ISRCTN16150211 https://doi.org/10.1186/ISRCTN16150211

Improving chronic kidney disease identification and assessing its association with health inequalities in coding practices

Submission date
16/04/2026

Recruitment status
Recruiting

Registration date
22/04/2026

Overall study status
Ongoing

Last Edited
21/04/2026

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Chronic Kidney Disease (CKD) is a global public health problem. It is a long-term condition that gradually damages the kidneys and can lead to serious health problems if not detected early. It is defined as a sustained reduction in the glomerular filtration rate (GFR) of less than 60 ml/min /1.73m2 for 3 months or more, and/or urinary abnormalities or structural abnormalities of the kidney tract. All patients with CKD should be coded in their primary care electronic health records. Accurate coding supports pathways that ensure regular review and monitoring through the CKD register and enhance safe prescribing via automated decision-support alerts.

However, CKD is often under-recorded in primary care because systems may lack reliable disease detection tools, and GPs may not have full access to hospital blood and urine results. As a result, some patients miss essential care, while others are incorrectly coded as having CKD when they do not. These issues are more common in socially deprived areas and among ethnic minority groups, where CKD prevalence is higher.

This project aims to transform CKD detection through a data-driven tool that addresses coding inaccuracies, health inequities, and economic burdens. The early stage of the study consists of three parts:
1) Development and pilot testing of a novel CKD detection algorithm designed to identify undiagnosed CKD cases and incorrect CKD coding.
2) Optimisation and validation of the algorithm to improve CKD classification accuracy by enhancing its sensitivity and specificity.
3) Analysis of kidney care inequalities by comparing coded and uncoded CKD groups, stratified by socioeconomic status, age, sex, ethnicity, other health conditions (comorbidities) and major complications related to CKD (sequelae) including cerebrovascular disease.

Who can participate?
Adult volunteers aged 18 or over (and no upper age limit) who are registered with GP practices located within Lancashire & South Cumbria (L&SC).

What does the study involve?
This study uses existing health records and does not involve any direct patient contact activity. The study comprises the collection of information that is already routinely recorded as part of standard care. Once the CKD detection algorithm is validated in the real-world population, the next step will be to implement it across Lancashire and South Cumbria. The algorithm will then be compared against current practice to assess its impact on clinical outcomes and economic implications. For example, improved CKD coding could prompt timely medication reviews, ensuring that patients receive appropriate treatments, such as sodium–glucose co-transporter 2 (SGLT2) inhibitors, to help slow disease progression. By identifying and coding patients who were previously missed from CKD registers, the tool may also help reduce the financial burden associated with CKD complications, including late presentation with kidney failure requiring urgent dialysis, unplanned hospital admissions, and mortality. Additionally, it may support earlier referral to secondary care services when needed.

What are the possible benefits and risks of participating?
The study aims to improve the detection and coding of CKD in primary care electronic health records. Conversely, patients who have been incorrectly coded as having CKD could be identified and removed from the register, avoiding unnecessary interventions. This would reduce the workload for GPs and provide reassurance to patients. A cost analysis will also be conducted to estimate savings resulting from fewer unnecessary or duplicated appointments and investigations.

As there will be no direct patient contact for research purposes, there will be no risk of intrusion, inconvenience, or any change in the relationship between participants and their general practitioner or kidney specialists (if they are under specialist care).
The main potential risk relates to data confidentiality. To minimise this risk, strict measures will be in place throughout the study:
- Participating GP practices will provide only the NHS numbers of their registered patients and their CKD registers to enable the CKD detection algorithm to run. No other identifiable information will be required from primary care providers.
- The research team will only access identifiable information on a strict need-to-know basis.
- All data will be stored and shared securely using approved platforms within Lancashire Teaching Hospitals NHS Foundation Trust (LTHTR), such as secure email and Microsoft shared folders linked to LTHTR accounts.
- Lower-layer Super Output Area (LSOA), rather than postcode, will be used to assess socioeconomic status to better maintain anonymity.
With these safeguards in place, the risk to participants is considered very low.

Where is the study run from?
Renal Department, Royal Preston Hospital, UK.

When is the study starting and how long is it expected to run for?
April 2026 to July 2028.

Who is funding the study?
Lancashire Teaching Hospitals NHS Foundation Trust, UK.

Who is the main contact?
Dr Wing Yin Leung, w.leung@nhs.net.

Contact information

Type(s)
Principal investigator, Scientific, Public

Contact name
Dr Wing Yin Leung

ORCID ID
https://orcid.org/0000-0003-4191-2762

Contact details
Renal Department
Royal Preston Hospital
Preston
United Kingdom
PR2 9HT
+44 1772 716565
wingyin.leung@lthtr.nhs.uk

Additional identifiers

Integrated Research Application System (IRAS)
357027

Study information

Scientific Title
Algorithm-based approach to CKD identification and its association with health inequalities in coding practices

Acronym
CKD-ID

Study objectives
Objectives
This study aims to answer the key question: Can a new algorithm improve the identification of Chronic Kidney Disease (CKD) in primary care?

Primary objective
1. To develop, test and refine a novel CKD detection algorithm using longitudinal kidney test data to accurately identify CKD and optimise coding accuracy in primary care electronic health record.

Secondary objective
1. To analyse inequalities in kidney care by comparing patients who have CKD correctly recorded (“coded”) in their primary care records with those who do not. The comparison will consider factors such as socioeconomic status, age, sex, ethnicity and comorbidities. We are particularly interested in whether missing CKD coding is linked to major complication related to CKD (sequelae), such as stroke or heart-related problems.

Ethics approval required

Ethics approval required

Ethics approval(s)
1. Approved 05/03/2026, North East - Newcastle & North Tyneside 1 Research Ethics Committee (REC) (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +442071048384; newcastlenorthtyneside1.rec@hra.nhs.uk), ref: 26/NE/0030

2. Approved 05/03/2026, Confidentiality Advisory Group (CAG) (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44207 104 8353; cag@hra.nhs.uk), ref: 26/CAG/0026

Primary study design
Observational

Secondary study design
Data-only observational study

Study type(s)

Health condition(s) or problem(s) studied
Chronic Kidney Disease

Interventions
This project aims to transform CKD detection through a data-driven tool that addresses coding inaccuracies, health inequities, and economic burdens. The early stage of the study consists of three parts:

1. Development and pilot testing of a novel CKD detection algorithm designed to identify undiagnosed CKD cases and incorrect CKD coding.
2. Optimisation and validation of the algorithm to improve CKD classification accuracy by enhancing its sensitivity and specificity.
3. Analysis of kidney care inequalities by comparing coded and uncoded CKD groups, stratified by socioeconomic status, age, sex, ethnicity, other health conditions (comorbidities) and major complications related to CKD (sequelae), including cerebrovascular disease.

The study does not involve any patient contact and uses existing health records only. There is no additional sample or collection of data beyond what is routinely generated during standard care. How the participants' data is handled during the study (full details can also be found in the Protocol 6.4 Overview of data):
GP practices securely send NHS numbers and CKD registers for all registered patients to the research team under Section 251 approval. No other identifiers are shared. Once received, NHS numbers are immediately converted into unique pseudo IDs within secure LTHTR systems. After conversion, all processing and analysis use only pseudo IDs. The original NHS number file is stored separately in an encrypted, access-restricted area. Laboratory results from the OMOP database are linked using pseudo IDs to combine serial tests for each patient. All data processing takes place within the Lancashire and South Cumbria Secure Data Environment. A pseudonymised analysis dataset is then created containing pseudo IDs, lab results, demographics, and comorbidity information. This dataset supports CKD algorithm development, performance testing, and inequalities analysis. All analyses use pseudonymised data only. Algorithm outputs remain pseudonymised unless clinical verification is required. When verification is needed, secure re-linkage to NHS numbers occurs within the SDE so GP practices and specialists can review results.

Intervention Type
Other

Primary outcome(s)
1. Diagnostic performance of the Chronic Kidney Disease (CKD) detection algorithm when applied to primary care electronic health record data measured using standard performance metrics, including sensitivity and specificity, calculated at the point of algorithm application using all available historical kidney test data within the study period, at retrospective data collection only

Key secondary outcome(s)
1. Assessment of inequalities in kidney care associated with CKD coding status in primary care measured using an evaluation comparing patients with correctly coded CKD to those with uncoded CKD across key demographic and clinical characteristics, including socioeconomic status, age, sex, ethnicity, and relevant comorbidities, including CKD-related sequelae, at retrospective data collection only

Completion date
19/07/2028

Eligibility

Key inclusion criteria
1. Adults aged 18 or over (and no upper age limit)
2. Patients registered with GP practices located within Lancashire & South Cumbria (L&SC) participating in the study
3. No other specific inclusion criteria apply

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Patients under the age of 18
2. Patients registered with GP practices outside Lancashire & South Cumbria (L&SC)
3. No other exclusion criteria apply

Date of first enrolment
20/04/2026

Date of final enrolment
19/04/2028

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Lancashire Teaching Hospitals NHS Foundation Trust
Royal Preston Hospital
Sharoe Green Lane
Fulwood
Preston
England
PR2 9HT

Study participating centre
Chorley and South Ribble Network (Primary Care Network)
Buckshaw Village Surgery, Buckshaw Village, Chorley PR7 7HZ
Adlington Medical Centre, Chorley PR6 9NW
Chorley
England
PR7 7HZ

Study participating centre
Stonebridge Surgery
Preston Road
Longridge
Preston
England
PR3 3AP

Study participating centre
Garstang Medical Practice
Garstang Medical Centre
Kepple Lane

Garstang
Preston
England
PR3 1PB

Sponsor information

Organisation
Lancashire Teaching Hospitals NHS Foundation Trust

ROR
https://ror.org/02j7n9748

Funder(s)

Funder type

Funder Name
Lancashire Teaching Hospitals NHS Foundation Trust

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	version 1.1	10/02/2026	21/04/2026	No	No
Protocol file	version 1.1	10/02/2026	21/04/2026	No	No