

Modelling the effects of integrating diabetic retinopathy services in the Malawi health system

Submission date 27/03/2025	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/04/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/06/2025	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Diabetes is a growing problem in Africa, with 24 million adults currently affected and this number expected to rise to 55 million by 2045. One of the most common complications of diabetes is diabetic retinopathy (DR), which can lead to blindness. In Malawi, 500,000 people with diabetes need regular eye screenings to prevent sight loss. This study aims to reduce sight loss from diabetes in Malawi by developing models to integrate DR screening and treatment into the health system. These models will help health policymakers decide which interventions to prioritize.

Who can participate?

Adults aged 18 and over, policy stakeholders involved in non-communicable diseases (NCDs) and DR, and patients with diabetes who are attending DR screening.

What does the study involve? (for participants)

Participants will be involved in various activities, including providing information through cross-sectional studies to understand the magnitude and risk factors for DR, participating in interviews and document reviews for policy coherence analysis, and engaging with the research team to help develop and refine the models for DR service delivery.

What are the possible benefits and risks of participating?

The benefits include contributing to research that aims to improve DR services and prevent blindness in Malawi, and helping to shape health policies that could benefit many people with diabetes. The risks are minimal, mainly related to the time and effort required to participate in the study activities.

Where is the study run from?

The study is run from Malawi, with key partnerships including the International Centre for Eye Health (ICEH) at the London School of Hygiene and Tropical Medicine, the Malawi Ministry of Health, and Kamuzu University of Health Sciences (KUHeS).

When is the study starting and how long is it expected to run for?
October 2024 to September 2027

Who is funding the study?
NIHR Global Health Policy and Systems Research Programme (UK)

Who is the main contact?
Dr Covadonga Bascaran (covadonga.bascaran@lshtm.ac.uk)

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Modelling the health system to assess the health gains of diabetic retinopathy service delivery models in Malawi

Acronym

MEDREM

Study objectives

Modelling the health system can help inform policy makers on the health values attached to integrating DR services in health delivery

Ethics approval required

Ethics approval required

Ethics approval(s)

notYetSubmitted 27/02/2025, London School of Hygiene & Tropical Medicine (Keppel Street, London, WC1E 7HT, United Kingdom)

Study design

Observational mixed methods

Primary study design

Observational

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Diabetic retinopathy

Interventions

1. Secondary data analysis

- Scoping review of the models used to deliver DR services in LMICs
- Cross-sectional study that will be performed through secondary data analysis of hospital based-data and population-based data
 - Population-based records of patients recruited in a previous survey (WP2), where some were diagnosed with DM (n = 45) and some had pre-diabetes (n=275)
 - Hospital records of patients with DM who underwent DR screening between April 2023 and December 2024 (n = 720)
 - Hospital records of patients with DM who underwent DR screening between August 2021 to August 2022 and underwent follow-up DR screening at any point one year after the initial screening (n =129)

2. Primary data collection

- Health policy analysis on service delivery for DM and DR in Malawi
 - Participants: DR policy actors i.e. representatives of stakeholder who influence or are affected by policies relevant to DR in Malawi : n ≥ 16 ; Semi structured interviews.
- Health systems assessment of DR services in Malawi
 - DR stakeholder representatives in the health system in Malawi : n ≥ 16 ; Semistructured interviews
- Cross-sectional study on the eye health-seeking behaviour of PLWD in Malawi (WP5)
 - Participants: Patients accessing primary, secondary and tertiary-level DM care from 16 health facilities across 12 districts in Malawi: n = 411; Structured Questionnaires

3. An economic modelling study

- Of the health system for diabetes and DR to compare the cost-effectiveness and health gains of different DR service delivery models in Malawi

Intervention Type

Other

Primary outcome(s)

1. Proportion of PLWD that have DR measured using patient records
2. Proportion of PLWD who develop DR over a 4 year period measured using patient records
3. Proportion of PLWD who have had a retinal examination measured using patient records
4. QALYs gained, resulting from DR screening and treatment interventions measured using patient records

Key secondary outcome(s))

There are no secondary outcome measures

Completion date

30/09/2027

Eligibility

Key inclusion criteria

1. Adults ≥ 18 years old
2. Policy stakeholders in NCDs and DR
3. Patients with diabetes attending DR screening

Participant type(s)

Patient, Employee

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

100 years

Sex

All

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

15/07/2025

Date of final enrolment

01/06/2026

Locations

Countries of recruitment

Malawi

Study participating centre

Kamuzu Universtiy of Health Sciences

52X8+782, Mahatma Gandhi Rd

Blantyre

Malawi

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Sponsor information

Organisation

London School of Hygiene & Tropical Medicine

ROR

<https://ror.org/00a0jsq62>

Funder(s)

Funder type

Government

Funder Name

NIHR Global Health Policy and Systems Research Programme

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

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

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IPD sharing plan summary

Available on request