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# A programme to spread glomerular filtration rate (eGFR) graph surveillance for the early identification, support and treatment of people with progressive chronic kidney disease

**Submission date**
10/10/2016

**Recruitment status**
No longer recruiting

**Registration date**
11/01/2017

**Overall study status**
Completed

**Last Edited**
07/01/2022

**Condition category**
Urological and Genital Diseases

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

## Plain English summary of protocol

Background and study aims
Chronic kidney disease (CKD) is a long-term condition where the kidneys do not work properly. In a healthy person, the kidneys are vital for filtering out the waste products and excess water in the blood, and converting them into urine. In patients suffering from CKD, the kidneys are unable to do this, and so the body is unable to get rid of the waste products building up in the blood. CKD is common, affecting over 10% of the adult population. It is frequently unrecognised since it causes no symptoms in the early stages. CKD often exists together with other conditions, particularly high blood pressure and diabetes. Some people with CKD develop kidney disease that worsens over time (progressive disease). In the most advanced stages, treatment using machines to do the work of the kidneys (dialysis) or transplants are the only way to keep people alive. People with progressive disease who are referred late by their GPs to kidney units treatment have a lower risk of surviving. Late referral is therefore a major, and preventable, cause of harm in these people. Early identification of people with progressive disease would also create opportunities to start treatment to slow disease progression. The aim of this project is to improve the treatment and outcomes of CKD patients at high risk of kidney failure and other complications.

Who can participate?
Patients with chronic kidney disease.

What does the study involve?
Information on each of the participants on pathology computer systems are used to generate a graph of kidney function over time. In cases where the graph shows that kidney function is getting worse, these are highlighted for review by a laboratory scientist. For participants that are identified as being of “high-risk” a paper copy of the graph is sent to the general practitioner with a prompt that further action may be needed. In this way the project takes information already available and highlights trends over time to primary care. The intervention is to be rolled-out sequentially, with renal centres (and their associated pathology laboratories) starting eGFR

graph reporting at staggered time points. Four or five renal centres begin the intervention at each step with a six-month interval between steps.
(Removed 20/05/2019: The start time of the program is chosen randomly.)

What are the possible benefits and risks of participating?
Individual patients do not have any additional testing and there are no significant burdens or risks.

Where is the study run from?
22 NHS sites in the UK

When is the study starting and how long is it expected to run for?
September 2014 to December 2017

Who is funding the study?
Health Foundation (UK)

Who is the main contact?
1. Dr Hugh Gallagher (scientific)
2. Ms Rowena Sampson (public)
Assist@kidneyresearchuk.org

### Study website
https://assist-ckd.org/

# Contact information

### Type(s)
Scientific

### Contact name
Dr Hugh Gallagher

### Contact details
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### Type(s)
Public

### Contact name
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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
Health Foundation Unique Award Reference Number: 7349

# Study information

### Scientific Title
A programme to spread eGFR graph surveillance for the early identification, support and treatment of people with progressive chronic kidney disease (ASSIST-CKD): stepped wedge implementation and evaluation of an intervention to reduce late presentation for renal replacement therapy

### Acronym
ASSIST-CKD

### Study objectives
The aim of this study is to evaluate the implementation of this intervention across a large population served by a number of UK renal centres using a mixed methods approach.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
The project was considered by the National Research Ethics Service (South East Coast-Surrey) on 16th January 2015 and determined to be service evaluation, not requiring ethical review by an NHS Research Ethics Committee. The project does not involve allocation to different interventions across patient groups; there are no significant risks or burdens to patients; and outcome data are already routinely collected by the UK Renal Registry.

The intervention was introduced as a local quality improvement project in the Heart of England Foundation Trust in 2012. The subsequent fall in late presentation rate has been documented and published. A number of sites, such as the West Midlands Strategic Clinical Network, are routinely introducing the intervention outside this project on the basis of this evidence.

### Study design
Current study design as of 20/05/2019:
Quasi-experimental study (changed in Sept 2017)

Previous study design:
Multicentre stepped wedge randomised control study

## Primary study design
Interventional

## Secondary study design
Quasi-experimental study

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied
Chronic kidney disease

## Interventions
Reporting of eGFR graphs by pathology laboratories to primary care. The intervention takes the information on pathology computer systems and automatically generates a graph of kidney function over time for individuals. Graphs where the kidney function is deteriorating are flagged for review by a laboratory scientist – for those patients determined to be “high-risk” a paper copy of the graph is sent to the general practitioner with a prompt that further action may be needed. In this way the project takes information already available and highlights trends over time to primary care. Individual patients do not have any additional testing and there are no significant burdens or risks.

The intervention will be rolled-out sequentially, with renal centres (and their associated pathology laboratories) commencing eGFR graph reporting at staggered time points. The plan is for four or five renal centres to begin implementation at each step with a six-month interval between steps. The time of intervention initiation will be randomised.

UPDATE 20/05/2019:
Randomisation proved extremely difficult to follow, with only very few laboratories being able to activate the intervention in the period they were randomised to. Therefore in September 2017 it was decided to proceed with analysis based on a quasi-experimental design, where the study is not considered ‘experimental’ because of lack of randomisation, but there is still account for control periods, a staggered intervention that allows for more robust analysis of possible confounding time effect, and also the inclusion of more controls (non-participants clusters, never randomised, never started on intervention, areas with no similar interventions).

## Intervention Type
Other

## Primary outcome measure
Incidence of late presentation for renal replacement therapy, defined as any patient first seen by renal services within 90 days of starting renal replacement therapy. These data will aggregate into six-month time periods, two per calendar year (Jan to June; July to December).

## Secondary outcome measures

1. The use of temporary vascular access for starting dialysis
2. Estimated Glomerular Filtration Rate (eGFR) measured within two weeks of start of renal replacement therapy (RRT)
3. Mortality at 6 months from start of RRT in new RRT patients
4. The incident rate of end-stage renal disease, measured annually

All outcomes measures are routinely collected by the UK Renal Registry with the exception of vascular access, which is collected annually as part of the Registry's Multisite Dialysis Access Audit. Routinely collected baseline data will be provided by the UK Renal Registry and baseline referral rates supplied by participating centres. Outcomes will be measured before and during intervention roll-out at each site.

The number of new patient referrals (per quarter) will be recorded as a balancing measure. These data are readily extractable from renal centre appointment systems.

A qualitative evaluation will also be performed with:
1. Semi-structured interviews with laboratory staff, renal centre staff and service commissioners, in order to find out about the drivers and enablers to the intervention being implemented and also to find out what these groups think the effect of the intervention might be
2. Online survey of GPs receiving the intervention, that is, asking GPs how useful the graph is in identifying people at risk of progressive disease, and how helpful it is in providing education about what to do next
3. Focus groups of primary care staff, where questions will examine in more detail the implementation of the intervention (what happens once the graph arrives in the Practice) and what potential difference the graphs make to patient care

### Overall study start date
01/09/2014

### Completion date
31/12/2017

## Eligibility

### Key inclusion criteria
1. Patients <65 years with eGFR <50 ml/min/1.73m2
2. Patients >65 years with eGFR <40 ml/min/1.73m2

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
Pathology laboratories serving 16-20 UK renal units

### Key exclusion criteria

Participants not fulfilling inclusion criteria.

### Date of first enrolment
31/07/2015

### Date of final enrolment
01/01/2017

## Locations

### Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

Wales

### Study participating centre
**Royal Cornwall Hospital NHS Trust**
Royal Cornwall Hospital
2 Penventinnie Lane
Treliske
Truro
United Kingdom
TR1 3LJ

### Study participating centre
**NHS Lanarkshire Hospitals**
Monklands Hospital
Monkscourt Avenue
Airdrie
United Kingdom
ML6 0JS

### Study participating centre
**Wirral University Teaching Hospitals NHS Trust**
Arrowe Park Hospital
Upton
Wirral
United Kingdom
CH49 5PE

**Study participating centre**
**Countess of Chester Hospital NHS Foundation Trust**
The Countess Of Chester Health Park
Liverpool Road
Chester
United Kingdom
CH2 1UL

**Study participating centre**
**Doncaster and Bassetlaw Hospitals NHS Foundation Trust**
Armthorpe Road
Doncaster
United Kingdom
DN2 5LT

**Study participating centre**
**Liverpool Clinical Laboratories**
Aintree University Hospital NHS Trust/Royal Liverpool and Broadgreen University Hospitals NHS Trust
Liverpool
United Kingdom
L69 3GA

**Study participating centre**
**Southport and Ormskirk Hospital NHS Trust**
Southport and Formby District General Hospital
Town Lane
Kew
Southport
United Kingdom
PR8 6PN

**Study participating centre**
**Newcastle Upon Tyne Hospitals NHS Foundation Trust**
Freeman Road
High Heaton
Newcastle-upon-Tyne
United Kingdom
NE7 7DN

**Study participating centre**
**Southern Health and Social Care Trust**
John Mitchel Place
Newry
United Kingdom
BT35 8DR

**Study participating centre**
**Southend University Hospital NHS Foundation Trust**
Prittlewell Chase
Westcliff-on-Sea
United Kingdom
SS0 0RY

**Study participating centre**
**South Eastern Health and Social Care Trust**
Upper Newtownards Road
Ulster
United Kingdom
BT16 1RH

**Study participating centre**
**Northern Health and Social Care Trust**
Services Yard Antrim Area Hospital
45 Bush Road
Antrim
United Kingdom
BT41 2RL

**Study participating centre**
**Betsi Cadwaladr University Health Board**
Wrexham Maelor Hospital
Croesnewydd Road
Wrexham
United Kingdom
LL13 7TD

**Study participating centre**
**Epsom and St Helier University Hospitals NHS Trust**
Wrythe Lane

Carshalton
London
United Kingdom
SM5 1AA

**Study participating centre**
**Surrey Pathology Services**
Royal Surrey County Hospital NHS Foundation Trust/Ashford and St Peter's Foundation Trust /Frimley Health NHS Foundation Trust
Surrey
United Kingdom
GU2 7XX

**Study participating centre**
**Hull and East Yorkshire NHS Foundation Trust**
Anlaby Road
Hull
United Kingdom
HU3 2JZ

**Study participating centre**
**Betsi Cadwaladr University Health Board**
Ysbyty Gwynedd
Bangor
United Kingdom
LL57 2PW

**Study participating centre**
**Western Health and Social Care Trust**
106 Irish Street
Derry
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BT47 6SB

**Study participating centre**
**Derby Teaching Hospitals NHS Foundation Trust**
Royal Derby Hospital
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

**Study participating centre**
**Betsi Cadwaladr University Health Board**
Glan Clwyd Hospital
Rhuddlan Road
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LL18 5UJ

**Study participating centre**
**ABM University Health Board**
Morriston Hospital
Heol Maes Eglwys
Morriston
Swansea
United Kingdom
SA6 6NL

**Study participating centre**
**City Hospitals Sunderland NHS Foundation Trust**
Sunderland Royal Hospital
Kayll Road
Sunderland
United Kingdom
SR4 7TP

# Sponsor information

**Organisation**
Kidney Research UK

**Sponsor details**
Nene Hall
Peterborough
United Kingdom
PE2 6FZ

**Sponsor type**
Charity

**ROR**

https://ror.org/02kx7se86

# Funder(s)

### Funder type
Charity

### Funder Name
Health Foundation

# Results and Publications

### Publication and dissemination plan
The results of the project will be analysed in 2018. Outputs will be disseminated at national and international meetings and via peer reviewed journals.

### Intention to publish date
31/12/2018

### Individual participant data (IPD) sharing plan
1. Individual patient level data are stored, which can also be analysed at centre level. The repository name is the UK Renal Registry (UKRR): www.renalreg.org
2. Access to the data will not be limited, except patient or centre identifiable information. The process to access data can be found here: https://www.renalreg.org/about-us/working-with-us/
3. Data are made available to researchers promptly after completion of the approved process including peer review and completion of data sharing agreement as outlined on the UKRR website

### IPD sharing plan summary
Stored in repository

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Interim results article | | 09/01/2017 | 07/01/2022 | Yes | No |
| Protocol article | | 11/04/2017 | 07/01/2022 | Yes | No |