the table. The advantage of this approach is that it allows for a comprehensive and structured analysis of the factors involved in the policy decision in Tanzania. A limitation is that there may be other relevant elements which are not in the framework, the subjectivity in assessing the relative weight of the different factors and difficulty in controlling for confounding variables. The framework has been used extensively to study the issues of maternal mortality and newborn survival but has also used in a wide range of health issues including mental health and global surgery. [86] [87] [88] This framework was chosen for this thesis as one of its advantages is that its use allows comparability of child eye health with these other health issues. This will allow an understanding of the factors which may have held back child eye health receiving priority and what factors need to be addressed to scale up its integration within the global child health agenda.

Table 4: Shiffman and Smith Framework

Element	Description	Factors shaping political priority
Actor power	The strength of the individuals and organisations concerned with the issue	Policy community cohesion: the degree of coalescence among the network of individuals and organisations that are centrally involved with the issue at the global level Leadership: the presence of individuals capable of uniting the policy community and acknowledged as particularly strong champions for the cause Guiding institutions: the effectiveness of organisations or co-ordinating mechanisms with a mandate to lead the initiative Civil society mobilisation: the extent to which grassroots organisations have mobilised to press international and national political authorities to address the issue at the global level
Ideas	The ways in which those involved with the issue understand and portray it	Internal frame: the degree to which the policy community agrees on the definition of, causes of, and solutions to the problem External frame: public portrayals of the issue in ways that resonate with external audiences, especially the political leaders who control resources
Political contexts	The environments in which actors operate	Policy windows: political moments when global conditions align favourably for an issue, presenting opportunities for advocates to influence decision makers Global governance structure: the degree to which norms and institutions operating in a sector provide a platform for effective collective action

Issue characteristics	Features of the problem	Credible indicators: clear measures that show the severity of the problem and that can be used to monitor progress Severity: the size of the burden relative to other problems, as indicated by objective measures such as mortality levels Effective interventions: the extent to which proposed means of addressing the problem are clearly explained, cost-effective, backed by scientific evidence, simple to implement, and inexpensive

Lessons from using Shiffman framework in other health issues

Applying their framework to the Safe Motherhood Initiative, Shiffman and Smith found that in every category the initiative had major challenges. [79] They concluded that building policy community cohesion to take advantage of a major policy window from the Millennium Development Goals (MDGs) with a new global governance structure, a clearer external frame and building stronger links with national initiatives and civil society would generate the needed political support.

The framework was further used to understand the factors that lead to an increase in global political attention to newborn survival from 2000 to 2010. [86] In 2000 there were only a few individuals working on the initiative with no guiding institution, neonates were not recognised as a separate global health category, there was limited evidence or knowledge on the size of the problem or solutions, and few global health organisations addressing newborn survival. Over the course of the decade, they found the formation of an informal global network alongside an effective global guiding institution, evidence of severity of the issue with cost-effective solutions, led to many more organisations addressing the issue and it being recognised as an important component of MDG 4. This has important lessons for any issue aiming to increase global political attention on the importance of networks, building global institutions and evidence to take a neglected issue more into prominence. It

also highlighted another important factor not highlighted in the original Shiffman framework which is that of networks.

Shiffman et al created a framework to understand the effectiveness of global health networks, [89] which they define as "webs of individuals and organizations linked by a shared concern for a health condition". The categories overlap with the original Shiffman and Smith framework and include; 1) network and actor features including leadership, governance and framing, 2) policy environment including funding, allies, opponents and norms and 3) issues characteristics including severity, tractability and affected groups. The study was part of the Global Health Advocacy and Policy Project, a research initiative examining networks in six global health problems: tuberculosis, pneumonia, tobacco use, alcohol harm, neonatal mortality, and maternal mortality. The six case studies contributed to the development of the framework. The case study of newborn survival also reviewed the development of increasing political priority from pre-1999 to 2010-2015. [90] The key factors for the rise in priority was the production of a substantial body of evidence on severity and solutions, which could then be leveraged by the leadership and emerging governance structure to link newborn survival to the important policy window of the time which was around MDG 4. However, the disadvantage of having a largely technical network with a lack of political advocates hampered their success. The study shows the clear role of specific evidence with broad leadership in generating political support for a health issue.

The use of the Shiffman and Smith framework in a diverse range of health issues highlights the most common pitfalls and priority actions. [85 87 88 91 92] When examining why mental health had not yet received policy or funding attention in low resource settings, Tomlinson and Lund concluded that greater policy community cohesion and international governance structures needed to be developed, with a coherent evidence base for scalable interventions showing both economic impact as well as on well-being. They considered that mental health be framed within social justice and human rights agendas and initiatives. Shawar et al applied the framework to the issue of global surgery and found a fragmented policy community without unifying leadership, guiding institutions, clear external framing, or credible indicators. [87] However, there were committed networks with growing research agendas, with potential to links to other global health priorities. They recommended the

development of an effective governance structure and of a clear external frame as the two key areas of focus for global surgery advocates.

National level agenda setting

The Shiffman and Smith framework or adaptations of it have been applied in many national level policy studies. [93-95] One study compared national level political commitment to newborn survival in Bolivia, Malawi and Nepal, which found that the three major implications at a national level were: 1) solutions with demonstrated efficacy in low-resource settings, (2) building on existing and emerging national priorities and (3) developing a strong network of domestic and international support. [96] This is important for national level advocates as potential areas of focus which can be used to generate priority nationally if global level advocacy or initiatives are lacking.

Shiffman (2007) used a case study approach to understand the political priority to maternal mortality reduction in five countries: Guatemala, Honduras, India, Indonesia, and Nigeria. [97] Countries were selected due to their focus on the Safe Motherhood Initiative and their potential to show different underlying factors in maternal mortality reduction agenda setting. There were nine key factors which were divided into three categories: transnational influences, domestic advocacy, and the national political environment.

The use of the framework at the national level gave important insights for national level advocates and for the issue in other contexts with also some lessons for the global level. Thus, in our study Tanzania was chosen as a case study to understand the factors affecting the political commitment to child eye health with the purpose of determining key factors which could influence the political priority given to child eye health in other countries and at a global level.

Tanzania as a case study

In Tanzania the prevalence of childhood blindness (under 15 years old) is approximately 8/10,000 children and is likely to be higher in poorer communities. This prevalence includes two new cases of retinoblastoma and 20-30 new cases of cataract per million population per year. Other eye conditions include strabismus which affects 1-2% of young children, and conjunctivitis, which is one of the ten commonest conditions seen in clinics delivering reproductive and child health services in Tanzania (unpublished MOH data).

A pilot study conducted by Mafwiri and colleagues in Dar-es-Salaam in 2013 showed that PHWs knowledge of childhood eye conditions including common conditions such as conjunctivitis was low, and they suggested inappropriate treatments. [98] After a single training day on childhood eye conditions there was an improvement in knowledge which was retained a year later with 61% of trained staff able to explain the correct management of purulent conjunctivitis compared with 30% of untrained staff, while 82% of those trained compared to 33% of those not trained were able to correctly diagnose a cataract. [98] Following on from this study a Steering Committee was convened by the LSHTM project team in Tanzania with representatives from the Ministry of Health, WHO, UNICEF, international non-government organizations supporting eye care, the National Prevention of Blindness Co-ordinator, the researchers, and technical experts. A draft theory of change was constructed and approved by the Committee (Figure 5). There were three causal pathways identified which were; 1) actions by mothers to prevent blinding eye disease, 2) actions by staff to prevent eye disease, and 3) detection and referral of children with serious eye conditions.

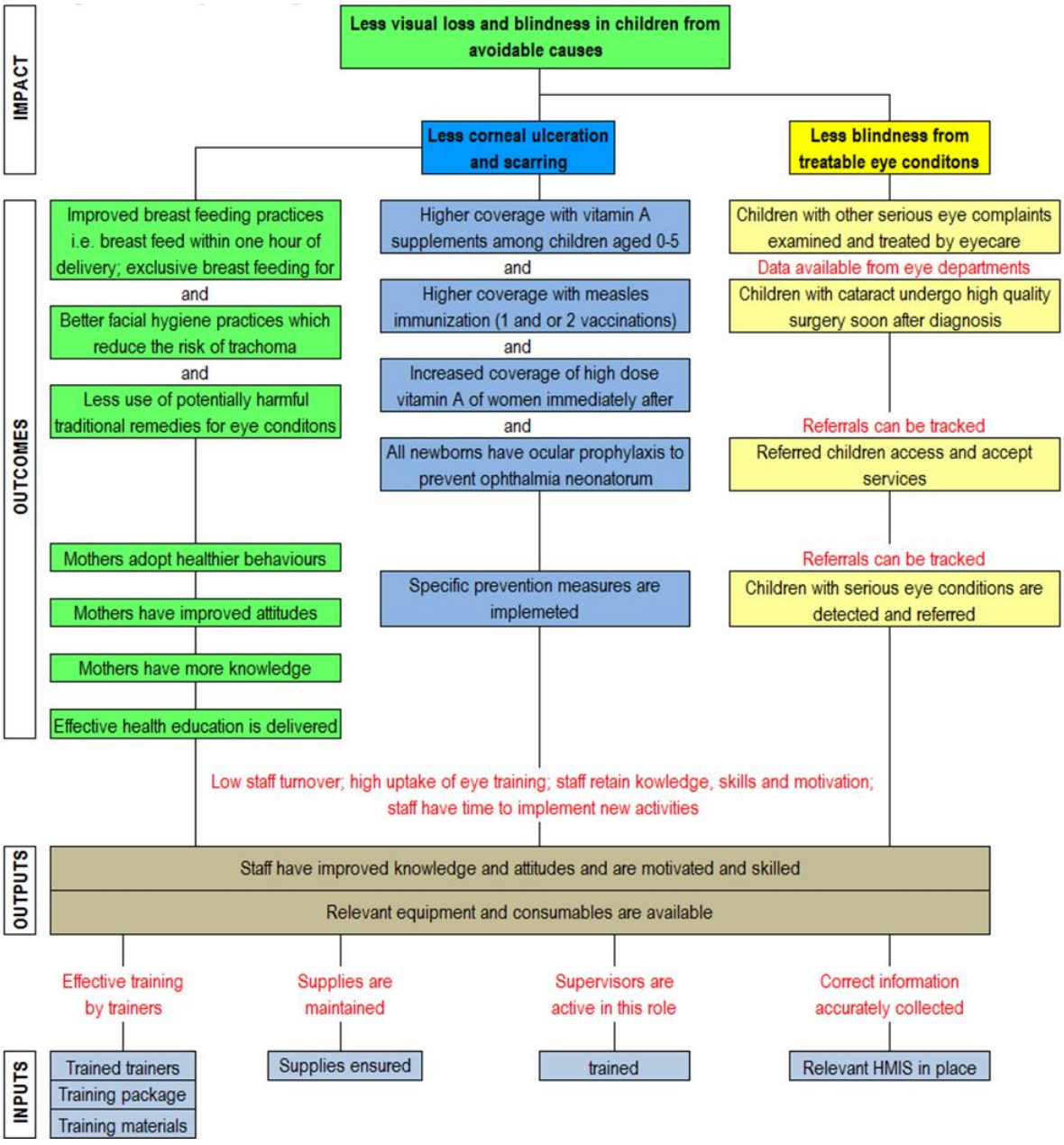


Figure 5: Theory of Change addressing reducing visual loss and blindness in children from avoidable causes

The Committee agreed that the next step would be to conduct formative research in an area of rural Tanzania. The purpose of the research was to explore current service delivery for eye care for children, to assess barriers and assumptions along the causal pathways, and identify outcome measures that could be used in an evaluation. The specific objectives focused on current service delivery in RCH clinics and service outputs; the knowledge, attitudes and health seeking behaviour of mothers and community members; the current

provision of eye care in Singida region, and elements of the health system to be strengthened. The main findings of the formative research included: 70% of mothers had delivered their child in a health facility, over 90% mothers reported that their child had received vitamin A but documented coverage was 70% at nine months, and 20% and 8% at 15 and 21 months respectively; 85% had documented evidence of measles immunization, 30% of mothers said their child had had an eye problem, 36% of PHWs said they saw at least one child a week with an eye condition, 60% said they did not feel confident in examining children's eyes. 58% of the facilities performing deliveries used ocular prophylaxis routinely, with one limiting this to women known to have a STDs. Topical and systemic antibiotics were available in 88% facilities but only five had functional torches and sterile eye pads (unpublished data).

IMNCI in Tanzania

In a study in Tanzania IMCI was found to be associated with a reduction of 13% of under-five mortality rates.[99] The annual cost of caring for children in Tanzania using IMCI was 44% lower than in areas without IMCI. [100] Even if not all this difference in cost is attributable to IMCI it showed that IMCI was not associated with higher costs than standard care while also improving the quality of care.

The standard IMCI training package was introduced in Tanzania in 1996 and was initially delivered as a 11 day in-service training programme. The cost of this standard training is a barrier to scale up. [69] WHO produced a set of distance learning modules to reduce the duration of face-to-face training and its cost. [101] This was adapted in Tanzania by the Ministry of Health and began to be used in 2012. [102] The distance learning course runs over a period of 10-12 weeks with three face-to -face days in between two self-study periods of 3-4 weeks then 8-9 weeks (Figure 6).

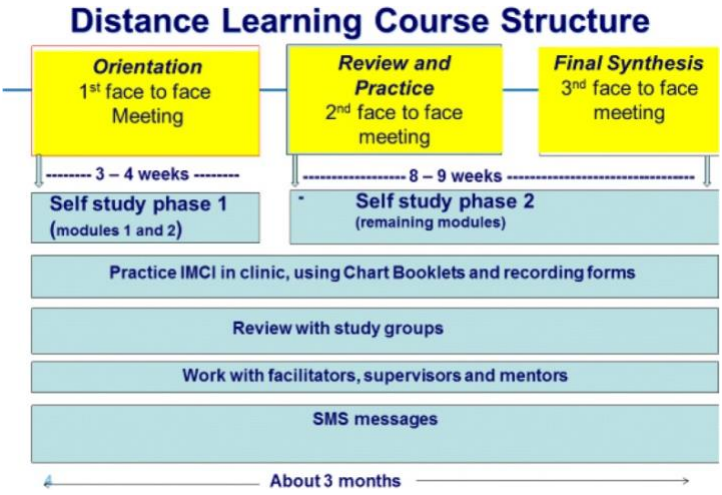


Figure 6: Distance learning IMCI course structure in Tanzania[102]

There is a one-day classroom-based session at the start of the training to orientate the PHWs to the IMCI approach and provide guidance about how the course will run. During the second and third classroom-based days, the IMCI facilitator provides an overview of the modules and there is some time for supervised clinical practice. The intervening periods are for the PHWs self-study but with some support from the IMCI facilitators who text the PHWs by text and conduct at least one site visit at the PHWs place of work. The PHWs are also assigned to groups of 2–5 colleagues who are close to their own health facility and encouraged to work together in groups. The PHWs take an examination at the end which they must pass to receive a certificate. Approximately 4-6 weeks after the completion of the training there are follow-up visits by the IMCI facilitators to reinforce clinical skills and support through supervision at their workplace. [103] The IMCI facilitators should also correct any issues they note about clinical skills and solve supply issues. This distance learning approach has been evaluated in Tanzania and the PHWs trained in distance learning IMCI were found to perform equally well as those trained in the standard IMCI course in their assessment, treatment, and counselling as even better in assessing “danger signs”. [102] The distance learning IMCI costs 70% less than standard IMCI training.

Aim and objectives of thesis

The overall aim of this thesis is to understand how eye health could be included in child health programmes and policies, using the inclusion of eye health into the IMNCI strategy in Tanzania as a model.

The objectives of the thesis are:

1) To synthesise existing evidence on how universal screening of the eye within eight weeks of birth improves newborn and infant vision and health outcomes
2) To evaluate whether including eye care in the training curriculum of IMNCI in Tanzania for PHWs improves their knowledge and skills in eye care for children, and whether the training is accessible and acceptable to PHWs
3) To explore key factors which led to the decision to include eye health in the IMNCI strategy in Tanzania
4) To synthesise findings from the first three objectives to present policy implications and recommendations for policy makers and practitioners on integrating eye health into child health policies and programmes

Objectives 1-3 are directly answered in the corresponding research papers 1-3 (chapters 4-6) and objective 4 is answered in the discussion in chapter 7. The following chapter 3 covers the methods used for all three research papers.

References

1. Burton MJ, Ramke J, Marques AP, et al. The Lancet Global Health Commission on Global Eye Health: vision beyond 2020. *Lancet Glob Health* 2021;9(4):e489-e551. doi: 10.1016/s2214-109x(20)30488-5 [published Online First: 2021/02/20]
2. Rahi JS, Cable N. Severe visual impairment and blindness in children in the UK. *Lancet* 2003;362(9393):1359-65. doi: 10.1016/s0140-6736(03)14631-4

3. Muhit MA, Shah SP, Gilbert CE, et al. The key informant method: a novel means of ascertaining blind children in Bangladesh. *Br J Ophthalmol* 2007;91(8):995-9. doi: 10.1136/bjo.2006.108027 [published Online First: 20070412]
4. Reis LM, Semina EV. Genetic landscape of isolated pediatric cataracts: extreme heterogeneity and variable inheritance patterns within genes. *Hum Genet* 2019;138(8-9):847-63. doi: 10.1007/s00439-018-1932-x [published Online First: 2018/09/07]
5. Fabian ID, Abdallah E, Abdullahi SU, et al. Global Retinoblastoma Study Group. Global Retinoblastoma Presentation and Analysis by National Income Level. *JAMA Oncol* 2020;6(5):685-95. doi: 10.1001/jamaoncol.2019.6716
6. Dimaras H, Kimani K, Dimba EA, et al. Retinoblastoma. *Lancet (London, England)* 2012;379(9824):1436-46. doi: 10.1016/s0140-6736(11)61137-9 [published Online First: 2012/03/15]
7. Soliman SE, Dimaras H, Khetan V, et al. Prenatal versus Postnatal Screening for Familial Retinoblastoma. *Ophthalmology* 2016;123(12):2610-17. doi: 10.1016/j.ophtha.2016.08.027 [published Online First: 2016/10/08]
8. Papadopoulos M, Cable N, Rahi J, et al. The British Infantile and Childhood Glaucoma (BIG) Eye Study. *Invest Ophthalmol Vis Sci* 2007;48(9):4100-6. doi: 10.1167/iovs.06-1350 [published Online First: 2007/08/29]
9. Beck D, Galea M, Loo CY, et al. Paediatric glaucoma in Scotland. *BMC Ophthalmol* 2020;20(1):76. doi: 10.1186/s12886-020-01347-7 [published Online First: 2020/02/28]
10. European network of population-based registries for the epidemiological surveillance of congenital anomalies. [Available from: https://eu-rd-platform.jrc.ec.europa.eu/eurocat/eurocat-data/prevalence_en. accessed July 2020.
11. Yasmeen A, Riazuddin SA, Kaul H, et al. Autosomal recessive congenital cataract in consanguineous Pakistani families is associated with mutations in GALK1. *Mol Vis* 2010;16:682-8. [published Online First: 2010/04/21]
12. Fujiki K, Nakajima A, Yasuda N, et al. Genetic analysis of microphthalmos. *Ophthalmic Paediatrics and Genetics* 1982;1(2):139-49. doi: 10.3109/13816818209031458

13. Hansen RM FA, Mayer DL. Clinical aspects of normal and abnormal visual development and delayed visual maturatio. *in Pediatric Ophthalmology and Strabismus* 2017;S.L.a.C. Lyons., Editor.
14. Fitxpatrick D. Developmental Biology of the Eye. *in Pediatric Ophthalmology and Strabismus,* 2017;S.L.a.C. Lyons, Editor
15. Hamm LM, Black J, Dai S, et al. Global processing in amblyopia: a review. *Front Psychol* 2014;5:583. doi: 10.3389/fpsyg.2014.00583 [published Online First: 2014/07/06]
16. Sonksen PM, Dale N. Visual impairment in infancy: impact on neurodevelopmental and neurobiological processes. *Dev Med Child Neurol* 2002;44(11):782-91. doi: 10.1017/s0012162201002936 [published Online First: 2002/11/07]
17. Stoll C, Alembik Y, Dott B, et al. Epidemiology of congenital eye malformations in 131,760 consecutive births. *Ophthalmic Paediatr Genet* 1992;13(3):179-86. doi: 10.3109/13816819209046487
18. Watts P, Maguire S, Kwok T, et al. Newborn retinal hemorrhages: a systematic review. *J aapos* 2013;17(1):70-8. doi: 10.1016/j.jaapos.2012.07.012 [published Online First: 20130128]
19. American Academy of Pediatrics, Section on Ophthalmology. American Association for Pediatric Ophthalmology and Strabismus. American Academy of Ophthalmology. American Association of Certified Orthoptists. Red reflex examination in neonates, infants, and children. *Pediatrics* 2008;122(6):1401-4. doi: 10.1542/peds.2008-2624 [published Online First: 2008/12/03]
20. Duret A, Humphries R, Ramanujam S, et al. The infrared reflex: a potential new method for congenital cataract screening. *Eye (Lond)* 2019;33(12):1865-70. doi: 10.1038/s41433-019-0509-9 [published Online First: 2019/07/04]
21. Moorfields Eye Hospital, London. Checking the red reflex. [Available from: https://www.moorfields.nhs.uk/news/checking-red-reflex accessed June 2020.
22. Abramson DH, Beaverson K, Sangani P, et al. Screening for retinoblastoma: presenting signs as prognosticators of patient and ocular survival. *Pediatrics* 2003;112(6 Pt 1):1248-55. doi: 10.1542/peds.112.6.1248 [published Online First: 2003/12/05]
23. Khan AO, Al-Mesfer S. Lack of efficacy of dilated screening for retinoblastoma. *J Pediatr Ophthalmol Strabismus* 2005;42(4):205-10; quiz 33-4. [published Online First: 2005/08/27]

24. Arclight™ ophthalmoscope [Available from: http://arclightscope.com/ accessed July 7 2020.
25. Khedekar A, Devarajan B, Ramasamy K, et al. Smartphone-based application improves the detection of retinoblastoma. *Eye (Lond)* 2019;33(6):896-901. doi: 10.1038/s41433-018-0333-7 [published Online First: 2019/01/13]
26. Mndeme FG MB, Kim MJ, Sinke L, Allen L, Mgaya E, Bastawrous A, MacLeod D, Burton MJ, Gilber C, Bowman R. Red reflex examination in reproductive and child health clinics for early detection of paediatric cataract and ocular media disorders: cross-sectional diagnostic accuracy and
feasibility studies from Kilimanjaro, Tanzania. *Eye* 2020
27. People RNIfB. Key Statistics on Pupils with Vision Impairment. . 2017 *Available from: https://wwwrniborguk/insight-online/statistics-pupils-vision-impairment*
28. Lambert. S. Chapter 37 Childhood cataracts. In: David Taylor CH, ed. Taylor and Hoyt's Paediatric Ophthalmology and Strabismus 5th ed: Elsevier 2016.
29. Chak M, Wade A, Rahi JS, et al. Long-term visual acuity and its predictors after surgery for congenital cataract: findings of the British congenital cataract study. *Invest Ophthalmol Vis Sci* 2006;47(10):4262-9. doi: 10.1167/iovs.05-1160 [published Online First: 2006/09/28]
30. Lambert SR, Lynn MJ, Reeves R, et al. Is there a latent period for the surgical treatment of children with dense bilateral congenital cataracts? *J AAPOS* 2006;10(1):30-6. doi: 10.1016/j.jaapos.2005.10.002 [published Online First: 2006/03/11]
31. Gichigo EN, Kariuki-Wanyoike MM, Kimani K, et al. [Retinoblastoma in Kenya: survival and prognostic factors]. *Ophthalmologe* 2015;112(3):255-60. doi: 10.1007/s00347-014-3123-z [published Online First: 2014/11/08]
32. Jin L, Zhang W, Pan H, et al. Retrospective investigation of retinoblastoma in Chinese patients. *Oncotarget* 2017;8(65):108492-97. doi: 10.18632/oncotarget.18174 [published Online First: 2018/01/10]
33. *https://wwwnhsuk/conditions/eye-tests-in-children/*
34. *https://wwwaaoorg/eye-health/tips-prevention/children-eye-screening*
35. Sloot F, Hoeve HL, de Kroon ML, et al. Inventory of current EU paediatric vision and hearing screening programmes. *J Med Screen* 2015;22(2):55-64. doi: 10.1177/0969141315572403 [published Online First: 2015/03/07]

36. Recommendations for the prevention of neonatal ophthalmia. *Paediatrics & Child Health* 2002;7(7):480-83.
37. World Health Organization. A five year project for the prevention of childhood blindness: Report of a WHO Consultation: World Health Organisation, 2002.
38. Imdad A, Mayo-Wilson E, Herzer K, et al. Vitamin A supplementation for preventing morbidity and mortality in children from six months to five years of age. *Cochrane Database of Systematic Reviews* 2017(3) doi: 10.1002/14651858.CD008524.pub3
39. Fransen L, Nsanze H, Klauss V, et al. Ophthalmia neonatorum in Nairobi, Kenya: the roles of Neisseria gonorrhoeae and Chlamydia trachomatis. *The Journal of infectious diseases* 1986;153(5):862-9. [published Online First: 1986/05/01]
40. Taskforce UP. Ocular Prophylaxis for Gonococcal Ophthalmia Neonatorum: Preventive Medication. 2019;https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/ocular-prophylaxis-for-gonococcal-ophthalmia-neonatorum-preventive-medication
41. Moore DL, MacDonald NE, Canadian Paediatric S, et al. Preventing ophthalmia neonatorum. *Paediatrics & Child Health* 2015;20(2):93-96. doi: 10.1093/pch/20.2.93
42. Laga M, Meheus A, Piot P. Epidemiology and control of gonococcal ophthalmia neonatorum. *Bulletin of the World Health Organization* 1989;67(5):471-77.
43. Newman L, Rowley J, Vander Hoorn S, et al. Global Estimates of the Prevalence and Incidence of Four Curable Sexually Transmitted Infections in 2012 Based on Systematic Review and Global Reporting. *PloS one* 2015;10(12):e0143304. doi: 10.1371/journal.pone.0143304 [published Online First: 2015/12/10]
44. Kapoor VS, Evans JR, Vedula SS. Interventions for preventing ophthalmia neonatorum. *Cochrane Database Syst Rev* 2020;9(9):Cd001862. doi: 10.1002/14651858.CD001862.pub4 [published Online First: 20200921]
45. Malik ANJ, Gilbert C. Cochrane corner: interventions for preventing ophthalmia neonatorum. *Eye (Lond)* 2022;36(2):356-57. doi: 10.1038/s41433-021-01803-8 [published Online First: 20211012]
46. Segal S, Anyan WB, Hill RM, et al. Prophylaxis and Treatment of Neonatal Gonococcal Infections. *Pediatrics* 1980;65(5):1047-48.

47. Force UPST. Ocular Prophylaxis for Gonococcal Ophthalmia Neonatorum: US Preventive Services Task Force Reaffirmation Recommendation Statement. *JAMA* 2019;321(4):394-98. doi: 10.1001/jama.2018.21367
48. (CDC) CfDCaP. Sexually transmitted disease surveillance 2017. *CDC website https://wwwcdcgov/std/stats17/defaulthtm* 2018
49. World Health Organisation. Global Elimination of Trachoma documents. http://wwwwhoint/blindness/publications/get2020/en/, 2013.
50. Health OW. Trachoma. *https://wwwwhoint/news-room/fact-sheets/detail/trachoma* 2022
51. Rahi JG, CE. Epidemiology of visual impairment in children. 4th ed: Elsevier 2016.
52. Sheeladevi S, Lawrenson JG, Fielder AR, et al. Global prevalence of childhood cataract: a systematic review. *Eye* 2016;30(9):1160-69. doi: 10.1038/eye.2016.156
53. Lambert SR. The timing of surgery for congenital cataracts: Minimizing the risk of glaucoma following cataract surgery while optimizing the visual outcome. *Journal of AAPOS : the official publication of the American Association for Pediatric Ophthalmology and Strabismus* 2016;20(3):191-2. doi: 10.1016/j.jaapos.2016.04.003 [published Online First: 2016/05/18]
54. Mwende J, Bronsard A, Mosha M, et al. Delay in presentation to hospital for surgery for congenital and developmental cataract in Tanzania. *The British journal of ophthalmology* 2005;89(11):1478-82. doi: 10.1136/bjo.2005.074146 [published Online First: 2005/10/20]
55. England UPH. Newborn and infant physical examination (NIPE) screening programme handbook. *https://wwwgovuk/government/publications/newborn-and-infant-physical-examination-programme-handbook/newborn-and-infant-physical-examination-screening-programme-handbook* 2019
56. Donahue SP, Nixon CN. Visual System Assessment in Infants, Children, and Young Adults by Pediatricians. *Pediatrics* 2016;137(1):28-30. doi: 10.1542/peds.2015-3596 [published Online First: 2016/01/01]
57. Foster A, Johnson GG. Traditional eye medicines--good or bad news? *The British journal of ophthalmology* 1994;78(11):807. [published Online First: 1994/11/01]
58. Courtright P, Lewallen S, Kanjaloti S. Changing patterns of corneal disease and associated vision loss at a rural African hospital following a training programme for traditional

healers. *The British journal of ophthalmology* 1996;80(8):694-7. [published Online First: 1996/08/01]

59. Negrel AD, Thylefors B. The global impact of eye injuries. *Ophthalmic epidemiology* 1998;5(3):143-69. [published Online First: 1998/11/07]
60. Abbott J, Shah P. The epidemiology and etiology of pediatric ocular trauma. *Survey of ophthalmology* 2013;58(5):476-85. doi: 10.1016/j.survophthal.2012.10.007 [published Online First: 2013/08/24]
61. Malik ANJ, Mafwiri M, Gilbert C. Integrating primary eye care into global child health policies. *Arch Dis Child* 2018;103(2):176-80. doi: 10.1136/archdischild-2017-313536 [published Online First: 2017/10/11]
62. World Health Organization. Integrated Management of Childhood Illness. *http://wwwwhoint/maternal_child_adolescent/topics/child/imci/en/* 2017

63.https://www.open.edu/openlearncreate/mod/oucontent/view.php?id=245&printable=1

64. Gera T, Shah D, Garner P, et al. Integrated management of childhood illness (IMCI) strategy for children under five. *Cochrane Database Syst Rev* 2016(6):Cd010123. doi: 10.1002/14651858.CD010123.pub2 [published Online First: 20160622]
65. O'Loughlin F, Phangmanixay S, Sisouk K, et al. Integrated Management of Neonatal and Childhood Illness Training in Lao PDR: A Pilot Study of an Adaptable Approach to Training and Supervision. *Am J Trop Med Hyg* 2021;105(6):1618-23. doi: 10.4269/ajtmh.21-0544 [published Online First: 20210907]
66. Bhandari N, Mazumder S, Taneja S, et al. Effect of implementation of Integrated Management of Neonatal and Childhood Illness (IMNCI) programme on neonatal and infant mortality: cluster randomised controlled trial. *BMJ (Clinical research ed)* 2012;344:e1634. doi: 10.1136/bmj.e1634 [published Online First: 20120321]
67. Qazi SA, Muhe LM. Integrating HIV management for children into the Integrated Management of Childhood Illness guidelines. *Trans R Soc Trop Med Hyg* 2006;100(1):10-3. doi: 10.1016/j.trstmh.2005.05.013 [published Online First: 20051027]
68. Mets MB, Chhabra MS. Eye manifestations of intrauterine infections and their impact on childhood blindness. *Surv Ophthalmol* 2008;53(2):95-111. doi: 10.1016/j.survophthal.2007.12.003

69. Goga AE, Muhe LM. Global challenges with scale-up of the integrated management of childhood illness strategy: results of a multi-country survey. *BMC Public Health* 2011;11:503. doi: 10.1186/1471-2458-11-503 [published Online First: 20110627]
70. Mwinga K, Siziya S, Kasungami D, et al. Comparative study of two types of IMCI Case Management courses in Zambia. *World Health Organisation Technical Consultation of IMCI inservice and preservice training approaches and methods, Geneva* 2007
71. Rowe AK, Rowe SY, Holloway KA, et al. Does shortening the training on Integrated Management of Childhood Illness guidelines reduce its effectiveness? A systematic review. *Health Policy Plan* 2012;27(3):179-93. doi: 10.1093/heapol/czr033 [published Online First: 20110423]
72. Walt G, Gilson L. Reforming the health sector in developing countries: the central role of policy analysis. *Health Policy Plan* 1994;9(4):353-70. doi: 10.1093/heapol/9.4.353 [published Online First: 1994/11/04]
73. Gilson L, Raphaely N. The terrain of health policy analysis in low and middle income countries: a review of published literature 1994-2007. *Health Policy Plan* 2008;23(5):294-307. doi: 10.1093/heapol/czn019 [published Online First: 20080722]
74. Rogers EM, Dearing JW, Bregman D. The anatomy of agenda-setting research. *Journal of communication* 1993;43(2):68-84.
75. Howlett M RM, Perl A. Studying Public Policy: Policy Cycles and Policy Subsystems. *Toronto: Oxford University Press* 1995
76. Buse K, Mays N, Walt G. Making health policy: McGraw-hill education (UK) 2012.
77. Sabatier PA, Weible CM. Theories of the policy process: Westview press 2014.
78. Kingdon JW, Stano E. Agendas, alternatives, and public policies: Little, Brown Boston 1984.
79. Shiffman J, Smith S. Generation of political priority for global health initiatives: a framework and case study of maternal mortality. *Lancet* 2007;370(9595):1370-9. doi: 10.1016/s0140-6736(07)61579-7 [published Online First: 2007/10/16]
80. Ha BT, Mirzoev T, Mukhopadhyay M. Shaping the Health Policy Agenda: The Case of Safe Motherhood Policy in Vietnam. *Int J Health Policy Manag* 2015;4(11):741-6. doi: 10.15171/ijhpm.2015.153 [published Online First: 20150816]
81. Agide FD, Garmaroudi G, Sadeghi R, et al. Application of Kingdon and Hall Models to Review Environmental Sanitation and Health Promotion Policy in Ethiopia: A

Professional Perspective as a Review. *Ethiop J Health Sci* 2019;29(2):277-86. doi: 10.4314/ejhs.v29i2.15

82. Fischer SE, Strandberg-Larsen M. Power and Agenda-Setting in Tanzanian Health Policy: An Analysis of Stakeholder Perspectives. *Int J Health Policy Manag* 2016;5(6):355-63. doi: 10.15171/ijhpm.2016.09 [published Online First: 20160209]
83. Baumgartner FR, Jones BD. Agenda dynamics and policy subsystems. *The journal of Politics* 1991;53(4):1044-74.
84. Stone DA. Causal stories and the formation of policy agendas. *Political science quarterly* 1989;104(2):281-300.
85. Walt G, Gilson L. Can frameworks inform knowledge about health policy processes? Reviewing health policy papers on agenda setting and testing them against a specific priority-setting framework. *Health Policy and Planning* 2014;29(suppl_3):iii6-iii22. doi: 10.1093/heapol/czu081
86. Shiffman J. Issue attention in global health: the case of newborn survival. *Lancet* 2010;375(9730):2045-9. doi: 10.1016/s0140-6736(10)60710-6 [published Online First: 2010/06/24]
87. Shawar YR, Shiffman J, Spiegel DA. Generation of political priority for global surgery: a qualitative policy analysis. *Lancet Glob Health* 2015;3(8):e487-e95. doi: 10.1016/s2214-109x(15)00098-4 [published Online First: 2015/07/19]
88. Tomlinson M, Lund C. Why does mental health not get the attention it deserves? An application of the Shiffman and Smith framework. *PLoS Med* 2012;9(2):e1001178. doi: 10.1371/journal.pmed.1001178 [published Online First: 20120228]
89. Shiffman J, Quissell K, Schmitz HP, et al. A framework on the emergence and effectiveness of global health networks. *Health Policy Plan* 2016;31 Suppl 1(Suppl 1):i3-16. doi: 10.1093/heapol/czu046 [published Online First: 2015/09/01]
90. Shiffman J. Network advocacy and the emergence of global attention to newborn survival. *Health Policy Plan* 2016;31 Suppl 1(Suppl 1):i60-73. doi: 10.1093/heapol/czv092 [published Online First: 2015/09/26]
91. Hafner T, Shiffman J. The emergence of global attention to health systems strengthening. *Health Policy Plan* 2013;28(1):41-50. doi: 10.1093/heapol/czs023 [published Online First: 20120308]

92. Shawar YR, Shiffman J. Generation of global political priority for early childhood development: the challenges of framing and governance. *Lancet* 2017;389(10064):119-24. doi: 10.1016/s0140-6736(16)31574-4 [published Online First: 2016/10/09]
93. Shiffman J, Sultana S. Generating political priority for neonatal mortality reduction in Bangladesh. *Am J Public Health* 2013;103(4):623-31. doi: 10.2105/ajph.2012.300919 [published Online First: 20121213]
94. Shiffman J. Generating political will for safe motherhood in Indonesia. *Soc Sci Med* 2003;56(6):1197-207. doi: 10.1016/s0277-9536(02)00119-3
95. Shiffman J, Okonofua FE. The state of political priority for safe motherhood in Nigeria. *Bjog* 2007;114(2):127-33. doi: 10.1111/j.1471-0528.2006.01184.x
96. Smith SL, Shiffman J, Kazembe A. Generating political priority for newborn survival in three low-income countries. *Glob Public Health* 2014;9(5):538-54. doi: 10.1080/17441692.2014.904918 [published Online First: 2014/04/29]
97. Shiffman J. Generating political priority for maternal mortality reduction in 5 developing countries. *Am J Public Health* 2007;97(5):796-803. doi: 10.2105/ajph.2006.095455 [published Online First: 20070329]
98. Mafwiri MM, Kisenge R, Gilbert CE. A pilot study to evaluate incorporating eye care for children into reproductive and child health services in Dar-es-Salaam, Tanzania: a historical comparison study. *BMC nursing* 2014;13:15. doi: 10.1186/1472-6955-13-15 [published Online First: 2014/06/17]
99. Armstrong Schellenberg JR, Adam T, Mshinda H, et al. Effectiveness and cost of facility-based Integrated Management of Childhood Illness (IMCI) in Tanzania. *Lancet* 2004;364(9445):1583-94. doi: 10.1016/s0140-6736(04)17311-x
100. Adam T, Manzi F, Schellenberg JA, et al. Does the Integrated Management of Childhood Illness cost more than routine care? Results from the United Republic of Tanzania. *Bull World Health Organ* 2005;83(5):369-77. [published Online First: 20050624]
101. Wordl Health Organization. IMCI set of distance learning modules: WHO Geneva, 2014.
102. Muhe LM, Iriya N, Bundala F, et al. Evaluation of distance learning IMCI training program: the case of Tanzania. *BMC Health Serv Res* 2018;18(1):547. doi: 10.1186/s12913-018-3336-y [published Online First: 20180713]

103. World Health Organization. Guidelines for follow-up after training in the WHO: World Health Organization, 1999

Chapter 3 Methodology

This chapter will summarise the methodology for the research in this thesis which comprised three papers with three separate methodologies which address the first three objectives of the thesis.

For my first objective, I conducted a systematic review of the evidence for universal NES, and a scoping review of the relevant guidelines.[1] For my second objective I used a before and after study to examine the impact on the knowledge and skills of PHWs of including eye care during routine training within the IMNCI programme in Tanzania, using both quantitative and qualitative data.[2] This study used questionaries before and after the training intervention which gave total scores for knowledge and skills with both categorical and continuous data analysed with linear regression analysis. Semi -structured interviews were also conducted with PHWs and the qualitative responses analysed thematically to understand the views of the PHWs on the intervention and any challenges. For my third objective I conducted a qualitative health policy analysis using in-depth semi-structured interviews and analysed using the Shiffman and Smith health policy framework.[3] Table 1 in the following page summarises these three papers, methodologies and outcomes.

Table 5: Summary of objectives, methodology and research outcomes

Research objective	Methodology	Research outcomes
To synthesise existing evidence on how universal screening of the eye within 8 weeks of birth improves newborn and infant vision and health outcomes	a) Systematic literature review b) Scoping guideline review	Outcomes of universal eye screening newborns compared to no or targeted screening, and newborn guidelines including; 1. Which eye conditions should be screened for 2. What screening test/method should be used and by whom 3. The optimal postnatal age for screening
To evaluate whether including eye care in the training curriculum of IMNCI in Tanzania for PHWs improves their knowledge and skills in eye care for children and is accessible and acceptable to PHWs	a) Development of eye module to train PHWs b) Training of PHWs by IMNCI Facilitators c) Structured assessments before, after and 6 months after training of PHWs d) Semi structured interviews with PHWs 6 months after training on their views of the training and implementation in routine practice e) Thematic qualitative analysis of interview data	1. Change in PHWs knowledge and skills in eye care for children before and after training 2. PHW views on inclusion eye care into IMNCI and implementation in routine practice
To explore key factors which led to the decision to include eye health in the national IMNCI strategy in Tanzania	a) Semi-structured in-depth interviews b) Iterative qualitative analysis using Shiffman and Smith health policy framework	Key factors, including enablers and barriers, influencing policy decision to include eye care WHO/UNICEF IMNCI programme

Research Paper 1: Systematic review

Research objective: To synthesise existing evidence on how universal screening of the eye within 8 weeks of birth improves newborn and infant vision and health outcomes

Methodology:

A systematic review was used to synthesise the evidence on newborn eye screening as it uses explicit, structured approach to minimize bias, and provide results that are reliable to guide the development of guidelines for delivery of care.[4 5] This systematic review of newborn eye screening was used as part of a process to inform evidence based guidelines for postnatal care.[6] A scoping review was used to assess guidelines already in place for newborn eye screening to map the key concepts that underpin a research area, to identify any gaps in the research knowledge, and report on the types of evidence that inform practice in the field.[7 8]

The full protocol was published on Prospero. The key aspects of the methods undertaken is outlined.

Criteria for considering studies for the literature review

Types of Studies

The types of studies included were:

1. Intervention studies (randomized trials/ cluster randomized trials/ non-randomized trials/before and after/interrupted time-series).
2. Comparative observational studies (cohort/case-control/cross-sectional/ecological studies)
3. Studies of universal screening with no comparator group, if the study has been undertaken in the real world and is feasible to be used for this purpose in real-life settings based on expert judgment
4. Studies to assess diagnostic test accuracy (cross sectional studies)

There were no language, location or date restrictions.

Types of participants

All newborns, within 8 weeks of birth, irrespective of risk factors and/or complications were included, excluding studies which were for screening of retinopathy of prematurity.

Types of interventions

The intervention is universal newborn screening for abnormalities of the eye, using any suitable ophthalmic device which has been used for newborn screening which is feasible to use in a real life setting. The devices can include the following:

1. torch light can be used to assess the eye lids, whether the corneas are clear, whether the pupils of the eyes are round and central, and whether the eyes are of normal and equal size, but cannot check the red reflex
2. direct ophthalmoscope or other suitable devices to elicit the red reflex
3. widefield digital retinal imaging

Table 6: Types of outcome measures

Primary outcomes	1. Proportion of newborns within 8 weeks of birth with clinically significant eye conditions
	2. Age in months at clinical management of eye condition
	3. Outcome of the management of the eye condition in terms of mortality (retinoblastoma) or visual function (eye conditions)
Secondary outcomes	1. Diagnostic test accuracy of the tests/devices which have been used
	2. Adverse effects of eye screening
	3. Cost benefit, cost effectiveness or cost estimates
	4. Uptake of referrals by infants who screen positive

Clinically significant eye conditions were classified as:

1. Conditions likely to be visually impairing which can be treated clinically or with optical correction, such as abnormalities of the eyelid(s) which obscure the pupil;
    a. congenital cataract
    b. congenital glaucoma
    c. retinoblastoma
    d. inflammatory or vascular conditions on the retina
    e. congenital anomalies, abnormally small eyes (microphthalmos)
    f. ptosis (dropping eye lid)
2. Conditions which cannot be treated but where early vision rehabilitation is required;
    a. absent iris (aniridia)
    b. coloboma (uveal defects)
    c. corneal opacities
    d. most optic nerve and retina conditions

Search methods for identification of studies

The Cochrane Eyes and Vision Information Specialist conducted systematic searches of relevant databases, trial registers and grey literature to identify potentially relevant reports for inclusion in the review on 13th April 2020 and were updated on 30 March and 8 September 2021. Conference abstracts were not included for this review.

Data collection and analysis

Selection of studies

Titles and abstracts were reviewed independently by two experts (AM, CG). The findings were reviewed, and conflicts resolved by discussion. The appointed adjudicator was not required. All articles excluded at the final stage were listed with a reason for exclusion. A PRISMA flow chart was constructed to show the results of the search.

Data extraction and management

A standardised form was developed to extract data from the different types of study and to appraise the quality of each included study. This was pilot tested on a small number of studies, adapted and then used for all the studies. Data were extracted independently by the same two experts with expertise in paediatric ophthalmology. Findings were compared and discrepancies resolved by discussion.

Assessing risk of bias of included studies

Risk of bias was planned to be assessed at the study and outcome levels, using modified Joanna Briggs critical appraisal tools (https://joannabriggs.org/ebp/critical_appraisal_tools). The protocol was modified for the primary comparison, and ROBINS-I tool for non-randomised trials of interventions was used by three authors (AM, CG, JE) for studies included in the quantitative analysis.[9]

Data synthesis.

Analysis of primary outcomes

Standard methods for analysis of intervention studies comparing the primary outcomes in intervention and comparator arms using risk ratios and mean differences, with 95% confidence intervals were used. There were no studies similar enough to be suitable for meta-analysis therefore this was not performed. Appropriate measures of effect (e.g., risk ratios, odds ratios), adjusted for confounding as reported by the primary study were used for comparative observational studies. Relevant effect measures (risk ratio with 95% confidence intervals) and sensitivity, specificity and positive predictive value were calculated where necessary using Revman5.4 and Medcalc.[10-12] The outcomes were compared separately for healthy term newborns with sick or sick and preterm. The certainty of the evidence was assessed using the GRADE approach.[13]

Criteria for considering guidelines for the review

Guidelines from global, regional, and national organizations were reviewed to identify:

1. Additional sources of evidence not identified in the literature search, particularly studies in languages other than English
2. Recommendations for newborn eye screening

The guidelines were not reviewed for the quality of evidence or processes used to develop the recommendations. The following data was extracted: organization and country; date; conditions being screened for; tests recommended; age group to be included; who should perform the screening/examination.

Research Paper 2: Quantitative and qualitative analysis of impact of including eye care in the training curriculum of IMNCI in Tanzania for PHWs on their knowledge and skills in eye care for children and its acceptability

Research objective: To evaluate whether including eye care in the training curriculum of IMNCI in Tanzania for primary child health care workers improves their knowledge and skills in eye care for children and is accessible and acceptable

Methodology: A mixed methods before and after study was conducted. The first stage was the with the development of the eye module and the second stage the use of the eye module within a routine IMNCI training programme with data collection before and after the training. A control group was not used due to limitations in resources and as this was conducted as a pilot study to assess whether the newly developed eye module was feasible in the setting within routine IMNCI training. It was expected that the next step would be to conduct an evaluation to assess the impact of training with the eye module.[14] The outcomes were limited to direct knowledge of the PHWs, self-testing of skills and qualitative assessment of PHWs attitude towards training with the eye module in terms of ease of use, level of content, applicability and challenges in routine clinical practice.

Further details of the methods for research paper 2 are given in the publication in chapter 5 therefore the above summary is presented here only.

Research Paper 3: Qualitative Health policy analysis of the global and national influences on integrating eye health in child health policy in Tanzania

Research objective: To explore key factors which led to the decision to include eye health in the national IMNCI strategy in Tanzania.

Methodology: A qualitative health policy analysis using in-depth semi-structured interviews and analysed with the Shiffman and Smith framework was conducted.

Theoretical health policy framework for qualitative policy research

After the development of the eye module and the evaluation of training PHWs in eye care the MoH in Tanzania included the eye module into their national IMNCI training programme. This was ratified at an IMNCI review meeting in May 2018 and subsequently all IMNCI training for PHWs has included eye care. This national health policy is in contrast with the global IMNCI programme, which still does not include eye health.

An understanding of the key factors in the decision making which led to this important policy decision could be used to build on these decisions to lead to more widespread integration of eye care into child health policies and programmes.

The Shiffman and Smith framework was used in this study as it focuses specifically on health.[3] The advantage of this approach is that it allows for a comprehensive and structured analysis of the factors involved in the policy decision in Tanzania. Some elements are likely not to apply to the policy decision but using the framework in this context of national policy setting will allow consideration of factors which may influence other national and global actors and be generalisable to other settings as well as greater comparison with other health policy settings. Other limitations are that there may be other relevant elements which are not in the framework, therefore other elements from the Gill and Walt framework were also included and global level actors were interviewed to provide a global context to the study and the national decision.[15 16] Further limitations of the framework can

include the subjectivity in assessing the relative weight of the different factors and difficulty in controlling for confounding variables. Another advantage of using the framework is that its use will allow comparability of child eye health with many other health issues.[17 18 19] This will allow an understanding of the factors which may have held back child eye health receiving priority and what factors need to be addressed to scale up its integration within the global child health agenda.

Table 4: Adapted Shiffman and Smith framework

ELEMENT	DESCRIPTION	FACTORS SHAPING POLITICAL PRIORITY
ACTOR POWER WITHIN EYE AND CHILD HEALTH COMMUNITY AT NATIONAL AND GLOBAL LEVEL	The strength of the different sets of individuals and organisations concerned with the issue	Policy community cohesion: coalescence among the network and influence of global actors on national level actors Leadership: individuals uniting the policy community and/or champions of the cause Guiding institutions: organisations or co-ordinating mechanisms with a mandate to lead the initiative Civil society mobilisation
IDEAS AND INFLUENCE OF GLOBAL IDEAS ON NATIONAL CONTEXT	The ways in which the eye and child health communities understand and portray ideas	Internal frame: the degree to which the policy community agrees on the definition of, causes of, and solutions to the child eye health External frame: portrayals of issue to resonate with the policy makers
POLITICAL CONTEXTS GLOBAL AND NATIONAL (ADAPTED FROM GILL AND WALT)[15]	The environments in which actors operate	Policy windows: political moments when global or national conditions align favourably presenting opportunities to influence decision makers Global governance structure: institutions providing a platform for effective collective action

		Historical experience Political feasibility: of ideas and solutions Culture Recent shifts and changes in policy: effect of changes in global policy at national level
ISSUE CHARACTERISTICS NATIONAL CONTEXT	Features of the problem	Credible indicators: measures of severity for monitoring progress Severity: size of the burden Effective interventions: availability of cost-effective, backed by scientific evidence, simple to implement, and inexpensive at local level

Semi structured interviews

An initial interview topic guide based on the Shiffman and Smith framework and the research questions was drafted to guide the interviews. Interviews were conducted in person for all those based in Tanzania in a location of the participants choice for their convenience, which included their workplaces, in the office of the co-PI located in Muhimbili University of Health and Allied Sciences (MUHAS), in one case in a cafe or in one other case at a conference location. The in-person interviews were conducted in June 2022 and were led by author AM with co-author MM also present and participating. The interviews conducted by Zoom online were for participants who were in multiple countries globally where in-person interviews were not practically feasible. Consent forms and participant information sheets were sent by email prior to interviews taking place. Some participants returned the forms signed prior to the interview, otherwise oral consent was taken and recorded before the start of the interview. The interviews lasted 45-60 minutes and were audio recorded. The zoom interviews were conducted over a period of 3 months from July to September 2021. All the interviews were conducted by the lead author (AM).

In- depth semi structured interviews were chosen as the method of enquiry to allow for flexibility in exploring concepts and ideas that evolve over the course of the interviews,

while maintaining a comparable structure for each interview. Flexibility in the questions is important as it was anticipated that there would be important topics discussed which were not in the framework and the topic guides would need to be adapted in later interviews to take account of issues raised in earlier interviews.

The interviews were audio recorded and transcribed, detailed notes were taken. The interview data was anonymised to protect confidentiality. Informed consent was taken in writing or verbally before each interview.

Sampling strategy

There were 31 interviews conducted in total with 14 actors based in Tanzania and 17 actors based in different countries globally.

The key actors were identified in several ways: through the authors knowledge of the Tanzania health policy actors, identification from the policy documents in particular the global policy "Survive and Thrive: transforming care for every small and sick newborn" and asking known child health leaders who they believe to be key actors. Actors were deliberately chosen from key organisations such as the Ministry of Health (maternal and child health department, IMNCI lead and eye health leads), international bodies (WHO, UNICEF), national experts in child eye health or IMNCI, all eye NGOs working within Tanzania and the managing editors, first authors and content leads pf the global policy paper were all invited to participate. Five participants suggested by the managing editors and first authors and were also interviewed. A USAID representative based in Tanzania was invited for interview but did not respond. There were no other individuals who declined to be interviewed. There were no repeat interviews.

A summary of the organisations, roles of those interviewed and demographic data is in table 7. To ensure a good representation of views participants chosen were key informants and experts on eye health or child health at national or global level at the relevant roles across the range of all the key organisations.

Table 7: Key actors interviewed

Key actor category	Institution/ department/role	Gender	Current base country
Ministry of Health officials (3)	• Maternal and Child Health • Eye Health	• M=2 • F=1	• Tanzania
International bodies (8)	• WHO • UNICEF	• F=5 • M=3	• Tanzania (2) • US (4) • Switzerland (2)
Academia/ Technical experts (11)	• Ophthalmologists • Paediatrician • IMNCI national facilitators • Universities/academics	• F=9 • M=2	• Tanzania (5) • USA, Canada, Australia (3) • UK (3)
NGO national representatives (7)	• Five international NGOs	• F=6 • M=1	• Tanzania (4) • US (3)
Key funding agencies (2)	• USAID • Gates Foundation	• F=2 • M=0	• US =2

Data analysis

A data extraction template was designed, based on the adapted Shiffman and Smith framework. This template was adapted as required during the interview process, but the initial codes were based on the framework determinants. Each participants data was summarised according to these initial codes/framework elements "working down" to form a coding matrix with the adapted framework determinants used to form the second level sub codes. Data was analysed iteratively. As interviews progressed earlier interview transcripts and notes were reviewed and were reflected in an adapted topic guide with new questions to test emerging themes. New data was then compared with the codes and categories and developing themes tested. Participant feedback on themes was used during the interviews with key ideas being tested/discussed. This process was continuous throughout the

interviews. At the end of the interviews the main themes were defined and refined using all the interview data and then tested using multiple sources for example, different interest groups (Ministry of Health officials, funders, health professionals) were compared and written sources (minutes of meetings). Any contrasts and 'outliers' were actively sought out and reviewed. Policy literature, in particular those studies using the Shiffman and Smith framework were reviewed and ideas compared and contrasted. The analysis was done in Microsoft Word and the lead author conducted all the coding. The Consolidated Criteria for Reporting Qualitative Research (COREQ) has been used to ensure comprehensive reporting.[20]

Language considerations

There was a Swahili translator available (co-PI) but all the interviews were conducted in English as preferred by key actors. It had been planned that for any interviews not in English they would be transcribed verbatim in the language of the interview and then back translated into English.

Reliability and Validity using COREQ checklist[20]

Domain 1: Research team and Reflexivity

Both the PI (AM) and co-PI (MM) are paediatric ophthalmologists and researchers in Tanzanian child eye health. They were both involved in a pilot study to test an eye module for inclusion in the IMNCI programme in Tanzania which was then included by the Ministry of Health and led to the national policy change to include eye health in the IMNCI training programme therefore they were both key actors themselves in the Tanzanian IMNCI policy making process. This has important effects on the data collection, analysis, and results. The characteristics of the researchers are such that they had close knowledge of many of the events and participants and hence there is a risk of personal bias and assumptions of the topic. However, the advantage was the knowledge of the context of the history of the topic which adds a depth to the analysis. Some study participants were known to the researchers and those which were not were aware of their credentials and experience. It is highly likely

the data collected was influenced by the participants knowing the authors/interviewers, including not stating certain information which was commonly known and also being more positive (and not divulging anything negative) towards the interviewers and the organisations they represented (LSHTM and MUHAS), which is important as both individuals and the institutions they represented were key within Tanzanian IMNCI policy making and there is a risk their role would be overstated by the participants.

For the interviews with global actors the lead author (AM) conducted all the interviews. All except one participant were not known to the author. The authors used contacts known to her who also may know the participants to obtain contact details and introductions which would have influenced the participants perceptions. The participants were all aware of the authors credentials and experience in child eye health and this could have skewed their telling of information to give greater importance to eye health than they would have in usual practice or to another interviewer.

Overall, the lead authors personal interest and expertise in the topic of child eye health would influence how the data was collected, analysed and presented. Personal knowledge would have a greater role on data collection and analysis would be influenced by personal interest on how the data could be used for advocacy for greater inclusion of eye health in child health policies and programmes in the future. There may be areas where there is greater depth of analysis due to personal knowledge of the topic and people involved but also miss key questions and analysis which a more 'impartial' researcher would have noted.

Domain 2: Study design

Shiffman and Smith framework was used for reasons already stated, as it allowed for greater structure and comparability with other studies.

Purposive and snowball sampling is an efficient way to reach data saturation as those participants which best fit the aims of the research are chosen. A disadvantage of the sampling is that it is more prone to researcher bias and making subjective assumptions, but

this is limited in this study where there are clear definitions of actors by their direct involvement in the policy making process.

In this study the actors in Tanzania were interviewed face to face compared to the global actors which were interviewed online. There is a difference in the level of rapport and people's interactions in face to face versus online interactions. However, for most global actors online meetings are the norm therefore would be unlikely to cause meaningful differences between meeting them face to face. The content of the interviews can also be important in this context, and this may have been more challenging with more sensitive or controversial subjects for actors, which was not the case in this research study.

Reviewing of interview transcripts by participants is often used in qualitative research is the process where interviewees are provided with verbatim transcripts of their interviews for the purposes of verifying accuracy, correcting errors, and providing clarifications. The advantages of having transcripts reviewed is that it allows interviewees the opportunity to edit or clarify information provided in the original interview and in some cases, adding new material to their transcripts. There are also potential disadvantages, such as a bias created by the loss of data when an interviewee chooses to remove information. Therefore there can be both positive and negative effects and in one study the process added little to the accuracy of the transcript.[21] Transcripts were not returned in this study to participants for comments for a number of reasons. All the actors were professionals discussing their perceptions, opinions and recollection of certain events and it was anticipated that there would be few, if any changes in these circumstances. They were all offered the opportunity verbally in the interview to contact the author by email after the interview if there was anything they wanted to add/change to what they had said in the interview, but no participant did this. There was also a risk with asking the participants to review the transcripts that many/most would not have time to do this or consider it a priority therefore it would not be done or only a small number would review, and this could also be a potential source of bias if it was not done consistently by all the participants.

Domain 3: analysis and findings

The author was the only data coder and identified the themes and conducted all the analysis. There is a risk of bias using only one coder and there was number of methods used to minimise this bias. The author checked emerging themes from early interviews with actors in later interviews. There was some triangulation of data as policy documents and minutes from stakeholder meeting were reviewed, but there were not many documents, and this added a limited amount to the analysis. Direct quotations were used of different categories of actors to add transparency to the findings and interpretations. The use of the adapted Shiffman and Smith framework allowed for a comprehensive, transparent approach to data presentation and analysis. The themes and analysis were compared with similar literature on health policy analysis to review for consistency or any contrasting themes.

Ethical Approval

There was no ethical approval required for the systematic review.

Ethical approval for research study two was obtained from LSHTM on 3rd October 2017 (LSHTM Ethics Ref: 13484), Muhimbili University of Health and Allied Sciences on 23rd November 2017 (MUHAS) and National Institute for Medical Research (NIMR) Tanzania on 6th November 2017.

Ethical approval for research study three was obtained from London School of Hygiene and Tropical Medicine (LSHTM) on 5th March 2021, Muhimbili University of Health and Allied Sciences on 21st of October 2021 (MUHAS) and National Institute for Medical Research (NIMR) Tanzania on 17th March 2022.

Information sheets and consent forms were sent to potential participants by email before the interviews. Some participants returned the signed forms prior to the interview, otherwise written or oral consent was taken and recorded before the interview started. Confidentiality was maintained by using unique codes for each participant to store recordings and transcripts, and only key roles have been used for direct quotes. All data are stored on a secure server (LSHTM) with access only by AM. After the study has been published, all data will be held in LSHTM's secure server and audio recordings destroyed.

References

1. Malik AN, Evans JR, Gupta S, et al. Universal newborn eye screening: a systematic review of the literature and review of international guidelines. *J Glob Health* 2022;12:12003. doi: 10.7189/jogh.12.12003 [published Online First: 2022/10/22]
2. Malik ANJ, Mafwiri M, Gilbert C, et al. Integrating eye health training into the primary child healthcare programme in Tanzania: a pre-training and post-training study. *BMJ Paediatrics Open* 2020;4(1):e000629. doi: 10.1136/bmjpo-2019-000629
3. Shiffman J, Smith S. Generation of political priority for global health initiatives: a framework and case study of maternal mortality. *Lancet (London, England)* 2007;370(9595):1370-9. doi: 10.1016/s0140-6736(07)61579-7 [published Online First: 2007/10/16]
4. Lund H, Brunnhuber K, Juhl C, et al. Towards evidence based research. *Bmj* 2016;355:i5440. doi: 10.1136/bmj.i5440 [published Online First: 20161021]
5. Moher D, Glasziou P, Chalmers I, et al. Increasing value and reducing waste in biomedical research: who's listening? *Lancet* 2016;387(10027):1573-86. doi: 10.1016/s0140-6736(15)00307-4 [published Online First: 20150927]
6. Geneva WHO. WHO recommendations on maternal and newborn care for a positive postnatal experience. 2022;https://www.who.int/publications/i/item/9789240045989
7. Arksey H, O'Malley L. Scoping studies: towards a methodological framework. *International journal of social research methodology* 2005;8(1):19-32.
8. Peters MD, Godfrey CM, Khalil H, et al. Guidance for conducting systematic scoping reviews. *JBI Evidence Implementation* 2015;13(3):141-46.
9. Sterne JA, Hernán MA, Reeves BC, et al. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions. *Bmj* 2016;355:i4919. doi: 10.1136/bmj.i4919 [published Online First: 20161012]
10. Cochrane Training [Available from: https://training.cochrane.org/online-learning/core-software-cochrane-reviews/revman/revman-5-download.
11. MedCalc. Comparison of proportions [Available from: https://www.medcalc.org/calc/comparison_of_proportions.php.

12. MedCalc Diagnostic test accuracy [Available from: https://www.medcalc.org/calc/diagnostic_test.php
13. The GRADE working group [Available from: https://www.gradeworkinggroup.org/
14. Habicht JP, Victora CG, Vaughan JP. Evaluation designs for adequacy, plausibility and probability of public health programme performance and impact. *International Journal of Epidemiology* 1999;28(1):10-18. doi: 10.1093/ije/28.1.10
15. Walt G, Gilson L. Reforming the health sector in developing countries: the central role of policy analysis. *Health Policy Plan* 1994;9(4):353-70. doi: 10.1093/heapol/9.4.353 [published Online First: 1994/11/04]
16. Walt G, Gilson L. Can frameworks inform knowledge about health policy processes? Reviewing health policy papers on agenda setting and testing them against a specific priority-setting framework. *Health Policy and Planning* 2014;29(suppl_3):iii6-iii22. doi: 10.1093/heapol/czu081
17. Shiffman J. Issue attention in global health: the case of newborn survival. *Lancet* 2010;375(9730):2045-9. doi: 10.1016/s0140-6736(10)60710-6 [published Online First: 2010/06/24]
18. Shawar YR, Shiffman J, Spiegel DA. Generation of political priority for global surgery: a qualitative policy analysis. *Lancet Glob Health* 2015;3(8):e487-e95. doi: 10.1016/s2214-109x(15)00098-4 [published Online First: 2015/07/19]
19. Tomlinson M, Lund C. Why does mental health not get the attention it deserves? An application of the Shiffman and Smith framework. *PLoS Med* 2012;9(2):e1001178. doi: 10.1371/journal.pmed.1001178 [published Online First: 20120228]
20. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care* 2007;19(6):349-57. doi: 10.1093/intqhc/mzm042
21. Hagens V, Dobrow MJ, Chafe R. Interviewee Transcript Review: assessing the impact on qualitative research. *BMC Medical Research Methodology* 2009;9(1):47. doi: 10.1186/1471-2288-9-47

CHAPTER 4 Results

Research Paper 1 (Publication): Universal newborn eye screening: a systematic review of the literature and review of international guidelines

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

T: +44 (0)20 7299 4646
F: +44 (0)20 7299 4656
www.lshtm.ac.uk

RESEARCH PAPER COVER SHEET

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

SECTION A – Student Details

Student ID Number	085114	**Title**	Dr
First Name(s)	Aeesha NJ		
Surname/Family Name	Malik		
Thesis Title	Integrating primary eye care into child health policies and programmes: A case study from Tanzania		
Primary Supervisor	Prof Joanna Schellenberg		

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?	Journal of Global Health		
When was the work published?	Nov 2022		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	n/a		
Have you retained the copyright for the work?*	Choose an item.	Was the work subject to academic peer review?	**Yes**

*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?	
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)	I reviewed the studies for eligibility independantly then compared with my co-author. Any studies where there was disagreement between the co-author and I was discussed before a final joint decicion on inclusion or exclusion was reached. I extracted data from the studies and analysed and interpreted data, which was compared and discussed with my co-authors. I wrote the first draft of the manuscript which was reviewed by all the co-authors before submission.

SECTION E

Student Signature	
Date	21/2/23

Supervisor Signature	
Date	23/02/23

Electronic supplementary material:
The online version of this article contains supplementary material.

journal of global health

© 2022 The Author(s)
JoGH © 2022 ISoGH

Cite as: Malik ANJ, Evans JR, Gupta S, Mariotti S, Gordon I, Bowman R, Gilbert C. Universal newborn eye screening: a systematic review of the literature and review of international guidelines. J Glob Health 2022;12:12003.

Universal newborn eye screening: a systematic review of the literature and review of international guidelines

Aeesha NJ Malik[1],
Jennifer R Evans[1,2]
Shuchita Gupta[3],
Silvio Mariotti[4],
Iris Gordon[1,2],
Richard Bowman[1],
Clare Gilbert[1]

[1]Department of Clinical Research, London School of Hygiene and Tropical Medicine, London, UK
[2]Cochrane Eyes and Vision, Centre for Public Health, Queen's University Belfast, Belfast, UK
[3]Department of Maternal, Newborn, Child and Adolescent Health (MCA), World Health Organization, Geneva, Switzerland
[4]Department of Noncommunicable Diseases, Eye and Vision Care, World Health Organization, Geneva, Switzerland

Background This systematic review assessed the effectiveness of universal screening for newborn eye abnormalities compared with no screening in improving infant vision and health outcomes.

Methods We searched CENTRAL (Cochrane Library), MEDLINE, Embase, Global Health, Global Index Medicus, clinical trials databases, and bibliographies of relevant articles. We included randomized and observational studies of all newborns, regardless of illness or risk factors, that compared universal screening for any eye abnormality by eight weeks of age with no universal screening. Two authors independently selected studies, extracted data, and evaluated the risk of bias. We used GRADE to assess the certainty of evidence. We also reviewed available recommendations on newborn eye screening.

Results Fourteen studies were identified but only three compared universal red reflex screening with no screening. Findings suggest that universal red reflex testing in maternity wards (MWs) may increase the number of newborns with congenital cataracts referred for eye care from MWs or well-baby clinics (WBCs) in the first year of life (risk ratio (RR) = 9.83, 95% confidence interval (CI) = 1.36-71.20; low certainty evidence). However, the effect of screening in WBC is uncertain (RR = 6.62, 95% CI = 0.87-50.09). The effect of MW or WBC screening on referral from any health care facility (MWs, WBCs, paediatrician clinic, other) in the first year is uncertain (MW screening: RR = 1.22, 95% CI = 0.63-2.39; WBC screening: RR = 0.97, 95% CI = 0.46-2.05). However, referral or surgery by 6 weeks of age may be higher with universal MW screening (early referral: RR = 4.61, 95% CI = 1.12-19.01; early surgery: RR = 8.23, 95% CI = 1.13-59.80; low certainty evidence). The effect of WBC screening on early referral and surgery is uncertain (early referral: RR = 1.98, 95% CI = 0.43-9.19; early surgery: RR = 3.97, 95% CI = 0.50-31.33; very low certainty evidence). Universal red reflex testing may increase clinical conjunctivitis (OR = 1.22, 95% CI = 1.01-1.47; low certainty evidence) but the effect on confirmed bacterial conjunctivitis is uncertain (OR = 1.20, 95% CI = 0.76-1.90; very low-certainty evidence). Nine guidelines recommended universal newborn eye screening using red reflex testing.

Conclusions Evidence supports the role of red reflex testing shortly after birth to increase early identification, referral, and surgery for congenital cataracts.

Registration PROSPERO (reference CRD42020180524).

Correspondence to:
Aeesha NJ Malik
International Centre of Eye Health
Department of Clinical Research
London School of Hygiene & Tropical Medicine
Keppel Street
London WC1V 7HT
aeesha.malik@lshtm.ac.uk

In 2020, 1.44 million children aged 0-14 years were estimated to be blind or severely visually impaired [1]. Most blind children are either born blind from congenital conditions or become blind before the age of 5 years from acquired conditions [2,3].

The birth prevalence of eye anomalies in 21 European countries was 36.2 (95% CI = 34.6-37.9) per 100 000 births between 2011 and 2017. A third had congenital cataract [4]. The birth prevalence in low- and middle-income countries is likely to be higher due to a higher incidence of intrauterine infections, and consanguinity which increases the incidence of autosomal recessive conditions, such as cataract and glaucoma [5-7].

Treatable conditions which are potentially visually impairing, or which threaten life, need to be detected and managed early, as this gives better functional and survival outcomes. In high-income countries, surgery for dense bilateral congenital cataracts is usually performed 6-7 weeks after birth, as earlier surgery is associated with serious complications [8], and later surgery increases the risk of amblyopia [8,9]. In retinoblastoma, small lesions, if detected early, can be managed effectively, which preserves sight and improves survival [10-12]. In low and middle-income countries, mortality rates from retinoblastoma are far higher than in high-income countries, largely due to late presentation [13].

Newborn eye screening (NES) relies on examining the eyes and eliciting clinical signs. Methods include a torchlight examination of the external structures, and red reflex testing or wide-field digital imaging for internal structures. Red reflex testing, also called fundal reflex testing, refers to the reddish glow elicited within the pupil by light reflected from the retina when a light is shone directly into the eyes. Red reflex testing requires a handheld device, commonly a direct ophthalmoscope, and can be performed by anyone trained to deliver the test [14]. Wide-field imaging provides a view of all the intraocular structures but currently requires very expensive equipment which has limited availability. Assessment of visual acuity (ie, the ability to recognise small objects) is not possible in newborns.

In high-income countries, universal newborn eye screening (UNES) is the standard of care. However, in resource-constrained settings, UNES is often not included in newborn and child health policies or practiced routinely for all term healthy newborns. We conducted this systematic review to assess the evidence for the effectiveness of UNES to inform evidence-based guidelines for high, middle, and low-income countries. The primary objective was to assess the effect of UNES compared with no universal screening on newborn and infant vision and health outcomes. We also conducted a review of global, regional, and national guidelines to identify recommendations on UNES.

METHODS

Eligibility criteria

We included intervention studies and comparative observational studies (cohort/case-control/cross-sectional) if there was not adequate evidence from intervention studies. We included studies comparing universal screening for all newborns, irrespective of risk factors and complications compared to no universal screening. Studies enrolling only preterm infants were excluded. The intervention was defined as UNES within eight weeks of birth and the comparator was no UNES. The screening could be performed using any suitable ophthalmic device, ie, a torchlight to examine the eyelids and external eye, direct ophthalmoscope or other devices to elicit the red reflex, digital retinal imaging, and any other tests or devices which may be used for UNES in real-life settings. Studies in which screening was performed after eight weeks of age were excluded. We included studies from all country-income settings, conducted in health facilities or at home.

Outcomes

The primary outcomes were the proportion of newborns identified with clinically significant eye conditions (see below) and referred or treated by eight weeks of age, age in months at referral, and outcomes of the clinical management of the eye condition in terms of health (eg, mortality) and ocular outcomes (eg, visual acuity) The secondary outcomes were adverse effects of eye screening, diagnostic test accuracy, and cost-benefit, cost-effectiveness, or cost estimates.

Clinically significant eye conditions were classified as, 1. conditions likely to be visually impairing which can be treated clinically or with optical correction, such as abnormalities of the eyelid(s) which obscure the pupil (eg, drooping eyelids (ptosis); congenital cataract; congenital glaucoma; retinoblastoma; inflammatory or vascular conditions on the retina; congenital anomalies, abnormally small eyes (microphthalmos) [15] and 2. conditions which cannot be treated but where early vision rehabilitation is required, such as absent iris (aniridia), coloboma (uveal defects), corneal opacities and most optic nerve and retina conditions (Table S1 in the **Online Supplementary Document**).

Search strategy

An information scientist (IG) with experience in systematic reviews of eye conditions compiled the search terms with input from three of the study team who are paediatric ophthalmologists (AM/CG/RB). The electronic resources searched and the MEDLINE search strategy are provided in Appendix S1 and Appendix S2 in the **Online Supplementary Document**. Searches were conducted on April 13, 2020 and were updated on March 30 and September 8, 2021. No restrictions by language or publication year were applied. Conference abstracts were not searched. The MEDLINE search strategy was adapted to search the other resources listed (the Cochrane Library, Embase Ovid, Global Health Ovid, and Global Index Medicus).

Separate searches were not undertaken for the secondary outcomes of diagnostic test accuracy, cost-effectiveness, cost-benefit, or costing. These outcomes were documented in this review if they were reported in included studies or were identified in the search.

Selection of studies

Two experts independently reviewed the titles and abstracts for eligibility and full texts of all potentially relevant articles were reviewed independently for inclusion (AM, CG). Discrepancies at any stage were resolved through discussion. Articles in languages other than English were either sent to a bilingual ophthalmologist, with a list of questions to ascertain whether they fulfilled the inclusion criteria, and one was translated using Google translate. Articles excluded at this stage were listed giving a reason for exclusion (Appendix S3 in the **Online Supplementary Document**).

Data extraction

Data were extracted independently by two review authors (AM, CG) using a pre-piloted form. Findings were compared and discrepancies were resolved by discussion. The data extracted are detailed in Appendix S4 in the **Online Supplementary Document**. Authors of included studies were contacted, when necessary, for clarification or to provide additional data.

Risk of bias assessment

Risk of bias assessment was undertaken independently by three authors (JE, CG, AM) using the ROBINS-I tool for non-randomized trials of interventions for studies included in the quantitative analysis [16] Any discrepancies were resolved by discussion.

Analysis

Data from comparative studies were presented using appropriate measures of effect, where possible (eg, risk ratios, odds ratios). Adjusted estimates were used for observational studies when reported by the included studies. Relevant effect measures (risk ratio with 95% CI) and sensitivity, specificity, and positive predictive values (with 95% CI) were calculated using Revman 5.4 [17] and Medcalc [18,19]. We planned to undertake a meta-analysis if the heterogeneity in study designs, interventions, and outcomes allowed. The certainty of the evidence was assessed using the GRADE approach [20].

Review of guidelines

Databases of guidelines and websites were searched for NES guidelines (Appendix S1 in the **Online Supplementary Document**). The criteria for selection were any newborn, child health, or eye health guidelines that referred to NES. The target population, setting, and interventions were the same as for the systematic literature review.

RESULTS

We identified 14 studies on UNES involving 1 018 467 infants (Table S2a, Table S2b and Table S3 in the **Online Supplementary Document**). Only three of these studies compared UNES to no screening. Two of these three studies addressed the primary outcomes [21,22], and one addressed secondary outcomes [23] and were included in the quantitative analysis. (**Figure 1**, Table S3 in the **Online Supplementary Document**).

Of the remaining 11 studies, one study was a diagnostic test accuracy study [24], while the rest (10 studies) were descriptive, and did not have a comparator group. These studies described the proportion and type of

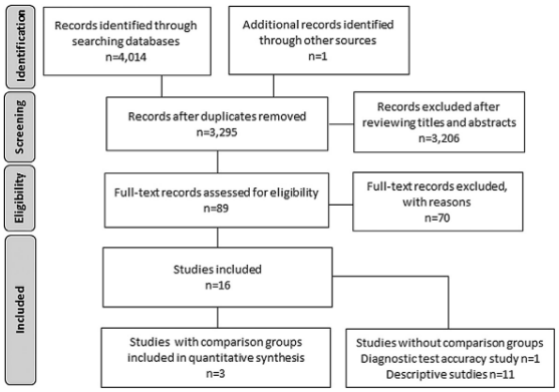


Figure 1. PRISMA flow diagram.

eye conditions identified by NES. We have summarized the results from these studies in Table S4a and Table S4b in the **Online Supplementary Document**. All the studies were undertaken in high-income or upper-middle-income settings.

All the three studies included in the quantitative analysis were undertaken in high-income countries (two in Sweden [21,22] and one in Israel [23]. The risk of bias assessments is summarized in Appendix S5 in the **Online Supplementary Document**.

Primary outcomes

None of the included studies reported visual acuity outcomes or neonatal/infant mortality or neurodevelopment outcomes.

Two included studies from Sweden, that compared UNES with no screening, reported the proportion of infants referred or treated by eight weeks of age [21,22]. The first study compared two regions (Region 1 and Region 2) where UNES using red reflex testing was undertaken in different locations (maternity wards or well-baby clinics) with another region (Region 3) where there was no UNES. The study period was from 1992 to 1998. The population covered by the three regions included an estimated 396 000 newborns. Region 1 established universal red reflex testing with an external eye examination in the maternity ward during the first few days after birth. Region 2 used the same screening test performed in well-baby clinics at around 6 weeks of age while Region 3 did not have UNES. The second study added national data from 2007 to 2009 to the first study, when UNES was a routine procedure in 90% of maternity wards (estimated total population 328 523 newborns). No details are provided on who performed the screening.

Both studies compared UNES using red reflex testing with no screening. Both were facility-based, retrospective cohort studies. Data on the outcomes were extracted by the study authors from a Scandinavian register (PECARE) of children operated for unilateral or bilateral cataract by 8 years of age in Scandinavian countries. The data were limited to children who had cataract surgery during the first year of life in Sweden, after excluding children with traumatic cataract.

The studies reported the proportion of newborns referred or operated on by six weeks of age. The babies could be referred from maternity wards, well-baby clinics, or any other facility (eg, paediatric clinic). The studies reported data separately for babies screened in maternity wards, well-baby clinics, or who were referred from any location (maternity wards, well-baby clinics, or any other facility) in the first year of life and during the first six weeks after birth. A more detailed breakdown of the data was provided by the author (Gunilla Magnusson; personal communication). Both studies were considered to be at serious risk of bias (Appendix S5 in the **Online Supplementary Document**).

The data suggest that UNES using red reflex testing in maternity wards may increase the proportion of newborns referred with congenital cataract from maternity wards or well-baby clinics in their first year compared with no screening (one study, 394 438 infants; RR = 9.83, 95% CI = 1.36-71.20; low certainty evidence), but the effect of well-baby clinic screening on this outcome is uncertain (one study, 215 347 infants, RR = 6.62, 95% CI = 0.87-50.09; very low certainty evidence) (**Table 1**).

It is uncertain whether UNES using red reflex in maternity wards or the well-baby clinics has an effect on the proportion of newborns with congenital cataract referred from any health facility (maternity ward, well-baby clinic, by a paediatrician, or other) in the first year compared with no screening (one study, 394 438 infants; RR = 1.22, 95% CI = 0.63-2.39 for maternity ward screening and RR = 0.97, 95% CI = 0.46-2.05 for well-baby clinic screening; very low certainty evidence).

UNES using red reflex in maternity wards may increase the proportion of newborns with congenital cataract referred early, ie, by 6 weeks of age from any health care facility compared with no screening (one study, 394 438 infants; RR = 4.61, 95% CI = 1.12-19.01), but the effect of universal screening in well-baby clinics on this outcome is uncertain (one study, 215 347 infants, RR = 1.98, 95% CI = 0.43-9.19; very low certainty evidence) (**Table 1**).

Table 1. Summary of findings table for universal newborn screening vs no screening: proportion of newborns with congenital cataract referred within the first year of life (outcome a and b), and referred and operated by six weeks of age (outcome c and d) [21,22]

	Studies (participants)	Event n/N		Effect (95% CI)		Certainty of evidence (GRADE)
		Universal screening	No universal screening (Region 3, 1992-98)	Relative risk	Absolute risk, per 1000 neonates	
Outcome A) newborns with congenital cataract referred from maternity wards or well-baby clinics by the age of one year						
Maternity ward screening (national data; 2007-09)*	1 (n = 394 438)	49/328 523	1/65 915	9.83 (1.36-71.20)	0 fewer per 1000 (from 0 fewer to 1 more)	Low†
Well-baby clinic screening (Region 2; 1992-98)	1 (n = 215 347)	15/149 432	1/65 915	6.62 (0.87-50.09)	0 fewer per 1000 (from 0 fewer to 1 more)	Very low‡
Outcome B) newborn with congenital cataract referred from any health care facility* by the age of one year						
Maternity ward screening* (national data; 2007-09)	1 (n = 394 438)	61/328 523	10/65 915	1.22 (0.63-2.39)	0 fewer per 1000 (from 0 fewer to 0 fewer)	Very low§
Well-baby clinic screening (Region 2; 1992-98)	1 (n = 215 347)	22/149 432	10/65 915	0.97 (0.46-2.05)	0 fewer per 1000 (from 0 fewer to 0 fewer	Very low§
Outcome C) newborns with congenital cataract referred by 6 weeks of age from any health care facility*						
Maternity ward screening* (national data; 2007-09)	1 (n = 394 438)	46/328 523	2/65 915	4.61 (1.12-19.01)	0 fewer per 1000 (from 0 fewer to 1 more)	Low†
Well-baby clinic screening (Region 2; 1992-98)	1 (n = 215 347)	9/149 432	2/65 915	1.98 (0.43-9.19)	0 fewer per 1000 (from 0 fewer to 0 fewer)	Very low‡
Outcome D) newborn with congenital cataract operated by 6 weeks of age referred from any health care facility*						
Maternity ward screening* (National data; 2007-09)	1 (n = 394 438)	41/328 523	1/65 915	8.23 (1.13-59.80)	0 fewer per 1000 (from 0 fewer to 1 more)	Low†
Well-baby clinic screening (Region 2; 1992-98)	1 (n = 215 347)	9/149 432	1/65 915	3.97 (0.50-31.33)	0 fewer per 1000 (from 0 fewer to 0 fewer)	Very low‡

CI – confidence interval
*Maternity ward, well-baby clinics, paediatrician clinic, or other.
†Downgraded by two levels due to very serious risk of bias.
‡Downgraded by more than three levels due to very serious risk of bias and very serious imprecision.
§Downgraded by three levels due to very serious risk of bias and serious imprecision..

UNES using red reflex testing in maternity wards may increase the proportion of newborns with congenital cataract referred from any health care facility who are operated early, ie, by 6 weeks of age, compared with no screening (one study, 394 438 infants; RR = 8.23, 95% CI = 1.13-59.80; low certainty evidence). It is uncertain whether universal screening in well-baby clinics has any effect on the proportion of newborns with congenital cataract operated by 6 weeks of age compared with no screening (one study, 215 347 infants, RR = 3.97, 95% CI = 0.50-31.33; very low-certainty evidence).

Secondary outcomes

Adverse effects

One hospital-based, before-and-after study in a maternity unit in Israel, reported adverse events associated with UNES using red reflex testing [23] The study evaluated whether introducing red reflex testing of newborns by a physician increased the proportion of newborns with clinical conjunctivitis and with microbiologically confirmed bacterial conjunctivitis. Pre-intervention data (2008/2009) were compared with data post-intervention data (2010/2011) among a total of 18 872 newborns. This study was judged to be at serious risk of bias due to confounding (Appendix S5 in the **Online Supplementary Document**).

Universal screening using red reflex testing may increase the occurrence of clinical conjunctivitis compared with no screening (OR = 1.22, 95% CI = 1.01-1.47; low certainty evidence), but the effect on confirmed bacterial conjunctivitis is uncertain (OR = 1.20, 95% CI = 0.76-1.90; very low-certainty evidence) (**Table 2**).

Table 2. Universal red reflex screening vs no screening: adverse effects [23]

Neonatal outcomes	Studies (neonates)	Effect: odds ratio (95% CI)	Effect: Absolute risk, per 1000 neonates (95% CI)	Certainty of evidence (GRADE)
Clinical conjunctivitis	1 (n = 18 870)	1.220 (1.01-1.47)	5 more per 1000 (from 0 fewer to 10 more)	Low*
Confirmed bacterial conjunctivitis	1 (n = 18 870)	1.20 (0.76-1.90)	1 more per 1000 (from 1 fewer to 3 more)	Very low†

CI – confidence interval
*Downgraded by two levels due to very serious risk of bias.
†Downgraded by three levels due to very serious risk of bias and serious imprecision.

Diagnostic test accuracy

One study in China of 7641 consecutive, healthy, full-term newborns in a large maternity unit assessed diagnostic test accuracy (DTA) of red reflex testing with an external examination of the eye using torchlight 2-4 days after birth [24] The gold standard was dilated anterior and posterior segment wide-field imaging, which was performed immediately after red reflex testing. Those with undiagnosed ocular abnormalities subsequently underwent indirect ophthalmoscopy and ultrasound. All procedures were conducted by a paediatric ophthalmologist. Data were extracted on clinically significant eye conditions only by the review authors for analysis. This study was considered to be at high risk of bias as the same examiner performed both tests which were undertaken sequentially.

For all clinically significant eye conditions the sensitivity of red reflex testing was 3.5% (0.4%-12.1%) with a specificity of 96.0% (95.6%-96.5%) and a positive predictive value of 0.7% (0.2%-2.6%). The sensitivity was 66.7% (9.4%-99.2%) for anterior segment conditions only, and 0% for posterior segment conditions only.

Review of recommendations

Eight national publications were identified which recommend UNES (Appendix S6 in the **Online Supplementary Document**, **Table 3**). Four were published by professional associations (in Canada, the United States of America (3 documents)), and four were produced by Ministries of Health or government bodies (in Canada, United Kingdom, India, and New Zealand). All the recommendations were based on expert consensus and used limited direct evidence. We also identified a training manual from the World Health Organization's European Office, which included NES as part of the newborn assessment in the Integrated Management of Childhood Illness. A relevant policy document could not be identified.

Table 3. Recommendations for newborn eye screening in guidelines / preferred practice recommendations

Organization, country, title	Year/ income	Age at screening	Screening test	Person conducting screening/location of screening
American Academy of Ophthalmology. Vision Screening for Infants and Children. A joint statement of the American Association for Pediatric Ophthalmology and Strabismus, and the American Academy of Ophthalmology.	2013/ High	Newborn	• RRT • "General eye health"	• Ophthalmologist, pediatrician, family doctor, trained health professional • "Newborn nursery"
American Academy of Ophthalmology. Paediatric Eye Evaluations Preferred Practice Pattern	2017/ High	Newborn-6 mo	• RRT with ophthalmoscope • External eye examination • Pupil examination	• Trained physicians, nurses, others • Primary care/community health professional
American Academy of Pediatricians. Policy document with American Academy of Ophthalmology/American Association for Pediatric Ophthalmology and American Association of Orthoptists Red reflex examination in neonates, infants, and children.	2016/ High	Newborn-6 mo	• RRT • External eye examination • History	• Paediatricians
Public Health England. Newborn and infant physical examination (NIPE) screening programme handbook. Updated 27 August 2019.	2016/ 2019/ High	Newborn (within 72 h) and 6-8 weeks	• RRT with ophthalmoscope • External eye examination • History	• Paediatric doctor, family doctor • Maternity unit, well-child visit
Joint Clinical Practice Guideline Expert Committee of the Canadian Association of Optometrists and the Canadian Ophthalmological Society. Evidence-based clinical practice guidelines for the periodic eye examination in children aged 0-5 y in Canada.	2019/ High	Newborn - 3 mo	• RRT with ophthalmoscope • External eye examination	• Primary care provider/non ophthalmological personnel • Well baby visit
Government of Canada, First Nations and Inuit Health Branch. Clinical Practice Guidelines for Nurses in Primary Care, Chapter 8: Pediatric and Adolescent Care – Eyes.	2010/ High	Newborn - 3 mo	• RRT with ophthalmoscope • External eye examination • Corneal reflex for strabismus	• Nurses • Primary care
Ministry of Health, New Zealand. Well Child / Tamariki Ora Programme Practitioner Handbook: Supporting families and whānau to promote their child's health and development. Revised 2014.	2014/ High	Newborn - 7 d	• RRT with ophthalmoscope • External eye examination	• "Practitioner trained to use a direct ophthalmoscope"
Ministry of Health and Family Welfare, Government of India, Rashtriya Bal Swasthya Karyakram. Guidelines for universal eye screening in newborns including retinopathy of prematurity.	2017/ Lower middle	Newborn - 48-72 h	• RRT with ophthalmoscope • External eye examination • White reflex with torch • History	• Medical officers, pediatricians, nurses • Place of delivery/neonatal units
World Health Organization, Office for Europe. Effective Perinatal Care (EPC) Training Package. 2nd edition [25]	2015/ Most high	Newborn, day 3, 7-14, week 6	• RRT with ophthalmoscope • External eye examination	• Doctors, nurses, midwives

RRT - red reflex test

All documents recommended red reflex testing and external eye examination, with four also recommending taking a history. One also recommended a torch examination to elicit a white reflex (eg, for dense cataract). All the guidelines recommended testing shortly after birth, and the age range varied from within days of birth to 6 months, but most (78%) recommended before three months of age. A wide range of personnel was recommended to carry out the examination, including ophthalmologists, paediatricians, family doctors, primary care providers, nurses, and midwives. The location of screening, where specified, was at the place of birth or in a primary care setting. All guidelines, apart from the training curriculum, recommended referral for infants with an abnormal red reflex, with five specifying referral to a tertiary eye care facility or an ophthalmologist.

DISCUSSION

Our review of three comparative studies involving over 780 000 newborns suggests that UNES using red reflex testing in maternity wards, ie, shortly after birth, may increase the number of newborns with congenital cataract who are referred and operated on early, ie, by six weeks of age. The direction of effect was similar for universal screening conducted in well-baby clinics but the certainty of the evidence was very low. There is no evidence that red reflex testing increases adverse events though the data were very limited.

One study assessed the diagnostic test accuracy of red reflex testing suggests that it has a sensitivity of 67% for clinically significant conditions in the anterior segment and a specificity of 96% for anterior plus posterior segment conditions. We identified one study which estimated the cost-effectiveness of adding a second screening site, which was not included in the review as it did not assess screening vs no screening [26]. We may have missed other studies of cost-effectiveness and DTA as specific searches were not conducted for these outcomes.

All three studies included in the quantitative analysis [21-23] were undertaken in high-income countries and the DTA study was undertaken in China, an upper-middle-income country [24]. The studies from Sweden suggest that UNES using red reflex testing shortly after birth may lead to higher detection of congenital cataract, and earlier referral and uptake of cataract surgery. The value of UNES is also supported by a surveillance study of infantile cataract (ie, present at birth or developed by one year of age) in the United Kingdom in which almost half the children had been detected by red reflex testing shortly after birth or at 6-8 weeks [27]. These studies highlight the importance of UNES even in high-income countries where parents are well educated and health services are generally accessible and of high quality. Early referral and treatment are especially relevant in low-income settings as children with early-onset cataract often present very late for surgery [28], which compromises visual outcomes [29-31]. Children with retinoblastoma also often present very late, with local extraocular spread or widespread dissemination, which limits their life expectancy [32]. In these settings young children often have limited access to services after birth, and parents can be poorly educated and not aware of the signs of clinically significant eye conditions. UNES will enable early detection and timely referral of newborns with eye abnormalities in these settings.

None of the studies had the longer-term objective of evaluating whether UNES leads to better clinical outcomes. However, evidence from the case series shows that early referral and management leads to better outcomes than late treatment [8,9]. This is an important consideration in low-resource settings because screening should be followed by appropriate diagnosis and management to ensure optimal outcomes. This requires well-equipped tertiary-level eye care facilities for young children, with a trained team led by a pediatric ophthalmologist. Diagnostic and surgical equipment and consumables for cataract surgery in young children are needed, including vitrectomy machines, high-power intraocular lenses, and small spectacle frames [33].

Our review suggests that red reflex testing is reasonably sensitive (67%, 95% CI = 9%-99%) for clinically significant anterior segment conditions, which is acceptable for screening purposes in most settings. However, we identified only one high-quality study [24] We identified two other DTA reviews of red reflex testing in newborns, which report lower sensitivities (23% and 17.5%) [34,35]. The high specificities reported (98% and 97.5%) are comparable to the study we report. The variation in sensitivities may reflect differences in the primary studies in terms of methodology and sample size, and all eye conditions were included in these two reviews, regardless of their clinical significance.

In ten of the descriptive studies, the proportion of newborns identified with clinically significant eye conditions in different contexts varied considerably regardless of the screening method used (red reflex testing or widefield imaging) (Table S4a and Table S4b in the **Online Supplementary Document**). While this may reflect true differences in the prevalence of these conditions in different populations, it may also reflect variation in the skills of those performing the test. Selection bias in the included studies is also likely, as sicker newborns, such as those with cataract from intrauterine infection, may have had a longer inpatient stay than healthy newborns in some settings, and so would still be inpatients if NES was performed a few days after birth. Retino-

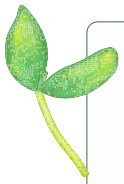
blastoma was more likely to be detected by imaging than by red reflex testing, as widefield imaging can detect small and peripheral lesions in addition to central tumours, which can also be detected by red reflex testing.

The studies informing the primary outcomes in this review only provided data on congenital cataract. The evidence was also primarily on red reflex testing, with limited data on other modalities such as wide-field digital imaging, which is likely to be more effective than red reflex testing for conditions such as retinoblastoma. However, it might be premature to propose wide-field imaging for UNES owing to the limited evidence on effectiveness and high cost of the device. In addition, current devices need contact with the cornea, which has implications for the skills and training required.

Our review of clinical guidelines suggests a high level of consensus among professional associations and pediatric and ophthalmology experts on UNES using red reflex testing. There are several reasons why recommendations are in place despite limited published evidence of effectiveness. First, case series show the benefits of early management of clinically significant eye conditions which can be present at birth, such as cataract and retinoblastoma, in terms of visual acuity and complications and survival, respectively. Second, red reflex testing is safe with minimal harm as it is a non-contact test that only takes a few minutes to perform. Third, many different health care professionals can be trained to become highly competent at red reflex testing, making it feasible in most settings. Lastly, several different devices are available for red reflex testing at a range of prices, which makes the equipment relatively affordable.

Our search did not identify any guidelines on UNES for any low-income and only one European country, the United Kingdom. In Europe, red reflex testing is included in the training materials for newborn care in the World Health Organization's Integrated Management of Childhood Illness. This probably explains why a study of 35 European countries (2013-4) showed that 28 (80%) had a national UNES programme and the remaining seven had regional screening programmes [36]. In Tanzania, following a study that evaluated an eye care training module that included red reflex testing by primary child health care workers, eye screening was included in the curriculum of the Integrated Management of Childhood Illness. More than 3000 staff have since been trained to perform eye screening in newborns and young children [37]. Another study in Tanzania assessed the feasibility of different devices for red reflex screening, including a novel, low-cost direct ophthalmoscope [38]. Primary health workers found the device easy to use and having a device increased their sense of professionalism. Subsequently, large-scale red reflex testing resulted in a large number of children aged 0-5 years being detected with cataract in the community, demonstrating the feasibility of red reflex testing in low-income settings [39]. Another advantage of this device is that it can be attached to a mobile phone, and images of the reflex can be captured to educate parents or they can be forwarded for a second opinion.

The limited published evidence highlighted by this review is a major limitation of the study. Two studies were an evaluation of a screening programme in Sweden and the third was a before and after study; both of these study designs are subject to bias and the influence of confounding and external factors which weaken the level of evidence. The lack of evidence may reflect the fact that UNES is standard practice in many high-income countries and further studies of effectiveness may not be considered ethical. It is, therefore, unlikely that further effectiveness studies will be undertaken. New screening devices are also being developed, including a device that uses infrared light [40], and these need to be compared with existing devices in terms of DTA, ease of use, image quality, and cost. Further studies are needed in resource-poor settings to assess the feasibility, acceptability, and cost of including red reflex testing as an integral component of the standard newborn assessment in all facilities delivering babies.



Acknowledgements: We thank Dr Gunilla Magnusson for supplying further breakdown of the data from her studies in Sweden, and Dr Karen Edmond for her comments on the review.

Disclaimer: The authors alone are responsible for the views expressed in this publication and they do not necessarily represent the views, decisions or policies of the World Health Organization.

Funding: Clare Gilbert and Iris Gordon received a WHO consultancy fee for this review.

Authorship contributions: IG conducted the literature search, removed duplicates and screened titles. AM, CG and RB reviewed the studies for eligibility, and along with JE extracted, analysed and interpreted data. SG and SM contributed to the interpretation of data. AM prepared the first draft of the manuscript. CG, SG, JE, SM and RB critically reviewed the manuscript.

Disclosure of interest: The authors completed the ICMJE Disclosure of Interest Form (available upon request from the corresponding author) and declare the following activities and relationships: Silvio Mariotti and Shuchita Gupta are staff members of WHO.

Additional material
Online Supplementary Document

REFERENCES

1 Burton MJ, Ramke J, Marques AP, Bourne RRA, Congdon N, Jones I, et al. The Lancet Global Health Commission on Global Eye Health: vision beyond 2020. Lancet Glob Health. 2021;9:e489-551. Medline:33607016 doi:10.1016/S2214-109X(20)30488-5

2 Rahi JS, Cable N. British Childhood Visual Impairment Study G. Severe visual impairment and blindness in children in the UK. Lancet. 2003;362:1359-65. Medline:14585637 doi:10.1016/S0140-6736(03)14631-4

3 Muhit MA, Shah SP, Gilbert CE, Hartley SD, Foster A. The key informant method: a novel means of ascertaining blind children in Bangladesh. Br J Ophthalmol. 2007;91:995-9. Medline:17431019 doi:10.1136/bjo.2006.108027

4 European network of population-based registries for the epidemiological surveillance of congenital anomalies. Available: https://eu-rd-platform.jrc.ec.europa.eu/eurocat/eurocat-data/prevalence_en. Accessed: 1 July 2020.

5 Papadopoulos M, Cable N, Rahi J, Khaw PT, Investigators BIGES. The British Infantile and Childhood Glaucoma (BIG) Eye Study. Invest Ophthalmol Vis Sci. 2007;48:4100-6. Medline:17724193 doi:10.1167/iovs.06-1350

6 Yasmeen A, Riazuddin SA, Kaul H, Mohsin S, Khan M, Qazi ZA, et al. Autosomal recessive congenital cataract in consanguineous Pakistani families is associated with mutations in GALK1. Mol Vis. 2010;16:682-8. Medline:20405025

7 Fujiki K, Nakajima A, Yasuda N, Tanabe U, Kabasawa K. Genetic analysis of microphthalmos. Ophthalmic Paediatr Genet. 1982;1:139-49. doi:10.3109/13816818209031458

8 Birch EE, Stager DR. The critical period for surgical treatment of dense congenital unilateral cataract. Invest Ophthalmol Vis Sci. 1996;37:1532-8. Medline:8675395 doi:10.1016/S0002-9394(14)70512-4

9 Self JE, Taylor R, Solebo AL, Biswas S, Parulekar M, Dev Borman A, et al. Cataract management in children: a review of the literature and current practice across five large UK centres. Eye (Lond). 2020;34:2197-218. Medline:32778738 doi:10.1038/s41433-020-1115-6

10 Abramson DH, Beaverson K, Sangani P, Vora RA, Lee TC, Hochberg HM, et al. Screening for retinoblastoma: presenting signs as prognosticators of patient and ocular survival. Pediatrics. 2003;112:1248-55. Medline:14654593 doi:10.1542/peds.112.6.1248

11 Gichigo EN, Kariuki-Wanyoike MM, Kimani K, Nentwich MM. Retinoblastoma in Kenya: survival and prognostic factors. Ophthalmologe. 2015;112:255-60. Medline:25378130 doi:10.1007/s00347-014-3123-z

12 Jin L, Zhang W, Pan H, Li T, Liu B, Zhao J, et al. Retrospective investigation of retinoblastoma in Chinese patients. Oncotarget. 2017;8:108492-7. Medline:29312545 doi:10.18632/oncotarget.18174

13 Dimaras H, Kimani K, Dimba EA, Gronsdahl P, White A, Chan HS, et al. Retinoblastoma. Lancet. 2012;379:1436-46. Medline:22414599 doi:10.1016/S0140-6736(11)61137-9

14 American Academy of Pediatrics. Section on Ophthalmology. American Association for Pediatric Ophthalmology and Strabismus. American Academy of Ophthalmology. American Association of Certified Orthoptists. Red reflex examination in neonates, infants, and children. Pediatrics. 2008;122:1401-4.

15 Stoll C, Alembik Y, Dott B, Roth MP. Epidemiology of congenital eye malformations in 131,760 consecutive births. Ophthalmic Paediatr Genet. 1992;13:179-86. Medline:1484696 doi:10.3109/13816819209046487

16 Sterne JA, Hernan MA, Reeves BC, Savovic J, Berkman ND, Viswanathan M, et al. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions. BMJ. 2016;355:i4919. Medline:27733354 doi:10.1136/bmj.i4919

17 Cochrane Training. Available: https://training.cochrane.org/online-learning/core-software/revman/revman-5-download. Accessed: 1 June 2022.

18 MedCalc. Comparison of proportions. Available: https://www.medcalc.org/calc/comparison_of_proportions.php. Accessed: 1 June 2022.

19 MedCalc Diagnostic test accuracy. Available: https://www.medcalc.org/calc/diagnostic_test.php. Accessd: 1 June 2022.

20 The GRADE working group [Available from: https://www.gradeworkinggroup.org/. Accessed June 2022.

21 Magnusson G, Bizjajeva S, Haargaard B, Lundstrom M, Nystrom A, Tornqvist K. Congenital cataract screening in maternity wards is effective: evaluation of the Paediatric Cataract Register of Sweden. Acta Paediatr. 2013;102:263-7. Medline:23205674 doi:10.1111/apa.12111

22 Magnusson G, Jakobsson P, Kugelberg U, Lundvall A, Maly E, Tornqvist K, et al. Evaluation of screening procedures for congenital cataracts. Acta Paediatr. 2003;92:1468-73. Medline:14971800 doi:10.1111/j.1651-2227.2003.tb00833.x

23 Ulanovsky I, Shnaider M, Geffen Y, Smolkin T, Mashiach T, Blazer S, et al. Performing red reflex eye examinations increases the rate of neonatal conjunctivitis. Acta Paediatr. 2015;104:e541-5. Medline:26362116 doi:10.1111/apa.13170

24 Sun M, Ma A, Li F, Cheng K, Zhang M, Yang H, et al. Sensitivity and Specificity of Red Reflex Test in Newborn Eye Screening. J Pediatr. 2016;179:192-196.e4. Medline:27640356 doi:10.1016/j.jpeds.2016.08.048

25 World Health Organization, Office for Europe. Effective Perinatal Care (EPC) Training Package. 2nd edition. 2015. Available: https://euro.sharefile.com/share/view/s6b0b7a5012d4999b. Accessed 1 June 2022.

26 Magnusson G, Persson U. Screening for congenital cataracts: a cost-consequence analysis of eye examination at maternity wards in comparison to well-baby clinics. Acta Paediatr. 2005;94:1089-95. Medline:16188854 doi:10.1111/j.1651-2227.2005.tb02050.x

27 Rahi JS, Dezateux C. National cross sectional study of detection of congenital and infantile cataract in the United Kingdom: role of childhood screening and surveillance. The British Congenital Cataract Interest Group. BMJ. 1999;318:362-5. Medline:9933197 doi:10.1136/bmj.318.7180.362

28 Mwende J, Bronsard A, Mosha M, Bowman R, Geneau R, Courtright P. Delay in presentation to hospital for surgery for congenital and developmental cataract in Tanzania. Br J Ophthalmol. 2005;89:1478-82. Medline:16234457 doi:10.1136/bjo.2005.074146

29 Bowman RJ, Kabiru J, Negretti G, Wood ML. Outcomes of bilateral cataract surgery in Tanzanian children. Ophthalmology. 2007;114:2287-92. Medline:17448539 doi:10.1016/j.ophtha.2007.01.030

30 Yorston D, Wood M, Foster A. Results of cataract surgery in young children in east Africa. Br J Ophthalmol. 2001;85:267-71. Medline:11222328 doi:10.1136/bjo.85.3.267

REFERENCES

31 Thakur J, Reddy H, Wilson ME Jr, Paudyal G, Gurung R, Thapa S, et al. Pediatric cataract surgery in Nepal. J Cataract Refract Surg. 2004;30:1629-35. Medline:15313283 doi:10.1016/j.jcrs.2003.12.047

32 Fabian ID, Abdallah E, Abdullahi SU, Abdulqader RA, Adamou Boubacar S, Ademola-Popoola DS, et al; Global Retinoblastoma Study Group. Global Retinoblastoma Presentation and Analysis by National Income Level. JAMA Oncol. 2020;6:685-95. Medline:32105305 doi:10.1001/jamaoncol.2019.6716

33 World Health Organization. 2000. Preventing Blindness in Children. Geneva, Switzerland.

34 Taksande A, Jameel PZ, Taksande B, Meshram R. Red reflex test screening for neonates: A systematic review and meta analysis. Indian J Ophthalmol. 2021;69:1994-2003. Medline:34304165 doi:10.4103/ijo.IJO_3632_20

35 Subhi Y, Schmidt DC, Al-Bakri M, Bach-Holm D, Kessel L. Diagnostic Test Accuracy of the Red Reflex Test for Ocular Pathology in Infants: A Meta-analysis. JAMA Ophthalmol. 2021;139:33-40. Medline:33180103 doi:10.1001/jamaophthalmol.2020.4854

36 Sloot F, Hoeve HL, de Kroon ML, Goedegebure A, Carlton J, Griffiths HJ, et al. Inventory of current EU paediatric vision and hearing screening programmes. J Med Screen. 2015;22:55-64. Medline:25742803 doi:10.1177/0969141315572403

37 Malik ANJ, Mafwiri M, Gilbert C, Kim MJ, Schellenberg J. Integrating eye health training into the primary child healthcare programme in Tanzania: a pre-training and post-training study. BMJ Paediatr Open. 2020;4:e000629. Medline:32671232 doi:10.1136/bmjpo-2019-000629

38 Blundell R, Roberts D, Fioratou E, Abraham C, Msosa J, Chirambo T, et al. Comparative evaluation of a novel solar powered low-cost ophthalmoscope (Arclight) by eye healthcare workers in Malawi. BMJ Innov. 2018;4:98-102. Medline:29670760 doi:10.1136/bmjinnov-2017-000225

39 Mndeme FG, Mmbaga BT, Kim MJ, Sinke L, Allen L, Mgaya E, et al. Red reflex examination in reproductive and child health clinics for early detection of paediatric cataract and ocular media disorders: cross-sectional diagnostic accuracy and feasibility studies from Kilimanjaro, Tanzania. Eye (Lond). 2021;35:1347-53. Medline:32546747 doi:10.1038/s41433-020-1019-5

40 Duret A, Humphries R, Ramanujam S, Te Water Naude A, Reid C, Allen LE. The infrared reflex: a potential new method for congenital cataract screening. Eye (Lond). 2019;33:1865-70. Medline:31267092 doi:10.1038/s41433-019-0509-9

CHAPTER 5 Results

Research Paper 2 (Publication): Integrating eye health training into the primary child healthcare programme in Tanzania: a pre and post training study

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

T: +44 (0)20 7299 4646
F: +44 (0)20 7299 4656
www.lshtm.ac.uk

RESEARCH PAPER COVER SHEET

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

SECTION A – Student Details

Student ID Number	085114	**Title**	Dr
First Name(s)	Aeesha NJ		
Surname/Family Name	Malik		
Thesis Title	Integrating primary eye care into child health policies and programmes: A case study from Tanzania		
Primary Supervisor	Prof Joanna Schellenberg		

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?	BMJ Paediatrics Open		
When was the work published?	June 2020		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	n/a		
Have you retained the copyright for the work?*	Choose an item.	Was the work subject to academic peer review?	**Yes**

*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?	
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)	I reviewed the studies for eligibility independantly then compared with my co-author. Any studies where there was disagreement between the co-author and I was discussed before a final joint decicion on inclusion or exclusion was reached. I extracted data from the studies and analysed and interpreted data, which was compared and discussed with my co-authors. I wrote the first draft of the manuscript which was reviewed by all the co-authors before submission.

SECTION E

Student Signature	[redacted]
Date	21/2/23

Supervisor Signature	[redacted]
Date	23 feb 2023

BMJ Paediatrics Open

Integrating eye health training into the primary child healthcare programme in Tanzania: a pre-training and post-training study

Aeesha N J Malik ,[1] Mlika Mafwiri,[2] Clare Gilbert,[1] Min J Kim,[3] Joanna Schellenberg[1]

To cite: Malik ANJ, Mafwiri M, Gilbert C, *et al*. Integrating eye health training into the primary child healthcare programme in Tanzania: a pre-training and post-training study. *BMJ Paediatrics Open* 2020;**4**:e000629. doi:10.1136/bmjpo-2019-000629

► Additional material is published online only. To view please visit the journal online (http://dx.doi.org/10.1136/bmjpo-2019-000629).

Received 18 December 2019
Revised 27 May 2020
Accepted 30 May 2020

Check for updates

© Author(s) (or their employer(s)) 2020. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

[1]International Centre of Eye Health, London School of Hygiene and Tropical Medicine, London, UK
[2]Department of Ophthalmology, Muhimbili University of Health and Allied Sciences, Dar es Salaam, United Republic of Tanzania
[3]Department of Infectious Disease Epidemiology, London School of Hygiene and Tropical Medicine, London, UK

Correspondence to
Dr Aeesha N J Malik; aeesha.malik@lshtm.ac.uk

ABSTRACT

Objectives To evaluate a primary child eye care training module for use in the WHO/UNICEF Integrated Management of Newborn and Childhood Illness (IMNCI) programme by primary healthcare workers.

Design Pre-training and post-training study.

Setting Primary healthcare facilities in a semirural district, central Tanzania.

Participants 54 primary healthcare workers selected by the Ministry of Health were trained during routine IMNCI training. All these healthcare workers were assessed pre-intervention and post-intervention. A subgroup of 40 were also assessed 6 months after the completion of training.

Intervention Training in an IMNCI eye module, developed for child primary healthcare workers with the Tanzania Ministry of Health and eye care experts.

Main outcome measures Knowledge, skills and attitudes were assessed using multiple choice questions, case studies and a self-assessment of skills using a Likert scale before and immediately after training, and 6 months later. A total score was derived. At 6 months, attitudes were assessed in semistructured interviews.

Results 69% PHWs trained were nurses. The baseline (before training) score was 29.9 (95% CI 27.5 to 32.4) and increased by 11.2 points (95% CI 8.3 to 14) immediately after training, and by 12.4 points (95% CI 9.2 to 15.6) at 6 months post the training. Therefore, the post-training scores increased and there was no evident difference in scores from immediately after training to 6 months later. Self-assessed confidence in skills decreased from 9/18 (95% CI 9 to 10) to 6/18 (95% CI 6 to 7). At 6 months, the module was reported as easy to understand and use, with challenges including difficulties in examining children's eyes and poor referral systems.

Conclusions The module increased knowledge of child eye health in primary healthcare workers, which was maintained, and was acceptable. The module has since been included into the national IMNCI health policy in Tanzania.

What is known about the subject?

- Many children in low-income countries present too late for effective management, leading to avoidable blindness.
- There is a critical shortage of primary level eye care services for children in low-income countries.
- There are evidence-based primary level interventions which can prevent avoidable blindness in children but these are not being implemented by primary healthcare workers (PHWs) as they are not included in child health training programmes.

What this study adds?

- Eye care training integrated into a child health training programme for primary healthcare workers improved their knowledge and case management of children's eye conditions.
- Including eye care into the child health training programme is acceptable to PHWs and they were able to implement it within their routine care.
- Tanzanian national health policy now includes eye care in the Integrated Management of Newborn and Childhood Illness programme demonstrating it is a feasible model for scale-up in other countries.

INTRODUCTION

Approximately 75% of the 1.2 million blind children in the world live in low-income and middle-income countries (LMICs), approximately half of whom are blind from avoidable causes that is, conditions which are either preventable or treatable.[1] Preventable causes include corneal scarring from vitamin A deficiency, measles infection, conjunctivitis of the newborn and use of harmful eye remedies. As vitamin A deficiency and measles are declining due to public health interventions, treatable causes such as cataract, glaucoma and retinoblastoma are assuming greater importance. These conditions need to be detected and treated early, as delayed management leads to poorer outcomes due to delayed visual development.[2–4] The prevalence of blindness in children aged 0–15 years in low-income countries is approximately 0.1%, with 80%

bmjpo: first published as 10.1136/bmjpo-2019-000629 on 9 July 2020. Downloaded from http://bmjpaedsopen.bmj.com/ on February 21, 2023 by guest. Protected by copyright.

of these children being either born blind or becoming blind before the age of 5 years.[5] Eye care services for preschool age children are, therefore, a critical target for child health programmes in order to prevent life-long visual impairment, blindness and mortality.

The WHO has identified strengthening primary healthcare as a critical component of Universal Health Coverage throughout LMICs.[6] In 2002, WHO identified 10 evidence-based 'key activities for healthy eyes in children' for primary care. These interventions include vitamin A supplementation and measles immunisation as well as ocular prophylaxis of the newborn and early screening for cataract.[4] WHO recommended these activities be included in primary level child-health services and national prevention of blindness plans.[7] However, the eye-specific components have not been included in child health programmes.[8]

In 1995, WHO launched the Integrated Management of Childhood Illness (IMCI) which has become the blueprint for primary care of children in over 100 countries.[9] Care of the newborn has since been added (IMNCI). The goal of IMNCI is to reduce mortality, illness and disability, and promote growth and development. It includes prevention as well as treatment. Health worker training is conducted using modules which cover the management of conditions such as fever, diarrhoea and ear infections. However, IMNCI does not include an eye care module.

In Tanzania, 63% of live births occur in healthcare facilities, and the prevalence of blindness in children aged 0–15 years is estimated to be 8/10 000 children, and likely higher in poor, rural communities.[10] Tanzania has an active IMNCI programme with continuous training of primary healthcare workers (PHWs).

A pilot study conducted in Dar es Salaam showed that PHWs had poor knowledge of eye conditions in children which improved after a brief training and was retained at 1 year.[11] Sixty-one per cent of trained staff knew how to manage purulent conjunctivitis compared with 30% of untrained staff (30 different staff in 15 clinics); 82% of those trained and 33% of those not trained were able to correctly diagnose a cataract. Leading on from this pilot work, the aim of the current study was to address the gap in primary eye care for children by developing and evaluating an eye module for PHWs which could be included in the IMNCI programme in Tanzania. This study reports how the eye module was developed and the findings of a pretraining and post-training assessment to ensure fidelity before advocating for wider adoption of the eye care module for PHWs.

METHODS

Development of the eye module

The eye module comprised a detailed manual, and additions to the Facilitator's Guide, User Log and 'Chart Book'. The latter comprises a series of algorithms which classifies the severity of conditions as severe, not severe or not present based on clinical signs and symptoms,

SYMPTOM	CLASSIFICATION	IDENTIFY TREATMENT
• Injury or foreign object in the eye OR • Poor vision or blindness OR • Whitening or clouding over the pupil or cornea of one/both eyes OR • Pain in eye(s) OR • Larger/smaller eyes than normal OR • Squint or darting eyes OR • Unable to examine the child/ Not certain of the diagnosis	SEVERE EYE PROBLEM	**If it is something foreign, or an injury/ulcer/pain in the eye** • Administer antibiotics • Administer the first dosage of pain killers • Cover the eye with a clean bandage and plaster **If it is a chemical injury** • Irrigate the eye for 30 minutes, and then administer antibiotics • **Give him/her an URGENT referral to the hospital with a specialist eye service**
• Red eye(s) and discharge OR • Itching eyes/watering without redness	EYE PROBLEM	• Clean the eye(s) with cotton and clean water. • Administer a course of antibiotics drops three times per day for five days • Advise the parent/carer of when it is urgent to return • Follow up with the child after five days
• There is no eye disorder AND • The child has good sight	NO EYE PROBLEM	• No further treatment necessary • Educate the parent/carer how to prevent eye infections

Figure 1 The classification of eye diseases summarised in the IMNCI 'chart' or algorithm. IMNCI, Integrated Management of Newborn and Childhood Illness.

and the management required (figure 1). A Steering Committee was convened for the study comprising stakeholders from the Ministry of Health, Community Development, Gender, Elderly and Children (referred to here as Ministry of Health), WHO, UNICEF, Non-Governmental Organisations and technical experts. A working group comprising IMNCI facilitators and technical experts developed the eye module in a series of meetings in Dar es Salaam. The manual was developed in Swahili and translated into English. The final version was reviewed and approved by the Ministry of Health in May 2018. The module included training on the Arclight, an innovative evidence-based low-cost ophthalmoscope to assess the red reflex for conditions such as cataract, which was given to every PHW.[12]

PATIENT AND PUBLIC INVOLVEMENT

This research was done without patient involvement. Patients were not invited to comment on the study design and were not consulted to develop patient relevant outcomes or interpret the results. Patients were not invited to contribute to the writing or editing of this document for readability or accuracy.

STUDY POPULATION

The study population comprised PHWs in dispensaries and health centres in Bahi district, Dodoma region. The PHWs comprised of registered and enrolled nurses who have at least 3 years nurse training and are the main providers of antenatal care, deliveries and care for children below 5 years. Clinical officers are trained for at least 2 years after secondary school education in general medical problems. Assistant medical officers are clinical officers who have completed at least 2 years

bmjpo: first published as 10.1136/bmjpo-2019-000629 on 9 July 2020. Downloaded from http://bmjpaedsopen.bmj.com/ on February 21, 2023 by guest. Protected by copyright.

further training mainly in clinical medicine for common diseases. Medical attendants have primary or secondary education and assist in supportive roles in healthcare facilities alongside the nurses and clinical officers.

The location was selected by the Ministry of Health as part of their routine IMNCI training schedule. Selection of participants for training was according to IMNCI guidelines to ensure at least 50% of PHWs delivering IMNCI were trained.

Routine IMNCI training

Routine IMNCI training was conducted using the WHO distance learning approach.[13] Phase I has 1 day of face-to-face teaching, where the first six modules are introduced. The training is conducted by Ministry of Health IMNCI facilitators who are usually paediatricians from tertiary hospitals who have been trained as facilitators. The teaching includes formal presentations and teaching on each module to highlight important points and any recent changes in practice. This is followed by time for questions. There is a short skills training session at a nearby local health centre. PHWs are then allocated into small 'study' groups led by one of the IMNCI's facilitators. Over the next 6 weeks trainees study the modules alone and with their group, and put into practice what they have learnt. During this phase they have access to the IMNCI facilitator for advice. In phase II there is a further face-to-face 1 day meeting when the remaining modules are introduced, and there is time for questions arising from phase I and practise in their own setting. After another 6 weeks there is the third and final phase with a 1 day meeting to answer questions and summarise the main learning points. A final test is undertaken before certification.

Assessment tools

A range of tools were developed to assess the knowledge, skills and attitudes of PHWs in relation to eye conditions in children and how they should be prevented or managed at the primary level. All assessment tools were developed in English, translated into Swahili and back-translated into English (online supplementary appendix 1). The tools were pretested on a group of 10 PHWs in Dar es Salaam and the findings were used to refine the assessment tools.

The tools included multiple choice questions (MCQs, 'True/False' and 'Best of 4') to test basic knowledge of eye conditions, identification of eye conditions from photographs ('Image' questions) and questions on common childhood eye conditions or scenarios which required written answers ('Case Studies'). This assessed knowledge of conditions, classification, management and referral criteria. A Likert scale was used for self-assessment of confidence in skills PHWs had in the examination, diagnosis and treatment of eye conditions in children ('Skills').

A semistructured topic guide with open-ended questions was developed for face-to-face interviews to seek

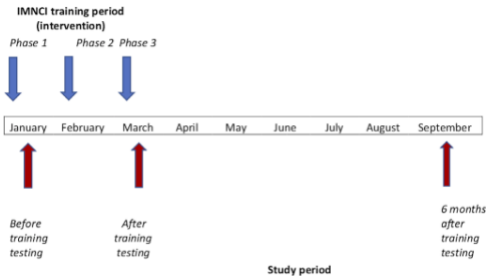


Figure 2 Study and intervention timeline 2018. IMNCI, Integrated Management of Newborn and Childhood Illness.

PHWs' views and attitudes towards the eye module in terms ease of use, level of content, applicability of use and challenges in daily practice. Interviews were conducted in Swahili by Tanzanian healthcare professionals at 6 months after the completion of training. Responses to questions were written down verbatim and translated into English.

The assessments were undertaken in the training facility immediately before phase I and after the final phase of the training period. Six months after completion of the training the PHWs were visited in their facilities where they completed the assessment tools again and the semi-structured interviews took place (figure 2).

Data management and analysis

Data were entered into Microsoft Excel (v 2016) with precoded macros. Results from the questionnaires and the entries were checked by three members of the study team.

A total score was derived by the addition of the individual scores for the MCQs ('True/False' and 'Best of 4'), the 'Image' questions and 'Case Studies' which was then adjusted as a score out of 100 for ease of comparison. The MCQs were marked by awarding +1 for a correct score, −1 point for an incorrect answer and 0 for no answer. Likert scales for the 'Skills' assessment were analysed separately.

Qualitative responses were grouped under common themes by two members of the study team and reported verbatim with a narrative description of experiences and perceptions. The content was analysed and coded according to the responses to the main elements of the interviews (online supplementary appendix 2).

Fisher's exact test was used for categorical data and the rank sum test for continuous data to compare the characteristics and baseline scores of PHWs who were and who were not traced at 6 months. A multilevel mixed-effects linear regression analysis was used for analysis of the total score. The model used time (before, after and at 6 months postintervention) as an exposure with total score as an outcome. Random effects at person level were used to account for repeated measures at three time points of an individual. STATA (Release 16, StataCorp LLC, College Station, Texas, USA) was used for statistical analysis.

bmjpo: first published as 10.1136/bmjpo-2019-000629 on 9 July 2020. Downloaded from http://bmjpaedsopen.bmj.com/ on February 21, 2023 by guest. Protected by copyright.

RESULTS

Fifty-four PHWs were trained from January to March 2018. The majority were nurses (37, 69%), 19% (10) were clinical officers, 9% (5) were assistant medical officers and 4% (2) were medical attendants (table 1). A very high proportion (48, 89%) saw children with eye problems at least once a month, but only 5% (3) had been trained in eye care. The most common eye condition they encountered was conjunctivitis, followed by injuries or foreign bodies and corneal ulcers. Only 4% (2) mentioned other conditions. However, 37% (20) said they referred children with eye conditions for further medical advice at least once a month.

The mean total knowledge score improved from 40% (95% CI 37% to 43%) before training to 54% (95% CI 52% to 58%) immediately after training (table 2). Scores increased for all aspects of knowledge assessed. The self-assessed Likert scale score for skills decreased from 9/18 (95% CI 8 to 10) to 7/18 (95% CI 6 to 7).

Forty (75%) PHWs were followed up at 6 months. There was no evidence of a difference between the PHWs who were and who were not reassessed in terms of baseline characteristics or total knowledge score (p=0.46 and p=0.33, respectively).

Using a multilevel mixed-effects linear regression model, the baseline (before training) score was 29.9 (95% CI 27.5 to 32.4). The total knowledge scores (excluding skills) increased by 11.2 points (95% CI 8.3 to 14) immediately after training. Subsequently at 6 months post the training the increase in score was 12.4 points (95% CI 9.2 to 15.6, figure 3). Overall post-training scores increased but there was no evident difference in scores from immediately after training to 6 months later. There was evidence of variation between PHWs; the random effect estimate at individual level was 25.5 (95% CI 12.5 to 52.3), and residual variance was 57.5 (95% CI 43.3 to 76.3).

Table 3 gives the breakdown of the total score by the individual components of the testing. 'Case study' scores improved from a mean of 11 (95% CI 9 to 13) to 12 (95% CI 7 to 15) after training then to 16 (95% CI 14 to 18) after 6 months (p<0.05). Likert scales assessment of 'Skills' reduced from 9 (95% CI 8 to 10) before training to 6 (95% CI 6 to 7) at 6 months, with 27 having lower scores after training, five having the same scores and seven having higher scores.

There was little evidence of a difference in scores (p=0.92) between nurses and the clinical and medical officers at baseline: nurses mean 39% (95% CI 35% to 42%) and medical officers mean 45% (95% CI 37% to 52 %) or at 6 months after training: nurses mean 56% (95% CI 49.7% to 61.9 %) and medical officers mean 57% (95% CI 51.9% to 61.7%).

Key findings from the interviews included that the majority of staff found the module easy to understand, with a similar level of complexity to the other IMNCI modules. Only 5 (12%) reported it to be more complex and challenging. All reported they had been able to apply the skills they had learnt but some reported difficulties in

Table 1 Baseline characteristics in PHWs

Characteristics	N	%
Demographic		
Sex		
Male	18	33
Female	36	67
Age		
20–30 years	28	52
31–40 years	14	26
41–50 years	6	11
51–60 years	4	7
Unknown	2	4
Work		
Clinical grade		
Assistant medical officer	5	9
Clinical officer	10	19
Registered nurse	7	13
Enrolled nurse	30	56
Medical attendants	2	4
Years worked		
Less than a year	2	4
1–5 years	32	59
5–10 years	8	15
More than 10 years	10	19
Unknown	2	4
Eye-related experience		
Previous training in eye care		
Yes	3	6
No	50	93
Unknown	1	2
Frequency eye problems seen		
Once a week or more	40	74
Approximately once a month	8	15
Less than once a month	5	9
Unknown	1	2
Most common eye problems		
Conjunctivitis/red eye in older children	35	65
Conjunctivitis in infants	21	39
Injuries or foreign bodies	10	19
Corneal ulcer	2	4
Other	2	4
Referral		
Once a week or more	5	9
About once a month	15	28
Less than once a month	32	59
Unknown	2	4

PHWs, primary healthcare workers.

bmjpo: first published as 10.1136/bmjpo-2019-000629 on 9 July 2020. Downloaded from http://bmjpaedsopen.bmj.com/ on February 21, 2023 by guest. Protected by copyright.

Table 2 Comparison of individual skills and knowledge scores before intervention and immediately after training (n=54)

	Before training		After training	
Characteristics	Mean	95% CI	Mean	95% CI
MCQ score (out of 10)	5	4 to 6	8	8 to 9
Best of 4 MCQ score (out of 10)	4	3 to 5	7	6 to 7
Image score (out of 19)	10	9 to 11	14	13 to 15
Case study score (out of 30)	11	9 to 13	12	11 to 13
Skills (out of 18)	9	8 to 10	7	6 to 7
Total score excluding skills (%)	40	37 to 43	55	52 to 56

MCQ, multiple choice question.

examining the eyes of children. Challenges they encountered were lack of community awareness about eye conditions and poor referral systems. Participants recommended more practical skills training, and video clips to assist in recognising conditions and performing procedures they were not familiar with. All except one replied that they used Arclight for red reflex testing on a regular basis. The most common changes in clinical practices were that they were examining children's eyes for the first time, referring more patients and several had reinstated ocular prophylaxis of the newborn.

DISCUSSION

Our study demonstrates the benefits of including eye health in the curriculum of healthcare workers delivering IMNCI. The advantage of including eye care in IMNCI is that it is a well-established global programme delivered by health workers who are ideally placed to implement primary eye care for young children. Including eye care in the curriculum also means it is seen as an integral component of their routine responsibilities. The IMNCI curriculum is modular, structured and symptom led which made including eye conditions relatively straightforward. The eye module follows the same structure as other modules, indicating which specific symptoms and signs to look for, which if present lead to a management decision and how PHWs should counsel the mother. This means that the PHWs are not expected to 'diagnose' eye conditions, which overcomes the perceptions that eye conditions require higher levels of expertise than PHWs can achieve. The challenges included introducing PHWs to new skills during the short training period, overburdening them in their work, difficulty in eliciting symptoms and signs of eye disease in children and having appropriate equipment.

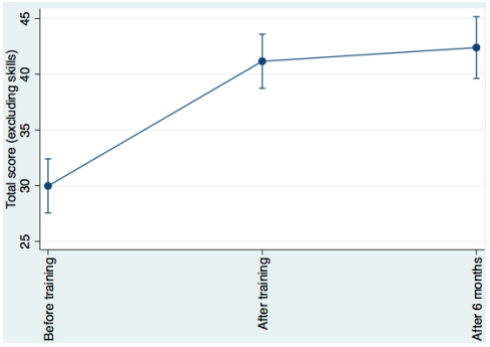


Figure 3 Change in total scores for PHWs from before training to immediately after training and 6 months after training. PHWs, primary healthcare workers

The module was acceptable to the PHWs who were able to include eye care into their daily practice. Most found it straightforward and at a similar level to the rest of their training. The key aspects of eye care were distilled into a familiar-looking algorithm. This ensured PHWs were not overburdened with information. The critical part of the examination is testing of the red reflex using an Arclight, which with experience, takes less than a minute to complete. The PHWs were also able to include eye care into their health talks with mothers. An educational poster for mothers/caregivers attending clinics was produced and used in this pilot study. However, the poster has not been used in subsequent training by the Ministry of Health as posters are not routine for the other modules.

The eye module and training improved knowledge scores, and the improvement was sustained over 6 months. The next step would be to demonstrate that these changes are sustained over a longer period of time, and to evaluate whether training leads to sustained change in practices and has a positive impact on children's eye health. Moreover, training alone is likely not sufficient for lasting impact at scale: reinforcement of skills, for example through routine supervision or quality improvement, is also important.[14]

The PHWs self-assessed confidence in diagnosing and managing eye conditions decreased after training, which might reflect a more realistic assessment and better understanding of eye problems. It has been noted previously that PHWs often have misconceptions about eye conditions, thinking they are not serious or not treatable.[11] Many PHWs requested that the training be augmented by video clips, as in other IMNCI modules.

bmjpo: first published as 10.1136/bmjpo-2019-000629 on 9 July 2020. Downloaded from http://bmjpaedsopen.bmj.com/ on February 21, 2023 by guest. Protected by copyright.

Table 3 Comparison of skills and knowledge scores before intervention and at 6 month follow-up (n=40)

	Before training		After training		6 Months after training	
Characteristics	Mean	95% CI	Mean	95% CI	Mean	95% CI
MCQ score (out of 10)	5	4 to 6	8	8 to 9	7	6 to 8
Best of 4 MCQ score (out of 10)	4	3 to 5	7	6 to 7	6	5 to 6
Image score (out of 19)	10	9 to 11	14	13 to 15	14	13 to 15
Case study score (out of 30)	11	9 to 13	12	10 to 13	16	14 to 18
Skills (out of 18)	9	8 to 10	6	6 to 7	6	6 to 7

MCQ, multiple choice question.

Following this study, six short videos were made to accompany the module which are now used in the training (https://www.lshtm.ac.uk/research/centres-projects-groups/gcehp#resources). While most PHWs found the information in the eye module to be at a similar level to the other IMNCI modules, they found examining children and eliciting the 'symptoms' and signs indicated in the eye algorithm more challenging. We anticipate that the videos will improve PHWs confidence and skills but this will require further evaluation. During the interviews PHWs did not indicate that they lacked time to examine the eyes of children, nor that this was too much to do on top of their current routine work. However, a key issue identified by PHWs was the poor referral system with lack of feedback, which is critical in enabling children to access appropriate care, and to improve PHWs learning and engagement. This was discussed with the Ministry of Health and one solution would be for the IMNCI supervisor's role to be expanded to include supporting referrals and feedback.

A limitation of the study is that we were not able to assess PHWs skills with patients and used photographs and case studies instead. This is because serious eye conditions in children are uncommon and children need to be treated promptly. While simulation models have been developed for eye care training this has tended to be for specialists examining the fundus rather than for red reflex testing.

We are aware of one study in Tanzania which is in press and another unpublished study in Nigeria in which nurses were trained to elicit the red reflex of children to detect eye conditions such as cataract.[15] In one study three devices were assessed, one of which was the Arclight. Both studies demonstrated that nurses can correctly and reliably undertake this screening test (personal communications). However, neither study addressed the need for comprehensive primary eye care for children, nor how red reflex testing could be integrated into routine care for children. One of the key challenges has been ensuring eye care (including red reflex testing) is part of routine child healthcare programmes for children. The importance of integrating eye care into the IMNCI programme is that it becomes sustainable and scalable at national and global levels, rather than dependant on short-term funding in vertical programmes.

During the study, the eye module was adopted for scale-up by the Ministry of Health in Tanzania and is now part of routine IMNCI training. To date over 3000 PHWs delivering IMNCI have been trained in child eye health. The African regional office for WHO has recently published a primary eye care training manual for all ages, which includes an algorithm for managing eye conditions in children.[16] It is important to build on this integrated training programme towards a comprehensive primary eye care approach for children under 5 years of age. Our study has shown that eye care can be integrated into a routine child health programme at primary care level which could address the gap in primary child eye care in LMICs. A larger scale evaluation of training is required, alongside enhancing supervisory support, to assess if PHWs are able to include the knowledge and skills from the eye module into their routine practice and ultimately improve child health.

Twitter Aeesha N J Malik @aeeshamalik

Acknowledgements Dr Naibu Mkongwa, Ministry of Health, Dr Frank Albert, Dr Jacinta Feksi and all the members of the steering committee in Tanzania.

Contributors ANJM, MM and CG conceptualised and designed the study. ANM and MM led the collection of data. All authors analysed the data. MJK undertook the statistical analysis of the data. ANM wrote the first draft and revised the manuscript with all authors contributing to revisions.

Funding This work was supported by the British Council for Prevention of Blindness (BCPB) grant number 14836 and CBM grant number 3324-MYP.

Competing interests None declared.

Patient consent for publication Not required.

Ethics approval Ethical approval was obtained from LSHTM Ethics Committee (Ref: 13484), MUHAS Ethics committee (Ref: 2017-12-21/AEC/Vol.XII/84) and the Tanzania National Institute for Medical Research (Ref: NIMR/HQ/R.8a/Vol.IX/2622). Permission to conduct the study was given by the Regional and District Executive Secretaries. All PHWs gave written informed consent to participate.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. All data relevant to the study are included in the article or uploaded as supplementary information. Further deidentified participant data are available by email to: aeesha.malik@lshtm.ac.uk.

Open access This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: http://creativecommons.org/licenses/by-nc/4.0/.

bmjpo: first published as 10.1136/bmjpo-2019-000629 on 9 July 2020. Downloaded from http://bmjpaedsopen.bmj.com/ on February 21, 2023 by guest. Protected by copyright.

ORCID iD
Aeesha N J Malik http://orcid.org/0000-0002-9379-4350

REFERENCES

1 Rahi JG CE. *Epidemiology of visual impairment in children*. 4th edn. Elsevier, 2016.
2 World Health Organisation. Universal eye health: a global action plan 2014–2019, 2013. Available: http://whoint/blindness/actionplan/en/
3 Gilbert C, Foster A. Childhood blindness in the context of VISION 2020-the right to sight. *Bull World Health Organ* 2001;79:227–32.
4 World Health Organization. *A five year project for the prevention of childhood blindness: report of a who consultation*. World Health Organization, 2002.
5 World Health Organization. Vision 2020 global initiative for the elimination of avoidable blindness action plan 2006–2011. 2007.
6 World Health Organization. Ten years in public health, 2007–2017: report by DR Margaret Chan, Director-General 2017.
7 World Health Organisation,. International Agency for the Prevention of Blindness. Preventing blindness in children : report of a WHO/IAPB scientific meeting, Hyderabad, India, 13-17 April 1999 2020.
8 Malik ANJ, Mafwiri M, Gilbert C. Integrating primary eye care into global child health policies. *Arch Dis Child* 2018;103:176–80.
9 World Health Organization. Integrated management of childhood illness, 2017. Available: http://wwwwhoint/maternal_child_adolescent/topics/child/imci/en/
10 UNICEF. UNICEF Republic of Tanzania data. Available: https://datauniceforg/country/tza/
11 Mafwiri MM, Kisenge R, Gilbert CE. A pilot study to evaluate incorporating eye care for children into reproductive and child health services in Dar-es-Salaam, Tanzania: a historical comparison study. *BMC Nurs* 2014;13:15.
12 Blaikie A, Sandford-Smith J, Tuteja SY, *et al*. Arclight: a pocket ophthalmoscope for the 21st century. *BMJ* 2016;355:i6637.
13 World Health Organization. IMCI set of distance learning modules, 2014. Available: https://wwwwhoint/maternal_child_adolescent/documents/9789241506823/en/
14 Rowe AK, Rowe SY, Peters DH, *et al*. Effectiveness of strategies to improve health-care provider practices in low-income and middle-income countries: a systematic review. *Lancet Glob Health* 2018;6:e1163–75.
15 Mndeme FG, Mmbaga BT, Kim MJ, *et al*. Red reflex examination in reproductive and child health clinics for early detection of paediatric cataract and ocular media disorders: cross-sectional diagnostic accuracy and feasibility studies from Kilimanjaro, Tanzania. *Eye* 2020. doi:10.1038/s41433-020-1019-5. [Epub ahead of print: 16 Jun 2020].
16 World Health Organization. Brazzaville, Regional Office for Africa. PRIMARY EYE CARE TRAINING MANUAL - A course to strengthen the capacity of health personnel to manage eye patients at primary-level health facilities in the African Region, 2018. Available: https://www.afro.who.int/sites/default/files/2018-06/WEB-2835-OMS-Afro-PrimaryEyeCaretrainingmanual-20180406.pdf

bmjpo: first published as 10.1136/bmjpo-2019-000629 on 9 July 2020. Downloaded from http://bmjpaedsopen.bmj.com/ on February 21, 2023 by guest. Protected by copyright.

CHAPTER 6 Results

Research Paper 3 (Submitted Publication): "Eye health, just ... part of helping a child to thrive": Global and national influences on integrating eye health into a child health policy in Tanzania

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

T: +44 (0)20 7299 4646
F: +44 (0)20 7299 4656
www.lshtm.ac.uk

RESEARCH PAPER COVER SHEET

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

SECTION A – Student Details

Student ID Number	085114	**Title**	Dr
First Name(s)	Aeesha NJ		
Surname/Family Name	Malik		
Thesis Title	Integrating primary eye care into child health policies and programmes: A case study from Tanzania		
Primary Supervisor	Prof Joanna Schellenberg		

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?	Globalization and Health
Please list the paper's authors in the intended authorship order:	Aeesha Nusrat Jehan Malik, Neil Spicer, Milka Mafwiri, Clare Gilbert, Joanna Schellenberg
Stage of publication	**Submitted**

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I conceived of the study and designed the study with my co-authors. I led the data collection and analysis. I completed the first draft of the manuscript and revised the manuscript with contributions from all the authors.

SECTION E

Student Signature	[redacted]
Date	21/2/23

Supervisor Signature	[redacted]
Date	23 feb 2023

"Eye health, just ... part of helping a child to thrive": Global and national influences on integrating eye health into a child health policy in Tanzania

Aeesha Nusrat Jehan Malik[1*], Neil Spicer[2], Milka Mafwiri[3], Clare Gilbert[1], Joanna Schellenberg[2]

1. International Centre of Eye Health, London School of Hygiene and Tropical Medicine, London, UK

2. Department of Infectious Disease Epidemiology, London School of Hygiene and Tropical Medicine, London, UK

3. Department of Ophthalmology, Muhimbili University of Health and Allied Sciences, Dar es Salaam, United Republic of Tanzania

*Corresponding author

Aeesha.malik@lshtm.ac.uk

ABSTRACT

Background

Blindness and visual loss in early childhood can affect psychomotor, cognitive, and social development leading to life-long consequences on educational attainment, employment, economic and social status, and wellbeing. Despite this, eye health for children under the age of five has been neglected, with little political priority as a child health issue. In Tanzania, policy makers decided in 2019 to include eye conditions in the national Integrated Management of Newborn and Childhood Illness (IMNCI) strategy, despite eye health not being in the global WHO/UNICEF strategy for IMNCI.

Results

We conducted a qualitative policy analysis to explore enabling factors and barriers to this policy change, using semi-structured interviews with key actors involved in child and eye health at national level and explored if there were global level influencing factors. We found that the key determinants were the leveraging of existing policy communities and networks; clear consensus on framing of ideas within the policy and advocacy community and to policy makers; generating local evidence with policy communities; and a critical IMNCI policy window in Tanzania, together with the expansion of global child health policy which now includes early childhood development. Global governance structures, guiding institutions, and major funding or civil societies did not influence the policy change in Tanzania.

Conclusions

This study shows how child eye health advocates and funders can influence integration of eye health into the IMNCI strategy in one country. A global policy shift in child health to enable young children to 'thrive' as well as 'survive' provides a major window of opportunity in over 100 countries for eye health to be integrated into IMNCI and other national and global child health policies. Generating local evidence in collaboration with policy makers and child health policy communities, and a clear framing of the problems and their solutions will be critical factors in enabling the inclusion of eye health into child health policies.

WC 313

KEY WORDS

Child health, health policy, eye health

BACKGROUND

Blindness and vision loss in early childhood can have far reaching consequences for the child, affecting their psychomotor and cognitive development, educational attainment, employment, economic and social status, and wellbeing.[1 2] Children who are blind are also more likely to die in childhood than those with good vision, particularly if they live in low resource settings.[3] Most blind children are either born blind from congenital conditions or become blind before the age of five years from acquired conditions.[4]

Sight (or life)-threatening treatable eye conditions need to be detected and managed early to have the best visual, developmental and survival outcomes. [5] [6] However, eye screening is not routinely conducted in low resource settings nor is eye health included in child health programmes or policies.[7] [8] There has been a presumption that child eye care is too specialized, expensive, difficult or time-consuming for routine child health programmes or health workers.[9] Recent studies have shown how eye screening can be included in child health programmes[10] [11], but gaps remain in policies and practice.

The World Health Organization's (WHO) Prevention of Blindness Program first recommended integrating eye care into child health policies in 2002 when thirteen targets for child eye health were recommended.[12] However, the first major global report to include eye care as an integral component of child health was in 2019 when the joint WHO/UNICEF "Survive and Thrive: transforming care for every small and sick newborn" report was published.[13] In addition, WHO revised their postnatal care guidelines in 2022, and these now include newborn eye screening for the first time.[14] At a national level, the Tanzania Ministry of Health included eye health in their Integrated Management of Newborn and Childhood Illness (IMNCI) strategy in 2019.[11] IMNCI is a joint WHO/UNICEF global strategy designed to reduce morbidity and mortality and promote development in children aged 0-5 years. It includes major life-threatening diseases in childhood such as pneumonia, diarrhoea, and neonatal illness, and although it includes ear conditions it does not include eye care.[15] There is a lack of evidence on what influences or hinders the inclusion of eye care for children in child health policy at global or national levels.

This study used Tanzania as a model for how eye health can be included in child health policies in other countries. The timing of the study is critical due to the publication in 2022 of global guidelines including eye screening of newborns and premature babies. The specific aims of the study were to understand the enabling factors and barriers to the inclusion of eye health in the national IMNCI strategy in Tanzania, and to explore the influence of global level factors at the national level. Understanding these key factors will be of value to child eye health advocates and policy makers in other countries to address the gap in child eye health in low resource settings, through the inclusion of eye health into the IMNCI strategy and more broadly into child health policies. The adapted Shiffman and Smith framework used in this study can also be applied by other policy researchers to study agenda setting for eye health into child health policies in other settings.

METHODS

Adaptation of the Shiffman and Smith Health Policy Framework

The Shiffman and Smith framework was chosen as it focuses on health, drawing on evidence from a number of case studies which assessed factors which led to some issues being prioritized over others in health policy agenda setting.[16] The framework allows a structured, comprehensive critical analysis, and comparability with health policy change in other settings.[17-19] Comparability with other health policy issues is important for this study as there are no other known studies on integrating eye health into child health policies, and very few studies from low resource settings on eye health policy change. The framework has been applied most prominently to maternal mortality and newborn survival but has also

been used to understand which factors have shaped priority for mental health and global surgery. Another advantage of the framework is that it has been used at both national and global levels in key health areas such as newborn health and so is applicable in the national context of this study while also exploring global influences.[20]

Walt and Gilson developed a health policy analysis framework which incorporates the concepts of context, process, and actors as well as content, with the aim that policy makers and researchers will be able to better understand the process of health policy reform, and to plan for more effective implementation.[21] The Shiffman and Smith framework was adapted for the current study by including elements of Walt and Gilson's framework, such as the historical context, political feasibility, culture and recent shifts and changes in policy. The extent to which national level policy decisions are influenced by global level policy and the role of local determinants in decision making were also included (Table 1).

Table 1: Adapted Shiffman and Smith framework

ELEMENT	DESCRIPTION	FACTORS SHAPING POLITICAL PRIORITY
Actor power within eye and child health community at national and global level	The strength of the different sets of individuals and organisations concerned with the issue	Policy community cohesion: coalescence among the network and influence of global actors on national level actors Leadership: individuals uniting the policy community and/or champions of the cause Guiding institutions: organisations or co-ordinating

		mechanisms with a mandate to lead the initiative Civil society mobilisation
Ideas and influence of global ideas on national context	The ways in which the eye and child health communities understand and portray ideas	Internal frame: the degree to which the policy community agrees on the definition of, causes of, and solutions to the child eye health External frame: portrayals of issue to resonate with the policy makers
Political contexts global and national (adapted from Gill and Walt)[21]	The environments in which actors operate	Policy windows: political moments when global or national conditions align favourably presenting opportunities to influence decision makers Global governance structure: institutions providing a platform for effective collective action Historical experience Political feasibility: of ideas and solutions Culture Recent shifts and changes in policy: effect of changes in global policy at national level
Issue characteristics at the national level	Features of the problem	Credible indicators: measures of severity for monitoring progress Severity: size of the burden Effective interventions: availability of cost-effective, backed by scientific evidence, simple to implement, and inexpensive at local level

Key actor interviews

Initial interview topic guides were based on the adapted framework (Table 1) (Appendix 1). Key actors were invited for in-depth semi-structured interviews. This method of enquiry was chosen as it allows exploration of concepts and ideas that emerge and evolve over the course of the interviews, while maintaining a comparable structure for each interview. Flexibility in the questions asked was deemed important, as it was anticipated that key topics would be raised which were not included in the framework. The topic guides could therefore be adapted in later interviews to take account of issues raised in earlier interviews.

Interviews were conducted in person for all participants based in Tanzania, in a location of their choice, which included their workplaces, the office of the co-PI at Muhimbili University of Health and Allied Sciences (MUHAS), or elsewhere. The in-person interviews were conducted in June 2022 and were led by AM with MM taking notes. Other participants, who were located in multiple countries, were interviewed online using Zoom (Zoom Video Communications Inc version 5.12.2The online interviews were conducted by AM over a period of three months from July to September 2021. The interviews, which lasted 45-60 minutes, were all undertaken in English, and were audio recorded.

The interviews were transcribed and detailed notes were also taken during the interviews. Transcriptions were made by a professional transcriber and checked for accuracy by AM. Transcriptions were not shared with participants. The interview data were anonymised to protect confidentiality.

Sampling of key actors

The key actors were selected based on their influence and involvement in a) the development of the eye module in the IMNCI programme in Tanzania, b) eye or child health in Tanzania, and c) global level policy involvement in child or newborn health.

Purposive sampling was used because many of the key actors were identified through their involvement in the policy making process and policy documents. Snowball sampling was also used during interviewing, and participants were specifically asked if there were other actors who would be relevant to interview who were then invited to participate. The use of both purposive and snowball sampling allowed data saturation to be reached, where all major themes had been identified and additional interviews were unlikely to reveal new information.

Sampling strategy

The key actors were identified in several ways: through the author's knowledge of Tanzanian health policy actors, identification from policy documents, in particular the joint WHO/ UNICEF report ""Survive and Thrive: transforming care for every small and sick newborn", and asking known child health leaders about who they believed to be key actors. Actors were purposively chosen from key organisations such as the Ministry of Health (maternal and child health and eye health departments), international bodies (WHO, UNICEF), national experts in child eye health or IMNCI, non-governmental organizations

(NGOs) supporting eye care in Tanzania, funders and the managing editors, first authors and content leads of the WHO/UNICEF report in order to ensure a good representation of views.[22] Five participants suggested by the managing editors and first authors of the joint WHO/ UNICEF report were also interviewed. One funding agency representative was invited but did not respond. No other individuals declined to be interviewed and no interviews were repeated.

A summary of the organisations represented, the roles of those interviewed and their gender are shown in Table 2.

Table 2: Key actors interviewed

Key actor category	**Institution/ department/role**	**Gender**	**Current base country**
Ministry of Health officials (3)	• Maternal and Child Health • Eye Health	Male 2 Female 1	• Tanzania (3)
International bodies (8)	• World Health Organization • UNICEF	Female 5 Male 3	• Tanzania (2) • USA (4) • Switzerland (2)
Academia/ Technical experts (11)	• Ophthalmologists, Paediatricians, IMNCI national facilitators • Universities/ academics	Female 9 Male 2	• Tanzania (5) • USA, Canada, Australia (3) • UK (3)

National representatives of NGOs who support eye care (7)	• Five international NGOs working within Tanzania	Female 6 Male 1	• Tanzania (4) • USA (3)
Key funding agencies (2)	• Two global funding agencies	Female 2 Male 0	• USA (2)

Data analysis

A data extraction template was designed, based on the adapted Shiffman and Smith framework (Table 1). The template was adapted as required during the interview process and during analysis, but the initial codes were based on the framework determinants. Each participant's data were summarised using these framework elements as initial codes, "working down" to form a coding matrix with the adapted framework factors used to form second level sub codes. Data were analysed iteratively as soon as possible after the interview. As interviews progressed, earlier interview transcripts and notes were reviewed and were reflected in an adapted topic guide with new questions to test emerging themes. New data were then compared and contrasted with the codes and categories, and developing themes were tested during subsequent interviews. This process was continuous throughout the interviews.

At the end of the interviews the main themes were defined and refined using all the interview data and then tested using multiple sources. For example, different interest

groups (Ministry of Health officials, funders, health professionals) were compared, as were different written sources of information. Any contrasting views and 'outliers' were actively sought and reviewed. Policy literature, particularly studies using the Shiffman and Smith framework, were reviewed and ideas compared and contrasted. The data were analysed in Microsoft Word (Version 16.54 licence 2019) and the lead author conducted all the coding. The Consolidated Criteria for Reporting Qualitative Research (COREQ) has been used to ensure comprehensive reporting.

Policy content and context

Integrated Management of Newborn and Childhood Illness (IMNCI) in Tanzania

In 1995 WHO and UNICEF launched the IMCI strategy to promote integrated services to reduce mortality and morbidity among young children from the main treatable and preventable diseases in countries with high under five mortality rates.[15] Care of newborns was added in 2003 (IMNCI) as it became clear that newborn deaths were an important cause of under 5 mortality in low resource settings. IMNCI is an algorithm based, symptom-led approach, which enables primary healthcare workers to complete a structured assessment of the child which leads to classification of the condition and its severity and a specific management plan with guidance on how to counsel the mother. Over 100 countries have adopted IMNCI to varying degrees. Although IMNCI includes ear conditions, eye conditions were not included, with the only mention of eye diseases initially being that "children with measles may develop conjunctivitis, which should be treated with

tetracycline eye ointment" and then later, when newborns were included, ocular prophylaxis for ophthalmia neonatorum.

During 2017-18 LSHTM and MUHAS conducted a pilot study with the Tanzanian Ministry of Health to develop and test an eye health module for inclusion in the IMNCI strategy.[11] The eye health module aligns with the other modules, with an algorithm for eye conditions for children aged 0-5 years. The eye health module was endorsed in 2019 at a national IMNCI meeting and included in the national strategy and IMNCI programme. Since 2019 the Ministry of Health has trained more than 3,500 primary health care workers in IMNCI, including the eye health module.

"Survive and thrive: transforming care for every small and sick newborn": a joint WHO and UNICEF global report (2019)

The first major global report to include eye care in child health was "Survive and Thrive: transforming care for every small and sick newborn (2019)".[13] The report highlights the importance of quality inpatient neonatal care and facilities for specialized and intensive newborn care. The report states that screening and treatment for retinopathy of prematurity (ROP) should be standard care for newborns in tertiary level facilities. ROP is an eye condition exclusively of premature, low birthweight babies with a higher risk associated with increasing prematurity, poor quality neonatal care and other complications of preterm birth.[23 24]

<u>Reflexivity</u>

Both AM and MM are paediatric ophthalmologists and researchers in Tanzanian child eye health and both were involved in the pilot study to test an eye module for inclusion in the IMNCI programme in Tanzania.[11] The evidence generated contributed to the Ministry of Health decision to include eye health in the IMNCI national strategy, and so both were key actors in the IMNCI policy making process in Tanzania. This had important implications for data collection, analysis, and interpretation of results. Both researchers had intimate knowledge of many of the events and knew some of the participants and hence there is a risk of bias from assumptions. However, the advantage was a greater awareness of the context and the history of events which added depth to the analysis. Study participants who were not known to the researchers were aware of their credentials, experience, and the institutions they represented (LSHTM and MUHAS). It is, therefore, likely that the data collected were influenced by the participants knowing the interviewers, which may have led them to withhold information which was commonly known, and to being more positive (or not divulging anything that could be construed negatively towards the researchers) in their responses.

RESULTS

Thirty-one interviews were conducted with fourteen actors based in Tanzania and seventeen based in different countries. Interviews were analysed using the adapted Shiffman and Smith framework (table 1) and are presented by category. Interviews with the global health actors were analysed to understand the global policy context and what effect, if any, the global level context had on the policy change in Tanzania.

‘Actor power’ within eye and child health community at national and global level

Policy Community Cohesion

From the interviews it became clear that there was a small group of key actors in child eye health in Tanzania who both knew each other well and were well-connected to policy makers. This is not unexpected from such a highly specialised area of health care. During the interviews it was clear that NGOs and technical experts who were advocates for eye health () had a high degree of cohesion on issues and worked together to advocate for child eye health. As an NGO interviewee stated: *“we have been working on this issue for a long time and know we are a small community so it is important for us to support each other”.* This cohesion meant that when the opportunity to include eye health in IMNCI arose there was already strong cohesion on other aspects of child eye health, and as one technical expert put it “*there is no good reason why this [eye health] should not be included [in IMNCI]”.* The IMNCI official from the Ministry of Health (MOH) also noted the *“the agreement between the [technical experts] was clear”.* Thus, the cohesion was noted from those external to the child eye health community which contributed to the actor’s power to influence the MOH.

There was also community cohesion amongst the global actors regarding the inclusion of eye care in newborn health guidelines, specifically for ROP services. The policy community in newborn health was described by one of the NGO actors as *“quite a small group working on newborn [care] and... those relationships... go back at least a decade, I think”*. It was, therefore, a close-knit community and many of the issues of newborn health, including eye health, had been discussed over many years in technical sessions and discussions, as

explained by this funder: *"Those of us in a global public health space were pretty much at the same knowledge level around things like preventing child blindness, ROP, oxygen use..... [I] just learned an extraordinary amount through the various technical sessions and discussions"*. Therefore, the issue of including eye health benefitted from having a relatively small and well-formed group who had been working together for many years on newborn health. The policy level discussions on ROP at an international level were separate from the policy community in Tanzania and there was no crossover. Therefore, the local policy community in Tanzania remained distinct and separate and was able to lead on its own national priorities.

Leadership

Leadership in this case was provided by an academic collaboration between two universities, one national and one international. The MOH IMNCI official noticed that this collaboration was *"clearly ..... capable of leading [the initiative]".* The interviews suggested that these institutions were respected by the other key actors and NGO community and one NGO representative commented *"we had worked with them before and it has been a fruitful partnership"* as well as noting *"it is important to have their technical expertise"*. There was also a sense from the NGO interviews that being separate from the NGOs and not part of implementation gave some 'neutrality' or independence, thus it was easier for the community to unite, which would, for example, have been more difficult if another NGO was leading. This meant that the leadership was effective in bringing together all the key actors to focus on the issue.

The global child health community, outside Tanzania, also benefitted from leadership, as noted by one NGO representative *"So there are some people who are very strong in this community. So, advocates at WHO, UNICEF, also, voices like …. have been incredibly powerful in this community in pushing the agenda forward …and really good at making sure that the things get done and that the pieces of research are out there, etc."* However, this leadership, although important at the global level, did not influence the actors in Tanzania.

Guiding Institutions and Civil Society Mobilisation

There are no specific guiding institutions for child eye health in Tanzania, although there are professional associations for child and eye health separately. Instead, there was a small group of actors who worked collectively with leadership to advocate for change. The global actors had also formed informal networks which guided their work on newborn health, but this did not include eye health or influence the Tanzanian policy. Grassroots organisations and civil societies were not at involved any stage.

<u>'Ideas' and influence of global ideas on national context</u>

Internal Frame

The internal frame and the agreement of the policy community on the causes of child eye problems were high and there was an openness to solutions. Many actors referred to the long-standing relationships between the child eye health community in Tanzania, who had a "*history of collaboration*" on funded projects. An example mentioned by one of the NGOs

was a project between the NGO and the two academic institutions (MUHAS and LSHTM) on primary eye care for children, which had taken place five years previously, undertaken by two of the co-authors (MM, CG). This was described by the NGO representative as *"very helpful for us to understand this problem in Tanzania"* and that it *"really spurred so many of us on to take action"*. During this project a Theory of Change (TOC) was developed collaboratively which was described as *"such an important process"* and that *"we have used that [theory of change] for many funding applications after", "it made it easier for us to understand the issues and explain it to others with a local context".* Although the TOC provided a common understanding of the causes of the problem of blinding eye diseases in children, the solutions were less clear. Most actors admitted during interviews that they had not heard of IMNCI before the first stakeholder meeting at the start of the project but found it to be a "*common sense*" approach and "*very practical*" saying *"we must try every approach and do everything we can that could work".* The key actors, therefore, felt able to support the inclusion of eye care in the IMNCI strategy as a potential solution.

The global actors focussed specifically on ROP within newborn health and considered it a quality of care issue, as noted by one academic: "*[ROP is a] quality improvement issue ... it's like a 'signal issue' .... if they can't manage that [ROP] well, then they probably can't manage all the other critical care issues that will arise"*. Awareness of the impact of poor-quality neonatal care on the eye was a very powerful internal frame used by global actors. However, this did not affect the frame in Tanzania which focused on primary level care.

External Frame

The external frame focussed on eye health being 'missing' from IMNCI. When the solution of including eye care in IMNCI was advocated to the MOH they were also able to see *"all the experts and organisations - local and international - seem to be in agreement"* which *"made us feel we will be able to make this [the eye IMNCI strategy] work well".*

One powerful strength noted in the interviews from this external frame was that including child eye health became an issue for the policy makers (in this case the MOH) as well as for the policy community. This was reflected in interviews with MOH representatives with their repeated use of the word "*we*" when discussing the eye IMNCI strategy: *"We could see that this idea [including eye health in IMNCI] was something that made sense for all of us, why would we not do it?".* This sense of ownership by the MOH became apparent after the first stakeholder meeting of the research project, as the MOH led the development of the eye module. The MOH used their own team and processes and took responsibility for the production of the module, stating: "*We felt we could manage this well within our department and it was our responsibility for our people to make sure it was done in the proper manner"*. The eye module was initially developed in Swahili (the national language of Tanzania) with technical assistance from the academic collaboration, and was then translated into English. The MOH used their own team and processes and took responsibility for the production of the module which was critical in their ownership of the programme and influential for the policy change.

<u>'Political contexts' global and national</u>

Policy Windows

Policy windows are "a favourable confluence of events providing an opportunity for advocates to press political leaders".[16] Unknown to the child eye health advocates in Tanzania, an IMNCI strategy review by the MOH and key stake holders, including WHO AFRO, was planned for May 2019. The meeting took place shortly after the eye health module had been pilot tested. This meant that the inclusion of eye health in the IMNCI strategy could be ratified and included in national policy very quickly. The MOH interviewee said *"the timing [of the IMNCI pilot study] was perfect"*. The WHO representative also said *"the timing could not have been better [for the development of the eye module]"* as they described the timing of the development of the eye module and the internal review at WHO's national and regional offices. The WHO AFRO interviewee described the regional and global shift in WHO strategic thinking on how IMNCI could move beyond child survival to support the child "thrive" agenda.

The global policy window was occasioned by the shift of the global child health agenda from 'survive' to 'thrive', which provided an opportunity to advocate for the importance of including eye health. There was also a general move towards more comprehensive care for the newborn, as noted by one global level NGO interviewee as: *"Making sure that it's comprehensive care, that you're not just trying to focus on one thing. So that might be why [eye health is gaining prominence]; it might just part of the overall trend."*

Global Governance Structure and Historical Experience

No global governance structure influenced the inclusion of eye health in the IMNCI strategy, and it was not on the global agenda.

There was also no historical experience of including eye health in general child health polices nor the IMNCI strategy. The eye NGO representatives in their interviews noted that IMNCI was not a strategy they knew much about, and explained that their child eye health programmes had been vertical and limited to specific geographical areas. However, the strength of historical experience among the eye health community in working in child eye health set the environment where the idea was well received, as noted by one NGO *"We did not know about IMNCI but the idea made common sense"*.

Political Feasibility, Culture and Recent shifts and changes

The MOH in Tanzania has an assigned specific person to lead the IMNCI strategy which indicates that it is given some political priority. One of the characteristics of the IMNCI strategy is that although it is globally led, there is scope for national adaptation, and new modules can be introduced without affecting the rest of the strategy. The MOH interviewees explained that there was a precedent to adapt the strategy nationally: *"we added 'well child' and 'severe bacterial infections' at the last [IMNCI] review"*. Although these modules had been guided by global leverage, the experience meant the policy makers were open to adaptation at a national level.

MOH interviewees also explained that in-service training of the primary health care workers in IMNCI had changed from an eleven day face-to-face training programme to distance

learning with three face-to-face training days over a three-month period. The MOH representative indicated that this had practical and economic implications: "*it was not possible before to add more as the training was already too long and expensive…. But now this training is very flexible"*. The change to distance learning drastically reduced costs (by 70%), reducing the burden on health facilities as staff were not required to be absent for 11 days, and allowed the MOH greater flexibility to make changes to the training programme.

At the global level there is a move in the childhood agenda to focus on more than 'survival' issues, meaning that child development and reducing morbidity and disability also require consideration. A global level academic reflected on this, saying: "*So not just the survive but the thrive - and as soon as you move into the thrive you have to be much more intentional on every aspect of the baby, not just their eyes alone but eyes and brain, and growth, and bonding, and support, and support to families and so on;".* Another global level NGO actor corroborated this: "*so we needed to go beyond survival and think about ... how can the babies thrive?"* and *"Eye health, just ... part of helping a child to thrive".*

<u>'Issue characteristics' at a national level</u>

Credible indicators, Severity and Effective interventions

From a public health perspective, the eye health of children has several challenges compared with other child health issues. Firstly, the outcome of most interventions, visual acuity, is not measurable in infants and is difficult to measure in pre-school age children. In addition, due to visual development and neuroplasticity the final acuity outcome needs to

be measured at the age of five years or above. Secondly, visually impairing conditions are not as common as other childhood conditions and there is a paucity of prevalence and incidence data which hinders advocacy efforts.[7] Thirdly, while there are effective methods for child eye screening, they are not as easy to administer as screening methods for other childhood conditions and are often viewed as *"too specialised"* for routine child healthcare workers.[9]

One advantage in the Tanzania setting was the presence of local evidence of the burden of child eye problems and potential solutions from recent published and unpublished studies.[8] [25] [26] Studies had also shown that training primary health workers in child eye health was effective at detecting eye conditions at the primary care level.[10] [11] The MOH representative explained that this local evidence was vital for their decision to include the eye health module: *"the evidence was clear that this was an issue we had to address for the children in Tanzania, and that we could"* and "*we have local evidence of what is the problem and what can be the solutions in Tanzania*". The IMNCI representative said, "*we thought it may be difficult to include eye health but after seeing it has been implemented in parts of the country, we thought we can do this everywhere*".

Another important factor highlighted was the availability of a simple, low-cost ophthalmoscope, called the 'Arclight', which can be used by primary healthcare workers to examine children's eyes. This technology has been tested and validated in Tanzania and other low resource settings, providing evidence that it can be effective.[10] [11] Testing children's eyes with the Arclight was included in the eye health module and its importance was noted by the MOH*: "this Arclight is really useful as we can give one to every primary*

healthcare worker" and also by the WHO Tanzania representative: *"now we have something [the Arclight] that they [primary health workers] can use which makes [eye examination]possible".*

Table 2: Summary of key determinants in policy change in Tanzania

ELEMENT	FACTORS SHAPING POLITICAL PRIORITY	KEY DETERMINANTS IN TANZANIA
Actor power within eye and child health community at national and global level	• Policy community cohesion local and global • Leadership • Guiding institutions • Civil society mobilisation	• Strong community cohesion with history of collaboration on eye health, even though not on specific issue of including eye health in IMNCI, benefitted the issue of integration • Joint leadership through national and international academics widely respected • No guiding institutions • No civil society mobilisation
Ideas and influence of global ideas on national context	• Internal frame • External frame	• Consensus on problem and solutions on eye health in general with agreed Theory of Change allowed for idea of inclusion of eye health in IMNCI, as fitted within an already agreed framework • Global influence of presentation of eye health being part of child development, quality of care and comprehensive care was important external frame which leveraged the shift in global policies around child health

		• Presentation of eye health as 'missing' from IMNCI and a gap of child health resonated strongly as external frame
Political contexts global and national (adapted from Gill and Walt)[21]	• Policy windows • Global governance structure • Historical experience • Political feasibility • Culture • Recent shifts and changes	• IMNCI national review timing (unknown to policy community) allowed for ratification of inclusion of eye health within national policy • Benefits from global shift in child health agenda from 'survival' to 'thrive' and supporting early childhood development • No global governance on issue or historical experience of including eye health in child health policies • Politically feasible due to how IMNCI managed with flexibility at national level • Recent changes in structure of strategy allowing greater flexibility and feasibility to include eye health
Issue characteristics national context	• Credible indicators • Severity • Effective interventions	• Paucity of data in low resource settings but local evidence of burden and solutions which was used effectively • New low-cost technologies available were important turning point

DISCUSSION

This study identified the key determinants of policy change in Tanzania and highlights the influence of the global context. A small cohesive policy community with consensus on the framing of ideas combined with historical experience and an opportune policy window were the critical factors which allowed eye health to be included in WHO/UNICEF's IMNCI strategy in Tanzania.

There was no direct global influence on the change of policy in Tanzania, but the global shift in the child health agenda to a focus on early childhood development created a favourable policy context, which the key actors were aware of. The policy change in Tanzania showed that if key factors are in place the lack of other major determinants, such as global governance structures, guiding institutions, major funding or civil society mobilisation, need not be barriers to policy change.

Policy community cohesion

Policy communities are networks of individuals (including researchers, advocates, policy-makers and technical officials) and organizations (including governments, NGOs, United Nations agencies, foundations and donor agencies) that share a concern for a particular issue.[27] The cohesiveness of the policy community was an important factor in influencing the inclusion of eye health in child health, although the focus of the policy community was not on including eye health in child health, but child health or eye health. Cohesion is important in effective advocacy, a factor which has been reported as missing in other areas of health, such as surgery and mental health.[28 29] In Tanzania the policy community had a

history of working together and undertaking studies in Tanzania, in collaboration with the MOH. The local evidence generated, which included evidence of the effectiveness of solutions, influenced the decision of the MOH to include eye health in the IMNCI strategy. The involvement of the MOH at an early stage in the research activities was also influential as they became involved in the development and delivery of the eye care module.[11]

In the global policy, it was the newborn health community who were unified and organised, as they had been advocating for greater political support for newborn health. Although the global policy community did not focus on the inclusion of eye health in child health policies, they were in agreement on the importance of eye health so that when the opportunity arose through policy windows and shifts, they were able to greatly influence the framing of ideas both internally and externally.

Networks

The importance of global networks ("cross-national webs of individuals and organizations linked by a shared concern to address a particular health problem global in scope")[30], has been highlighted in a policy framework designed to better understand their role in building political priority, drawing on examples from emergency medicine, maternal health and musculoskeletal conditions.[15 31-33] Tanzania benefited from a national network (rather than cross-national) which was effective in framing the issue of including eye health by working in the policy environment with the MOH which gave a sense of priority to the issue.

Local issue characteristics- credible indicators, severity and effective interventions

A critical determinant in the Tanzania context was local evidence of the severity of child eye health problems, with evidence of effective interventions, and credible indicators for child eye health. These factors highlight the importance of building a local research agenda. Essential and affordable equipment for eye examination (the Arclight) could also be made readily available locally.

A study in three countries (Bolivia, Malawi and Nepal) explored the determinants of newborn health priorities at a national level. Key findings were that the efficacy of solutions needed to have been demonstrated in low resource settings, and advocacy should build on existing national priorities with a strong network of national and global leaders.[20] Contextually relevant evidence may be particularly influential, as decision-makers want to invest in policy solutions that are likely to give results. The same applied in Tanzania, where local evidence of the scale of the problem and the testing of solutions locally were key in influencing policy makers.

Internal Framing

The opportunity to link health issues with existing or emerging political priorities gained traction in Tanzania where IMNCI was a political priority and relatively well funded. Using the IMNCI strategy meant that eye health was placed within a strategy which already had its own priority. Once included within the IMNCI strategy, primary health workers are trained in eye care as the IMNCI has its own funding stream. Indeed, sustainability is one of the advantages of integrating eye care into child health policies and programmes. However,

integration can have disadvantages: if, for example, eye care is seen as less important than other aspects of newborn or child health, eye care may still be neglected. However, the alternative is usually no eye care for children at the primary level.

A study from Argentina, which focussed on reducing blindness from ROP through policy change and implementation, also found local factors to be important. Key factors were persistent advocacy by a group of national professionals, legislation initiated by a mother of an ROP blind child, and action by the Pan American Health Organization (PAHO) which all set the agenda for policy change for the control of ROP in Argentina. [34] The framing of eye health as 'missing' from IMNCI in Tanzania was also effective because the strategy was designed to be comprehensive. Local evidence of the size of the problem alongside a solution were compelling for policy makers.

Implications of the study

Leveraging existing small and cohesive policy communities and networks with wider interests (both eye and child health) is a key factor which can be used by child eye health advocates in other countries. The framing of child eye health as being necessary for comprehensive child health and/or child development with clear outlining of the problem and the solutions internally (within the policy community) and within the global policy agenda can be highly influential for policy makers. However, policy makers need to see that implementing a policy change is feasible, and it is vital that all the equipment necessary for the solution is affordable and locally available, as was the case in Tanzania. In the longer term it is important for child eye health communities to build relationships with policy

makers through collaborative research and other programmes so that 'buy-in' is achieved early and grows with the development of the research and policy agenda. In addition, determining how essential equipment could be made affordably available, if needed, is also important for policy change.

The importance of local rather than international evidence was a clear decision-making factor for policy makers which was important implications for researchers. This requires a focus on producing local and, at a minimum, regional evidence on the epidemiology of eye diseases in children and the effectiveness of solutions which are applicable to the setting. The adapted Shiffman and Smith framework used in this study can be used by other researchers to analyse agenda setting factors in other national and regional contexts.

The case study in Tanzania illustrates how national policy makers can make locally impactful policy changes without a related global policy agenda. It is important for national policy makers to work with their own national policy communities to determine national priorities and use policy windows to really make an impact for their own populations without 'waiting' for global health policy change.

CONCLUSIONS

A global policy window has opened over the last five years, with the shift in child health policy moving beyond the 'survival' focus to how a child can 'thrive'. This window provides a major opportunity for the inclusion of eye health not only in IMNCI strategies but also other national and global child health policies for young children. The lessons from the Tanzania

context can be used in other countries showing that it is possible for eye health to be given political priority by: (1) leveraging existing policy communities and networks and (2) ensuring ideas are presented clearly within the context of current child health priorities internally and externally and (3) developing local evidence collaboratively with the policy community. The timing is now critical to address the 'gap' and for governments, donors and advocates to work together to ensure eye health becomes an integral component of IMNCI and other child health policies in other countries and at a global level.

ABBREVIATIONS

IMNCI Integrated Management of Newborn and Childhood lllness

LSHTM London School of Hygiene and Tropical Medicine, UK

MOH Ministry of Health

MUHAS Muhimbili University of Health and Allied Sciences, Tanzania

NGO Non governmental Organzation

PAHO Pan American Health Organization

ROP Retinopathy of Prematurity

TOC Theory of Change

WHO World Health Organization

DECLARATIONS

Ethical approval

Information sheets and consent forms were sent to potential participants by email before the interviews. Some participants returned the signed forms prior to the interview, otherwise written or oral consent was taken and recorded before the interview started. Confidentiality was maintained by using unique codes for each participant to store recordings and transcripts, and only key roles have been used for direct quotes. All data are stored on a secure server (LSHTM) with access only by AM. After the study has been published, all data will be held in LSHTM's secure server and audio recordings destroyed.

Ethical approval of the study was obtained from London School of Hygiene and Tropical Medicine (LSHTM) on 5th March 2021 (LSHTM Ethics Ref: 22842), Muhimbili University of Health and Allied Sciences on 21st October 2021 (MUHAS) and National Institute for Medical Research (NIMR) Tanzania on 17th March 2022.

Consent for Publication

Not applicable

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests

Funding

This research was funded by Christian Blind Mission (CBM) and the Queen Elizabeth Diamond Jubilee Trust. They were not involved in the design of the study and collection, analysis, interpretation of data and in writing.

Authors' contributions

AM conceived of the study and designed the study with NS, CG and JS. AM led the data collection and analysis, completed the first draft of the manuscript and made revisions after contributions from all the authors to complete the manuscript for submission. NS contributed to the design of the study, interpretation and write up of the data analysis and revised the manuscript. MM contributed to data collection and revised the manuscript. CG and JS contributed to design of the study and revisions of the manuscripts. All authors read and approved the final manuscript.

Acknowledgements

Not applicable

REFERENCES

1. Solebo AL, Teoh L, Rahi J. Epidemiology of blindness in children. *Archives of Disease in Childhood* 2017 doi: 10.1136/archdischild-2016-310532

2. Keil S, Fielder A, Sargent J. Management of children and young people with vision impairment: diagnosis, developmental challenges and outcomes. *Archives of Disease in Childhood* 2016 doi: 10.1136/archdischild-2016-311775

3. World Health Organisation, International Agency for the Prevention of Blindness. Preventing blindness in children : report of a WHO/IAPB scientific meeting, Hyderabad, India, 13-17 April 1999, 2000 WHO_PBL_00.77.

4. Rahi JG, CE. Epidemiology and world-wide impact of visual impairment in children. 4th ed: Elsevier 2022.

5. Dimaras H, Kimani K, Dimba EA, et al. Retinoblastoma. *Lancet (London, England)* 2012;379(9824):1436-46. doi: 10.1016/s0140-6736(11)61137-9 [published Online First: 2012/03/15]

6. Fabian ID, Abdallah E, Abdullahi SU, et al. Global Retinoblastoma Presentation and Analysis by National Income Level. *JAMA Oncol* 2020;6(5):685-695. doi: 10.1001/jamaoncol.2019.6716 [published Online First: 2020/02/28]

7. Burton MJ, Ramke J, Marques AP, et al. The Lancet Global Health Commission on Global Eye Health: vision beyond 2020. *Lancet Glob Health* 2021;9(4):e489-e551. doi: 10.1016/s2214-109x(20)30488-5 [published Online First: 2021/02/20]

8. Mafwiri MM, Kisenge R, Gilbert CE. A pilot study to evaluate incorporating eye care for children into reproductive and child health services in Dar-es-Salaam, Tanzania: a

historical comparison study. *BMC nursing* 2014;13:15. doi: 10.1186/1472-6955-13-15 [published Online First: 2014/06/17]

9. Malik ANJ, Mafwiri M, Gilbert C. Integrating primary eye care into global child health policies. *Arch Dis Child* 2018;103(2):176-80. doi: 10.1136/archdischild-2017-313536 [published Online First: 2017/10/11]

10. Mndeme FG MB, Kim MJ, Sinke L, Allen L, Mgaya E, Bastawrous A, MacLeod D, Burton MJ, Gilber C, Bowman R. Red reflex examination in reproductive and child health clinics for early detection of paediatric cataract and ocular media disorders: cross-sectional diagnostic accuracy and

feasibility studies from Kilimanjaro, Tanzania. *Eye* 2020

11. Malik ANJ, Mafwiri M, Gilbert C, et al. Integrating eye health training into the primary child healthcare programme in Tanzania: a pre-training and post-training study. *BMJ Paediatr Open* 2020;4(1):e000629. doi: 10.1136/bmjpo-2019-000629 [published Online First: 2020/07/17]

12. World Health Organization. A five year project for the prevention of childhood blindness: Report of a WHO Consultation: World Health Organisation, 2002.

13. WHO. Survive and thrive: transforming care for every small and sick newborn. *https://wwwwhoint/maternal_child_adolescent/documents/care-small-sick-newborns-survive-thrive/en/* 2019

14. Organization GWH. WHO recommendations on maternal and newborn care for a positive postnatal experience. *https://wwwwhoint/publications/i/item/9789240045989* 2022;Licence: CC BY-NC-SA 3.0 IGO.

15. Shiffman J, Quissell K, Schmitz HP, et al. A framework on the emergence and effectiveness of global health networks. *Health Policy Plan* 2016;31 Suppl 1(Suppl 1):i3-16. doi: 10.1093/heapol/czu046 [published Online First: 2015/09/01]

16. Shiffman J, Smith S. Generation of political priority for global health initiatives: a framework and case study of maternal mortality. *Lancet* 2007;370(9595):1370-9. doi: 10.1016/s0140-6736(07)61579-7 [published Online First: 2007/10/16]

17. Walt G, Gilson L. Can frameworks inform knowledge about health policy processes? Reviewing health policy papers on agenda setting and testing them against a specific priority-setting framework. *Health Policy and Planning* 2014;29(suppl_3):iii6-iii22. doi: 10.1093/heapol/czu081

18. Adam T, de Savigny D. Systems thinking for strengthening health systems in LMICs: need for a paradigm shift. *Health Policy Plan* 2012;27 Suppl 4:iv1-3. doi: 10.1093/heapol/czs084 [published Online First: 2012/10/04]

19. Walt G, Shiffman J, Schneider H, et al. 'Doing' health policy analysis: methodological and conceptual reflections and challenges. *Health Policy Plan* 2008;23(5):308-17. doi: 10.1093/heapol/czn024 [published Online First: 2008/08/15]

20. Smith SL, Shiffman J, Kazembe A. Generating political priority for newborn survival in three low-income countries. *Glob Public Health* 2014;9(5):538-54. doi: 10.1080/17441692.2014.904918 [published Online First: 2014/04/29]

21. Walt G, Gilson L. Reforming the health sector in developing countries: the central role of policy analysis. *Health Policy Plan* 1994;9(4):353-70. doi: 10.1093/heapol/9.4.353 [published Online First: 1994/11/04]

22. Organization GWH. Survive and thrive: transforming care for every small and sick newborn. . https://wwwwhoint/publications/i/item/9789241515887 2019;Licence: CC BY-NC-SA 3.0 IGO

23. Kim SJ, Port AD, Swan R, et al. Retinopathy of prematurity: a review of risk factors and their clinical significance. *Surv Ophthalmol* 2018;63(5):618-637. doi: 10.1016/j.survophthal.2018.04.002 [published Online First: 2018/04/22]

24. Good WV, Hardy RJ, Dobson V, et al. The incidence and course of retinopathy of prematurity: findings from the early treatment for retinopathy of prematurity study. *Pediatrics* 2005;116(1):15-23. doi: 10.1542/peds.2004-1413 [published Online First: 2005/07/05]

25. Mafwiri MM, C Mosenene, S Fakir, A. The Causes of Visual Impairment and Blindness among Children: A case study of Mbarali District in Southern Tanzania (personal communciation). In: (unpublished), ed.: Department of Epidemiology and Biostatistics, Muhimbili University of Health and Allied Sciences, 2016.

26. Mwende J, Bronsard A, Mosha M, et al. Delay in presentation to hospital for surgery for congenital and developmental cataract in Tanzania. *The British journal of ophthalmology* 2005;89(11):1478-82. doi: 10.1136/bjo.2005.074146 [published Online First: 2005/10/20]

27. Shiffman J. A social explanation for the rise and fall of global health issues. *Bull World Health Organ* 2009;87(8):608-13. doi: 10.2471/blt.08.060749 [published Online First: 2009/08/26]

28. Shawar YR, Shiffman J, Spiegel DA. Generation of political priority for global surgery: a qualitative policy analysis. *Lancet Glob Health* 2015;3(8):e487-e495. doi: 10.1016/s2214-109x(15)00098-4 [published Online First: 2015/07/19]

29. Tomlinson M, Lund C. Why does mental health not get the attention it deserves? An application of the Shiffman and Smith framework. *PLoS Med* 2012;9(2):e1001178. doi: 10.1371/journal.pmed.1001178 [published Online First: 2012/03/06]

30. Shiffman J. Network advocacy and the emergence of global attention to newborn survival. *Health Policy Plan* 2016;31 Suppl 1(Suppl 1):i60-73. doi: 10.1093/heapol/czv092 [published Online First: 2015/09/26]

31. Shiffman J. Agency, Structure and the Power of Global Health Networks. *Int J Health Policy Manag* 2018;7(10):879-884. doi: 10.15171/ijhpm.2018.71 [published Online First: 2018/10/15]

32. Briggs AM, Shiffman J, Shawar YR, et al. Global health policy in the 21st century: Challenges and opportunities to arrest the global disability burden from musculoskeletal health conditions. *Best Pract Res Clin Rheumatol* 2020;34(5):101549. doi: 10.1016/j.berh.2020.101549 [published Online First: 2020/07/28]

33. Chipendo PI, Shawar YR, Shiffman J, et al. Understanding factors impacting global priority of emergency care: a qualitative policy analysis. *BMJ Glob Health* 2021;6(12) doi: 10.1136/bmjgh-2021-006681 [published Online First: 2022/01/01]

34. Hariharan L, Gilbert CE, Quinn GE, et al. Reducing Blindness from Retinopathy of Prematurity (ROP) in Argentina Through Collaboration, Advocacy and Policy Implementation. *Health Policy Plan* 2018;33(5):654-665. doi: 10.1093/heapol/czy004 [published Online First: 2018/04/19]

CHAPTER 7 Synthesis and Discussion

In this chapter I will discuss the main findings of this thesis within the context of existing published evidence, focussing on implementation and policy issues of integrating eye health into child health policies and programmes. I will also reflect on limitations of the research and highlight important research gaps. Finally, the chapter will conclude with my recommendations for programmes, policy and research based on the findings from this thesis.

Eye health for children under 5 years old, including NES, remains a neglected issue in low resource settings and presents challenges both in policy and implementation. This thesis covers a wide range of issues from uncovering the evidence base, testing a potential implementation model for integrating eye health in a child health programme, through to exploring how a specific child health strategy in Tanzania was influenced to include eye health. The overall goal is to use the research findings as lessons for scaling up integration of eye health into child health within Tanzania, in other countries and at a global level.

Newborn Eye Screening

The systematic review (Chapter 4) demonstrates that there is evidence from high income settings that NES in maternity wards is effective in increasing detection of newborns with congenital cataract, referrals and the number of babies operated on by 6 weeks of age.[1] The effect was similar for NES in well-baby clinics (before 6 weeks of age) but the certainty of the evidence was very low. These studies were undertaken in a high-income setting and the primary outcomes were designed for that context where best practice guidelines aim to operate on newborns with congenital cataracts by 6 weeks of age. A study of infantile cataract (birth- 1 year) in the United Kingdom showed that almost half the children had been detected by routine RRT screening or birth or at 6-8 weeks (which are two points of newborn screening in the UK).[2] The review of guidelines which include NES (chapter 4) found eight guidelines from five countries (US, Canada, UK, New Zealand and India) which recommended universal NES. All the recommendations were based on expert opinion rather than on empirical evidence, demonstrating expert consensus on the value of universal NES in early detection of eye problems.

However, even in high resource settings there is concern that the number of skilled healthcare workers is inadequate to conduct the screening.[3] Currently the recommended RRT detects conditions mainly at the front of the eye such as cataracts (although also can detect large retinoblastomas which are at the back of the eye). Recently fundal telemedicine imaging systems have been trialled in India, China and the US.[4-7] These studies use fundus cameras and telemedicine approaches which allow detection of certain conditions in the posterior eye (retina) where prompt clinical treatment could improve visual or clinical outcomes, but also detection of other findings where the clinical significance is less clear. For example, the prevalence of retinal haemorrhages seen through NES using fundal camera screening has varied widely in studies, from 2 to 50%.[6-8] Sampling bias affects the prevalence of retinal haemorrhages, because assisted vaginal delivery is associated with a higher risk of retinal haemorrhages, and most retinal haemorrhage resolves within 1-2 weeks of birth.[9 4 7] Some retinal haemorrhages persist for longer, which has led some authors to hypothesize that they could impact early vision development and potentially lead to amblyopia later in life.[5]

In one study the cost benefit of the screening with fundal imaging was estimated and found overall that there was a net monetary gain when balanced with the potential financial loss incurred by a blind child.[7] However, a major factor is the initial cost of the fundus camera which would be prohibitive in low resource settings. To determine the true cost-effectiveness of universal NES with a fundus camera, there would need to be evidence of cost benefit of detecting treatable disease that would not be detected with current screening methods.

In high resource settings the issues of NES have moved into considering what conditions could be identified and the use of fundus cameras. However, in low resource settings NES with even basic equipment that would detect the most common blinding eye conditions in babies is still not being done.

The systematic review[1] in Chapter 4 was completed as part of the evidence gathering and review process by WHO in their development of the first Postnatal Care guidelines (2022).[10] In these guidelines NES has been included as a recommendation as:

"*Universal newborn screening for abnormalities of the eye is recommended and should be accompanied by diagnostic and management services for children identified with an abnormality."* and *"Universal newborn screening for abnormalities of the eye should be done prior to discharge after a health-facility birth or at the first postnatal care contact in an outpatient setting after a home birth. Ideally, the screening should be done within the first six weeks after birth. An external examination of the eye and red reflex test should be done using standard equipment (e.g., a direct ophthalmoscope) by a trained health worker."*

These recommendations by WHO are the first time NES has been recommended as part of the general assessment of the newborn in a global policy which outlines the resources required for implementation. However there is a paucity of evidence on how universal NES could be implemented within a general assessment of the newborn in low resource settings.[11]

Implementation Issues of Integrating Child Eye Health

The practicalities of implementing primary level child eye health including NES requires there to be trained staff (neonatologists, midwives, nurses), appropriate available working equipment and infrastructure, time and supervision as well appropriate referrals systems to specialist diagnostic and treatment facilities for children diagnosed with an abnormality.[10]

Primary eye care

Primary care workers and maternity staff are usually the first point of healthcare contact for any mother and baby during the crucial first months of a baby's life. Since eye health has not traditionally been part of a PHWs training or role, the inclusion within a child health programme is important for both training and implementation. The WHO recommended

"10 key activities to promote healthy eyes in children" which emphasised the links between child health and eye health by the inclusion of vitamin A supplementation and measles vaccination as well as RRT to give a comprehensive foundation of primary eye care in children under 5 years old.[12] The inclusion of child health interventions in the '10 key activities' allows PHWs to see the links between eye and child health and were designed to fit within child health services and training. These 10 activities have not been taken up by maternal and child health programmes to be implemented or evaluated as a comprehensive package. There is one published pilot study (2014) which did use the '10 key activities' to train PHWs based in primary health clinics in Dar es Salaam. The study showed an improvement of knowledge of eye conditions and case management after training that was retained one year later. [13] Some clinics had stopped ocular prophylaxis for ophthalmia neonatorum as they did not know why it was used but then restarted the practice after training.[13]

Primary eye care for children comprises different elements and it is important to implement the whole package, as individual components delivered separately may not have the desired impact.[14] For example, improving mothers health seeking behaviour and educating to avoiding traditional eye medicines needs to be done with training PHWs on how to check children's eye and RRT. Including comprehensive primary eye care in child health programmes (including but not limited to NES) is important both for potential impact and so that PHWs perceive eye health as part of child health rather than being very highly specialized and not part of their role.

The 'gap' and the need for integration

The 'gap' of eye care in the WHO/UNICEF IMNCI strategy is important as it highlights how a strategy designed to be an integrated approach to child health does not include eye health. It can be argued that no package or strategy can include all conditions and there are important considerations of how much responsibility should be given to PHWs in these settings. It was also the case that at its inception IMCI focussed on the five leading causes of death in children under five. However, IMCI included ear health from its inception which is also a specialist area and not a cause of childhood mortality.

In our policy study (Chapter 6, Paper 3), interviews with key actors in eye health and child health highlighted that the more traditional, vertical approach, where PHWs are trained by eye specialists or eye care NGOs, eye care tends to be seen as 'separate' to child health care and issues. This 'separation' has in part contributed to child eye care being neglected in low resource settings or being left to eye NGOs delivering short-term vertical programmes focussed on specific geographical areas and which end when programme funding ends. This more 'vertical' approach is exemplified in another study in Tanzania by Mnedeme et al where nurses were given a separate two day training specifically in RRT using the Arclight.[15] In contrast, in our study in Tanzania (Chapter 5, Paper 2) we developed and tested an eye module for inclusion in the IMNCI strategy.[16] This novel approach meant that all the training was integrated from the start with IMNCI facilitators conducting the training in eye care for children including RRT. The study results showed a marked increase in knowledge and confidence; and qualitative interviews showed that PHW found the module easy to understand and apply in their setting.

The need for a comprehensive, sustainable solution to delivering eye health for children under 5 years old in lower resource settings for all children is clear. The purpose of developing and testing the eye module as part of the IMNCI strategy in Tanzania was not only to develop an IMNCI model but also to give an example of what could be possible in other child health programmes. The key concepts of this model are:
(1) PHWs with no previous training or experience in eye care can be trained to deliver eye care for children,
(2) PHWs training can be conducted by non-specialist trainers,
(3) when eye care training is conducted within the child health system, eye care is seen as easier to understand and implement by PHWs,
(4) when eye care is viewed as part of routine child health care then it can be implemented by general PHWs in their routine daily work,
(5) policy decisions to include eye care into child health programmes can be made when policy makers are convinced of a need for child eye care and a workable solution is provided.

The first three concepts of the model were tested in the IMNCI study in Tanzania (Chapter 5, Paper 2). The testing of the fourth concept of the model in paper 2 was limited to the qualitative part of the study but requires a full evaluation of the national IMNCI strategy in Tanzania. The fifth concept was tested in our third study (Chapter 6). The impact of the study 2 was greater than expected, because the MOH in Tanzania ratified the eye care module to be included in the national IMNCI strategy and therefore it became part of routine IMNCI training. The MOH have since trained more than 3000 primary healthcare workers in IMNCI including eye health. This shows the sustainability of the model and potential for scaling up at a national level to reach every child.

IMCI implementation

The IMCI strategy (Newborn care was not included at that time) was evaluated in Tanzania in 2004 as part of a multi-country evaluation of IMCI and found to reduce mortality rates in children under 5 years old, with similar or lower costs for case management compared to those without IMCI.[17] The observed quality of care in children in Tanzania being treated by PHWs trained in IMCI was also better than those without IMCI training.[18] For PHWs trained in IMCI, the assessment of children's health problems was more thorough, they were more likely to be diagnosed and receive correct treatment, as well as give more appropriate counselling compared to PHWs without IMCI training. Other evaluations of IMCI have found strong evidence that IMCI improved case management of children despite the remaining challenges in service quality.[19 20 21] A Cochrane review concluded that IMCI may reduce child mortality, and packages that include interventions for the neonatal period may reduce infant mortality.[22] However there was little or no evidence of effects on nutritional status or vaccine coverage, and mixed results regarding maternal care seeking behaviour and breastfeeding. Other studies have highlighted the wider factors affecting the success of the IMCI strategy including supervision, availability of essential drugs, vaccines, and equipment.[19-21 23]

Appropriate referrals are an important part of the eye care module developed for IMNCI in paper 2 (Chapter 5) as serious, potentially blinding eye conditions in children need to be treated at tertiary level. Our study did not study referral rates, but this will be a key

determinant of success due to the importance of appropriate, timely referrals in the primary care setting. A study conducted in Tanzania prior to IMCI found the rate of paediatric referrals from primary care level to be very low (less than 1% of cases seen).[24] It had been anticipated that the introduction of IMCI would increase the referral rate. However, one Tanzanian study reported that fewer than a fifth of children needing referral were actually referred to higher level facilities.[18] Another study reported that in Tanzania more than 60% of primary healthcare centres were over 2 hours journey away from their closest referral centre and so proposed that not having transport, the costs and the need to care for other family members meant families were not able to travel with a sick child. [25] These two studies show that referrals in Tanzania and reaching appropriate care are affected by wider health system factors, infrastructure and social support.[25]

Primary health worker training

The foundation of IMCI is improving the skills of PHWs based in primary health care facilities through the structured IMCI training. A systematic review found IMCI training was associated with improvements in the skills of the PHWs and trained staff were more likely to correctly classify illnesses.[26] However, the review was limited by heterogeneity and only included observational studies. There were greater improvements in performance of PHWs when they were vaccinating children, prescribing medications, or counselling, especially when PHWs started with a lower baseline performance. The structured approach used by IMCI was important in our model (Chapter 5) as the PHWs ability to classify correctly in eye care improved as well as decide who required urgent referral.

The traditional IMCI training is 11 days face to face training, but this has been replaced in many settings with a distance learning approach. Tanzania uses the latter, with only three in-person days spaced approximately one month apart. The PHWs are expected to work through the modules in groups and individually between the in-person training days. The IMNCI facilitators are available to them by phone if they have any queries. Rowe et al found, based on limited evidence, that standard IMCI training seemed more effective than shortened training of 5-10 days (distance learning was not evaluated).[27] The advantages of the distance learning approach for our model was that it was more simple to include the eye

care module as much of the learning is conducted in the PHWs own time. The disadvantage was that with a much limited in-person time there is less time to allow PHWs to practice the RRT techniques. However, the limited in-person time is compensated with video training and practice in routine with support by the IMNCI facilitators.

Primary health worker performance

PHW performance is a key aspect of the implementation of IMNCI and its success. Integration of eye care in IMNCI gives additional tasks for PHWs and supporting their performance becomes even more critical. IMCI evaluations have had mixed results with improvements in PHW performance seen in disease classification, treatment, and counselling in several countries, but also shortcomings in overall implementation and continuation of harmful practices such as unnecessary treatments.[26 28 29 30 31] In our study (Chapter 5) we found that prior to the training there was harmful PHW beliefs and practices, such as not believing that certain eye conditions (e.g. squint) were treatable therefore not referring patients, or not knowing the urgency of referrals for cataracts etc.

Rowe et al in their review of achieving and maintaining high-quality PHWs performance in low-resource settings proposed a number of determinants as well as possible interventions including health worker factors, work factors, health facility environment, administrative environment and political and economic environment.[30] The sections below will consider each of these interventions in turn.

Health worker factors (knowledge and skills, motivation, perceptions of patient demands, understanding of work responsibilities)

PHWs have had to adapt their scope as greater demands have been placed on them due to greater health care needs of the population .[32] WHO published in 2018 a technical review on building the primary healthcare workforce, recommending approaches based around multidisciplinary teams with different skills and practices in order to respond to a much wider range of population needs and improve overall productivity.[33] However PHWs continue to face enormous challenges to deliver good quality of care for this wider range of

healthcare needs and are usually overstretched.[33-35] This is a challenge in the context of delivery of eye care to children at primary care level as it is an additional task for PHWs.

In paper 2 (chapter 5) we found that the knowledge and skills of the PHWs improved with IMNCI training which included eye care, and the PHWs were better able to diagnose serious eye conditions that required urgent referral, but performance was not directly assessed.[11] In the qualitative interviews we noted that PHWs were motivated to examine the children using the Arclight as it gave them a sense of professionalism, and they felt the mothers also respected their skills more and were reassured by the examination. The inclusion of the eye module within the IMNCI training also meant they understood eye examination to be part of their routine work responsibilities and acceptable. This benefit of integration is important as eye care has traditionally been viewed as too specialised and not part of PHW's role. In Tanzania, eye care problems in children (most commonly minor infections) are the one of the top five reported problems at primary care level (MOH primary care routine data) therefore the PHWs were motivated to learn about eye care problems as this was something they encountered frequently, and this contributed to the sense that examining children's eye was their responsibility.

Work factors (complexity and clarity of clinical guidelines, guidelines change over time)

PHWs reported that the eye care module was easy to use and was at the correct level of complexity (compared to other IMNCI modules) (Chapter 5). This is important as increasing complexity of guidelines was a predictor of lower PHW performance in IMCI training in Benin.[36]

Ownership of standards by setting standards collaboratively with PHWs has been suggested as an important determinant of performance.[30] In our Tanzania study (Chapter 5) the eye care module was developed collaboratively with the IMNCI facilitators and PHWs which would have facilitated the ownership of the. Feedback was gained through in-depth interviews and questionnaires from PHWs which were acted upon to improve the training materials.

Healthy facility environment (norms and attitudes of co-workers, caseload, availability of equipment and supplies, supervision, accreditation, evaluation, communication, charter of patient rights, performance contracts)

How much each PHW is being expected do in each interaction with a child is also important. PHWs have been asked to deliver more care, including delivering complex interventions, e.g. for HIV, TB, and in maternal and child health care settings.[37] A study based in Tanzania exploring motivation among PHWs found a number of issues, including understaffing leading to PHWs acting 'upwards' or 'downwards', which led to taking on more complex cases for which they were not trained or having to do non-medical work, such as cleaning.[38] The acting 'upwards' led them to seeing cases which they felt they could handle better given specific training, especially as patients were unwilling or unable to pay to be transferred or treated at district hospital level. There was also frustration about the lack of feedback once patients were referred to secondary or tertiary level. These points are important in relation to the IMNCI eye care module, as lack of feedback and difficulty with referrals in our study (Chapter 5). Which signs meant children should be referred and which signs or cases could be managed at the primary care level is a key component of the eye care module, especially as the sight-threatening diseases need to be managed at a tertiary level. Therefore, these health systems issues are a major issue in the delivery of eye care at primary care level.

The dissemination of written educational materials and guidelines alone, usually through in-service training courses, has been shown to not be enough to improve performance or quality of care unless additional post-training support is included.[39] It has been shown that the addition of supervision is also more effective than training alone in improving health care workers practices.[40 41] 'Supported supervision' is used to describe a range of activities where there is direct observation by a more senior health professional or supervisor to ensure that tasks are being performed effectively by PHWs and to give guidance and support to help them become more effective in their work.[30 42 43] Supported supervision moves beyond supervision and onto broader performance issues by using better communication, problem-solving, supporting teamwork, and leadership to empower PHWs to improve their own and others performance. [44]

In a study of primary eye care in Tanzania, enhanced supervision of PHWs improved their knowledge and skills although there was a high level of attrition of PHWs within one year (24%).[45] In comparison, in our study the knowledge and skills improved and even slightly improved six months later.[46]

It is important that eye care is included in the IMNCI supervisors' visits to PHWs. In Tanzania the IMNCI facilitators are responsible for the supportive supervision of PHWs and for providing any updates of training to them. The PHWs all know the IMNCI facilitators that cover their areas, have their phone numbers, and are encouraged to contact them both during the IMNCI training and after the training for any questions or issues. The peer group formed during the IMNCI distance training is maintained after training as further support and contact. This ongoing sustained relationship, with an emphasis on joint problem solving, mentoring, peer group/self-supervision and two-way communication, is considered the foundation of supportive supervision.[43 47] In Tanzania eye care was also added to the supervision of the PHWs after it inclusion in the national strategy which is extremely important to ensure they are supported after learning new skills in eye care.

Importance of new equipment: the Arclight

One important innovation in equipment has been the development and availability of the 'Arclight', which is a low-cost, solar powered alternative to the traditional battery operated direct ophthalmoscope.[16] It has been validated and tested in low resource settings and is just as effective and easier to use than a direct ophthalmoscope.[15] Previously, at best, there would be one direct ophthalmoscope for a busy clinic, often with missing batteries, possibly broken or lost. The features of the Arclight have overcome these issues and have changed the landscape for eye screening in low resource settings. Arclight is small and lightweight with an attachment that allows it to be worn around the neck; and due to its cost ($10-12 for bulk purchase compared to $51 for an ophthalmoscope) it can be given to every healthcare worker. A study in Tanzania assessed the feasibility of Arclight for RRT screening for children under 5 years old by trained nurses in primary healthcare centres. Most nurses could distinguish a normal from an abnormal red reflex very easily or easily and reported

that the examination took less than 2-3 minutes to perform in daily life. However, the PHWS also reported some challenges were challenges due to short shortages they were overstretched in their day-to-day activities because of staff shortages, combined with the large numbers of children and multiple responsibilities.

The PHWs in study 2 (Chapter 5) reported a lot of satisfaction with having the equipment (normally worn loosely around the neck) and repeatedly mentioned feeling 'more professional'. Also, although in this study we did not specifically ask for feedback from caregivers, the PHWs reported that the caregivers felt more satisfied with the examination of their children. A key challenge which presented at the completion of the study was the supply of Arclights. Initial production of Arclights was delayed; and later, they were not readily available for PHWs who had been trained as they were not included in the essential equipment list for primary care clinics.

Policy Issues of Integrating Child Eye Health

Many health issues from surgery to mental health have faced challenges in gaining political attention at national and global levels.[48-51] The integration of eye health within newborn health and early childhood development (ECD) is key, but interestingly both newborn health and ECD have themselves struggled to be prioritised by policy makers.[52 53] An understanding of how other health issues have increased their political importance (or not) can give valuable insights on how advocates could bring child eye health to the urgent attention of policy makers.

A case study approach was used to understand the political priority given to the reduction of maternal mortality in five countries: Guatemala, Honduras, India, Indonesia, and Nigeria.[54] This study provided important lessons as it was focussed at a national level and compared the differing actions and results in a wide range of countries. The key factors identified were divided into three categories: transnational influences, domestic advocacy, and the national political environment. The researchers reported that national health

advocates were more likely to be effective if they focussed on specific factors.[54] The sections below will explore each of these factors in turn.

1. Policy community cohesion: Uniting close and interconnected policy communities, to transform their potential moral and knowledge-based authority into real political power and influencing national political officials.
2. Political entrepreneurs: Have track records if highlighting public health issues and being influential, respected and well connected enough to place key issues on national agendas.
3. Credible measures: Are specific measurable outcomes showing the severity of the problem so that political leaders cannot deny that a problem exists.
4. Large focussing events: Examples of this include conferences, national forums which can bring together diverse stakeholders.
5. Clear policy alternatives: Present leaders with effective policy alternatives so that policy-makers come know how to 'solve the problem and what they can do.

1. Policy community cohesion

Policy community cohesion was an important factor in Tanzania (Chapter 6). Policy communities are "networks of actors from different types of organizations—government agencies, legislatures, NGOs, and others—committed to one issue". How the communities are organized and structured impacts on how successful they are at influencing national politics.[55 56] Knowledge, unity and moral authority are among some of the factors of the community which can affect their influence.[57] In Tanzania the policy community was formed of key stakeholders which had convened on a number of funded child eye projects consisting of local and international NGOs, academics, MOH, WHO and UNICEF. The focus of the group was not specifically on including eye health in child health, but they had a history of collaboration on child eye health issues which had generated local evidence. This evidence was also influential with the policy makers therefore the degree of knowledge from local evidence, authority (as providers and advocates of child eye care services) and coherence was high. This was similar to many other case studies, for example in Honduras where a highly effective working group formed with key stakeholders (MOH, UNFPA, USAID,

UNICEF, other donors and agencies) produced a national plan to reduce maternal mortality.[54]

2. Political entrepreneurs

Political entrepreneurs are "individuals that shape national political agenda setting and are politically influential and particularly capable individuals willing to exert effort to advance a cause".[55 58] Policy communities are more effective when combined with political entrepreneurs and this difference was noted to be particularly effective in reducing maternal mortality in countries, such as Indonesia, compared to other countries, such as India and Nigeria.[58] In Tanzania (Chapter 6) there were no specific political entrepreneurs but importantly the involvement of the MOH prior to the start of the study led to the MOH representative being an advocate for inclusion of eye health in the IMNCI strategy. Therefore, the involvement of policy makers in projects and studies which are intended to lead to policy change is key in enabling them to advocate and create change.

3. Credible measures

Credible measures are the indicators which can be followed to show the extent of the problems and then the success or failure of a policy.[55 59] These make a difference because they powerfully make visible issues which have remained hidden, and incentivise action. Without any credible measures issues can be ignored by policy makers. In Tanzania (Chapter 6), there was presence of local evidence which formed the credible indicators and inspired action from policy makers as it was clear there was a burden of childhood eye diseases which was not being addressed; when presented with a possible solution to the problem they were ready to act.

4. Large scale focussing events

Focusing events are "large-scale happenings such as crises, conferences, and discoveries that attract notice from a wide audience" which have agenda-setting power.[60] In Tanzania (Chapter 6), the actors identified the importance of a national IMNCI review conference

which was timed to occur after the completion of the IMNCI study (Chapter 5). The opportunity to present the study findings at this conference with all the national actors involved in IMNCI led to the inclusion of the eye health module into the national IMNCI strategy.

5. Clear policy alternatives

Presenting solutions to the issue clearly incentivise policy makers to act as they feel they can 'solve' the problem. When policy communities do not have coherent, accepted proposal on how to dela with the issue then they are less likely to be successful as policy makers want to focus their attention where decisive action can be taken to address the issue.[55 61] This was key in a number of the 'Safe Motherhood' national case studies, including Indonesia, where a village midwife program from the MOH ensured a midwife in every village and was seen as a clear solution.[54] In contrast the International Safe Motherhood Initiative had been criticized for proposing interventions which lacked evidence and using unclear language to describe interventions which all contributed to confusion on the solutions. [62] In Study 3 (Chapter 6) there was a presence of clear and effective solutions through both the proposed module for integration but also importantly the presence of the Arclight as a key piece of equipment which was already validated within Tanzania. The presence of the Arclight provided an evidence-based solution to RRT in the primary healthcare setting which was noted by the MOH as a key factor in motivating them to act.

Overall, the factors identified in the national case studies in these five countries as effective for policy change were present in our case study in Tanzania. These key factors can be used in settings where policy change for child eye health is desired to review where advocates should focus their attention to bring about policy change. For example, if three of the factors are already present but two are lacking then it creates clarity around what steps need to be taken to support the desired shift to integrate eye health into the child health policy agenda in that setting.

<u>Key Shiffman framework factors</u>

The Shiffman framework was central to the analysis in Study 3 (Chapter 6). There were several key factors from the Shiffman Framework which were critical in the change of policy in Tanzania which I will explore in more depth in the following section.

Issue characteristics: credible indicators

The availability of local evidence was a critical influencing factor in Tanzania, as has been reported in other national policy studies. This factor is similar to the 'credible measure' already described in the previous national studies of maternal mortality. In another study the determinants of newborn health at a national level were explored in three countries, Bolivia, Malawi, and Nepal.[48] They found that the solutions for newborn health needed to have demonstrated efficacy in low resource settings, while building on existing national priorities and developing a strong network of national and global leaders were the key factors.[48] Contextually relevant evidence was found to be particularly influential, as the policy makers wanted to invest in solutions that were likely to show good results. This concurs with our experience in Tanzania which showed that the local evidence, also clearly relevant to the local context, was a clear deciding factor on proceeding with policy change.

Issue characteristics: effective interventions

With respect to issue characteristics, newborn health was, in the past, perceived as an intractable problem in low resource setting with few solutions or only expensive ones. This perception shifted with the availability of cost-effective interventions and evidence of successful strategies being widely available making it accessible for policy makers and programme managers to act.[63] Child eye health for under 5 year olds has also seen a shift to both having more cost-effective screening with the Arclight at primary care level and more effective treatments at tertiary level. Therefore, one important factor for child eye health could be to focus on disseminating the strategies more widely and in accessible language while also building evidence on the implementation of these strategies. In our study in Tanzania (paper 3, Chapter 6) the policy context benefitted from having the innovation in the Arclight and the presentation of 'a solution' for a cost-effective screening strategy. This

could certainly be scaled up in other settings as the innovation is available and there is growing evidence of its effectiveness as a screening strategy.[16 64]

Ideas: external framing

With respect to ideas, in newborn health advocacy they went beyond drawing attention to existing problems to defining the issues.[48] During a period when few global health actors had considered the issue of newborn survival, the advocates helped to create a new global health category of vulnerable newborns ("the small and sick newborn") which then became the focus for solutions. Within child eye health there are also clear issues which fit into specific newborn and child health strategies. For example, universal NES for all healthy babies and infants before 6 months can be included in Postnatal care strategies and Retinopathy of Prematurity (ROP) screening for premature babies is within the 'small and sick newborn' strategies. Framing child eye health to fit clearly within existing maternal and child health strategies makes it easier for policy makers to include it knowing it already fits within a policy they are supporting.

Child eye health is also ideally placed within the ECD agenda given the vital role of vision in ECD, learning, education, and the child's future potential. However ECD has faced a number of challenges in gaining prominence itself, including framing and governance.[52] The ECD community initially disagreed on fundamental issues, such as the definition of the problem i.e., whether it should start at conception or birth, and whether it should end at 5 years old or also cover 6-8 years old,[52]and its solutions, including boundaries of the field, scope of services and age range of early childhood. There is tension between health and education sectors about what should be included in ECD, but eye health can be framed to cross over between health and education. There are also differing opinions on the solutions and multiple ECD frameworks have a different emphasis on education and health.[65-67] This is partly due to the wide number of sectors ECD encompasses and the lack of evidence for many interventions. There is fragmentation of ECD actors across different government ministries, development agencies, NGOs, private sector, and funding is usually directed for specific sectors. Despite these challenges, a growing number of global actors and funders focus on ECD and on co-ordinating efforts and forming new partnerships.[68-71] The World

Bank and UNICEF have established an ECD network, linking governments, civil society, development partners, funders, and private actors.[72] There are also ECD related targets in the SDGs, increasing evidence for ECD strategies, metrics and justification of ECD as an investment case.[67 73]

One of the challenges for eye health is how it should be framed within the ECD and newborn agendas. Existing reproductive, maternal, newborn and child health services have been proposed as the entry points for ECD interventions, so integration of eye care into these services allows the ease of integration in the ECD agenda as well.[67 74]

Political contexts

The opportunity to use existing or emerging political priorities and link health issues within those to gain traction was used successfully in Tanzania (Chapter 6). IMNCI is an established strategy and relatively well funded in Tanzania, therefore placing eye health within a strategy which already had priority led to its sustainability. Once eye health was included within the IMNCI strategy the PHWs continued to be trained in eye care after the completion of the study, as the IMNCI strategy had its own stream of funding. This sustainability within child health programmes and policies is one of the advantages of integration of eye care. It can have disadvantages if eye care is seen as less important than other aspects of newborn or child health so can still be neglected within an integrated policy, however the alternative is usually no eye care in that setting.

The adapted Shiffman framework used in our study was useful in drawing out the similarities between our study and other health issues. Both the maternal mortality and newborn health case studies show similar influencing factors for policy change as were seen in our study in Tanzania.

<u>Other Policy Factors important in Integration of Child Eye Health</u>

Competing health priorities

In most countries health issues compete against one another for scarce funding. Certain issues can receive priority based on external funding by donors and NGOs which then influence national governments to prioritise those issues. One example has been HIV/AIDS which has received priority due to greater international funding while other issues such as maternal mortality were side-lined for some time.[54] Integration of the eye care within IMNCI or other child health programmes avoids the issue of competing with other child health issues. Thus, donors such as USAID continue to fund the whole package of training of IMNCI which now includes eye care. This is a key factor in not only child eye health gaining priority but also the sustainability of having allocated resources.

Networks

One important development in actor power can be when instead of a few individuals working on an issue in isolation this changes into an informal network providing global leadership on the cause.[53] Networks are defined by Shiffman et al as "Global health networks are cross-national webs of individuals and organizations linked by a shared concern to address a particular health problem global in scope".[75] The small eye health network in Tanzania was important in providing evidence and a clear accepted framing of ideas to the MOH. However, this is factor which has not been fully utilised in child eye health and there is a less clear global network. In addition to creating a child eye health network there is also the opportunity for child eye health advocates to become part of other larger child health networks to progress policy change. For example, the 'small and sick newborn' global network would be key for ROP awareness and action and similarly becoming part of the newborn health networks is important for advocating for newborn eye health.

Transferability of research and policy

The case study in Tanzania has shown important influencing factors for integrating eye health into child health in policy and practice. But can the lessons drawn from our Tanzanian studies be used in development of policies and practice in other settings? Dolowitz and

Marsh proposed a framework for exploring the relationship between policy transfer and its success or failure based around six questions.[76 77] Policy lessons can be drawn from within one country, for example the national government learning from lower levels of government, nationally from one country to another, and also internationally. Policy transfer does not need to be 'all or nothing' and although some policies may be copied, others will involve the transfer of ideas only, combining multiple policies or even inspire policy change but not using the original policy change content. The role of consultants, international NGOs and international governing organisations has become increasingly important in policy transfer and influencing national policy makers directly, through both their policies and funds, and indirectly, through the shared knowledge at conferences and in reports at an international level.

The causes for the failure of policy transfer has been proposed to be divided into three main categories; uninformed transfer where the information about the policy and how it operated was insufficient; incomplete transfer where critical elements which made the policy successful are not transferred; and inappropriate transfer where the economic, social, political and ideological contexts are too different.[76] These factors would be important to consider for other countries considering using the Tanzania example to include eye care in their IMNCI strategy. In Tanzania, it was not only the eye module content but the process of developing it with all stakeholders using the local context that was critical to its successful adoption. Economic, social, political, and ideological contexts are also important as IMNCI is more appropriate in lower resource settings and certain countries. In Tanzania, IMNCI is given political priority, whereas other countries may have chosen a primary care system which does not use IMNCI. All these factors need to be considered when advocating for wider adoption of eye care in IMNCI.

Policy transfer is linked to evidence-based policy making as the same types of evidence which should inform policy making should be used in policy transfer. Evidence can be used in many ways in policy transfer, including;

1. 'Instrumentally' by using evidence to improve the outcomes of policy
2. 'Conceptually' by using evidence to increase knowledge on an issue
3. 'Symbolically' when policy makers use evidence to justify their own political agenda

Decisions in policy making are made in both rational and emotional ways, which require different forms of evidence. This is relevant to potential transfer of the inclusion of eye health in IMNCI or NES in postnatal care guidelines. The evidence from our studies in Tanzania covered both the rational (data driven) and emotional (qualitative and stories) which can be used in other settings when looking to influence their national agenda.

Witter et al studied policy transfer and the use of evidence in eight low- and middle-income settings on a range of policies, including IMNCI.[78] They structured their findings according to policy conceptualisation, policy uptake or implementation and further policy development. For conceptualisation, the authors found that all reforms start with local recognition of a problem before being influenced in several ways. Ideas from other contexts are often brought by international agencies who partner with government. The policy change needs to be seen as meeting local needs but also the development of the policy within country is critical. The example of IMNCI in Nepal followed this route of substantial within country conceptualisation with bilateral and multilateral partner support in policy transfer. This example could occur in other settings as IMNCI benefits from regional and national reviews which are an opportunity to exchange ideas between countries and from being a strategy which is designed to be flexible and adaptable. If local needs of child eye health are established, then external partners can support the concept of including eye health in IMNCI.

There can also be resistance to the acceptance or adoption of international ideas or rejection of advice from other countries. For example, Nepal resisted several WHO recommended adjustments to clinical guidelines as it did not fit into their wider health system strategy or capacity.[78] In Nepal, the drivers which led to guidelines being updated were from the local context and implementation issues .There was also greater credibility given to local evidence in Nepal with globally published evidence mentioned less often. Therefore the local context and politics is critical and even if evidence is lacking for a policy, if it fits well in the local socio-political context, then it could still be taken up.[78] Studies have shown evidence used to inform policy is often not scientifically collected or applied and it is important to highlight how evidence meets the socio-political concerns and priorities of the policy makers.[79] [80]

At country level, policy makers and technical staff often use relationships with development partners for advice at all policy stages, and these personal relationships can be very important especially in smaller countries with long-term partners.[78 79 81] International and regional meetings and technical assistance programmes can also influence learning, and within countries, pilot projects supported by international NGOs can play an important role in developing policies. In our case study in Tanzania the pilot study using international partners played an important role in policy update which could be used in other countries for policy transfer.

The relevance to integration of eye care into IMNCI or other child health policies in other low- and middle-income settings, is using the key factors for successful policy transfer to other settings by focussing on; local advocacy for recognition of the problem, the influence of partnerships with international agencies, regional examples and development of local evidence which is framed to fit with the local socio-political agenda.

Limitations

The systematic review (Study 1, Chapter 4) was limited by the lack of published evidence as only three studies fulfilled the inclusion criteria. Studies of NES vs no screening requires following up a very large number of babies due to the relatively low prevalence of detectable eye conditions at this age, such as congenital cataracts, and therefore studies are expensive and challenging to conduct, particularly in low-income settings. Since NES is standard practice in most high resource settings further studies are not seen as a priority.

Reviewing the integration of eye care in child health programmes or evaluating a primary care 'package' to improve child eye health would be more relevant evidence reviews but this was not possible to the lack of evidence of implementation. Thus, a limitation of the systematic review of NES is that it is a review of one specific intervention while the integration of eye care into child eye health involves several interventions as a package. While there is evidence that the individual interventions are effective there is little evidence of any evaluations of the whole package of the primary eye care for children.[14]

The study in Tanzania of integrating eye care into IMNCI (Study 2, Chapter 5) had several limitations. The PHWs were not assessed directly but photographs and case studies were used as a proxy for observation of case management, and self- structured face to face examinations, similar to standard medical or nursing exams but would have been more time and labour consuming. Other alternatives included direct observation of their skills in routine practice or use of simulation models to test their skills.

The outcome measures were limited to knowledge of PHWs and their feedback but a wider range of outcome measures, including the number of children examined during routine practice, referral rates, age at referral and clinical outcomes of children referred would be important to study in a larger scale evaluation. Further, estimates of cost of the intervention per child screened or per blind child prevented would be important for advocacy and policy makers.

A limitation of the qualitative policy study in Tanzania (Study 3, Chapter 6) is that all the interviews were analysed by one researcher which increases the possibility of bias from subjectivity. This was counteracted by using the Shiffman and Smith framework both in data collection and analysis as this more structured approach can reduce the subjectivity, as well as improve comparability.

Another limitation is that I was the PI in study 2 (Chapter 5). The evidence generated from study 2 contributed to the decision to include eye health into the national IMNCI strategy in Tanzania, which was the focus of study 3 (Chapter 6). This had important implications for data collection, analysis, and interpretation of results. I had knowledge of many of the events and knew some of the participants and hence there is a risk of bias from assumptions. However, the advantage of this was a more thorough awareness of the context of the policy change and history which can add greater depth to the quality of the analysis. Study participants were aware of my credentials as a paediatric ophthalmologist, experience in child eye health research and the institutions where I worked (LSHTM). It is, therefore, likely that the data collected were influenced by this knowledge, which may have led them to withhold commonly known information, and to be more positive towards the

institutions and actors involved. The interpretation of the data will also have been influenced by my prior knowledge of the issues and my professional interest in child eye health.

Implications for research

In Tanzania

An evaluation of the outcomes of this strategy at a national level is needed to provide important insights on the acceptability, appropriateness, feasibility, coverage, cost, and sustainability. The key overall questions could include:

1. How does integration affect PHWs' knowledge and management of eye conditions in children?
2. How does the integration affect referral rates, age at detection and uptake of referrals of children?
3. Which are the processes and health system and external factors which enable or hinder implementing integration of eye care in IMNCI?
4. What are the cost implications in terms of affordability and budgetary needs?
5. What is the cost-effectiveness of the intervention per child screened and per blind child prevented?
6. What are the unintended consequences of the intervention on the health system? E.g., on PHWs time and other duties
7. Specific questions embedded within the evaluation could include (but not be limited to):
    a) How acceptable (or not) is the Arclight in these settings for PHWs?
    b) Are there any concerns with using this or other technologies?
    c) How could the use of the technologies be improved?

The inclusion of eye care in child health programmes is a complex intervention which means that clinical and health system outcomes and impacts need to be considered.

In other countries

IMNCI is implemented in varying degrees in over 100 countries. Study 3 (Chapter 6) highlighted the importance of locally owned research therefore pilot studies in other countries from different regions is needed to build evidence of including eye health in IMNCI in other contexts. Therefore, implementation research on including eye care in IMNCI in

different countries with different contexts and challenges with a view to strengthen programmes is critical. A multi-country implementation research agenda can then be used to guide policy change at other national, regional, and global levels.

Other interventions

There are several other interventions which would be important to add, which could not be evaluated within the timeframe of these studies. One example is including eye care in pre-service training for PHWs in child health and comparing this approach in combination with in-service training to in-service training alone. Another intervention would be to add data fields on eye screening to the caregiver held growth and immunization charts, called "Road to Health" chart in Tanzania, to monitor the proportion who are screened and whether they are referred.

The inclusion of eye care in IMNCI is one example of a model of how eye care can be integrated into a child health programme and strategy. However, there are several opportunities to include eye health in child health other programmes and policies. For example, the recent WHO Postnatal Care guidelines recommended NES, and therefore evaluation of postnatal care where NES is included is also important. ECD programmes and policy are another area where there are multiple opportunities to include eye health, and this requires evaluating different approaches in different settings.

Policy research

Policy research is needed on where and why eye care has not received priority in child health policies at national and global levels in different contexts to understand fully the challenges faced as well as the opportunities. Policy research at a global level on why child eye health has remained less visible within the newborn and child health agenda to date, and what key factors would generate greater global priority are critical at this time due to the opportunities which have arisen due to expanding child health policies which now

include ‘thrive’ and childhood development. The adapted Shiffman and Smith framework developed in study 3 (Chapter 6) can be used to explore agenda setting in other countries.

Current research

I am currently leading an on-going study in Tanzania which has developed a series of training videos on RRT which are being used by MOH and WHO for in-service IMNCI training. The training is being undertaken during IMNCI supervision visits, and the number of children screened, referred, and treated for eye problems is being monitored. This research builds on the previous studies and is in response to the feedback from study 2 (Chapter 5) where PHWs requested video training. These videos have been developed in collaboration with WHO Tanzania and AFRO as well as the MOH. The project has been presented at a recent WHO AFRO IMNCI review meeting. Future collaborations are planned to scale up the programme within Tanzania with embedded evaluation research and consider in which other countries the model could be tested.

Implications for implementation and policy

National level

The case study in Tanzania is a model for how eye care can be included in IMNCI both at a programme and policy level. As IMNCI is in place in over 100 countries globally there is an opportunity for wide scale adoption alongside the research agenda outlined above. Using the lessons from successful policy transfer countries can adapt the eye care module for their own local context using local evidence and leveraging local networks of key stakeholders.

Global level

At a global policy level WHO Geneva review and manage IMNCI policy. The inclusion of eye care in the global IMNCI policy is critical endorsement of child eye health within their child policies. The inclusion of the eye health module at this level would have important far-reaching consequences in influencing agenda and priority setting for countries at a national

level and providing the needed technical support at country level to start planning and implementing child eye health through IMNCI.

Other health policies and programmes

The wider implication of the Tanzania model is that is illustrative of how eye care can be included in a child health programme and policy per se, and noy only in IMNCI. There are other child health programmes for newborns, ECD and others where eye health could, and should, be included. Adapting lessons from the Tanzania studies a similar approach can be used to develop materials and leverage opportunities for inclusion in other child health programmes and policies.

Conclusions

Integrating eye care into child health through policy and in practice covers a wide range of issues. The systematic review of NES showed evidence for the practice of NES but highlighted the lack of evidence in low resource settings. The guideline review showed that NES is an established practice in high income settings, but that there were no guidelines for NES in low resource settings. The studies in Tanzania showed a potential model for including eye health in a child health strategy using IMNCI that was acceptable and feasible within the setting. After Study 2 (Chapter 5) the inclusion of eye health was ratified with eye health becoming part of the national IMNCI strategy in Tanzania. The review of this policy change in Tanzania in study 3 (Chapter 6), taking into consideration global factors, illustrates several 'lessons' which could be applicable to wider scale up of this policy or other models of including eye care in child health.

This study of integrating eye health into child health policies and programmes using Tanzania as a case study demonstrated;

1) NES is an evidenced based screening strategy which is well established in high resource settings but missing in low resource settings

2) PHWs in a child health programme can be trained in eye care, including RRT screening of babies and children, which can lead to an increase in PHWs knowledge and skills

3) PHWs found the inclusion of eye health within their child health training to be acceptable
4) Local evidence and close relationships with policy makers during the research process was an important factor which led to local 'ownership' of the strategy and integration into national policy
5) Leveraging existing child health and eye health communities is key for a specialist issue such as child eye health and
6) There are opportunities for wide scale inclusion of eye health in child health policies given the shift in the global child health agenda to support children's early childhood development and to 'thrive' as well as 'survive'

This thesis has shown that there is a workable model for integrating eye care into child health at programme and policy level. Now is the time for this model to be scaled up rapidly regionally using Tanzania as an example with the support of WHO AFRO and UNICEF. Concurrently the inclusion of eye care into IMNCI policy at a global level should be endorsed by WHO Geneva. The inclusion in the policy at the global level would be a simple and effective way to influence and support countries globally to include eye care in their ongoing IMNCI strategies, with the potential to scale to 100 countries and affect millions of children. Embedded implementation research and evidence from different low resource settings would guide local adaptation of the IMNCI strategies and ongoing implementation.

In Tanzania there was a critical policy window which catalysed the inclusion into national policy. That critical policy window is now open for the global child eye health community. It is imperative that the child health community and leaders advocate and act for wide scale inclusion of eye health into IMNCI and other child health policies and programmes. Alongside there needs to be ongoing development, implementation, and evaluation of models of how integrated child eye health can be adapted for local contexts. This would have a lasting impact on children, reduce avoidable blindness and visual loss, and allow them to achieve their full potential.

References

1. Malik AN, Evans JR, Gupta S, et al. Universal newborn eye screening: a systematic review of the literature and review of international guidelines. *J Glob Health* 2022;12:12003. doi: 10.7189/jogh.12.12003 [published Online First: 2022/10/22]
2. Rahi JS, Dezateux C. National cross sectional study of detection of congenital and infantile cataract in the United Kingdom: role of childhood screening and surveillance. *BMJ : British Medical Journal* 1999;318(7180):362-65.
3. Chee RI, Chan RVP. Universal newborn eye screening: an effective strategy to improve ocular health? *Eye (Lond)* 2018;32(1):50-52. doi: 10.1038/eye.2017.133 [published Online First: 2017/07/22]
4. Callaway NF, Ludwig CA, Blumenkranz MS, et al. Retinal and Optic Nerve Hemorrhages in the Newborn Infant: One-Year Results of the Newborn Eye Screen Test Study. *Ophthalmology* 2016;123(5):1043-52. doi: 10.1016/j.ophtha.2016.01.004 [published Online First: 2016/02/15]
5. Li LH, Li N, Zhao JY, et al. Findings of perinatal ocular examination performed on 3573, healthy full-term newborns. *Br J Ophthalmol* 2013;97(5):588-91. doi: 10.1136/bjophthalmol-2012-302539 [published Online First: 2013/02/22]
6. Vinekar A, Govindaraj I, Jayadev C, et al. Universal ocular screening of 1021 term infants using wide-field digital imaging in a single public hospital in India - a pilot study. *Acta Ophthalmol* 2015;93(5):e372-6. doi: 10.1111/aos.12685 [published Online First: 2015/02/28]
7. Goyal P, Padhi TR, Das T, et al. Outcome of universal newborn eye screening with wide-field digital retinal image acquisition system: a pilot study. *Eye (Lond)* 2018;32(1):67-73. doi: 10.1038/eye.2017.129 [published Online First: 2017/07/25]
8. Egge K, Lyng G, Maltau JM. Retinal haemorrhages in the newborn. *Acta Ophthalmol (Copenh)* 1980;58(2):231-6. doi: 10.1111/j.1755-3768.1980.tb05715.x [published Online First: 1980/04/01]
9. Egge K, Lyng G, Maltau JM. Effect of instrumental delivery on the frequency and severity of retinal hemorrhages in the newborn. *Acta Obstet Gynecol Scand* 1981;60(2):153-5. [published Online First: 1981/01/01]

10. Geneva WHO. WHO recommendations on maternal and newborn care for a positive postnatal experience. *https://wwwwhoint/publications/i/item/9789240045989* 2022;Licence: CC BY-NC-SA 3.0 IGO.
11. Malik ANJ, Mafwiri M, Gilbert C, et al. Integrating eye health training into the primary child healthcare programme in Tanzania: a pre-training and post-training study. *BMJ Paediatr Open* 2020;4(1):e000629. doi: 10.1136/bmjpo-2019-000629 [published Online First: 2020/07/17]
12. World Health Organisation, International Agency for the Prevention of Blindness. Preventing blindness in children : report of a WHO/IAPB scientific meeting, Hyderabad, India, 13-17 April 1999, 2000 WHO_PBL_00.77.
13. Mafwiri MM, Kisenge R, Gilbert CE. A pilot study to evaluate incorporating eye care for children into reproductive and child health services in Dar-es-Salaam, Tanzania: a historical comparison study. *BMC nursing* 2014;13:15. doi: 10.1186/1472-6955-13-15 [published Online First: 2014/06/17]
14. Malik ANJ, Mafwiri M, Gilbert C. Integrating primary eye care into global child health policies. *Arch Dis Child* 2018;103(2):176-80. doi: 10.1136/archdischild-2017-313536 [published Online First: 2017/10/11]
15. Mndeme FG MB, Kim MJ, Sinke L, Allen L, Mgaya E, Bastawrous A, MacLeod D, Burton MJ, Gilber C, Bowman R. Red reflex examination in reproductive and child health clinics for early detection of paediatric cataract and ocular media disorders: cross-sectional diagnostic accuracy and
feasibility studies from Kilimanjaro, Tanzania. *Eye* 2020
16. Blundell R, Roberts D, Fioratou E, et al. Comparative evaluation of a novel solar powered low-cost ophthalmoscope (Arclight) by eye healthcare workers in Malawi. *BMJ Innov* 2018;4(2):98-102. doi: 10.1136/bmjinnov-2017-000225 [published Online First: 2018/04/20]
17. Armstrong Schellenberg JR, Adam T, Mshinda H, et al. Effectiveness and cost of facility-based Integrated Management of Childhood Illness (IMCI) in Tanzania. *Lancet* 2004;364(9445):1583-94. doi: 10.1016/s0140-6736(04)17311-x
18. Group TIM-CEHFSS. The effect of Integrated Management of Childhood Illness on observed quality of care of under-fives in rural Tanzania. *Health Policy and Planning* 2004;19(1):1-10. doi: 10.1093/heapol/czh001

19. Pariyo GW, Gouws E, Bryce J, et al. Improving facility-based care for sick children in Uganda: training is not enough. *Health Policy Plan* 2005;20 Suppl 1:i58-i68. doi: 10.1093/heapol/czi051
20. Kilov K, Hildenwall H, Dube A, et al. Integrated Management of Childhood Illnesses (IMCI): a mixed-methods study on implementation, knowledge and resource availability in Malawi. *BMJ Paediatr Open* 2021;5(1):e001044. doi: 10.1136/bmjpo-2021-001044 [published Online First: 20210430]
21. Arifeen SE, Bryce J, Gouws E, et al. Quality of care for under-fives in first-level health facilities in one district of Bangladesh. *Bull World Health Organ* 2005;83(4):260-7. [published Online First: 20050425]
22. Gera T, Shah D, Garner P, et al. Integrated management of childhood illness (IMCI) strategy for children under five. *Cochrane Database Syst Rev* 2016(6):Cd010123. doi: 10.1002/14651858.CD010123.pub2 [published Online First: 20160622]
23. Lulseged S. Integrated management of childhood illness: a review of the Ethiopian experience and prospects for child health. *Ethiop Med J* 2002;40(2):187-201.
24. Font F, Quinto L, Masanja H, et al. Paediatric referrals in rural Tanzania: the Kilombero District Study - a case series. *BMC Int Health Hum Rights* 2002;2(1):4. doi: 10.1186/1472-698x-2-4
25. Muela SH, Mushi AK, Ribera JM. The paradox of the cost and affordability of traditional and government health services in Tanzania. *Health Policy Plan* 2000;15(3):296-302. doi: 10.1093/heapol/15.3.296
26. Nguyen DT, Leung KK, McIntyre L, et al. Does integrated management of childhood illness (IMCI) training improve the skills of health workers? A systematic review and meta-analysis. *PloS one* 2013;8(6):e66030. doi: 10.1371/journal.pone.0066030 [published Online First: 20130612]
27. Rowe AK, Rowe SY, Holloway KA, et al. Does shortening the training on Integrated Management of Childhood Illness guidelines reduce its effectiveness? A systematic review. *Health Policy and Planning* 2011;27(3):179-93. doi: 10.1093/heapol/czr033
28. Gouws E, Bryce J, Habicht JP, et al. Improving antimicrobial use among health workers in first-level facilities: results from the multi-country evaluation of the Integrated Management of Childhood Illness strategy. *Bulletin of the World Health Organization* 2004;82(7):509-15.

29. Bryce J, Victora CG, Habicht JP, et al. Programmatic pathways to child survival: results of a multi-country evaluation of Integrated Management of Childhood Illness. *Health Policy Plan* 2005;20 Suppl 1:i5-i17. doi: 10.1093/heapol/czi055
30. Rowe AK, de Savigny D, Lanata CF, et al. How can we achieve and maintain high-quality performance of health workers in low-resource settings? *Lancet* 2005;366(9490):1026-35. doi: 10.1016/s0140-6736(05)67028-6
31. Rowe AK, Onikpo F, Lama M, et al. Management of childhood illness at health facilities in Benin: problems and their causes. *American journal of public health* 2001;91(10):1625-35. doi: 10.2105/ajph.91.10.1625
32. Vasan A, Mabey DC, Chaudhri S, et al. Support and performance improvement for primary health care workers in low- and middle-income countries: a scoping review of intervention design and methods. *Health Policy Plan* 2017;32(3):437-52. doi: 10.1093/heapol/czw144
33. Dussault G KR, Castro Lopes S, Campbell J. Building the primary health care workforce of the 21st century - Background paper to the Global Conference on Primary Health Care: From Alma-Ata Towards Universal Health Coverage and the Sustainable Development Goals. *Geneva : World Health Organization* 2018
34. Haines A, Sanders D, Lehmann U, et al. Achieving child survival goals: potential contribution of community health workers. *Lancet* 2007;369(9579):2121-31. doi: 10.1016/s0140-6736(07)60325-0
35. Geneva W. The World Report 2008. Primary Health Care: Now more than ever. *https://appswhoint/iris/bitstream/handle/10665/43949/9789241563734_engpdf?sequence=1&isAllowed=y* 2008
36. Steinhardt LC, Onikpo F, Kouamé J, et al. Predictors of health worker performance after Integrated Management of Childhood Illness training in Benin: a cohort study. *BMC health services research* 2015;15:276. doi: 10.1186/s12913-015-0910-4 [published Online First: 20150721]
37. Suthar AB, Rutherford GW, Horvath T, et al. Improving antiretroviral therapy scale-up and effectiveness through service integration and decentralization. *Aids* 2014;28 Suppl 2:S175-85. doi: 10.1097/qad.0000000000000259

38. Manongi RN, Marchant TC, Bygbjerg IC. Improving motivation among primary health care workers in Tanzania: a health worker perspective. *Hum Resour Health* 2006;4:6. doi: 10.1186/1478-4491-4-6 [published Online First: 20060307]

39. Rowe SY, Peters DH, Holloway KA, et al. A systematic review of the effectiveness of strategies to improve health care provider performance in low- and middle-income countries: Methods and descriptive results. *PloS one* 2019;14(5):e0217617. doi: 10.1371/journal.pone.0217617 [published Online First: 20190531]

40. Rowe AK, Rowe SY, Peters DH, et al. Effectiveness of strategies to improve health-care provider practices in low-income and middle-income countries: a systematic review. *Lancet Glob Health* 2018;6(11):e1163-e75. doi: 10.1016/s2214-109x(18)30398-x [published Online First: 2018/10/13]

41. Arsenault C, Rowe SY, Ross-Degnan D, et al. How does the effectiveness of strategies to improve healthcare provider practices in low-income and middle-income countries change after implementation? Secondary analysis of a systematic review. *BMJ Quality & Safety* 2022;31(2):123. doi: 10.1136/bmjqs-2020-011717

42. Djibuti M, Gotsadze G, Zoidze A, et al. The role of supportive supervision on immunization program outcome - a randomized field trial from Georgia. *BMC Int Health Hum Rights* 2009;9 Suppl 1(Suppl 1):S11. doi: 10.1186/1472-698x-9-s1-s11 [published Online First: 20091014]

43. L Marquez LK. Making Supervision Supportive and Sustainable: New Approaches to Old Problems. *https://pdfusaidgov/pdf_docs/PNACS924pdf*;MAQ PAPER NO. 4 . 2002

44. PATH CsVPa. Guidelines for Implementing Supportive Supervision: A step-by-step guide with tools to support immunization, 2003.

45. Okwen M, Lewallen S, Courtright P. Primary eye care skills scores for health workers in routine and enhanced supervision settings. *Public Health* 2014;128(1):96-100. doi: 10.1016/j.puhe.2013.10.007 [published Online First: 20131217]

46. Malik ANJ, Mafwiri M, Gilbert C, et al. Integrating eye health training into the primary child healthcare programme in Tanzania: a pre-training and post-training study. *BMJ Paediatrics Open* 2020;4(1):e000629. doi: 10.1136/bmjpo-2019-000629

47. Stinson W, Malianga L, Marquez L, et al. Quality supervision. *QA Brief* 1998;7(1):4-6.

48. Smith SL, Shiffman J, Kazembe A. Generating political priority for newborn survival in three low-income countries. *Glob Public Health* 2014;9(5):538-54. doi: 10.1080/17441692.2014.904918 [published Online First: 2014/04/29]
49. Shiffman J, Smith S. Generation of political priority for global health initiatives: a framework and case study of maternal mortality. *Lancet (London, England)* 2007;370(9595):1370-9. doi: 10.1016/s0140-6736(07)61579-7 [published Online First: 2007/10/16]
50. Shawar YR, Shiffman J, Spiegel DA. Generation of political priority for global surgery: a qualitative policy analysis. *Lancet Glob Health* 2015;3(8):e487-e95. doi: 10.1016/s2214-109x(15)00098-4 [published Online First: 2015/07/19]
51. Tomlinson M, Lund C. Why does mental health not get the attention it deserves? An application of the Shiffman and Smith framework. *PLoS Med* 2012;9(2):e1001178. doi: 10.1371/journal.pmed.1001178 [published Online First: 20120228]
52. Shawar YR, Shiffman J. Generation of global political priority for early childhood development: the challenges of framing and governance. *Lancet* 2017;389(10064):119-24. doi: 10.1016/s0140-6736(16)31574-4 [published Online First: 2016/10/09]
53. Shiffman J. Issue attention in global health: the case of newborn survival. *Lancet* 2010;375(9730):2045-9. doi: 10.1016/s0140-6736(10)60710-6 [published Online First: 2010/06/24]
54. Shiffman J. Generating political priority for maternal mortality reduction in 5 developing countries. *Am J Public Health* 2007;97(5):796-803. doi: 10.2105/ajph.2006.095455 [published Online First: 20070329]
55. Kingdon JW, Stano E. Agendas, alternatives, and public policies: Little, Brown Boston 1984.
56. Sabatier PA, Weible CM. Theories of the policy process: Westview press 2014.
57. PM H. Introduction: epistemic communities and international policy coordination. . *Int Organ* 1992;46:1-35.
58. Shiffman J. Generating political will for safe motherhood in Indonesia. *Soc Sci Med* 2003;56(6):1197-207. doi: 10.1016/s0277-9536(02)00119-3
59. Walker JL. Performance gaps, policy research, and political entrepreneurs: toward a theory of agenda setting. *Policy Studies Journal* 1974;3(1):112.

60. Birkland TA. After disaster: Agenda setting, public policy, and focusing events: Georgetown University Press 1997.
61. Sabatier PA. The advocacy coalition framework: revisions and relevance for Europe. *Journal of European public policy* 1998;5(1):98-130.
62. Hussein J, Clapham S. Message in a bottle: sinking in a sea of safe motherhood concepts. *Health Policy* 2005;73(3):294-302.
63. Shiffman J. Network advocacy and the emergence of global attention to newborn survival. *Health Policy Plan* 2016;31 Suppl 1(Suppl 1):i60-73. doi: 10.1093/heapol/czv092 [published Online First: 2015/09/26]
64. Hytiris ML, Fioratou E, Gillan SN. The Arclight vs. traditional ophthalmoscope: a cross-over trial. *Eye (Lond)* 2021;35(3):831-37. doi: 10.1038/s41433-020-0972-3 [published Online First: 20200528]
65. MJ Newman AD. What matter most for Early Childhood Development: A Framework paper. *World Bank* Jan 2013;SABER Working Paper Series
66. University CotDCaH. A science-based framework for early childhood policy: using evidence to improve outcomes in learning, behavior, and health for vulnerable children. *http://wwwdevelopingchildharvardedu/* 2007
67. Richter LM, Daelmans B, Lombardi J, et al. Investing in the foundation of sustainable development: pathways to scale up for early childhood development. *Lancet* 2017;389(10064):103-18. doi: 10.1016/s0140-6736(16)31698-1 [published Online First: 20161004]
68. http://www.savingbrainsinnovation.net/.
69. https://r4d.org/projects/fresh-focus-early-childhood-workforce/.
70. https://www.unesco.org/en/articles/supporting-childhood-care-and-education-key-success-sustainable-development-goals.
71. https://www.everywomaneverychild.org/about/#sect1.
72. Bank W. World Bank Group, UNICEF urge greater investment in early childhood development. *http://wwwworldbankorg/en/news/press-release/2016/04/14/world-bank-group-unicef-urge-greater-investment-in-early-childhood-development* April 2016

73. Smythe T, Zuurmond M, Tann CJ, et al. Early intervention for children with developmental disabilities in low and middle-income countries – the case for action. *International Health* 2020;13(3):222-31. doi: 10.1093/inthealth/ihaa044
74. Daelmans B, Black MM, Lombardi J, et al. Effective interventions and strategies for improving early child development. *Bmj* 2015;351:h4029. doi: 10.1136/bmj.h4029 [published Online First: 20150914]
75. Shiffman J, Quissell K, Schmitz HP, et al. A framework on the emergence and effectiveness of global health networks. *Health Policy Plan* 2016;31 Suppl 1(Suppl 1):i3-16. doi: 10.1093/heapol/czu046 [published Online First: 2015/09/01]
76. Dolowitz DP, Marsh D. Learning from abroad: The role of policy transfer in contemporary policy-making. *Governance* 2000;13(1):5-23.
77. Dolowitz D, Marsh D. Who Learns What from Whom: A Review of the Policy Transfer Literature. *Political Studies* 1996;44(2):343-57. doi: 10.1111/j.1467-9248.1996.tb00334.x
78. Witter S, Anderson I, Annear P, et al. What, why and how do health systems learn from one another? Insights from eight low- and middle-income country case studies. *Health Res Policy Syst* 2019;17(1):9. doi: 10.1186/s12961-018-0410-1 [published Online First: 20190121]
79. Lavis JN, Oxman AD, Moynihan R, et al. Evidence-informed health policy 1 - synthesis of findings from a multi-method study of organizations that support the use of research evidence. *Implement Sci* 2008;3:53. doi: 10.1186/1748-5908-3-53 [published Online First: 20081217]
80. Cairney P, Oliver K. Evidence-based policymaking is not like evidence-based medicine, so how far should you go to bridge the divide between evidence and policy? *Health Res Policy Syst* 2017;15(1):35. doi: 10.1186/s12961-017-0192-x [published Online First: 20170426]
81. Koon AD, Rao KD, Tran NT, et al. Embedding health policy and systems research into decision-making processes in low- and middle-income countries. *Health Res Policy Syst* 2013;11:30. doi: 10.1186/1478-4505-11-30 [published Online First: 20130808]

CHAPTER 8 Appendices

Appendix 1: Supplementary Materials for Introduction Section

Publication: Malik et al. Integrating primary eye care into global child health policies 2017

OPEN ACCESS

Integrating primary eye care into global child health policies

Aeesha Nusrat Jehan Malik,[1,2] Milka Mafwiri,[3] Clare Gilbert[1]

[1]Department of Clinical Research, International Centre of Eye Health, London School of Hygiene and Tropical Medicine, London, UK
[2]Moorfields Eye Hospital, London, UK
[3]Department of Ophthalmology, Muhimbili University of Health and Allied Sciences, Dares Salaam, Tanzania, UK

Correspondence to
Dr Aeesha Nusrat Jehan Malik, International Centre of Eye Health, London School of Hygiene and Tropical Medicine, Keppel Street, London WC1E7HT, UK;
aeesha.malik@lshtm.ac.uk, draeeshamalik@gmail.com

Received 10 June 2017
Revised 5 September 2017
Accepted 6 September 2017
Published Online First
7 October 2017

ABSTRACT
Globally, approximately 75% of blind children live in low-income countries (LICs). Almost half of blindness and low vision in LICs is due to avoidable causes such as corneal scarring from measles infection, vitamin A deficiency disorders, use of harmful traditional eye remedies, ophthalmia neonatorum and cataract.

BACKGROUND

Avoidable visual impairment and blindness in children

Blindness and vision loss in childhood can have far reaching consequences, impacting psychomotor and cognitive development, educational attainment, employment, earning potential and well-being.[1 2] There are often negative social and financial consequences for the child's family as well.[1] Children who are blind are also more likely to die in childhood than a child with good vision, particularly if they live in low-income countries (LICs).[3] The prevalence of blindness varies from 12 to 15 per 10 000 in very LICs compared with per 3–4 per 10 000 in high-income countries.[2] Approximately 75% of blind children live in LICs. These figures do not include uncorrected refractive errors, principally shortsightedness, which affects an estimated 2 million children globally, the majority of whom are aged 10 years and above.

The causes of blindness in children also vary, reflecting socioeconomic development, cultural practices (eg, consanguinity), coverage of preventive measures (eg, measles immunisation) and access to appropriate eye care and optical services. Vitamin A supplementation (VAS) and measles immunisation programmes in LICs have reduced corneal scarring and visual impairment as a cause of avoidable blindness.[2] However, in sub-Saharan Africa almost half of all blindness and low vision in children remain due to preventable or treatable causes.[4] In LICs, the majority of blind children, excluding those with refractive errors, are either born blind or become blind by the age of 6 years, so children of this age group and their mothers are key targets for intervention.[5]

Global child eye health policy

VISION 2020 was launched in 1999 by the WHO and the International Agency for the Prevention of Blindness (IAPB) to eliminate avoidable blindness globally by 2020, including blindness in children.[6] In 2002, WHO identified 13 targets for child eye health, which included reducing the global blindness prevalence from 7 to 4/10 000 children, eliminating corneal scarring and ensuring access to tertiary eye care services for children with cataract. Ten 'key activities for healthy eyes in children' were also recommended for integration into primary maternal and child health services and inclusion in national prevention of blindness plans, emphasising the close relationship between general child health and eye health[7] (table 1). Although there has been some progress in terms of tertiary eye care for children, little attention has been paid to primary eye care (PEC).

Rubella immunisation has not been included in these 'activities' as policies vary between countries dependent on the local epidemiology and immunisation rates. Retinopathy of prematurity is a growing cause of avoidable blindness in low and middle-income countries (LMICs) but the focus of prevention and intervention is either at maternal services or tertiary level neonatal services therefore not at primary care level for children.

Global child health policy

In 1995, WHO and Unicef launched the Integrated Management of Childhood Illness (IMCI) to promote integrated services to reduce mortality and morbidity from key treatable and preventable diseases in countries with high under-five mortality rates. Care of newborns was added in 2003 as Integrated Management of Neonatal and Childhood Illnesses (IMNCI). Over 100 countries have adopted IMNCI to varying degrees. Although IMNCI includes ear conditions, eye conditions are not included, with the only mention of eye diseases being that 'children with measles may develop conjunctivitis, which should be treated with tetracycline eye ointment.' As a consequence, staff providing primary level services for children are not trained in eye care nor do they have the awareness and skills to prevent and manage eye conditions.[8]

ADDRESSING AVOIDABLE VISUAL LOSS AND BLINDNESS IN CHILDREN THROUGH PEC

The WHO 'ten key activities for healthy eyes in children' provide a clear blueprint for what needs to be addressed at primary care level. They address both prevention and active management of eye diseases in children and fall into three categories: health promotion (eg, breast feeding, face washing), ensuring high coverage of specific preventive measures (eg, VAS, measles immunisation) and the detection and referral of treatable eye conditions (eg, cataract, glaucoma). Some of these 'activities' are already part of child health programmes and IMCI, such as breast feeding, VAS and measles

To cite: Malik ANJ, Mafwiri M, Gilbert C. *Arch Dis Child* 2018;**103**:176–180.

Table 1 Ten key activities to promote healthy eyes in children

Control of conditions which can be associated with visual loss	
Vitamin A deficiency	1. Give vitamin A supplements to children routinely. 2. Give vitamin A supplements to mothers after delivery. 3. Promote breast feeding and good nutrition.
Measles	4. Give vitamin A supplements to children with measles or malnutrition. 5. Immunise children against measles.
Control of ocular conditions	
Conjunctivitis of the newborn	6. Clean the eyes of babies at delivery and apply antibiotic drops.
Trachoma	7. Keep children's faces clean.
Cataract/retinoblastoma/ocular abnormalities	8. Refer children with poor vision, white pupils or ocular abnormality to an eye worker.
Traditional eye remedies	9. Avoid the use of traditional eye medicines.
Trauma	10. Refer children with history of injury to an eye worker.

Table 2 WHO recommendations for vitamin A supplementation of children[34]

Target group	Infants 6–11 months	Children aged 12–59 months
Dose	100 000 IU (30 mg retinol equivalent)	200 000 IU (60 mg retinol equivalent)
Frequency	Once	Every 4–6 months
Route of administration/ preparation	Oral liquid, oil-based preparation of retinyl palmitate or retinyl acetate	
Settings	Populations where the prevalence of night blindness is 1% or higher in children 24–59 months of age or where the prevalence of vitamin A deficiency (serum retinol 0.70 µmol/L or lower) is 20% or higher in infants and children 6–59 months of age	

immunisation, although primary care workers may have no knowledge that they relate to eye health. Other 'activities' would require primary care workers to acquire new skills and basic equipment, for example, to assess the red reflex of newborns to detect cataracts. We will now discuss the evidence base and rationale for the activities recommended.

Vitamin A deficiency: prevention

Strategies to prevent vitamin A deficiency include VAS, nutrition education and breast feeding. Vitamin A (retinol) has multiple functions and is essential for epithelial integrity, immune competence, growth and retinal function. Retinol deficiency is called vitamin A deficiency disorders (VADD) to reflect the wide impact on multiple systems. Some ocular signs of VADD reflect chronic deficiency (night blindness, Bitot's spots) while other signs reflect acute deficiency (corneal ulceration, keratomalacia) which can lead to blindness. Six monthly VAS from 6 to 59 months of age is one of the recommendations of IMCI due to its impact on childhood morbidity and mortality.

Data from population-based surveys between 1991 and 2013 indicate that VADDs remain prevalent in LMICs, despite improvement in coverage of VAS.[4] One possible explanation for this apparent inconsistency is that six monthly high-dose vitamin A may not maintain adequate serum retinol levels between dosing, and more emphasis should be placed on dietary intake. There are few recent data on the prevalence of corneal ulceration or blindness due to VADD, but VAS has been shown to reduce the ocular signs of chronic deficiency. For example, a Cochrane review and meta-analysis of VAS reviewed mortality and morbidity data from 43 trials involving 215 633 children aged 6 months to 5 years. The review showed that VAS was associated with significant reductions in Bitot's spots (risk ratio (RR) 0.42; 95% CI 0.33 to 0.53) and night blindness (RR 0.32; 95% CI 0.21 to 0.50).[9] However, there was considerable heterogeneity with three trials showing no effect on VADD while another two reported a 69% reduction in xerophthalmia. The largest trial was based in India and enrolled 1 million children. In this trial, a subgroup analysis of approximately 2500 children in each arm of the trial showed that serum retinol levels were slightly higher in supplemented children and the prevalence of severe deficiency was half that of the control group. The prevalence of Bitot's spots was also considerably lower among supplemented children (1.4% vs 3.5%). Notably, this trial did not show as large an effect on child mortality as expected from previous trials (20%–30%), but suggested a reduction of 5%–15%.[10]

Given the impact on child mortality, the WHO recommends VAS of children aged 6 months to 5 years in countries where VADDs are a public health problem (table 2).

Population level adherence is also an important issue as well as individual efficacy, and VAS as well as other strategies to improve nutrition are required to maintain and reduce ocular complications of VADD in children.

Measles blindness prevention and treatment

Measles infection can cause corneal blindness as a result of several mechanisms, including acute vitamin A deficiency (from increased demand, low intake and malabsorption), measles keratitis and herpes simplex keratitis, particularly in African children. Several doses of high-dose vitamin A are recommended during measles infection, principally to reduce mortality, which is included in IMCI guidelines. Conservative estimates suggest that 1% of children hospitalised for measles subsequently go blind, which does not include unilateral blindness.[11]

The epidemiology of measles and measles blindness has evolved due to increased coverage of measles immunisation and VAS as well as socioeconomic development which has improved nutrition, housing and crowding. For example, in Tanzania, as measles immunisation coverage improved from approximately 30% to 80% between 1982 and 1988, the number of children admitted to a rural eye hospital with corneal ulcers associated with measles declined by 87% during the same period.[12]

WHO statistics show that measles immunisation coverage among 1-year-olds in the African region was 74% in 2013, and 78% in the South-east Asia and Eastern Mediterranean regions. An estimated 20.8 million infants were not immunised.[13] Between 2000 and 2015, the incidence of measles declined from 146 to 35 cases per million population.[14] However, in a recent study of children in schools for the blind in Ethiopia, almost half were blind from corneal scarring which almost certainly reflects the low coverage of measles immunisation and VAS.[15]

Ophthalmia neonatorum prophylaxis

Ophthalmia neonatorum, defined as conjunctivitis within the first 28 days of life, can be caused by a variety of organisms, reflecting the local epidemiology of untreated sexually transmitted diseases (STDs) during pregnancy. Ophthalmia neonatorum due to *Neisseria* gonococcus can lead to corneal perforation and rapid visual loss, with up to 16% of affected infants in LICs having corneal

Arch Dis Child: first published as 10.1136/archdischild-2017-313536 on 7 October 2017. Downloaded from http://adc.bmj.com/ on February 21, 2023 by guest. Protected by copyright.

involvement at presentation.[16] Crede's prophylaxis was the original treatment which entailed cleaning the eyelids at birth and then instillation of topical silver nitrate solution and led to a marked reduction in blindness in children. As silver nitrate can cause chemical conjunctivitis, other topical antibiotics are now more commonly used, and more recently povidine iodine.

In high-income countries, ophthalmia neonatorum has become rare due to lower rates and better treatment of STDs in pregnant women, and ocular prophylaxis at birth. Universal ocular prophylaxis is recommended by the US Preventive Services Task Force based on the relatively high rate of gonococcal infection in the general population of 118.9/100 000 persons compared with the 19/100 000 target.[17] Globally, the prevalence of STDs remains high with 1 million incident cases in 2012, with 210 000 being due to chlamydia or gonorrhoea. Ninety-one per cent of these infections are in LMICs.[18] There is, therefore, a stronger case for universal ocular prophylaxis in LICs where rates of untreated STDs, particularly gonorrhoea, are likely to be far higher and where facilities for antenatal screening for gonococcal infection are inadequate.[18] However, recommendations regarding which prophylactic agent to use vary. The WHO/IAPB report of a scientific meeting on Preventing Blindness in Children recommends 2.5% aqueous solution of povidine iodine as prophylaxis.[3 19] The Canadian Paediatric Society recommends the following: 1% silver nitrate solution, or 0.5% erythromycin or 1% tetracycline ointment. The eyelids should be cleaned before instillation using a sterile swab for each eye, and the prophylaxis given within an hour of birth by the attending midwife or nurse.[20]

Even where universal prophylaxis is part of routine care it is often not undertaken. A study in Tanzania found that only 50% of births in dispensaries routinely applied ocular prophylaxis while 54% of deliveries took place there.[21] Often primary healthcare staff are not aware of the benefits and a pilot study showed that training primary healthcare workers in eye care increased their compliance with routine ocular prophylaxis.[8]

Face washing and trachoma

Trachoma, which is due to *Chlamydia trachomatis*, is the the most common cause of infectious blindness in adults, particularly in Africa, Asia and the Middle East. Trachoma is associated with poverty, overcrowding and poor personal and environmental hygiene. Active infection (conjunctivitis) is more common in children while the blinding complications occur in adulthood. Trachoma is estimated to cause visual impairment in 2.2 million people and irreversible blindness in 1.2 million people globally.[22]

Trachoma control uses the WHO-endorsed SAFE strategy (Surgery, Antibiotics, Facial Cleanliness, Environmental improvement) which entails 'Surgery' for adults with upper eyelid trichiasis, and mass drug administration of azithromycin ('Antibiotics') to reduce active infection. The aim of 'Facial cleanliness' and 'Environmental improvement' is to reduce transmission through improved access to water supplies and sanitation, with health education. Transmission occurs through close contact with eye and nasal secretions and by fomites and flies. Face washing in children is important as they are the main reservoir of infection. A Cochrane review, which identified only two randomised controlled trials, found only one trial which suggested that face washing combined with topical tetracycline may reduce active trachoma, and was inconclusive regarding whether face washing alone was effective.[23] However, a more recent review and meta-analysis of studies with a range of study designs found evidence to support face cleanliness which was generally defined as the lack of ocular discharge, nasal discharge, and/or flies on face at the time of clinical examination (OR 0.42, 95%CI 0.32 to 0.52), as well as the environmental components, such as access to sanitation (OR 0.67, 95%CI 0.55 to 0.78) of the SAFE strategy.[24]

Red reflex testing for cataract/retinoblastoma or other ocular abnormalities

Cataracts in children can be present at birth or develop during the first few years of life. If not detected early and operated on, late treatment can lead to amblyopia ('lazy eyes') and permanent visual loss. It is estimated that 200 000 children worldwide are blind due to cataract.[25] As a consequence of the reduction in blindness due to measles and VADD, cataract has become one of the major causes of treatable blindness in children in LICs. A systematic review of the epidemiology of childhood cataract found a wide range in the prevalence, from 0.2 to 22.9/10 000 children, with variation within as well as between regions. The review highlighted substantial gaps in the epidemiological data, particularly in LICs.[26]

Delay in surgery and the duration of visual deprivation before surgery are associated with an exponential decline in visual acuity after surgery. While there is some uncertainty regarding the optimal age of surgery for bilateral congenital cataracts, most paediatric ophthalmologists recommend surgery 4–8 weeks after birth. However, most children in LICs present far later than this for surgery. For example, in a study in Tanzania the mean delay between the cataract being detected and surgery was almost 3 years (median, 18 months).[27] While there are a number of factors which contribute to this delay, training health workers to test the red reflex of neonates to detect cataract and counsel the family is an important step.

Retinoblastoma is a rare but life-threatening eye cancer of childhood where survival and options for vision-saving surgery depend on the stage at presentation. LICs have the highest number of affected children due to high birth rates and the highest mortality rates. In Asia and Africa, 40%–70% of children with retinoblastoma die compared with 3%–5% in Europe and North America.[28] A white pupil, either noticed by the parents or detected by testing the red reflex, is the most common initial sign.

In most high-income countries, neonatal red reflex assessment is an essential component of newborn screening.[29] Currently, there are no specific guidelines in IMCI or child health programmes in LICs to test for the red reflex or training for primary health workers.

Traditional eye remedies

The use of traditional eye remedies is well documented in children as well as adults.[30] Some remedies are harmless while others are potentially harmful, such as instilling infusions made from vegetable matter, hot oil, human urine (which may be infected), or products which are acidic or alkaline. Many of the latter can cause trauma or corneal infection. They can therefore cause or exacerbate anterior segment eye disease, and lead to a delay in seeking more appropriate care.[31] Reasons for using these remedies include inadequate eye care services, greater accessibility for patients, lower cost, better communication between healer and patient and cultural beliefs, combined with low levels of education.[30] Educating mothers on the potential harm of traditional eye remedies at the primary level can address awareness, recognising there are other important elements to be addressed.[31]

Trauma

There are approximately 1.6 million people blind from ocular injuries and almost 19 million with unilateral blindness or low vision.[32] It has been estimated that 3.3–5.7 million children

Arch Dis Child: first published as 10.1136/archdischild-2017-313536 on 7 October 2017. Downloaded from http://adc.bmj.com/ on February 21, 2023 by guest. Protected by copyright.

sustain eye injuries annually.[33] There are very little data specifically for LICs or children. Early diagnosis, referral and treatment are key for the visual prognosis following an eye injury. Delays in seeking medical attention are known to occur in particular in LICs, and lead to worse visual prognosis.

PEC for children

Despite evidence of efficacy and good rationale for many of the individual components of the 10 activities recommended by WHO for children, there is little evidence that these have been implemented or evaluated as a comprehensive package. In a small pilot study in primary health clinics in Dar es Salaam, 30 staff were trained using materials based on WHO's 10 key activities. The study showed that pretraining knowledge of eye conditions was poor with poor case management, and some clinics had stopped ocular prophylaxis as they did not know why it was used. Knowledge improved after training, ocular prophylaxis was reinstated and staff included eye conditions in their health education sessions for mothers.[8] PEC for children is a complex intervention, comprising different elements some of which act independently while others may interact. Evaluation of the whole package is, therefore, important as individual components may not have the desired impact because all the elements required for effectiveness are not in place.

INTEGRATING EYE CARE INTO PRIMARY LEVEL CHILD HEALTH SERVICES THROUGH IMCI

IMCI is an integrated approach to child health that focuses on the whole child and aims to reduce death, illness, and disability, and promote improved growth and development in children under 5 years of age. The central component is the training of primary healthcare workers currently in nine topic areas, which include ear problems and care of the well child. There is a noticeable lack of promoting eye health and visual development, and the management of eye problems.

Integrating eye health into IMCI means these primary care workers will know how to prevent, detect and refer eye conditions in children. Several of the strategies are already components of IMCI. Expansion to include eye conditions would, therefore, strengthen existing elements of IMCI as well as add new elements including skills in eye examination and the red reflex for newborns.

The direct costs of providing PEC are minimal as no new medications would be required and the only equipment needed would be to test the red reflex (US$10 each). The benefit of PEC for children as an integral component of the continuum of care is potentially enormous in terms of preventing blindness in children and increasing access to special education and rehabilitation by incurably blind children.

CONCLUSIONS

Reducing blindness and visual loss in children remains a high priority in global eye health policy but there has been limited progress in implementing PEC for children as a key component of the continuum of care, despite evidence of effectiveness of many of the strategies.

As well as increasing access to high-quality tertiary eye care, PEC for children must also be addressed. Given the efficacy of many of the individual components of PEC, there is an urgent need to evaluate the effectiveness of integrating this package of interventions, and use the findings to advocate for policy change to increase coverage and access to PEC for children at global and national levels.

WHO definitions

- Blindness: visual acuity less than 3/60 or a corresponding visual field loss to less than 10° in the better eye with the best possible correction.
- Low vision: visual acuity of less than 6/18 but equal or better than 3/60, or a corresponding visual field loss to less than 20°, in the better eye with the best possible correction.
- Visual impairment: includes both low vision and blindness. Reference: VISION 2020 Global Initiative for the Elimination of Avoidable Blindness: action plan 2006–2011
- Bitot's spots: superficial keratin deposits on the conjunctiva, which are oval, trianguar or irregular in shape. Bitot's spots are a sign of chronic vitamin A deficiency and are associated with conjunctival dryness (xerosi)
- Keratomalacia: ulceration or melting of the cornea of the eye due to severe, acute vitamin A deficiency.

Competing interests None declared.

Provenance and peer review Not commissioned; externally peer reviewed.

Open Access This is an Open Access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited and the use is non-commercial. See: http://creativecommons.org/licenses/by-nc/4.0/

© Article author(s) (or their employer(s) unless otherwise stated in the text of the article) 2018. All rights reserved. No commercial use is permitted unless otherwise expressly granted.

REFERENCES

1 Keil S, Fielder A, Sargent J. Management of children and young people with vision impairment: diagnosis, developmental challenges and outcomes. *Arch Dis Child* 2017;102:566–71.
2 Solebo AL, Teoh L, Rahi J. Epidemiology of blindness in children. *Arch Dis Child* 2017;102:853–7.
3 World Health Organization International Agency for the Prevention of Blindness. *Preventing blindness in children : report of a WHO/IAPB scientific meeting*. Hyderabad, India. 17 April 1999 http://who.int/blindness/partnerships/vision2020/en/1999.
4 Stevens GA, Bennett JE, Hennocq Q, *et al*. Trends and mortality effects of vitamin A deficiency in children in 138 low-income and middle-income countries between 1991 and 2013: a pooled analysis of population-based surveys. *Lancet Glob Health* 2015;3:e528–36.
5 World Health Organization. VISION 2020 Global Initiative for the elimination of avoidable blindness: action plan 2006–2011. 2007.
6 World Health Organization. What is VISION 2020? http://who.int/blindness/partnerships/vision2020/en/1999.
7 World Health Organization. *A five year project for the prevention of childhood blindness: Report of a WHO Consultation*: World Health Organisation, 2002.
8 Mafwiri MM, Kisenge R, Gilbert CE. A pilot study to evaluate incorporating eye care for children into reproductive and child health services in Dar-es-Salaam, Tanzania: a historical comparison study. *BMC Nurs* 2014;13:15.
9 Imdad A, Mayo-Wilson E, Herzer K, *et al*. Vitamin A supplementation for preventing morbidity and mortality in children from six months to five years of age. *Cochrane Database Syst Rev* 2017;3:CD008524.
10 Awasthi S, Peto R, Read S, *et al*. DEVTA (Deworming and Enhanced Vitamin A) team. Vitamin A supplementation every 6 months with retinol in 1 million pre-school children in north India: DEVTA, a cluster-randomised trial. *Lancet* 2013;381:1469–77.
11 Semba RD, Bloem MW. Measles blindness. *Surv Ophthalmol* 2004;49:243–55.
12 Foster A, Yorston D. Corneal ulceration in Tanzanian children: relationship between measles and vitamin A deficiency. *Trans R Soc Trop Med Hyg* 1992;86:454–5.
13 World Health Organization. World Health Statistics 2015. 2015.
14 World Health Organization. Weekly epidemiological record. 2017:229–40.
15 Asferaw M, Woodruff G, Gilbert C. Causes of severe visual impairment and blindness in students in schools for the blind in Northwest Ethiopia. *BMJ Glob Health* 2017;2:e000264.
16 Fransen L, Nsanze H, Klauss V, *et al*. Ophthalmia neonatorum in Nairobi, Kenya: the roles of Neisseria gonorrhoeae and Chlamydia trachomatis. *J Infect Dis* 1986;153:862–9.

Arch Dis Child: first published as 10.1136/archdischild-2017-313536 on 7 October 2017. Downloaded from http://adc.bmj.com/ on February 21, 2023 by guest. Protected by copyright.

17 Force U. Final Recommendation Statement: Ocular Prophylaxis for Gonococcal Ophthalmia Neonatorum: Preventive Medication, 2016. https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/ocular-prophylaxis-for-gonococcal-ophthalmia-neonatorum-preventive-medication.
18 Newman L, Rowley J, Vander Hoorn S, *et al*. Global Estimates of the Prevalence and Incidence of Four Curable Sexually Transmitted Infections in 2012 Based on Systematic Review and Global Reporting. *PLoS One* 2015;10:e0143304.
19 Isenberg SJ, Apt L, Wood M. A controlled trial of povidone-iodine as prophylaxis against ophthalmia neonatorum. *N Engl J Med* 1995;332:562–6.
20 Recommendations for the prevention of neonatal ophthalmia. *Paediatr Child Health* 2002;7:480–3.
21 Hanson C, Ronsmans C, Penfold S, *et al*. Health system support for childbirth care in Southern Tanzania: results from a health facility census. *BMC Res Notes* 2013;6:435.
22 World Health Organization. *Weekly epidemiological record*. 88, 2013:241–56. (14 Jun 2013).
23 Ejere HO, Alhassan MB, Rabiu M. Face washing promotion for preventing active trachoma. *Cochrane Database Syst Rev* 2015:CD003659.
24 Stocks ME, Ogden S, Haddad D, *et al*. Effect of water, sanitation, and hygiene on the prevention of trachoma: a systematic review and meta-analysis. *PLoS Med* 2014;11:e1001605.
25 Foster A, Gilbert C, Rahi J. Epidemiology of cataract in childhood: a global perspective. *J Cataract Refract Surg* 1997;23(Suppl 1):601–4.
26 Sheeladevi S, Lawrenson JG, Fielder AR, *et al*. Global prevalence of childhood cataract: a systematic review. *Eye* 2016;30:1160–9.
27 Mwende J, Bronsard A, Mosha M, *et al*. Delay in presentation to hospital for surgery for congenital and developmental cataract in Tanzania. *Br J Ophthalmol* 2005;89:1478–82.
28 Dimaras H, Kimani K, Dimba EAO, *et al*. Retinoblastoma. *The Lancet* 2012;379:1436–46.
29 American Academy of PediatricsSection on OphthalmologyAmerican Association for Pediatric Ophthalmology And StrabismusAmerican Academy of OphthalmologyAmerican Association of Certified Orthoptists. Red reflex examination in neonates, infants, and children. *Pediatrics* 2008;122:1401–4.
30 Foster A, Johnson GG. Traditional eye medicines–good or bad news? *Br J Ophthalmol* 1994;78:807.
31 Courtright P, Lewallen S, Kanjaloti S. Changing patterns of corneal disease and associated vision loss at a rural African hospital following a training programme for traditional healers. *Br J Ophthalmol* 1996;80:694–7.
32 Négrel AD, Thylefors B. The global impact of eye injuries. *Ophthalmic Epidemiol* 1998;5:143–69.
33 Abbott J, Shah P. The epidemiology and etiology of pediatric ocular trauma. *Surv Ophthalmol* 2013;58:476–85.
34 Wordl Health Organization. WHO Guideline: Vitamin A supplementation in infants and children 6–59 months of age. 2011.

Arch Dis Child: first published as 10.1136/archdischild-2017-313536 on 7 October 2017. Downloaded from http://adc.bmj.com/ on February 21, 2023 by guest. Protected by copyright.

Appendix 2: Supplementary Materials for Research Paper 1

A. PROSPERO registration (reference CRD42020180524)

Newborn eye screening: protocol for a systematic review

Clare Gilbert, Aeesha Malik, Jennifer Evans, Iris Gordon

Citation

Clare Gilbert, Aeesha Malik, Jennifer Evans, Iris Gordon. Newborn eye screening: protocol for a systematic review . PROSPERO 2020 CRD42020180524 Available from: https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42020180524

Review question

For all newborns (P), does universal screening for abnormalities of the eye (I), compared with no screening/selective/targeted screening (C), improve newborn and infant vision and health outcomes (O)?
If this is the case:
• Which eye conditions should the newborn be screened for?
• Which screening test/method should be used?
• What should be the optimal postnatal age for such screening?

Searches

Databases
• The Cochrane Library https://www.cochranelibrary.com/
• MEDLINE Ovid https://www.ovid.com/product-details.901.html
• Embase Ovid https://www.ovid.com/product-details.903.html
• Global Health Ovid https://www.ovid.com/product-details.30.html
• Global Index Medicus https://www.who.int/library/about/The_Global_Index_Medicus/en/
Trials registers
• US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov www.ClinicalTrials.gov
• World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) www.who.int/ictrp
Grey literature
• OpenGrey http://www.opengrey.eu/
• PQDT Open Access Dissertations &Theses https://pqdtopen.proquest.com/search.html

No restrictions on date or language

Types of study to be included

1. Intervention studies (randomized trials/ cluster randomized trials/ non-randomized trials/before and after/interrupted time-series).
2. If there is not adequate evidence from intervention studies, we will include comparative observational studies (cohort/case-control/cross-sectional/ecological studies)
3. Studies of universal screening with no comparator group, if the study has been undertaken in the real world and has a large enough sample of newborns (10, 000 or more)
4. Studies to assess diagnostic test accuracy (cross sectional studies)

Condition or domain being studied

Clinically significant eye conditions will be included for which early detection and management give better outcomes than delayed management. This includes, but is not limited to congenital abnormalities of the eye lid(s) which may partly or completely obscure the pupil; unilateral or bilateral congenital cataract and retinoblastoma (characterized by an abnormality in the red reflex, see below), unilateral or bilateral glaucoma (characterized by enlargement of the eye(s) with or without corneal opacity) and congenital squints.

Participants/population

Inclusion criteria: All newborns, within 8 weeks of birth, irrespective of risk factors and/or complications
Exclusion criteria: Studies of newborns after 8 weeks of age; studies of screening for retinopathy of prematurity.

Intervention(s), exposure(s)

Universal newborn screening for abnormalities of the eye, using any suitable ophthalmic device, including a torch light, direct ophthalmoscope or other devices to elicit the red reflex, and digital retinal imaging, and any other tests / devices, which have been used for universal screening for all newborns that is feasible to be used for this purpose in real-life settings based on expert judgment.
A torch can be used to assess the eye lids, whether the corneas are clear, whether the pupils of the eyes are round and central, and whether the eyes are of normal and equal size.
The red reflex test is performed using a direct ophthalmoscope () or other another device (photo-refractometer). When using a direct ophthalmoscope the lens power should be set at “0”. In a darkened room, the ophthalmoscope light is shone onto both eyes simultaneously from approximately 45 cm / 18 inches. The presence and color of the reflex is then noted. An abnormal test is when the normally round, red reflex is partially or completely obscured, or is white in colour.
Wide-field retinal imaging is now also possible in newborns and will be included in the review.

Comparator(s)/control

Newborns who have not had an eye examination or red reflex testing (“no screening”) or who have been examined only for some indication (“selective” or “targeted” screening) within 8 weeks of life.

Main outcome(s)

Primary outcome
1. Proportion of newborns identified within 8 weeks of birth with clinically significant eye conditions
2. Age in months at clinical management of the eye condition
3. Outcome of the management of the eye condition in terms of mortality (retinoblastoma) or visual function (eye conditions)

* Measures of effect

We will use standard methods for analysis of intervention studies comparing the primary outcomes in intervention and comparator arms using risk ratios and mean differences, with 95% confidence intervals.

Additional outcome(s)

Secondary outcomes
1. Diagnostic test accuracy of the tests / devices which have been used
2. Adverse effects of eye screening
3. Cost benefit, cost effectiveness or cost estimates, if available
4. Uptake of referrals by infants who screen positive

* Measures of effect

As above

Data extraction (selection and coding)

Two review authors will extract data and assess risk of bias independently, discrepancies will be identified and resolved through discussion (with a third author where necessary). Missing data will be requested from study authors. Review management software will be used (to be confirmed).

Studies of effectiveness and diagnostic test accuracy:
• Standardised forms to extract data from the different types of study and to appraise the quality of each included study will be developed and pilot tested

• Extracted information will include: study setting and country; date; study population and participant demographics; type of study; details of the screening / examination method, who this was performed by and the age of newborns at screening/ examination; recruitment and study completion rates; validity and positive and negative predictive values (diagnostic test accuracy studies only); measures of effectiveness (as outlined above, for effectiveness studies only); outcomes indicators of acceptability to users; any adverse consequences to newborns or to the health system; information to assess the risk of bias;

Risk of bias (quality) assessment

Risk of bias will be assessed at the study and outcome levels using modified Joanna Briggs critical appraisal tools: (https://joannabriggs.org/ebp/critical_appraisal_tools), ensuring that the following are assessed:
o For randomized controlled trials:
? random sequence generation;
? concealment of allocation to treatment group;
? blinding of participants and investigators, particularly if the outcomes were measured subjectively and thus may be subject to bias;
? reporting of data on all study participants, including attrition and exclusions from analysis;
? complete reporting of all study outcomes that were specified a priori.
o For observational studies:
? application of appropriate eligibility criteria;
? use of an unbiased approach to measurement of exposure and outcomes;
? adequate control for confounding; and
? documentation and consideration of differential withdrawals of study participants across treatment groups.

We will assess the certainty of the evidence using the GRADE approach, adapted for the study designs anticipated (https://www.gradeworkinggroup.org/). We will apply GRADE irrespective of whether or not we can estimate a single measure of effect or association. Two authors working independently will assess the risk of bias, precision, directness, consistency of the effect estimates, and the likely extent of publication bias, to produce an overall judgement for each outcome. Disagreements will be resolved by discussion.

Strategy for data synthesis

Primary outcomes
1. If studies and outcomes are similar enough to allow for meta-analysis we will pool data using a random effects model taking account of the unit of analysis
2. If there is inadequate evidence from intervention studies, we will synthesise data from comparative observational studies, presenting appropriate measures of effect, if possible (e.g., risk ratios, odds ratios), adjusted for confounding as reported by the primary study. A meta-analysis is not anticipated as studies are likely to be heterogenous.

3. Findings from studies of universal screening without a comparator group, we will be used as follows: 1. comparison with epidemiological data (birth prevalence), 2. outcomes will be reported separately for well newborns and newborns at risk of eye conditions (positive family history; evidence of intrauterine infection).

Secondary outcomes
If there is enough evidence from the primary outcomes on which to make a recommendation on universal newborn eye screening, the secondary outcomes will be analysed.
1. Diagnostic test accuracy (cross sectional studies): sensitivity, sensitivity, positive and negative predictive values with 95% confidence intervals

We will describe

2. the uptake of referrals by infants who screen positive
3. adverse effects of eye screening as reported, including but not limited to false positive rates

4. available data on cost benefit, cost effectiveness or cost estimates
Other analyses

We will describe the context of screening, setting, personnel screening etc

Analysis of subgroups or subsets

Analysis if there is enough evidence to make a recommendation for universal newborn eye screening:
• To assess the optimal age within 8 weeks for eye screening
• As the red reflex from black eyes can be less bright than from white eyes, data will be presented and analysed by ethnic group for this screening method, if available
• Preterm (gestational age <37 weeks) compared with term infants
• Data will be analysed by socio-economic status using the World Bank classification of income (https://data helpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups).

Contact details for further information

Clare Gilbert
clare.gilbert@lshtm.ac.uk

Organisational affiliation of the review

London School of Hygiene & Tropical Medicine
https://www.lshtm.ac.uk/

Review team members and their organisational affiliations

Professor Clare Gilbert. London School of Hygiene & Tropical Medicine
Dr Aeesha Malik. London School of Hygiene & Tropical Medicine
Dr Jennifer Evans. London School f Hygiene & Topical Medicine
Ms Iris Gordon. London School of Hygiene & Tropical Medicine

Type and method of review

Systematic review

Anticipated or actual start date

20 April 2020

Anticipated completion date

31 May 2020

Funding sources/sponsors

World Health Organization

Conflicts of interest

Yes

Language

English

Country

England

Stage of review

Review Ongoing

Subject index terms status

Subject indexing assigned by CRD

Subject index terms

Eligibility Determination; Humans; Infant, Newborn; Neonatal Screening

Date of registration in PROSPERO
18 May 2020

Date of first submission
16 April 2020

Details of any existing review of the same topic by the same authors

Stage of review at time of this submission
The review has not started

Stage	Started	Completed
Preliminary searches	No	No
Piloting of the study selection process	No	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

The record owner confirms that the information they have supplied for this submission is accurate and complete and they understand that deliberate provision of inaccurate information or omission of data may be construed as scientific misconduct.

The record owner confirms that they will update the status of the review when it is completed and will add publication details in due course.

Versions
18 May 2020

PROSPERO
This information has been provided by the named contact for this review. CRD has accepted this information in good faith and registered the review in PROSPERO. The registrant confirms that the information supplied for this submission is accurate and complete. CRD bears no responsibility or liability for the content of this registration record, any associated files or external websites.

Appendix 2: Supplementary Materials for Research Paper 1

A. Supplementary Materials accompanying published paper

Table S1. Example of clinically significant and insignificant eye conditions from Tang et al(1)

Significant eye conditions	**N**	**N100,000**
Retinoblastoma	5	2.5
Cataract	39	19.9
Choroidal coloboma	95	48.4
Primary hyperplastic vitreous	25	12.7
Familial exudative vitreo-retinopathy	215	109.6
Insignificant eye conditions		
Retinal haemorrhage grade 3	12657	6454
ROP/ROP-like	114	58.1
Sub-conjunctival haemorrhage	254	129.5
Abnormal fundus pigment	1480	747.7
Persistent pupil membranes	105	53.5
Retinal dysplasia	191	97.4
Albinotic fundus	31	15.8
Venous tortuosity	228	116.3
Exudative changes ?diagnosis	1238	631.3
Retinal vessel hypoplasia	114	58.1
Abnormal retinal vessels	456	232.5
Other	391	199.4

Appendix S1. Information Sources

Electronic databases searched for systematic review:

Academic databases

- The Cochrane Library https://www.cochranelibrary.com/
- MEDLINE Ovid https://www.ovid.com/product-details.901.html
- Embase Ovid https://www.ovid.com/product-details.903.html
- Global Health Ovid https://www.ovid.com/product-details.30.html
- Global Index Medicus https://www.who.int/library/about/The_Global_Index_Medicus/en/

Trials registers

- US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov www.clinicaltrials.gov
- World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) www.who.int/ictrp

Grey literature

- OpenGrey http://www.opengrey.eu/
- PQDT Open Access Dissertations &Theses https://pqdtopen.proquest.com/search.html

Searching other sources

The bibliographies of all included studies and guidelines were reviewed.

Electronic databases searched for guidelines review:

The following databases were searched to identify guidelines of relevance:

- International Council of Ophthalmology and regional societies of ophthalmology
- Australian National Health and Medical Research Council clinical practice guidelines
- Canadian Medical Association Infobase of Clinical Practice Guidelines
- ECRI Guidelines Trust Database
- eGuidelines
- Guideline Central
- Guidelines International Network (GIN)
- National Institute for Clinical Excellence (UK) – NICE
- Scottish Intercollegiate Guidelines Network (SIGN)
- Trip Database
- US Preventive Services Task Force Guidelines
- WHO Guidelines

The bibliographies of papers included in the systematic review were also searched.

Appendix S2. MEDLINE search strategy

1. Neonatal Screening/
2. ((neonat$ or newborn$ or new born or new borns or newly born or baby$ or babies or infant or infants) adj2 screen$).tw.
3. ((neonat$ or newborn$ or new born or new borns or newly born or baby$ or babies or infant or infants) adj2 test$).tw.
4. ((neonat$ or newborn$ or new born or new borns or newly born or baby$ or babies or infant or infants) adj2 exam$).tw.
5. ((neonat$ or newborn$ or new born or new borns or newly born or baby$ or babies or infant or infants) adj2 assess$).tw.
6. or/1-5
7. Cataract/
8. cataract$.tw.
9. Glaucoma/
10. glaucoma$.tw.
11. Retinoblastoma/
12. retinoblastoma$.tw.
13. (retina$ adj3 (cancer$ or neoplas$ or tumor$ or tumour$ or malignan$ or carcinoma$ or adenocarcinoma$)).tw.
14. Eye Diseases/cn [Congenital]
15. exp Eye Abnormalities/
16. ((eye or ocular or vision or visual) adj2 (abnormal$ or patholog$)).tw.
17. (buphthalmos$ or buphthalmia$ or hydrophthalmos$).tw.
18. Eyelid Diseases/
19. Blepharoptosis/
20. (ptosis or blepharoptos$).tw.
21. Blepharophimosis/
22. blepharophimos$.tw.
23. (microphthalmos or nanophthalmos).tw.
24. leukoma.tw.
25. (congenital adj3 squint$).tw.
26. or/7-25
27. 6 and 26
28. Infant, Newborn/
29. Infant/
30. (neonat$ or newborn$ or new born or new borns or newly born or baby$ or babies or infant or infants).tw.
31. or/28-30
32. Reflex, Pupillary/
33. red reflex$.tw.
34. white reflex$.tw.
35. leukocoria.tw.
36. pupillary exam$.tw.
37. (cornea$ adj2 light adj2 reflex$).tw.
38. (photo adj1 refractometer).tw.
39. photorefraction.tw.
40. (Hirschberg adj2 (test$ or ratio$)).tw.
41. flashlight.tw.
42. Ophthalmoscopy/

43. ophthalmoscop$.tw.
44. Retinoscopy/
45. Retina/dg [Diagnostic Imaging]
46. retinoscop$.tw.
47. (wide adj1 field adj1 digital adj1 imag$).tw.
48. Vision Screening/
49. Diagnostic Techniques, Ophthalmological/
50. or/42-49
51. (retinopathy of prematurity or ROP).ti.
52. 50 not 51
53. 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 52
54. 31 and 53
55. (newborn adj2 eye adj2 (screen$ or exam$ or disease$)).tw.
56. ((neonatal or perinatal) adj2 (eye$ or ophthalmic or ocular) adj2 (screen$ or exam$ or imag$)).tw.
57. (universal adj2 (eye$ or ophthalmic or ocular) adj2 (screen$ or exam$ or imag$)).tw.
58. or/55-57
59. 27 or 54 or 58
60. exp case reports/
61. case report$.tw.
62. 60 or 61
63. 59 not 62
64. (mouse or mice or rat or rats or dog or dogs or monkey or monkeys).tw.
65. 63 not 64
66. limit 65 to (address or autobiography or bibliography or biography or clinical trial, veterinary or clinical trials, veterinary as topic or comment or editorial or "expression of concern" or festschrift or interactive tutorial or interview or lecture or legal case or legislation or letter or news or observational study, veterinary or periodical index or personal narrative or portrait or video-audio media or webcast)
67. 65 not 66

Appendix S3. Reasons for exclusion after full text review

Wrong study design	17
Wrong population	13
General review	11
Wrong outcomes	10
Small sample size	9
Wrong intervention	5
Wrong indication	1
Very old publication	1
Foreign language	1
Study protocol	1
Inadequate data	1
TOTAL	**70**

Appendix S4. Data variables extracted

The following data were extracted for all studies: author, study dates, country and income group, and study population and subgroups if relevant. Findings were reported according to the study design as follows:

- Observational studies of screening: data were extracted on the number of newborns eligible for screening; method, location and personnel screening; number screened by age, sex, ethnic group and subgroup. Data were extracted on the number of infants with clinically significant eye conditions overall and for most three most common eye conditions (cataract, glaucoma and retinoblastoma) and other significant conditions, and the proportions per 100,000 were calculated. Age at clinical management, and/or referral as an indirect measure, were extracted if available. Adverse events associated with screening were documented.
- Diagnostic test accuracy studies: data were extracted which would allow the construction of two by two tables for clinically significant eye conditions only.
- Other study designs, such as cost effectiveness studies. Data were extracted, as relevant.

The following data were extracted from the review of guidelines: organization and country; date of guideline; conditions being screened for; tests recommended and the quality of the evidence for the recommendation; age group to be included; who should perform the screening/examination, when this should occur and where this could be conducted.

Table S2a. Details of included studies

	Study / country/status*	Date conducted	Type of study	Study setting	Study population / ethnic group/% female	Exclusions	Number of newborns	Age at screening
	Included in quantitative analysis							
1	Magnusson 2003, Sweden, H(2)	1992 to 1998	Case only study to compare three regions	Maternity wards and well-baby clinics	All births/ no data/no data	Not specified	Total births in study populations 396,000	Two groups: within first or 6 weeks
2	Magnusson 2013, Sweden, H(3)	Jan 2007 to Dec 2009	Cases only study to compare national data and data from 3 regions in 2003 study	Maternity wards and well-baby clinics	All births/no data/no data	Not specified	Total births in study population 328,523	Not specified
3	Ulanovsky 2015, Israel, H(4)	2008 to 2009 and 2010 to 2011	Cross-sectional before-& after study	Well-baby nursery	All newborns/no data/no data	≤35 gestation; admitted to NICU; sepsis; congenital abnormalities of nasolacrimal duct/no data/52%	18,872	Within first week
	Diagnostic test accuracy							
4	Sun 2016,** China, UM(5)	Sept 2014 to March 2015	Cross-sectional	Maternity and child hospital	All full-term newborns	Preterm (<37 weeks); admitted to neonatal intensive care; ocular deformity/no data/48%	7,641	Within first week
	Descriptive studies – red reflex testing							
5	Baldino 2019, Brazil, UM(6)	Jan 2014 to Jan 2018	Cross-sectional with nested case-control	Tertiary hospital maternity unit	Full-term newborns/no data/ (51% control group)	In intensive or semi intensive care or incomplete medical records	11,833	Within first week
6	Cagini 2017, Italy, H(7)	Jan 2012 to Dec 2014	Cross-sectional;	Regional birth centres	All births/no data	Not specified	22,884	Within first week
7	Eventov-Friedman 2010, Israel, H(8)	2007 to 2008	Cross-sectional	General hospital	All newborns/no data/no data	Not specified	11,500	Within first week
8	Yazgan 2012, Turkey, M(9)	Jan 2007 to Jan 2010	Cross-sectional	Paediatric clinic in hospital	All newborns/no data/no data	Not specified/no data/50%	2,718	Within 8 weeks

	Descriptive studies – wide-field imaging							
9	Goyal 2018, India, LM(10)	March 2014 to Oct 2015	Cross-sectional / (Costing)	General hospital	"Apparently healthy" newborns/no data/52%	Babies >4 weeks/too sick for screening, at discretion of pediatrician	1,152	Within first 28 days
10	Li 2013, China, UM(11)	May 2010 to June 2011	Cross-sectional	Maternal and child hospital	Full-term newborns/no data/50%	<2500g; systemic disease; Apgar score <7; mother with infectious disease	3,573	Within first week
11	Li 2017, China, UM(12)	March 2010 to February 2014	Cross-sectional	Maternal and child hospital	Full-term newborns/no data/48%	As above	15,284	Within first 28 days
12	Ozkurt 2018, Turkey, UM(13)	June 2013 to August 2014	Cross-sectional	General hospital; maternity and child health hospital	Newborns in hospital in rooming-in unit and neonatal intensive care	Not specified/no data/no data	In neonatal unit: 800, in rooming-in unit, 558	Not specified
13	Tang 2018, China, UM(1)	May 2009 to June 2017	Cross-sectional with comparison of term vs preterm neonates	Eight maternal and child hospitals	All newborns whose parents could afford digital imaging	Term (>34 weeks and >2000g); preterm (≤34 weeks or ≤2000g)/no data/56%	199,851: 196,108 not preterm; 3,743 preterm	Within 6 weeks
14	Vinekar 2015, India, LM(14)	September 2012 to March 2013	Cross-sectional	General public hospital with maternity unit	Full-term newborns/no data/no data	Birthweight ≤2000g/no data/45%	1,021	Within first week

*H = high income; UM = upper middle income; LM= lower middle income; L=low income; DTA = diagnostic test accuracy;

**Reported diagnostic test accuracy and the clinical findings of screening

NIPE: Newborn and Infant Physical Examination; UK programme; ROP: retinopathy of prematurity; Full term: gestational age of 37 weeks or older; DTA: diagnostic test accuracy

Table S2b. Details of included studies

Study	Examination	Details	Who did the screening examination	Examination to confirm abnormality
Included in quantitative analysis				
Magnusson 2003	Red reflex test	Direct ophthalmoscope	"Doctors and nurses"	Referral to an ophthalmologist implied
Magnusson 2013	Red reflex test	Direct ophthalmoscope	Paediatrician	Referral to ophthalmologist implied
Ulanovsky 2015	Red reflex test	Direct ophthalmoscope	Physician	NA
Diagnostic test accuracy				
Sun 2016**	Comprehensive eye exam	External eye exam, dilation (trop and pheny), topical anaesthesia, speculum, Retcam3 (ant seg + 5 retinal images), handheld slit lamp	Ophthalmologist	Comprehensive eye examination by the same ophthalmologist
Descriptive studies – red reflex testing				
Baldino 2019	Red reflex test	Dilated; dark environment; indirect ophthalmoscope lens set at 0D; both eyes; at 45 cm.	Resident physicians (paediatrics)	Ophthalmologist with indirect ophthalmoscope before discharge
Cagini 2017	Red reflex test	Direct ophthalmoscope using standard methods	Paediatrician, neonatalogists	In nearest ophthalmology department; onward to tertiary centre if needed
Eventov-Friedman 2010	Red reflex test	Indirect ophthalmoscope set at 0 degrees	Resident physicians (paediatrics) & neonatologists	Not stated, but probably eye department in same hospital
Yazgan 2012	Red reflex test	Indirect ophthalmoscope in dark room	No details	Referred to an ophthalmologist
Descriptive studies – wide-field digital imaging				
Goyal 2018	Retinal imaging	Dilated, 130 degrees; RetCam; 5 fields	Optometrists	Images read by ophthalmology resident
Li 2013	Comprehensive eye exam	Undilated: torch (pupils, external eye, ant seg); Dilated: ant seg (RetCam), retinoscopy, hand held slit lamp, RR for media opacity; then wide field imaging (RetCam) 5 images	Ophthalmologist with assistant (and/or nurse)	Referral to ophthalmology clinic
Li 2017	Comprehensive eye exam	Undilated: torch (pupils, external eye; ant seg); Dilated: anterior segment examination (RetCam), wide field imaging (RetCam) 5 of images	Ophthalmologist with assistant	Further exam by ophthalmologist or referral to ophthalmology clinic
Ozkurt 2018	Comprehensive eye exam	Torch for external eye; RR using standard method with direct oph (no dilation)	Ophthalmologist	Same ophthalmologists
Tang 2018	Red reflex & wide field imaging	RR (no details ? with RetCam); Dilated wide field retinal imaging; 5 fields	Ophthalmologist with nurse assistant	Same ophthalmologist, or referred
Vinekar 2015	Retinal imaging	RetCam dilated anterior images; posterior segment video and images captured	Trained technician and nurse	Not clear who read images; ped retina specialist examined screen positive babies within 7 days

**Reported diagnostic test accuracy as well as the clinical findings of screening; NA = not applicable

Table S3. Included studies in relation to the comparisons and outcomes of the review

	Primary outcomes			Secondary outcomes		
	Proportion of newborns identified by 8 weeks of age with clinically significant eye conditions (12 studies)	**Age in months at clinical management of the eye condition (1 studies)**	**Outcome of management on mortality (retino-blastoma) or visual function (eye conditions) (0 studies)**	**Diagnostic test accuracy of the tests / devices used (1 study)**	**Adverse effects of eye screening (1 study)**	**Uptake of referral by infants who screen positive (0 studies)**
Studies with comparison groups						
Universal screening versus no screening (3 studies)	2 studies of congenital cataract (Sweden)	1 study: congenital cataract surgery before 42 days (Sweden)	-	-	1 study before and after introducing red reflex testing (Israel)	
Comparison of two different tests (1 studies)				1 study: red reflex testing vs imaging (China**)		
Descriptive studies						
Red reflex testing (4 studies)	4 studies (in Brazil, Israel, Italy, Turkey)	-				-
Imaging (6 studies)	6 studies (4 in China**, 2 jn India)	-				-

**One study in China reported two outcomes

Table S4a. Clinically significant eye conditions detected using red reflex testing

Author	Country/income(15)	Sample size	No of cases	Prevalence/ 100,000
All significant conditions*				
Yazgan(9)	Turkey, upper middle	2,715	3	111
Eventov-Friedman(8)	Israel, high	11,500	5	44
Baldino(6)	Brazil, upper middle	11,833	4	34
Cagini(7)	Italy, high	22,272	3	14
Cataract				
Yazgan	Turkey, upper middle	2,715	2	75
Eventov-Friedman	Israel, high	11,500	4	35
Cagini	Italy, high	22,272	2	9
Baldino	Brazil, upper middle	11,833	1	9
Retinoblastoma				
Yazgan	Turkey, upper middle	2,715	1	39
Cagini	Italy, high	22,272	1	5
Glaucoma				
Baldino	Brazil, upper middle	11,833	2	20
Other significant conditions*				
Eventov-Friedman	Israel, high	11,500	1	9
Baldino	Brazil, upper middle	11,833	1	9

Table S4b. Clinically significant eye conditions detected using widefield digital imaging

Author	Country/income(15)	Sample size	No of cases	Prevalence / 100,000
All significant conditions*				
Li (2013)(11)	China, upper middle	3,573	32	896
Vinekar (14)	India, lower middle	1,021	9	882
Sun (5)	China, upper middle	7,641	57	746
Li (2017)(12)	China, upper middle	14,786	80	541
Goyal(10)	India, lower middle	1,152	4	347
Tang (1)	China, upper middle	196,108	379	193
Cataract				
Vinekar	As above	1,021	1	98
Li (2017)	As above	14,786	11	74
Li (2013)	As above	3,573	2	56
Sun	As above	7,641	2	26
Tang	As above	196,108	39	20
Retinoblastoma				
Vinekar	As above	1,021	1	98
Li (2013)	As above	3,573	2	56
Li (2017)	As above	14,786	3	20
Sun	As above	7,641	1	13
Tang	As above	196,108	5	3
Glaucoma				
Goyal	As above	1,152	2	174
Other significant*				
Li (2013)	As above	3,573	28	784
Tang	As above	196,108	335	171
Sun	As above	7,641	53	694
Vinekar	As above	1,021	7	686
Li (2017)	As above	14,786	66	446
Goyal	As above	1,152	2	174

Table S5. Risk of bias in included studies

We assessed the risk of bias for included studies which provided comparative or diagnostic test accuracy data.

Comparative studies (ROBINS-1 checklist)

Potential source of bias	**Magnusson 2003**	**Magnusson 2013**	**Ulanovsky 2015**
Due to confounding	Serious	Serious	Serious
In selection of study participants	Low	Low	Low
Bias in classification of interventions	Low	Low	Low
Due to deviations from intended interventions	NI	NI	NI
Due to missing data	NI	Ni	NI
In measurement of outcomes	Moderate	Moderate	Moderate
In selection of reported result	Low	Low	Low
Overall risk of bias	Serious	Serious	Serious

NI: No information

Analytical cross-sectional studies (Joanna Briggs Institute checklist)

Potential source of bias	**Ozkurt 2018**	**Tang 2018**
Were criteria for inclusion in the sample clearly defined?	Yes	Yes
Were study subjects and the setting described in detail?	No	Yes
Was the exposure measured in a valid and reliable way?	No	Unclear
Were objective, standard criteria used to measure the condition?	Yes	Yes
Were confounding factors identified?	No	No
Were strategies to deal with confounding factors stated?	No	No
Were the outcomes measured in a valid and reliable way?	Yes	Unclear
Was appropriate statistical analysis used?	No	No
Overall risk of bias	**High**	**High**

Diagnostic test accuracy study (Joanna Briggs Institute checklist)

Potential source of bias	**Sun (2106)**
Was a consecutive or random sample of patients enrolled?	Yes
Was a case control design avoided?	Yes
Did the study avoid inappropriate exclusions?	Yes
Were index test results interpreted without knowledge of reference standard results?	Unclear
If a threshold was used, was it pre-specified?	NA
Is the reference standard likely to correctly classify the target condition?	Yes
Were reference standard results interpreted without knowledge of index test results?	No
Was there an appropriate interval between index test and reference standard?	No
Did all patients receive the same reference standard?	Yes
Were all patients included in the analysis?	Yes
Overall risk of bias	**High**

NA: Not applicable

Appendix S6. Scoping Guideline review

Nine guidelines were included (Figure 1). Four were national screening programme specifications (UK, Canada, New Zealand and India), three were ophthalmology/paediatric society guidelines (USA), one paediatric society guideline (Canada) and one WHO recommendation from a training package was identified on the WHO Europe Office website. Data from the latter were extracted from the online training module as the corresponding policy documents could not be identified despite online searches and contacting WHO.

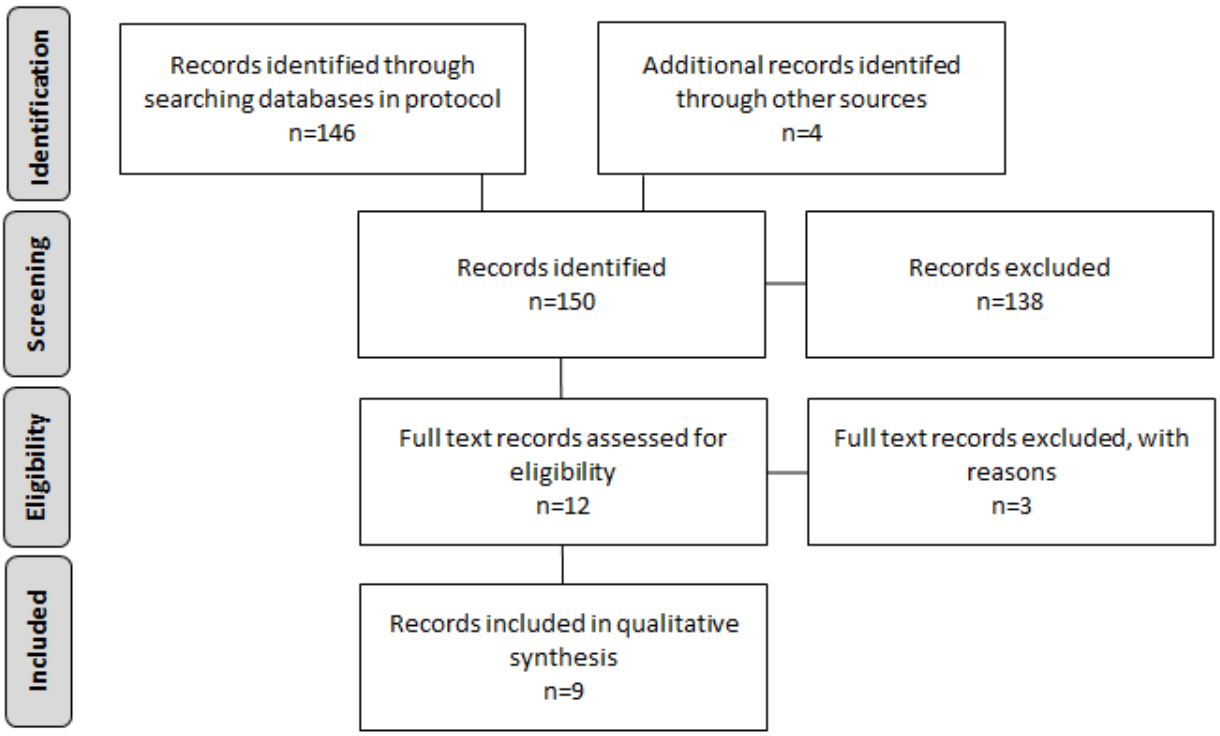


Figure: PRISMA chart for guideline review selection

Appendix S7. References of included studies

1. Tang H, Li N, Li Z, Zhang M, Wei M, Huang C, et al. Fundus examination of 199 851 newborns by digital imaging in China: a multicentre cross-sectional study. Br J Ophthalmol. 2018;102(12):1742-6.
2. Magnusson G, Jakobsson P, Kugelberg U, Lundvall A, Maly E, Tornqvist K, et al. Evaluation of screening procedures for congenital cataracts. Acta Paediatr. 2003;92(12):1468-73.
3. Magnusson G, Bizjajeva S, Haargaard B, Lundstrom M, Nystrom A, Tornqvist K. Congenital cataract screening in maternity wards is effective: evaluation of the Paediatric Cataract Register of Sweden. Acta Paediatr. 2013;102(3):263-7.
4. Ulanovsky I, Shnaider M, Geffen Y, Smolkin T, Mashiach T, Blazer S, et al. Performing red reflex eye examinations increases the rate of neonatal conjunctivitis. Acta Paediatr. 2015;104(12):e541-5.
5. Sun M, Ma A, Li F, Cheng K, Zhang M, Yang H, et al. Sensitivity and Specificity of Red Reflex Test in Newborn Eye Screening. J Pediatr. 2016;179:192-6 e4.
6. Baldino V, Eckert GU, Rossatto J, Wagner MB. Red reflex test at the maternity hospital: results from a tertiary hospital and variables associated with inconclusive test results. J Pediatr (Rio J). 2019.
7. Cagini C, Tosi G, Stracci F, Rinaldi VE, Verrotti A. Red reflex examination in neonates: evaluation of 3 years of screening. Int Ophthalmol. 2017;37(5):1199-204.
8. Eventov-Friedman S, Leiba H, Flidel-Rimon O, Juster-Reicher A, Shinwell ES. The red reflex examination in neonates: an efficient tool for early diagnosis of congenital ocular diseases. Isr Med Assoc J. 2010;12(5):259-61.
9. Hamza Yazgan AY, Esengül Keleş, Arzu Gebeşçi, Mehmet Demirdöven, Bülent Baştürk1, Selim Genç. Assessing the effectiveness of the red reflex test (Brückner) in early diagnosis of congenital eye disorders. Turk Arch Ped. 2012;47:163-4.
10. Goyal P, Padhi TR, Das T, Pradhan L, Sutar S, Butola S, et al. Outcome of universal newborn eye screening with wide-field digital retinal image acquisition system: a pilot study. Eye (Lond). 2018;32(1):67-73.

11. Li LH, Li N, Zhao JY, Fei P, Zhang GM, Mao JB, et al. Findings of perinatal ocular examination performed on 3573, healthy full-term newborns. Br J Ophthalmol. 2013;97(5):588-91.

12. Li LH, Wu WC, Li N, Lu J, Zhang GM, Zhao JY, et al. Full-Term Neonatal Ophthalmic Screening in China: A Review of 4-Year Outcomes. Ophthalmic Surg Lasers Imaging Retina. 2017;48(12):983-92.

13. Ozkurt Z, Balsak S, Yildirim Y, Yuksel H, Caca I. Associations between red reflex abnormality, consanguinity and intensive care hospitalization of newborns in Turkey. East Mediterr Health J. 2018;24(7):631-6.

14. Vinekar A, Govindaraj I, Jayadev C, Kumar AK, Sharma P, Mangalesh S, et al. Universal ocular screening of 1021 term infants using wide-field digital imaging in a single public hospital in India - a pilot study. Acta Ophthalmol. 2015;93(5):e372-6.

15. Bank W. World Bank Country and Lending Groups. [Available from: https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups.

Appendix 3: Supplementary Materials for Research Paper 2

A. Participant Information Sheet and Consent forms

Title of Project: Integration of primary eye care for children into primary health care in Tanzania: development and pilot testing of an Eye Module for inclusion in the curriculum of staff providing Reproductive and Child Health services

Name of PI/Researchers responsible for project: Dr Aeesha NJ Malik and Dr Milka Mafwiri

Statement	**Please initial each box**
I confirm that I have read and understood the information sheet dated……..(version…….) for the above named study. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.	
I understand that my consent is voluntary and that I am free to withdraw this consent at any time without giving any reason and without my legal rights being affected.	
I understand that my interviews will be recorded and transcribed and data collected during the study may be looked at by the researcher team responsible for this study lead by Dr Aeesha NJ Malik and Dr Milka Mafwiri. I give permission for these individuals to have access to these records.	
I understand that data from me may made available publicly or by sharing directly with other researchers, and that I will not be identifiable from this information	
I give permission for anonymous quotes to be used in reports, publications, presentations and research grant proposals.	
I agree to take part in the above named study.	

Printed name of participant	Signature of participant	Date

Printed name of person obtaining consent	Signature of person obtaining consent	Date

Integration of primary eye care for children into primary health care in Tanzania: development and pilot testing of an Eye Module for inclusion in the curriculum of staff providing Reproductive and Child Health services

Information Sheet for Key Stakeholders

Principal Investigators

Dr Aeesha NJ Malik
International Centre of Eye Health
London School of Hygiene & Tropical Medicine,
Kepple Street, London, WC1E 7HT
Aeesha.malik@lshtm.ac.uk

Dr Milka Mafwiri
Senior Lecturer and Consultant Ophthalmologist
Department of Ophthalmology
Muhimbilli University of Health and Allied Sciences (MUHAS)
Dar es Salaam
Tanzania
milkwisa@gmail.com

Introduction

We are doing a study to develop and test a teaching module for reproductive and child health workers to teach them how to examine a young child's eyes, what to look for, what basic treatment can be given, and when to refer onto an eye specialist. We are aiming that this module becomes part of IMCI in Tanzania and eventually throughout Africa.

You will be aware of this study as you are a key stakeholder. However we would also like you to be part of this study so that we can formally record your views on the eye health module and its inclusion into IMCI. Therefore we are inviting you to read the brief summary below in order to decide if you are willing to participate.

Why are we doing the Study?

Low vision or blindness in children has a major impact on the child, their family and community. Often these children do not go to school or get jobs later in life. In Tanzania many children become blind from eye diseases which are either treatable or preventable. These can include infectious diseases such as measles,

conjunctivitis or health issues such as vitamin A deficiency, or from cataracts. Many of these conditions can be prevented by specific actions by mothers or by treatments from primary health care staff such as giving eye drops, or referring children to an eye specialist. We know that RCH staff in Tanzania see nearly all children under 5 years. We also know that primary care staff who deliver IMCI are taught very little about eye diseases in children as this is not included in their curriculum.

In response to this, an eye module for IMCI has been developed through a collaborative process and a selection of RCH staff have been trained. We have also assessed any change in their knowledge, skills, practices and attitudes three months after training. Now this work has been completed we would like to seek your views on including eye care into IMCI in Tanzania.

Who is doing the Study?

This study is being done jointly by Muhimbilli University of Health and Allied Sciences, Dar es Salaam and the London School of Hygiene & Tropical Medicine, UK. It is funded by a charity - the British Council for the Prevention of Blindness.

What is involved in being part of the Study?

We would like to hold a one to one interview with you in a location of your choice. The interview will last 20-30 minutes. With your permission, the interview will be recorded so we do not have to reply on memory of what you said.

Are the results confidential?

Yes. We will do all that we can to keep everything that you say anonymous, but as we are only interviewing a few individuals such as yourself it might be possible for you to be identified because of your role. To keep this possibility to a minimum everything you say will only be heard or seen by members of the research team. All information will be stored securely and your name will not be used at any time. We will not give any information to anyone else.

What are the benefits or risks of taking part?

There are no direct benefits but what you say will help to guide the next steps, and there are no risks.

Do I have to take part?

No. You are entirely free to decide whether to take part or not. You do not have to give any reasons, and withdraw your consent at any time.

Will I be compensated for my time?

No, there will be no compensation unless the interview incurs travel costs in which case you will be reimbursed.

How will the study results be used?

The findings of this study will be used guide the next steps of integrating eye care for children into IMCI in Tanzania. All the findings will be written up in report which will be shared with all the key stake holders, and the main findings will be written up for publication in a peer reviewed journal.

Thank you for reading this. Your help will be very valuable to us.

You will be given a copy of this leaflet and the consent form.

If you have any further questions or would like to contact us about this study please contact:

Dr Aeesha NJ Malik
International Centre of Eye Health
London School of Hygiene & Tropical Medicine,
Kepple Street, London, WC1E 7HT
Aeesha.malik@lshtm.ac.uk

Integration of primary eye care for children into primary health care in Tanzania: development and pilot testing of an Eye Module for inclusion in the curriculum of staff providing Reproductive and Child Health services

Information Sheet for RCH staff

Principal Investigators

Dr Aeesha NJ Malik
International Centre of Eye Health
London School of Hygiene & Tropical Medicine,
Kepple Street, London, WC1E 7HT
Aeesha.malik@lshtm.ac.uk

Dr Milka Mafwiri
Senior Lecturer and Consultant Ophthalmologist
Department of Ophthalmology
Muhimbilli University of Health and Allied Sciences (MUHAS)
Dar es Salaam
Tanzania
milkwisa@gmail.com

Introduction

We are doing a study to develop and test a teaching module for reproductive and child health workers to teach them how to examine a young child's eyes, what to look for, what basic treatment can be given, and when to refer onto an eye specialist.

We would like you to be part of this study. Before you decide we would like you to read this leaflet to understand what we are doing and what your participation involves.

Why are we doing the Study?

Low vision or blindness in children has a major impact on the child, their family and community. Often these children do not go to school or get jobs later in life. In Tanzania many children become blind from eye diseases which are either treatable or preventable. These can include infectious diseases such as measles, conjunctivitis or health issues such as vitamin A deficiency or from cataracts. Many of these conditions can be prevented by specific actions from the mother or by treatments from primary health care staff such as giving eye drops, or referring

children to an eye specialist. We know that primary care staff see nearly all children under 5 years old. We also know that primary care staff are not taught about eye diseases. We want to see if we can help prevent or treat children's eye conditions by teaching and training primary health care staff about basic eye diseases.

Who is doing the Study?

This study is being done jointly by London School of Hygiene and Tropical Medicine and Muhimbilli University of Health and Allied Sciences. It is funded by a charity called the British Council for the Prevention of Blindness. The researchers are not connected with any of your regular work duties or training.

What is involved in being part of the Study?

The study will involve you completing a questionnaire with general questions and also questions on eye diseases. You will then receive training in the same style to your current training in Integrated Management of Childhood Illness (IMCI) but focussed on eye diseases in children. The training will be 4 days of face to face training followed by 4 weeks of self-learning and then another 2 days of face to face training and feedback. You will be given an eye health module, a poster, torch, batteries, eye drops and eye pads. Three months after the training is complete we will visit you again to complete a questionnaire, interview for your feedback and a demonstration of the clinical skills you have learnt. The interview will be recorded and the recording kept in a secure location to which only the study researchers will have access.

Are the results confidential?

Yes. All your answers and anything you say is completely confidential and will only be seen or heard by members of the research team. All information will be stored securely and your name will not be used. We will not be giving any information to your employers or people you work with. We will want to use anonymous quotes in reports, publications, presentations and research grant proposals. These will not have your name but be quoted as "RCH staff 1" etc.

What are the benefits of taking part?

You will receive high quality training in eye diseases for children and have more knowledge and skills at the end to deal with any children you see in your clinics. You will be contributing to improving training for all reproductive and child health workers in Tanzania.

What are the risks of taking part?

There are no risks to taking part in the study. You do not have to talk about or do anything you do not want to do.

Do I have to take part?

No. If you decide not to take part it will not have any effect on your job and daily work. You can also withdraw your consent at any time without giving any reason.

Will I be compensated for my time?

You will receive travel expenses for attending the face to face training courses and a stipend to cover your daily expenses during training days.

How will the study results be used?

The findings of this study will be used to develop the final eye module for IMCI. This will be reported to a wide range of people including the Department of Health Tanzania, UNICEF and WHO. We are planning a larger study using this eye module and to eventually integrate it into routine IMCI training in Tanzania.

Thank you for reading this. Your help will be very valuable to us.
Your participation will proceed once you have asked any questions you may have and signed the consent form. You will be given a copy of this leaflet and the consent form.

If you have any further questions or for any reason need to contact us about this study then please contact:

Dr Milka Mafwiri

Senior Lecturer and Consultant Ophthalmologist
Department of Ophthalmology
Muhimbilli University of Health and Allied Sciences (MUHAS)
Dar es Salaam, Tanzania milkwisa@gmail.com

Integration of primary eye care for children into primary health care in Tanzania: development and pilot testing of an Eye Module for inclusion in the curriculum of staff providing Reproductive and Child Health services

Information Sheet for RCH trainers

Principal Investigators

Dr Aeesha NJ Malik
International Centre of Eye Health
London School of Hygiene & Tropical Medicine,
Kepple Street, London, WC1E 7HT
Aeesha.malik@lshtm.ac.uk

Dr Milka Mafwiri
Senior Lecturer and Consultant Ophthalmologist
Department of Ophthalmology
Muhimbilli University of Health and Allied Sciences (MUHAS)
Dar es Salaam
Tanzania
milkwisa@gmail.com

Introduction

We are doing a study to develop and test a teaching module for reproductive and child health workers to teach them how to examine a young child's eyes, what to look for, what basic treatment can be given, and when to refer onto an eye specialist.

We would like you to be part of this study. Before you decide we would like you to read this leaflet to understand what we are doing and what your participation involves.

Why are we doing the Study?

Low vision or blindness in children has a major impact on the child, their family and community. Often these children do not go to school or get jobs later in life. In Tanzania many children become blind from eye diseases which are either treatable or preventable. These can include infectious diseases such as measles, conjunctivitis or health issues such as vitamin A deficiency or from cataracts. Many of these conditions can be prevented by specific actions from the mother or by treatments from primary health care staff such as giving eye drops, or referring

children to an eye specialist. We know that primary care staff see nearly all children under 5 years old. We also know that primary care staff are not taught about eye diseases. We want to see if we can help prevent or treat children's eye conditions by teaching and training primary health care staff about basic eye diseases.

Who is doing the Study?

This study is being done jointly by London School of Hygiene and Tropical Medicine and Muhimbilli University of Health and Allied Sciences. It is funded by a charity called the British Council for the Prevention of Blindness. The researchers are not connected with any of your regular work duties or training.

What is involved in being part of the Study?

The study will involve you being trained to train an eye health module in the same style as IMCI. You will then train the RCH workers in this eye module. The training will be 4 days of face to face training followed by 4 weeks of self-learning and then another 2 days of face to face training and feedback. Three months after the training is complete you will test the RCH workers on the clinical skills they have learnt. After the study is complete we will interview you about your views on the training module and how you felt teaching and assessing it. The interview will be recorded and the recording kept in a secure location to which only the study researchers will have access. We would like to record the interviews so we do not have to reply on memory of what you said, with your permission.

Are the results confidential?

Yes. All your answers and anything you say is completely confidential and will only be seen or heard by members of the research team. All information will be stored securely and your name will not be used. We will not be giving any information to your employers or people you work with. We will want to use anonymous quotes in reports, publications, presentations and research grant proposals. These will not have your name but be quoted as "RCH trainer 1" etc.

What are the benefits of taking part?

You will receive high quality training in eye diseases for children. You will be contributing to improving training for all reproductive and child health workers in Tanzania.

What are the risks of taking part?

There are no risks to taking part in the study. You do not have to talk about or do anything you do not want to do.

Do I have to take part?

No. If you decide not to take part it will not have any effect on your job and daily work. You can also withdraw your consent at any time without giving any reason.

Will I be compensated for my time?

You will receive travel expenses for attending the face to face training courses and a stipend to cover your daily expenses during training days.

How will the study results be used?

The findings of this study will be used to develop the final eye module for IMCI. This will be reported to a wide range of people including the Department of Health Tanzania, UNICEF and WHO. We are planning a larger study using this eye module and to eventually integrate it into routine IMCI training in Tanzania.

Thank you for reading this. Your help will be very valuable to us.

Your participation will proceed once you have asked any questions you may have and signed the consent form. You will be given a copy of this leaflet and the consent form.

If you have any further questions or for any reason need to contact us about this study then please contact:

Dr Milka Mafwiri

Senior Lecturer and Consultant Ophthalmologist
Department of Ophthalmology
Muhimbilli University of Health and Allied Sciences (MUHAS)
Dar es Salaam
Tanzania
milkwisa@gmail.com

B. Data Collection Tools: (i) Interview guide and (ii) Knowledge, skills and attitude assessment

Integration of primary eye care for children into primary health care in Tanzania: Development and pilot testing of an Eye Module for inclusion in the curriculum of staff providing Reproductive and Child Health services

Interview Guides

1. RCH trainers immediately after training

I would like to ask you some questions about the training you have delivered to RCH staff on eye conditions.

What are your opinions of the Eye Module: for example, was the information clear?

Was the training at the right level for the Clinical Offices and for the nurses?

Was enough time allocated to the training?

- Was there enough time for staff to learn new skills?

How might the module be improved?

Would you have liked any additional resource materials to assist you in training?

Would any additional resource material be helpful the Clinical Officers and nurses during training?

Could the you adequately answer any questions the Clinical Officers and nurses had during training?

What are your opinions about the training overall?

2. RCH staff 3 months after training

Study ID _____ District _____

Clinical Officer / Nurse _____

I am interested to know your views about the training you received on eye conditions in children.

Was the training at the right level for you, or was it too difficult or too simple?

What are your opinions of the Eye Module: for example, was the information clear?

How might the module be improved?

Would you have liked any additional resource materials?

How did you find the approach to training i.e., classroom teaching, then self learning?

Was there enough time for you to learn skills in relation to eye conditions in children, such as taking a history and examining the eyes?

Could the trainer adequately answer any questions you had?

What are your opinions about the training overall?

I would now like to ask some questions about your experiences since the training

Have you given any health talks to mothers on eye conditions?

- If yes, what topics did you talk about?

- What response did you get from mothers?

Would you like some additional resources for use in health education for mothers?

Since the training, have you come across any eye problems where you did not know what to do?

Have there been occasions when you have not been able to implement what you were trained to do?

What are the main challenges you had have in managing eye conditions in children?

Have there been any benefits to you being trained in eye conditions in children?

Do you have any other comments you would like to make?

3. International NGO representatives

INGO rep: _____

Our overall goal is to work with the Ministry of Health in Tanzania so that primary eye care for children becomes an integral component of the Integrated Management of Childhood and Newborn Illness. This will require a package of interventions including training materials for RCH staff and to train the trainers and supervisors; ensuring basic equipment, consumables and referral pathways, and health education materials for mothers.

Please can you let me know what your views are on this?

We have just developed and have assessed an Eye Module, working closely with the Ministry of Health, staff in the Tanzania WHO Office and others. The Module is

congruous with the other IMCNI Modules, and the next step is to undertake a large scale study to evaluate the effectiveness of this approach.

Might {...*name of INGO..}* be willing to support this evaluation?

4. Key stake holders

Organization _____

{As you are aware} Our overall goal is work with the Ministry of Health and WHO so that primary eye care for children becomes an integral component of the Integrated Management of Childhood and Newborn Illness in Tanzania. This will require a package of interventions including training materials for RCH staff and to train the trainers and supervisors; ensuring basic equipment, consumables and referral pathways, and health education materials for mothers.

Please can you let me know what your views are on this?

What challenges do you envisage?

We have just developed and have assessed an Eye Module, working closely with the Ministry of Health, staff in the WHO Office and others. The Module is congruous with the other IMCNI Modules, and the next step is to undertake a large scale study to evaluate the effectiveness of this approach.

Please can you let me know what your views are on this?

What challenges do you envisage?

Might {...*name of organization}* be willing to support this evaluation?

Integration of primary eye care for children into primary health care in Tanzania:
Development and pilot testing of an Eye Module for inclusion in the curriculum of staff
providing Reproductive and Child Health services

<u>Evaluation RCH staff</u>

RCH workers before and after training

Pre-training assessment

Study ID [ ][ ][ ] District _____

Type of facility
1 Health Cnetre
2 Dispensary

Cadre of staff
1 Clinical Officer
2 Nurse

Age [ ][ ] years Sex 1 Male 2 Female

Number of years worked in this facility [ ][ ] years

When was your last IMCI training? [ ][ ] years ago

Have you had any previous training in eye conditions in children?
1 Yes
2 No

If you have been trained in eye care, please give details of where, when and by whom _____

How often do you see children with eye conditions in the clinic?
1 Every day
2 Every week
3 Every month
4 Less than once a month

What are the commonest eye conditions you see?
1 Conjunctivitis in 1st month of birth/ophthalmia neonatorum)
2 Red eye / conjunctivitis in older children
3 Injuries or foreign bodies in the eye
4 Corneal ulcers
5 Other _____

Please tick <u>one</u> reponse for each question	Very confident	Confident	Not confident
How confident do you feel in examining the eyes of children?			
How confident do you feel in assessing the vision of children?			
How confident do you feel in knowing which eye conditions can be treated in this facility?			
How confident do you feel in knowing which children with eye conditions to refer?			
How confident do you feel in putting eye drops into the eys of children?			

Please name the different parts of the eye, seen from the front

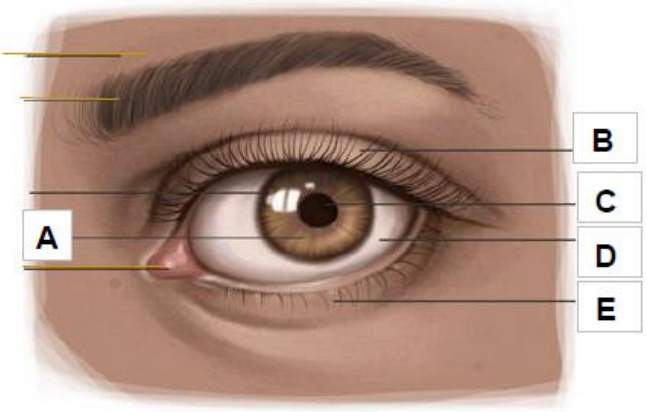
A = _____

B = _____

C = _____

D = _____

E = _____



Please name the different parts of the eye, seen in cross section

A = _____

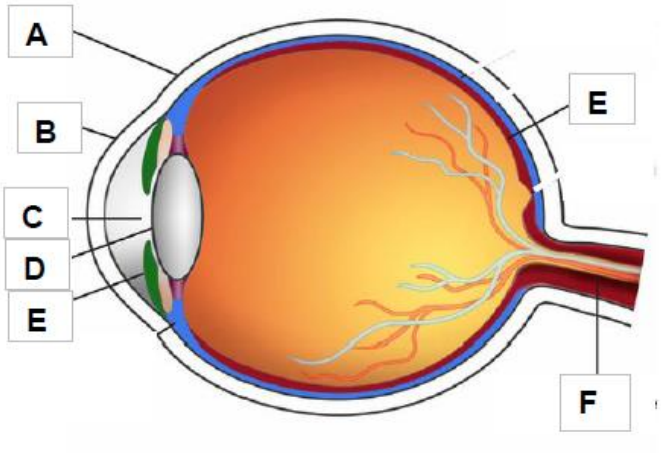
B = _____

C = _____

D =

E = _____

F =



KNOWLEDGE

Do you know why are children given vitamin A?
[You can give more than one answer]

- [1] To keep them healthy
- [2] To help them grow
- [3] To reduce mortality
- [4] To prevent loss of vision
- [5] To prevent loss of hearing

How often should children be given vitamin A supplements to children?

Every _____ months

How many measles immunizations each child should have?

[ ]

At what age should the first measles immunization be given?

[ ] months

KNOWLEDGE OF EYE CONDITIONS: IMAGES

Image 1

a What do you notice wrong with this young child's eyes? _____

b Have you seen this before?

- [1] Yes
- [2] No
- [3] Do not know

c What eye condition do you think this is? _____

d What would you do? _____

Image 2

a What do you notice wrong with this eye? _____

b What would you do? _____

Image 3

a What do you notice wrong with this young child's eyes? _____

b Have you seen this before?

- [1] Yes
- [2] No
- [3] Do not know

c What eye condition do you think this is? _____

d What would you do? _____

Image 4

a What do you notice wrong? _____

b Have you seen this before?

1	Yes
2	No
3	Do not know

d What would you do? _____

Image 5

a What is wrong with this child? _____

b Can this condition affect the eyes?

1	Yes
2	No
3	Do not know

c What can be done to prevent eye problems in this condition _____

Image 6

a What do you notice wrong with this young child's eyes? _____

b Have you seen this before?

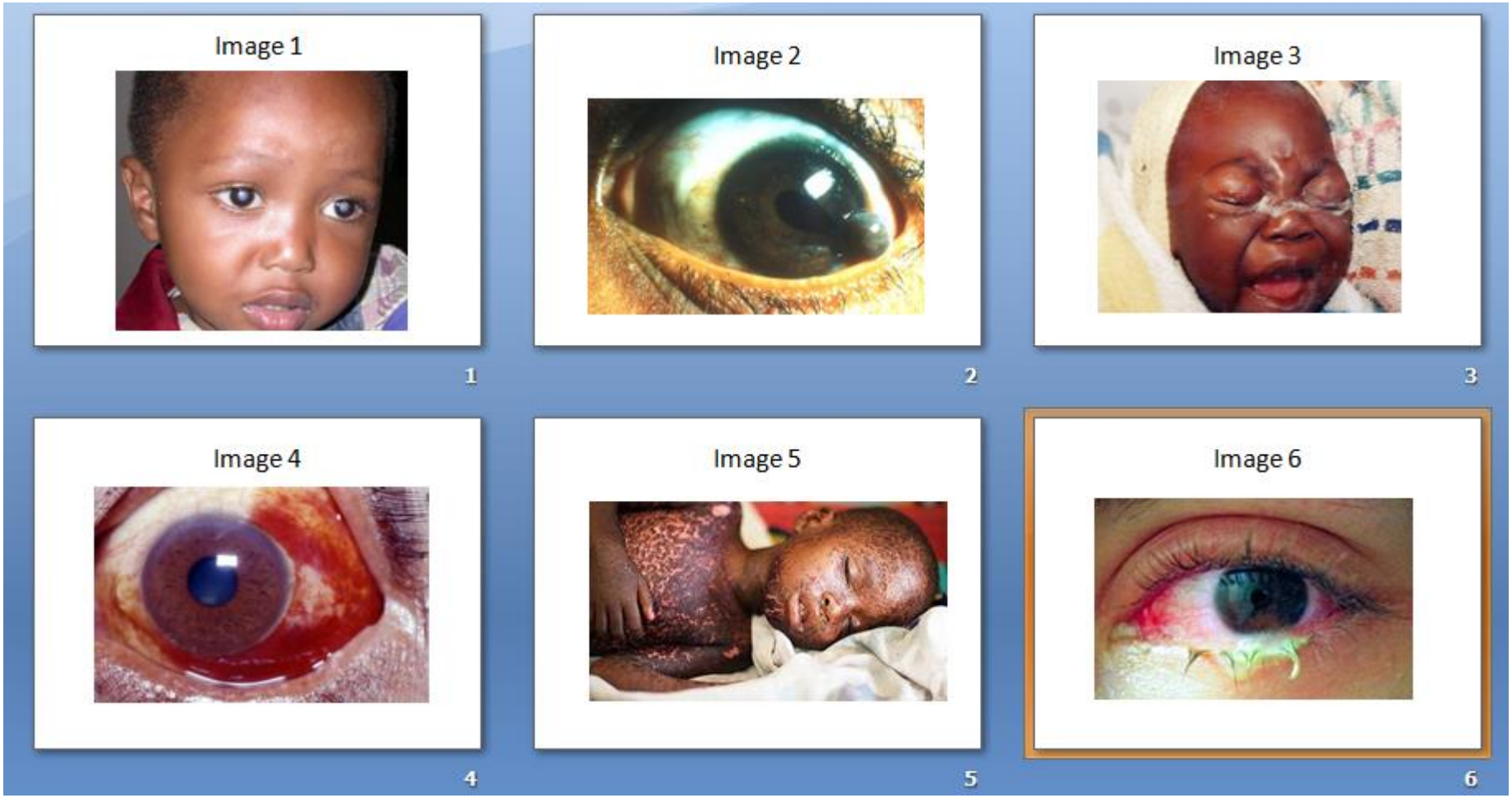
1	Yes
2	No
3	Do not know

c What eye condition do you think this is? _____

d What would you do? _____

e What would you tell the mother? _____

Images



CASE STUDIES

Case study 1:

A mother brings her infant to the clinic. She is still breast feeding the child. She says that she noticed something white insdie the eye while she was breast feeding him.

You look at the infants eyes, but cannot see anything wrong

What would you do?

Case study 2:

A 10 day old baby is brought to the clinic with red, puffy eye lids on both sides. The mother says the problem started 2 days ago, and she has tried to clean the eyelids as there is a discharge.

The baby was born at home.

What is the likely problem, and what would you do?

Case study 3:

A 5 year old child comes to the clinic and you notice that when he looks at you, one eye seems to be looking to the side

What is the likely problem, and what would you do?

Case study 4:

A four year old child has red, watery eyes, and her mother says that someone else in the family has had the same problem

What is the likely problem, and what would you do?

Case study 5:

A mother brings her 4 year old child to the clinic saying that the after the sun has gone down, the child sits in the home and doesn't want to go out to play

What is the likely problem, and what would you do?

Appendix 4: Supplementary Materials for Research Paper 3

A. Participant Information Sheet and Consent forms

Title of Project: Integrating eye health into child health policies

Name of PI/Researcher responsible for project: Dr Aeesha Malik

Statement	**Please initial each box or circle answer**
I confirm that I have read and understood the information sheet dated……..(version…….) for the above named study. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.	
I understand that my consent is voluntary and that I am free to withdraw this consent at any time without giving any reason and without my legal rights being affected.	
I understand that the interview will be audio recorded and reviewed by researchers in the study and I give permission for these individuals to have access to this recording.	
I understand that my interview will be transcribed and reviewed by researchers in the study and that directly identifiable details will be removed from this transcription for confidentiality.	
I agree that direct quotes from my interview may be used in the draft study report. I understand that I will be asked to review and approve my quotes before they are published or presented.	Y/N
I agree to taking part in the above named study.	

Printed name of participant	Signature of participant	Date

Printed name of person obtaining consent	Signature of person obtaining consent	Date

Participant Information Sheet

Title of Project: Integrating eye health into child health policies

Introduction

We would like to invite you to take part in a research study. Joining the study is entirely up to you. Before you decide, you need to understand why the research is being done and what it would involve. The lead researcher, Aeesha Malik, will discuss this information sheet with you, and answer any questions you may have. Ask questions if anything you read is not clear or you would like more information. Please feel free to talk to others about the study if you wish.

What is the purpose of the study?

The London School of Hygiene and Tropical Medicine (LSHTM) are conducting research to understand what issues influenced the inclusion of eye health in the child health policy document [Survive and Thrive/ IMNCI in Tanzania] and what factors may be important to consider in the more widespread inclusion of eye health into child health policies. This is a qualitative study using semi structured interviews.

Why have I been asked to take part?

You are being invited for interview due to your role and involvement in child health policy [in Tanzania/ in the 'Survive and Thrive' document] or because of your role in child health/eye health in this area.

Do I have to take part?

No. It is up to you to decide to take part or not. The study will be discussed with you and you have this information sheet. If you agree to take part, we will then ask you to sign a consent form.

What will be involved if I take part?

You will be invited to take part in an interview at a time and place of your convenience and will have a choice of face to face or over an online platform such as Zoom. The interview is expected to last approximately 30-60 minutes. The interview will be audio recorded, with your permission, and subsequently a transcript will be professionally produced. All the interviews will be conducted by Dr Aeesha Malik, as a researcher at LSHTM.

What are the possible risks and disadvantages?

Information from your interview may be used either as a direct quote or with descriptive text. Either way, we will not reveal your identity, but instead we will use general terms e.g. "an academic from a higher education institution". However there are relatively small numbers of participants and it may still be possible that you are identifiable. If you do not wish for your

quotes to be used you can opt out of this prior to the interview, or after the interview, or any time during the study. There will be no payments for the interviews.

What are the possible benefits?

Information from the study will improve knowledge and understanding of the inclusion of eye health in child health policy. The findings will be used to advise policy makers on how to include eye health into other child health policies at national and international levels.

Can I change my mind about taking part?

Yes. You can withdraw from the study at any time.

What will happen to information collected about me?

The interview transcript will be analysed by Dr Malik using a health policy framework to look for key themes alongside the other interviews. All the data (recordings and transcripts) will be securely stored on the LSHTM system. After the completion of the study the data will be stored in the LSHTM data repository (http://datacompass.lshtm.ac.uk) for the standard period of 10 years. The results of this study will form part of the work towards a PhD and will be presented at international meetings and published in peer reviewed journals.

What are your choices about how your information is used?

You will be asked whether you agree to direct quotes from your interview being used in the draft report. If you agree then you will be asked to review and approve any direct quotes before they are published or presented.

You can choose to withdraw part way through the study and your data will be destroyed and not used or stored.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- At https://www.lshtm.ac.uk/files/research-participant-privacy-notice.pdf
- by asking one of the research team
- by sending an email to DPO@lshtm.ac.uk

What will happen to the results of this study?

The study results will be published in a medical journal and presented at international meetings. Your personal information will not be included in the study report.

Who is organising and funding this study?

The London School of Hygiene & Tropical Medicine is the sponsor for the research and they have full responsibility for the project including the collection, storage and analysis of your data, and will act as the Data Controller for the study. This means that we are responsible for looking after your information and using it properly. CBM UK (a UK based disability charity) are funding the study.

Who has reviewed this study?

All research involving human participants is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by The London School of Hygiene and Tropical Medicine Research Ethics Committee.

Further information and contact details

Thank you for taking time to read this information sheet. If you think you will take part in the study please read and sign the consent form.

If you would like any further information, please contact:

Dr Aeesha Malik
aeesha.malik@lshtm.ac.uk

Appendix 4: Supplementary Materials for Research Paper 3

B. Data Collection Tools: Topic guides

Topic Guides

Topic guide 1: to explore key factors which led to the decision to include eye health in the IMNCI policy and programme in Tanzania

Intro

- What organizations/networks do you belong to? How long have you had this role[s]? Please describe your own role.
- What in your opinion were the most important factor(s) facilitating eye care being included into IMNCI
- What were the main barriers to inclusion and how were they overcome

Ideas/issue characteristics

- How would you define child eye health including:
    - the main issues in child eye health
- What do you understand to be the size of the child eye health problems in Tanzania
    - how does this compare to other child health/ other health issues
    - any measures/data you know about child eye health in Tanzania
- What do you consider to be the main solutions to improve child eye health (at primary care level) including:
    - any specific interventions and their effectiveness/cost effectiveness
- How important would you consider child eye health in comparison to other child health issues
- What level of evidence are you aware of for eye care interventions for children
- How was the case been made for including eye health into IMNCI

Actor power

- Who do you consider to be the key individuals in child health policy making in Tanzania
- Who would be considered leaders in the [eye health/ child health/ child eye health communities/policy makers] in Tanzania
- Which are key organisations in [eye health/ child health/ child eye health communities/policy making]
- Are there any grassroots organisations involved in advocacy for child eye health
    - If so, how have they been involved
- Do you think all those involved (above) work together collaboratively?
    - Were there any issues where all agreed upon
    - Were there any issues where there was any disagreements or tensions
- Who are the key individuals involved in IMNCI in Tanzania

Political context

- Can you think of any significant events or developments or individuals that have helped to draw attention to the child eye health in Tanzania?
    - Can you think of any events or developments that have detracted the attention from child eye health and/or any missed opportunities?
- Does child eye health align with child health strategies in Tanzania

    - If so, how?
    - what have been/ are the main child health strategies
- What factors about IMNCI influenced the ease of/hindered inclusion of eye health
    - is the training managed locally/ nationally
    - are there other examples of how IMNCI in Tanzania has been adapted and differs from the global policy
- How is IMNCI delivered in Tanzania
    - What has been adapted/adopted compared to the international programme
    - what key changes have occurred at the international level in IMNCI over recent years

Tanzania health system factors

- What is the structure of primary health care/ child health care in Tanzania
- Who are the PHWS and what level of eye health training would they have in the routine educations and training
- What are the current responsibilities on PHWs
- Where does the funding for PHC/ IMNCI/ child health in Tanzania come from

Tanzania historical perspective

- What in your opinion have been the most important eye health initiatives, and specifically in child eye health in Tanzania over the last 20 years (prompt: specific examples if none given by interviewee)
- Which key actors have worked to improve eye health/child eye health previously
- What components of primary eye care and specifically child eye health were already in place in Tanzania

Integration

- Are there other key child health issues which have been integrated in child health policy in recent years in Tanzania
- How else has policy on IMNCI changed since it first started in Tanzania

Policy transfer/ uptake/ adaptation/ evidence use

- Are there other examples of health initiatives in Tanzania where these have been included by adapting/adding to global health policies/programmes

Conclusion

- Are there any other topics you think are relevant which have not been covered
- Is there anyone else you recommend that I interview

Topic Guide 2

Intro

- What organizations/networks do you belong to? How long have you had this role[s]? Please describe your own role.
- What in your opinion was the most important factor(s) facilitating eye care being included into the initiative?
- What were the main barriers to inclusion and how were they overcome

Ideas/issue characteristics

- What other issues were considered to be included in "survive and thrive"
    - Were there any other issues that were considered and were not included?
    - How were issues prioritised
    - What were the processes used
- How would you define child eye health
- What were the main issues in child eye health presented/ the case for inclusion eye health presented
- What level of evidence was presented for eye care interventions for children/ that you know of
- How important do you consider eye health is in comparison to other child health issues
    - what is the size of the eye health problems in children
- What do you see as the main solutions to improve child eye health (at primary care level)
    - What are the specific interventions
    - How effective/cost effective are they

Actor power

- Who were the key actors (individuals, networks, organizations) in creating "survive and thrive"
- Who would you considered to be the leaders
- Were there any grassroots organisations involved in advocacy
- Are you aware of who were the key actors advocating for the inclusion of eye health
- How much agreement was there between the actors for the inclusion of eye health
    - Were there any actors against the inclusion

Political context

- Can you think of any significant events or developments which helped draw attention to the issues of child eye health in LMICs?
    - Any events/ developments which hindered inclusion
    - Any missed opportunities?
- Were there other examples/models of integrating eye care into child health presented or known

Integration/policy uptake/adaptation/evidence use

- What are other key child health issues/ new initiatives which have been gained further attention/ priority in recent years (prompt: nurturing care framework, disabilities caregivers)

- What do you think it has been about these issues that has made them a priority (prompt: evidence, advocacy)

Overall

- Are there any other topics you think are relevant which have not been covered
- Is there anyone else you recommend that I interview

Appendix 5: Ethical Approval Certificates

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

www.lshtm.ac.uk

Observational / Interventions Research Ethics Committee

Dr Aeesha Malik
Clinical Research Fellow International Eye health
Department of Clinical Research (CRD)
Infectious and Tropical Diseases (ITD)
LSHTM

3 October 2017

Dear Aeesha

Study Title: Developing and assessing an eye module for integration into IMCI in Tanzania

LSHTM Ethics Ref: 13484

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	CV Full Clare Gilbert revised Sept 21 2016	21/09/2016	1
Investigator CV	Aeesha NJ Malik CV Wellcome 2016 FINAL	01/03/2017	1
Information Sheet	Eye IMCI RCH staff Information sheet March 30 2017 v2	30/03/2017	2
Information Sheet	Eye IMCI RCH trainers Information Sheet March 30 2017 v2	30/03/2017	2
Investigator CV	CV Milka Mafwiri March 31 2017	31/03/2017	1
Protocol / Proposal	eyeIMCI Evaluation Tool RCH staff Pre-and post assessment April 15 2017	15/04/2017	1
Protocol / Proposal	Eye IMCI Protocol April 15 2017	15/04/2017	1
Information Sheet	Eye IMCI All participants consent form April 15 2017	15/04/2017	1
Information Sheet	Eye IMCI Information Sheet Key Stakeholder April 15 2017	15/04/2017	1
Protocol / Proposal	Eye IMCI Interview Guides v1 April 15 2017	15/04/2017	1
Protocol / Proposal	Eye IMCI Protocol April 15 2017 updated 25 09 17	25/09/2017	2
Protocol / Proposal	Reply to Ethics Committee request 25 09 17	25/09/2017	1
Covering Letter	Reply to Ethics Committee request 25 09 17	25/09/2017	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.

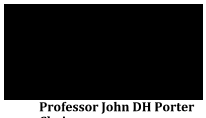
The CI or delegate is also required to notify the ethics committee of any protocol violations and/or Suspected Unexpected Serious Adverse Reactions (SUSARs) which occur during the project by submitting a Serious Adverse Event form.

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://leo.lshtm.ac.uk

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



Professor John DH Porter
Chair

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

Improving health worldwide

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

OFFICE OF THE DIRECTOR OF RESEARCH AND PUBLICATIONS

P.O. Box 65001
DAR ES SALAAM
TANZANIA
Web: www.muhas.ac.tz

Tel G/Line: +255-22-2150302/6 Ext: 1016
Direct Line: +255-22-2152489
Telefax: +255-22-2152489
E-mail: drp@muhas.ac.tz

Ref. No. 2017-12-21/AEC/Vol.XII/84

21st December, 2017

Dr. Milka Mafwiri,
Department of Ophthalmology,
School of Medicine,
MUHAS.

Re: Approval for Ethical Clearance for a study titled "Development and pilot testing of an Eye Health Module for inclusion in Integrated Management of Childhood Illness Training Programme in Tanzania"

Reference is made to the above heading.

I am pleased to inform you that the Chairperson, has on behalf of the University Senate, approved ethical clearance of the above mentioned study, on recommendation of the Senate Research and Publications Committee meeting.

The validity of this ethical clearance is one year effective from **23rd November, 2017** to **22nd November, 2018.** You will therefore be required to apply for renewal of ethical clearance on a yearly basis if the study is not completed at the end of this clearance.

You will also be expected to provide adverse events reports where applicable, six monthly progress report and final project upon completion of your study.

[redacted]

Dr. Fredrick Mashili
Acting Chairperson, Senate Research and Publications Committee

Muhimbili University of Health and Allied Sciences
DIRECTOR
Research & Publications
Box 65001

THE UNITED REPUBLIC OF TANZANIA

National Institute for Medical Research
3 Barack Obama Drive
P.O. Box 9653
11101 Dar es Salaam
Tel: 255 22 2121400
Fax: 255 22 2121360
E-mail: ethics@nimr.or.tz

Ministry of Health, Community Development, Gender, Elderly & Children
University of Dodoma, Faculty of Arts and Social Sciences
Building No 11
P.O. Box 743
40478 Dodoma

NIMR/HQ/R.8a/Vol. IX/2622

06th November 2017

Ms. Aeesha Malik
London School of Hygiene and Tropical Medicine
C/o Dr. Milka Madaha Mafwiri
Muhimbili University of Health and Allied Sciences
P. O. Box 65004
Dar es salaam

RE: ETHICAL CLEARANCE CERTIFICATE FOR CONDUCTING MEDICAL RESEARCH IN TANZANIA

This is to certify that the research entitled: Development and pilot testing of eye health module for inclusion in the integrated management of childhood illnesses (IMCI) training program (Malik A. *et al)* whose local investigator is Dr. Milka Madaha Mafwiri of Muhimbili University of Health and Allied Sciences has been granted ethical clearance to be conducted in Tanzania

The Principal Investigator of the study must ensure that the following conditions are fulfilled:

1. Progress report is submitted to the Ministry of Health, Community Development, Gender, Elderly & Children and the National Institute for Medical Research, Regional and District Medical Officers after every six months.
2. Permission to publish the results is obtained from National Institute for Medical Research.
3. Copies of final publications are made available to the Ministry of Health, Community Development, Gender, Elderly & Children and the National Institute for Medical Research.
4. Any researcher, who contravenes or fails to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine as per NIMR Act No. 23 of 1979, PART III Section 10(2).
5. Site: Dodoma

Approval is valid for one year: 06th November 2017 to 5th November 2018.

Name: Prof. Yunus Daud Mgaya

[redacted]

CHAIRPERSON
MEDICAL RESEARCH
COORDINATING COMMITTEE

Name: Prof. Muhammad Bakari Kambi

[redacted]

Signature
CHIEF MEDICAL OFFICER
MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY &CHILDREN

CC: RMO of Dodoma
DMO/ DED of Bahi district

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

www.lshtm.ac.uk

Observational / Interventions Research Ethics Committee

Dr. Aeesha Malik
LSHTM

5 March 2021

Dear Dr. Aeesha Malik

Study Title: Integrating primary eye care into child health policies

LSHTM Ethics Ref: 22842

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	CV ANJ Malik October 2020	23/11/2020	1.1
Protocol / Proposal	research protocol integrating eye care v1.3	30/11/2020	1.3
Protocol / Proposal	Topic Guides v1.3	30/11/2020	1.3
Information Sheet	Information Sheet Integrating eye health v1.3	30/11/2020	1.3
Information Sheet	Informed Consent integrating eye health into child health v1.2	30/11/2020	1.3
Investigator CV	Joanna Schellenberg 2-page CV jan2020	30/11/2020	2020
Information Sheet	Information Sheet Integrating eye health v1.4 02 02 21	02/02/2021	1.4
Covering Letter	Cover Letter ethics committee 02 02 21	02/02/2021	1.1
Covering Letter	Cover Letter ethics committee 24 02 21	24/02/2021	2
Information Sheet	Informed Consent integrating eye health into child health v1.3 23.2.21	24/02/2021	1,3
Information Sheet	Information Sheet Integrating eye health v1.5 24 02 21	24/02/2021	1.5
Information Sheet	Information Sheet Integrating eye health v1.6 02.03.21	02/03/2021	1.6
Covering Letter	Cover Letter ethics committee 03 03 21	03/03/2021	3

After ethical review

The Chief Investigator (CI) or delegate is responsible for informing the ethics committee of any subsequent changes to the application. These must be submitted to the Committee for review using an Amendment form. Amendments must not be initiated before receipt of written favourable opinion from the committee.

The CI or delegate is also required to notify the ethics committee of any protocol violations and/or Suspected Unexpected Serious Adverse Reactions (SUSARs) which occur during the project by submitting a Serious Adverse Event form.

An annual report should be submitted to the committee using an Annual Report form on the anniversary of the approval of the study during the lifetime of the study.

At the end of the study, the CI or delegate must notify the committee using an End of Study form.

All aforementioned forms are available on the ethics online applications website and can only be submitted to the committee via the website at: http://leo.lshtm.ac.uk

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

Yours sincerely

[redacted]

Professor Jimmy Whitworth
Chair

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

UNITED REPUBLIC OF TANZANIA

MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

OFFICE OF THE DIRECTOR - RESEARCH AND PUBLICATIONS

In reply quote;

Ref. No.DA.282/298/01.C/ Date: 21/10/2021

MUHAS-REC-10-2021-871

Prof. Milka Mafwiri
Principal Investigator,
Department of Ophthalmology,
School of Medicine
MUHAS

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: INTEGRATING PRIMARY EYE CARE INTO CHILD HEALTH POLICY IN TANZANIA: FACTORS THATINFLUENCED POLICY CHANGE.

Reference is made to the above heading.

I am pleased to inform you that the Chairman has on behalf of the University Senate, approved ethical clearance of the above-mentioned study, on recommendations of the Senate Research and Publications Committee meeting accordance with MUHAS research policy and Tanzania regulations governing human and animal subjects research.

APPROVAL DATE: 21/10/2021
EXPIRATION DATE OF APPROVAL: 20/10/2022

STUDY DESCRIPTION:
Purpose:

The purpose of this prospective observational cross sectional study is to To explore key factors which led to the decision to include eye health in the Integrated Management of Neonatal and Childhood Illnesses policy and programme in Tanzania.

The approved protocol and procedures for this study is attached and stamped with thisletter, and can be found in the link provided: https://irb.muhas.ac.tz/storage/Certificates/Certificate%20-%20878.pdf and in the MUHAS archives.

The PI is required to:

1. Submit bi-annual progress reports and final report upon completion of the study.
2. Report to the IRB any unanticipated problem involving risks to subjects or others including adverse events where applicable.
3. Apply for renewal of approval of ethical clearance one (1) month prior its expiration if the study is not completed at the end of this ethical approval. You may not continue with any research activity beyond the expiration date without the approval of the IRB. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.
4. Obtain IRB amendment (s) approval for any changes to any aspect of this study before they can be implemented.
5. Data security is ultimately the responsibility of the investigator.
6. Apply for and obtain data transfer agreement (DTA) from NIMR if data will be transferred to a foreign country.
7. Apply for and obtain material transfer agreement (MTA) from NIMR, if research materials (samples) will be shipped to a foreign country,
8. Any researcher, who contravenes or fail to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine as per NIMR Act No.23 of 1979, PART III section 10 (2)
9. The PI is required to ensure that the findings of the study are disseminated to relevant stake holders.
10. PI is required to be versed with necessary laws and regulatory policies that govern research in Tanzania. Some guidance is available on our website https://drp.muhas.ac.tz/.

[redacted]

Prof. Bruno Sunguya
Chairman, MUHAS Research and Ethics Committee

THE UNITED REPUBLIC OF TANZANIA

National Institute for Medical Research
3 Barack Obama Drive
P.O. Box 9653
11101 Dar es Salaam
Tel: 255 22 2121400
Fax: 255 22 2121360
E-mail: ethics@nimr.or.tz

Permanent Secretary
Ministry of Health
Government City Mtumba,
Health Road
P.O. Box 743
40478 Dodoma

NIMR/HQ/R.8a/Vol. IX/3965

17th March 2022

Prof. Milka M. Mafwiri
Muhimbili University of Health and Allied Sciences.
P O Box 65001
Dar es Salaam

RE: ETHICAL CLEARANCE CERTIFICATE FOR CONDUCTING MEDICAL RESEARCH IN TANZANIA

This is to certify that the research entitled: **Integrating primary eye care into child health policy in Tanzania: Factors that influenced policy change (Mafwiri M. M. et al.)**, has been granted ethical clearance to be conducted in Tanzania.

The Principal Investigator and supervisor of the study must ensure that the following conditions are fulfilled:

1. Progress report is submitted to the Ministry of Health and the National Institute for Medical Research, Regional and District Medical Officers after every six months.
2. Permission to publish the results is obtained from National Institute for Medical Research.
3. Copies of final publications are made available to the Ministry of Health and the National Institute for Medical Research.
4. Any researcher, who contravenes or fails to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine as per NIMR Act No. 23 of 1979, PART III Section 10(2).
5. Sites: Dodoma and Dar es Salaam regions.

Approval is valid for one year: 17th March 2022 to 16th March 2023.

Name: Prof. Yunus Daud Mgaya

[redacted]

Signature
CHAIRPERSON
MEDICAL RESEARCH
COORDINATING COMMITTEE

Name: Dr. Aifello Wedson Sichalwe

[redacted]

Signature
CHIEF MEDICAL OFFICER
MINISTRY OF HEALTH

CC: Director, Health Services-TAMISEMI, Dodoma.
RMO of Dodoma and Dar es Salaam regions.
DMO/DED of respective districts.