ISRCTN10051344 https://doi.org/10.1186/ISRCTN10051344

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

Submission date 27/03/2025	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 08/04/2025	**Overall study status** Ongoing	
Last Edited 06/06/2025	**Condition category** Eye Diseases	

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

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Additional identifiers

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)
Not yet submitted 27/02/2025, London School of Hygiente & Tropical Medicne (Keppel Street, London, WC1E 7HT, United Kingdom)

Primary study design
Observational

Study design
Observational mixed methods

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