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DemDx AI-driven Ophthalmology Triage System clinical evaluation in accident and emergency

Submission date	Recruitment status	[ ] Prospectively registered
16/02/2023	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/08/2023	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/09/2023	Eye Diseases	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
To meet the rising demand for emergency eye care, accurate triage in adult eye casualty is needed to appropriately provide emergency medical resources to those who most need them. This study will implement a previously developed Artificial Intelligence (AI) driven Clinical Decision Support System in adult eye casualty and evaluate the impact on nurses' triage performance.

Who can participate?
Registered nurses who have completed competency training for triage in adult eye casualty

What does the study involve?
The study will implement the DemDx AI-driven Triage System (DOTS) within adult eye casualty triage led by nurses. During the study, all participating nurses will be required to conduct triage using the device. The study will then evaluate the impact of the tool on triage performance by comparing it to triage performance in current practice without the device. Metrics for comparison include but are not limited to the proportion of correctly triaged urgent and non-urgent cases, the proportion of cases triaged as non-urgent and subsequently re-attended A&E, triage time, and cost.

What are the possible benefits and risks of participating?
Participating in the study gives participants the opportunity to gain first-hand experience using the DemDx AI-powered triage platform and use it to support their clinical decision-making and workflow. The researchers are not aware of the potential risks of participation as the safety and workflow feasibility of the AI support system has been previously demonstrated.

Where is the study run from?
Moorfields Eye Hospital (UK)

When is the study starting and how long is it expected to run for?
February 2022 to October 2023

Who is funding the study?
The study is funded by NIHR AI Award (AI_AWARD0167) (UK)

Who is the main contact?
Dr Mariane Melo
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Contact information

Type(s)
Principal Investigator

Contact name
Dr Mariane Melo

Contact details
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
310792

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
DAYA1006, IRAS 310792, CPMS 55499

Study information

Scientific Title
Clinical evaluation and implementation of DemDx AI-driven Ophthalmology Triage System (DOTS) in an adult eye casualty accident and emergency (A&E)

Acronym
DOTS

Study objectives

The primary hypothesis is that the use of the DemDX AI-driven Ophthalmology Triage System (DOTS) increases the accuracy of urgent referrals to adult eye casualty and reduces unnecessary appointments in accident and emergency (A&E). The secondary hypotheses include:
1. DOTS differential diagnoses suggestions have acceptably high sensitivity and specificity to support referral decision-making.
2. The use of DOTS decreases patient waiting time from referral to consultation for urgent referrals and does not increase resource usage.
3. The design of DOTS is user-centred and the workflow within the AI-driven pathway is non-inferior to its current counterpart.
4. Users trust the results given by the triage platform and follow the recommendations most of the time.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/05/2023, Yorkshire & The Humber - Sheffield Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8282, +44 (0) 207 104 8290; sheffield.rec@hra.nhs.uk), ref: 23/YH/0068

Study design
Single-centred pre-post quasi-experimental observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Triaging of patients who attend adult eye casualty

Interventions
The clinical investigation will be a pre-post quasi-experimental study, comparing the triage performance after implementing the AI-driven triage support tool A&E triage pathway to prospective cases using the existing triage pathway.

The A&E triage department at the enrolled site will have access to and be required to use DOTS throughout the trial period to support their triage decisions. Users will input the structured clinical representation of the case in the input form and state their own triage decision and submit it to the DOTS. DOTS will show the recommendations given by the AI algorithm on the

results page and refine the results with suggested additional clinical features. Participants will then record if they wish to follow the triage recommendation or not.

All cases classified as elective/low risk will be evaluated individually by an Ophthalmologist for cross-checking. Re-attendance of patients triaged as elective/low risk within 10 days will be audited by Ophthalmologist and classified as false negatives as appropriate. For quality control checks and to evaluate the reliance of the nurses using the DemDX DSS, the platform will not give a result in 10% of the cases but the data will still be recorded.

Data collected using DOTS will be linked with the outcomes triage referral outcome, discharge diagnoses and treatment recorded on the EMR system.

Performance data of the service and resource utilization will be analyzed and compared with the same period in the previous year.

Structured surveys will be sent to users to evaluate their trust in the users and their reliance on DOTS.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Phase I

Drug/device/biological/vaccine name(s)
DemDx AI-driven Ophthalmology Triage System (DOTS)

Primary outcome measure
The proportion of false positive referrals to same-day Eye Casualty A&E appointment or UCC (urgent care clinic, same-week appointments) consultations compared with retrospective data from matched cases in the study site. A false positive is a patient who has been inappropriately referred to same-day Eye Casualty A&E appointment or UCC consultation but who could have been given appropriate advice at triage and safely discharged without a face-to-face consultation. Adjusted relative risk (RR) will be reported. This is a before-and-after study where the triage data will be collected with the intervention for about 3 months and compared with the same period in the previous year. Patient data will be collected at one point during the trial but it will be monitored for 14 days for re-attendance.

Secondary outcome measures
1. In the accuracy sub-study, agreement levels of DOTS for suggesting urgent and non-urgent differential diagnoses will be compared with the diagnoses at discharge
2. Rate of Eye Casualty A&E re-attendance within 14 days (potential false negatives)
3. Patient waiting time compared to pre-intervention as previously reported by the Performance and Information team
4. Cost-effectiveness analysis of intervention using false positive referrals and resource utilisation as compared with pre-intervention data

This is a before-and-after study where the triage data will be collected with the intervention for about 3 months and compared with the same period in the previous year. Patient data will be collected at one point during the trial but it will be monitored for 14 days for re-attendance.

Overall study start date
02/02/2022

Completion date
01/10/2023

Eligibility

Key inclusion criteria
Registered nurses who have completed competency training in triage in adult eye casualty

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
20 triage nurses with target 1198 triage visits in A&E

Total final enrolment
15

Key exclusion criteria
1. Nurses who have not completed ophthalmic triage competency training
2. Triage nurses in paediatric eye casualty

Date of first enrolment
17/06/2023

Date of final enrolment
07/07/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
NIHR Moorfields Biomedical Research Centre
Moorfields Eye Hospital NHS Foundation Trust
162 City Road
London
United Kingdom
EC1V 2PD

Sponsor information

Organisation
Moorfields Eye Hospital NHS Foundation Trust

Sponsor details
162 City Road
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+44 (0)207 566 2059
rowena.vohora@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.moorfields.nhs.uk/

ROR
https://ror.org/03zaddr67

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

Publication and dissemination plan
1. Planned publication in a high-impact peer-reviewed journal
2. Clinical Evaluation Report for MHRA submission
3. International conference presentation

Intention to publish date
01/11/2023

Individual participant data (IPD) sharing plan
Anonymised data may be accessed upon request from the Chief Investigator, Alex Day (alex.day1@nhs.net) after the completion of the study (September 2023). Data will include information about triage cases, discharge diagnoses and the risk stratification given by the too. Consent will be obtained from participants (triage staff) but not patients, however, all patient-identifiable data will be anonymised by members of the direct care team.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			20/09/2023	No	No