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# Diabetic retinopathy (a complication of diabetes that affects the eyes), progression of the disease and how it responds to treatment - UK Model validation

**Submission date**
14/01/2023

**Recruitment status**
No longer recruiting

**Registration date**
17/01/2023

**Overall study status**
Completed

**Last Edited**
02/02/2026

**Condition category**
Eye Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Patients with diabetes are prone to develop complications at the back of the eye causing blindness, and are therefore screened yearly or two-yearly. If serious disease develops, additional hospital appointments are necessary for monitoring/treatment. Due to increasing pressure on hospital, it would be beneficial to have a system by which patients could be prioritised in terms of risk, and appointments allocated accordingly so the high-risk patients don't come to any harm due to delays. A model has been designed in general practitioner's gathered data.
Aims: Update already developed patient risk assessment model, test it in hospital population and measure its clinical benefit.

Who can participate?
The study will use routine practice data for patients (12 years or over) with diabetic retinopathy under care of hospital eye services.

What does the study involve?
Anonymised data will be gathered anonymously at three participating NHS trusts and analysed by researchers in the University of Birmingham. The benefits to both the patients and the care provider under different scenarios will then be measured. We will then present our findings in an expert meeting including patients where it can be discussed before making a final decision on the model’s efficacy and implementation. It does not involve any interference to the patient's ongoing treatment so there is no chance of harm.

What are the possible benefits and risks of participating?
None

Where is the study run from?
University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
July 2022 to December 2024

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Dr Sajjad Haider, s.haider.2@bham.ac.uk

# Contact information

### Type(s)
Principal investigator

### Contact name
Dr Sajjad Haider

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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### Integrated Research Application System (IRAS)
253774

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
RG_22-099, IRAS 253774, CPMS 54464

# Study information

### Scientific Title
Diabetic Retinopathy Progression in patients under monitoring for Treatment or Vision Loss: external validation, update, and net clinical benefit of a multivariable prediction model

## Acronym
DRPTVL-UK Model validation

## Study objectives
Diabetes mellitus is one of the most common chronic conditions affecting nearly 4.9 million people in UK as of 2021. With the prevalence rising each year, there is an ongoing global and UK wide increase in the number of people with diabetes mellitus and consequently DR. The detection of DR has also improved through wider population screening, further increasing the demand for Hospital Eye Services. There are delays in patients being seen, causing harm especially for the higher risk patients with diabetic retinopathy. Therefore, this bottleneck urgently needs addressing. We propose to mitigate this risk by stratifying these patients and prioritise care for higher risk patients by using a statistical model we developed in primary care data.
We now need to assess the model's performance in a secondary care population to ensure it performs adequately to identify patients at high risk of treatment or vision loss. If this model performs well for predicting risk at different time points in hospital eye services / surveillance clinics data during external validation, we propose that it could be used to prioritise individuals at higher risk of vision loss and potentially inform the length of the follow up intervals after referral to hospital eye services / surveillance clinics.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 24/11/2022, South Central - Hampshire A Research Ethics Committee (Temple Quay House, 2 The Square, Temple Quay, Bristol, BS1 6PN, UK; +44 207 104 8196; hampshirea.rec@hra.nhs.uk), ref: 22/SC/0425

## Study design
Mixed methods observational retrospective multicentre cohort study

## Primary study design
Observational

## Study type(s)
Other

## Health condition(s) or problem(s) studied
Diabetic Retinopathy

## Interventions
Routine practice anonymised data analysis, a retrospective observational cohort study. Enrolment is at referral from diabetic eye screening programme into hospital with diabetic retinopathy. Once they had an outcome whichever comes first (treatment/vision failure /discharge/transfer to another provider/study period end), the data extraction stops (censoring).

## Intervention Type
Other

## Primary outcome(s)

The first of any of these patient outcomes: date of treatment/vision loss of three lines in EDTRS chart/discharge/transfer to another provider/study period end, will be recorded in addition to the specific nature of the outcome like what treatment was given. Data is to be extracted from clinical notes/hospital electronic databases.

### Key secondary outcome(s))
There are no secondary outcome measures

### Completion date
31/12/2024

## Eligibility

### Key inclusion criteria
Patients with diabetes aged 12 years and over with referable diabetic retinopathy (patients enter the screening programme from age 12) will be identified at referral to the NHS hospital trusts from DESP between 2013 and 2016 for close monitoring and treatment.

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
12 years

### Upper age limit
99 years

### Sex
All

### Total final enrolment
3659

### Key exclusion criteria
Patients with the specific outcome of retinopathy treatment or vision loss at referral or those referred for reasons other than retinopathy will be excluded. Patients objecting to their information being used (through a local or national opt out scheme) will also be excluded.

### Date of first enrolment
28/06/2023

### Date of final enrolment
30/06/2024

# Locations

## Countries of recruitment
United Kingdom

England

Scotland

## Study participating centre
**Surrey and Sussex Healthcare NHS Trust**
Trust Headquarters
East Surrey Hospital
Canada Avenue
Redhill
England
RH1 5RH

## Study participating centre
**Sandwell and West Birmingham Hospitals NHS Trust**
City Hospital
Dudley Road
Birmingham
England
B18 7QH

## Study participating centre
**South Tyneside & Sunderland NHS Ft Sun**
Sunderlandchildrenscentre
Durham Road
Sunderland
England
SR3 4AG

## Study participating centre
**NHS Greater Glasgow and Clyde**
J B Russell House
Gartnavel Royal Hospital
1055 Great Western Road Glasgow
Glasgow
Scotland
G12 0XH

# Sponsor information

**Organisation**
University of Birmingham

**ROR**
https://ror.org/03angcq70

# Funder(s)

**Funder type**
Government

**Funder Name**
National Institute for Health and Care Research

**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 dataset generated during the study will be available upon request from s.haider.2@bham.ac.uk

**IPD sharing plan summary**
Available on request

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 03/04/2023 | 04/04/2023 | Yes | No |

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|---|---|---|---|---|---|
| Other unpublished results | Statistical analysis of results | | 02/02/2026 | No | No |
| Other unpublished results | Summary of results | | 02/02/2026 | No | No |
| Participant information sheet | Recruitment poster | 10/11/2022 | 16/01/2023 | No | Yes |
| Protocol file | version 1 | 19/08/2022 | 16/01/2023 | No | No |