ISRCTN17096714 https://doi.org/10.1186/ISRCTN17096714

Improving care for people admitted with diabetes-related emergencies

Submission date	Recruitment status	[_] Prospectively registered
15/06/2026	Recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/07/2026	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
25/09/2026	Nutritional, Metabolic, Endocrine	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Diabetic ketoacidosis (DKA) is a dangerous condition where the body lacks enough insulin, causing high blood sugar and acid levels. It's one of the most common reasons people with diabetes need emergency hospital care, with over 32,000 UK cases last year costing the NHS more than £90 million. If untreated, DKA can be life-threatening.

In 2020, researchers developed DEKODE, a digital tool helping hospitals track and improve DKA care. Early results showed care varies widely, even within the same hospital, but the reasons are unclear, and patient views haven't been captured. This study aims to understand why DKA care varies across the UK, explore patient and staff experiences, improve the DEKODE tool, investigate repeat DKA episodes, and assess whether DEKODE saves the NHS money

Who can participate?

1. Patients admitted to hospital with DKA (using anonymised hospital records from 2001 onwards)
2. Patients aged 16-99 years recently treated for DKA at University Hospitals Birmingham, and their carers
3. Healthcare professionals involved in DKA care at hospitals using DEKODE across the UK

What does the study involve?

The study has five parts: analysing anonymised NHS hospital records to see how DKA rates and outcomes differ by age, sex, ethnicity, deprivation and region; inviting patients, carers and staff to complete questionnaires and optional video interviews about their experiences; interviewing staff at hospitals using DEKODE to understand what helps or hinders its use; studying hospital data on people who've had DKA more than once; and calculating NHS treatment costs and whether DEKODE reduces them over time.

No new treatments are tested – the study focuses on experiences, care patterns and costs.

What are the possible benefits and risks of participating?

The risks are low to none. However, talking about a DKA episode may bring up difficult memories for some patients or carers. Information to seek support from a relevant patient support group (e.g., Diabetes UK) will be provided if needed. Participants won't directly benefit, but the study will help improve future DKA care.

Where is the study run from?
University of Birmingham. The wider DEKODE project involves hospitals across the UK.

When is the study starting and how long is it expected to run for?
June 2025 to August 2028

Who is funding the study?
NIHR Academy, via an NIHR Advanced Fellowship awarded to Dr Punith Kempegowda

Who is the main contact?
Dr Punith Kempegowda, p.kempegowda@bham.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Dr Punith Kempegowda

ORCID ID
https://orcid.org/0000-0003-0954-6512

Contact details
Department of Applied Health Sciences, University of Birmingham
Birmingham
United Kingdom
B15 2TT
+44 (0)7721 930777
p.kempegowda@bham.ac.uk

Type(s)
Scientific, Public

Contact name
Dr Kalyaani Persad

ORCID ID
https://orcid.org/0009-0009-1816-2909

Contact details
Department of Applied Health Sciences, University of Birmingham
Birmingham
United Kingdom
B15 2TT
+44 (0)7584811046
k.persad@bham.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
344284

Central Portfolio Management System (CPMS)
56443

National Institute for Health and Care Research (NIHR)
303671

Study information

Scientific Title
Developing a patient-physician co-created national diabetes-related emergencies management monitoring model

Acronym
DEKODE

Study objectives
1. To determine variations and inequalities in diabetes-related emergencies care outcomes in the UK across age, sex, ethnicity, deprivation, region, and vulnerable populations
2. To understand the experiences of people and their carers who have been treated for diabetes-related emergencies
3. To identify implementation principles for patient-centred care in people admitted with diabetes-related emergencies and through DEKODE
4. To investigate the predictors, clinical outcomes, and healthcare impact of recurrent diabetes-related emergencies episodes
5. To evaluate the cost-effectiveness of the DEKODE initiative

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/06/2025, HRA and Health and Care Research Wales (HCRW) (Health Research Authority, 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8144; socialcare.rec@hra.nhs.uk), ref: 25/IEC08/0011

Primary study design
Observational

Study design
Multi-component, mixed-methods study programme

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Diabetes mellitus

Interventions

The DEKODE study is designed to improve the care of people admitted to hospital with diabetes-related emergencies. It consists of four work packages, each focusing on a specific aspect of DKA care. Below is a summary of what will happen to participants in each work package, presented in a clear and straightforward way.

Work Package 1: Understanding Inequalities in DKA Care
We will use anonymised health records of patients with DKA from 2001 to 2023 to study differences in care and outcomes across regions, age groups, ethnicities, and other factors.
This part of the study does not involve direct interaction with participants.

Work Package 2: Exploring Lived Experiences of Patients, Carers, and Healthcare Professionals

Patients:
Patients treated for DKA will be invited to complete a short online questionnaire about their hospital experience.
Some patients will be invited for a one-on-one online interview lasting about 30 minutes, where they can share their experiences before, during, and after their hospital stay.
A follow-up questionnaire will be sent to patients 3 and 6 months after their discharge to understand any changes in their health and recovery.

Carers:
Carers (e.g., family members or friends) identified by the patients with their consent will also be invited to participate.
They will be interviewed separately to share their perspective on supporting someone with DKA.

Healthcare professionals:
Healthcare professionals involved in DKA care (e.g., doctors, nurses, and specialist teams) will be invited to take part in online interviews or focus groups. These will last about 30–60 minutes and explore their experiences in managing DKA.
All interviews and focus groups will take place online (e.g., via Zoom) and will be audio-recorded.

Work Package 3: Evaluating the Implementation of the DEKODE Model
Researchers will study how hospitals across the UK have adopted the DEKODE model for standardising DKA care.
Healthcare professionals from hospitals using the DEKODE system will be invited for interviews or focus groups to discuss the following:
1. How the model is being used in their hospital.
2. Any challenges or successes in implementing the system.
Around 20–30 professionals will participate in this part of the study.

Work Package 4: Investigating Recurrent DKA: A Retrospective Cohort Analysis Using DEKODE
This retrospective cohort study will analyse individuals with ≥2 DKA episodes using DEKODE data and hospital records to identify key clinical determinants, risk factors, and healthcare utilisation patterns associated with recurrent
DKA. Statistical analyses, including logistic regression and Kaplan-Meier survival analysis, will assess independent predictors of recurrence, clinical outcomes, and the impact of DEKODE implementation on reducing recurrence rates

Work Package 5: Health Economics Evaluation
Researchers will analyse the financial impact of using the DEKODE model in hospitals by

comparing the cost of DKA care before and after its implementation.
This part will rely on anonymised hospital data and does not involve any interaction with participants.

Intervention Type
Other

Primary outcome(s)
Work Package 1 – Assessing inequities in DKA care and outcomes in the UK
Objective 1.1: Crude incidence rate of DKA (number of new cases per 100,000 person-years), measured using CPRD Aurum/GOLD linked to HES (ICD-10 codes E10.0–E14.1), calculated annually from 01/01/2001 to 31/12/2023, stratified by age, sex, ethnicity, deprivation, mental health status, and region.
Objective 1.2: Length of hospitalisation, measured using HES data, at the index DKA admission.

Work Package 2 – Lived experiences of people treated for and treating DKA
Patient-reported experience of DKA care, measured using the NHS Inpatient Questionnaire for people with diabetes (Microsoft Forms) and the EQ-5D-Y questionnaire, at baseline (inpatient admission), 3 months and 6 months post-discharge.

Work Package 3 – DEKODE model implementation and effectiveness
Variation in DEKODE implementation across NHS Trusts, measured using thematic analysis of semi-structured interviews with stakeholders (applying NASSS and CFIR frameworks), at the time of interview across six consecutive quarterly DEKODE data cycles.

Work Package 4 – Investigating recurrent DKA
Frequency and predictors of recurrent DKA (defined as ≥2 DKA episodes), measured using pseudonymised DEKODE national audit data and NHS hospital records, across the full study period.

Work Package 5 – Health economics evaluation of the DEKODE model
Cost of managing a single DKA episode, measured using NHS procurement data and DEKODE audit data (direct and indirect costs), at baseline and at 12, 18, and 24 months after DEKODE adoption in participating institutions.

Key secondary outcome(s)
There are no secondary outcomes

Completion date
30/08/2028

Eligibility

Key inclusion criteria
Work Package 1:
Patients admitted with DKA from 1 January 2001 to 31 December 2023.

Work Package 2:
1. Patients:

1.1. Those admitted to the hospital with DKA
1.2. Have the capacity to provide consent
1.3. Aged 16-99 years

2. Carers:
2.1. Those who are identified by patients as recruited above
2.2. Have the capacity to provide consent
2.3. Aged 16-99 years

3. Healthcare workers:
3.1. Those involved in treating DKA for patients recruited above
3.2. Have the capacity to provide consent

Work Package 3:
Healthcare professionals involved in providing DKA care in hospitals participating in DEKODE

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 Years

Upper age limit
99 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Work Package 1:
Individuals with non-diabetic ketoacidosis or other metabolic disorders that could confound the study results

Work Package 2:
1. Patients without DKA
2. Providers not directly involved in DKA care
3. Unable to provide consent

Work Package 3:
Individuals who do not have sufficient interaction with the DKA care process

Date of first enrolment
23/06/2025

Date of final enrolment

31/08/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Birmingham
Department of Applied Health Sciences
Murray Learning Centre
Birmingham
England
B15 2TT

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
England
B15 2GW

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 datasets generated during and/or analysed during the current study will be available upon request from Punith Kempegowda (p.kempegowda@bham.ac.uk).
Type of data: Qualitative
When the data will become available and for how long: 2029, 4 years
By what access criteria data will be shared, including with whom: requests will be reviewed case-by-case, and data will be shared upon reasonable request
For what types of analyses: secondary qualitative analysis
What mechanism? Researchers wishing to access the pseudonymised dataset must submit a written request to the Chief Investigator (Dr Punith Kempegowda, p.kempegowda@bham.ac.uk), outlining the proposed analysis. These will then be reviewed on a case-by-case basis and access will require a signed data-sharing agreement with the University of Birmingham.
Whether consent from participants was obtained: Yes
Comments on data anonymisation: Only anonymised data will be provided
Any ethical or legal restrictions: the requesting researcher should have appropriate ethical and legal approval to request data for further analysis.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		09/09/2026	25/09/2026	Yes	No
Protocol file	version 2.0	11/07/2025	02/07/2026	No	No