Insight Research Programme: Application form

Click on any of the headings to start your form. Once you have completed all mandatory questions within a section and moved to the next, you will see a tick appear on the section tab. You can save and return to complete the form at any time by going to AIMS.health.org.uk and logging in.

Once you have completed all sections you can submit the form by clicking on "Save and Exit" and then "Yes, submit entire form now." We recommend you print or save a copy of the form before submitting it.

1. 1. Lead organisation

Please ensure that you have read the notes for applicants and the AIMS user guide before completing this application form. You can access this information on the Health Foundation website.

1.1 Application information *Please note: the person below will receive all communications regarding this application.*	
AIMS ID	565090
Programme	Insight Research Programme
Call	Round 3
	Please note this person will receive all communications regarding this application
Applicant Organisation	University of Manchester
Applicant name	Sabine van der Veer
Applicant job title	Research Fellow
Applicant email	sabine.vanderveer@manchester.ac.uk

1.2 Principal Investigator information	
Principal Investigator name	Sabine van der Veer
Principal Investigator job title	Research Fellow
Principal Investigator email	sabine.vanderveer@manchester.ac.uk

1.3 Lead organisation *Please note this will be the organisation that the award is made payable to.*	
Organisation name	University of Manchester
Type of organisation	Academic Institution
Website	https://www.herc.ac.uk/
Address line 1	Vaughan House
Address line 2	Portsmouth Street
Postcode:	M13 9GB

Country	☑ England ☐ Northern Ireland ☐ Scotland ☐ Wales ☐ International
Region	☐ East of England ☐ London ☐ Midlands ☐ North East ☑ North West ☐ South East ☐ South West ☐ Yorkshire and the Humber
☐ Please tick box if registered address is different than above:	
Company/Charity Registration Number (where appropriate)	
VAT Number (if applicable)	

2. 2. About your proposed research

Please ensure that you have read the notes for applicants and the AIMS user guide before completing this application form. You can access this information on the Health Foundation website.

2.1 Please indicate the award stream you are applying for.

Small scale awards are up to £100,000; maximum 18 month duration.
Large scale awards are between £300,000 and £400,000; maximum 36 month duration.

- ☐ Small scale award
- ☑ Large scale award

2.2 Please indicate which priority area your idea relates to. Select only one.

- ☑ Person-centred: making audits more person-centred, including the collection and use of patient reported outcomes
- ☐ Linking data: accelerating the use of linked data to improve the value of health care
- ☐ Reducing variation: using national clinical audits & registries to identify and reduce variation in quality

2.3 About your research proposal

Project title
Max 20 words
130 character limit (approximately 20 words). The count box below indicates the number of characters remaining.

Optimising engagement in routine collection of electronic patient-reported outcomes into disease registries

Project aim
Please provide a high level description of the aim of your project.
Max 50 words
375 character limit (approximately 50 words). The count box below indicates the number of characters remaining.

To develop, implement and evaluate a comprehensive strategy to engage patients, clinicians and commissioners in routine collection of electronic patient-reported outcomes (ePROs) into the UK Renal Registry, and to identify broader learning to guide routine ePRO collection by other disease registries.

Summary of your research proposal
1725 character limit (approximately 250 words). The count box below indicates the number of characters remaining

High quality patient-reported outcome data in disease registries can enrich national audits and research, enhance clinical care, and inform commissioning and redesign of health services. However, collecting these data routinely is only feasible and sustainable if done electronically and with support from patients, clinicians and commissioners.

Therefore, this proposal aims to deliver a strategy to engage these key stakeholders in routine collection of electronic patient-reported outcomes (ePROs) into the UK Renal Registry (UKRR), and to inform ePRO initiatives by other disease registries.

Our objectives are to:
1. Explore the needs of key stakeholders to engage in ePROs;
2. Develop an engagement strategy for the UKRR to optimise ePRO response rates across patient groups;
3. Implement, evaluate and further refine the strategy in routine care settings;
4. Produce a blueprint to inform ePRO collection by other disease registries.

For objective 1, we will interview kidney patients, clinical and administrative staff in renal units and commissioners, as well as observe clinic workflows to understand how to embed ePROs in routine care. This will result in the design of an ePRO engagement strategy, which we will then develop for objective 2.

For objective 3, we will implement the strategy across renal units, and iteratively refine it to engage a broader range of patients in ePROs. We will monitor response rates and conduct qualitative research to identify issues and address them as they arise.

For objective 4, we will synthesise all findings from the previous objectives to produce a blueprint, which will provide guidance for other disease registries on how to incorporate routine ePRO collection.

References

2.4 Proposal keywords

Please add up to five keywords that relate to your proposal. One keyword is mandatory.

1:	Electronic patient-reported outcomes (ePROs)
2:	Disease registries
3:	Long-term conditions
4:	Mixed-methods research
5:	Co-design

2.5 Rationale for the project

Please provide the rationale for the project, highlighting the gaps in knowledge your research is seeking to address. Please ensure this relates to the priority area you have selected.

1950 character limit (approximately 300 words). The count box below indicates the number of characters remaining. *

Patient-reported outcomes (PROs) reflect the personal impact of illness and treatment as assessed by patients (1). PROs have the potential to enrich national audits and research, improve disease management, and inform commissioning and improvement of healthcare services (1). To unlock this potential, this proposal aims to address the following knowledge gaps:

A. How to collect PROs electronically at a national scale?

Paper-based PRO collection is cumbersome, expensive and may lead to substantial delays in feedback of results (1). Electronic collection can overcome this, while also allowing tailoring of what, when and from whom data are captured. In addition, it facilitates centralised collection at scale, enabling PRO data to be collected once for multiple purposes, including national clinical audits and research. Previous initiatives collecting electronic PROs (ePROs) used local or regional infrastructures (2-5), but no ePRO initiative has yet deployed a national infrastructure.

B. How to optimise ePRO response rates for people with long-term conditions (LTCs) in routine care?

There is currently no evidence to inform optimisation of ePRO response rates for people with LTCs in routine care. A study in cancer survivors consented 55% of invited patients, with consent varying across age and deprivation levels (2). In consenters, initial and follow-up response rates were 85% and 66%, respectively, but these may not generalise to a routine care context. A study of responses in routine surgical outpatient settings was conducted in a single centre, with patients completing a one-off questionnaire (3).

C. How can PROs inform commissioning for people with LTCs?

PROs are seen as valuable for assessing NHS services and inform commissioning decisions (6,7), but are currently only used for surgical procedures (8,9). It is unclear how this translates to services for people with LTCs.

References

1. Coulter A, Potter C, Peters M, Fitzpatrick R. Cancer PROMs: a scoping study [Internet]. 2015. Available from: www.pssru.ac.uk/archive/pdf/5079.pdf

2. Ashley L, Jones H, Thomas J, Newsham A, Downing A, Brown J, et al. Integrating Patient Reported Outcomes With Clinical Cancer Registry Data : A Feasibility Study of the Electronic Patient-Reported Outcomes From Cancer Survivors (ePOCS) System. J Med Internet Res. 2013;15:1–19.

3. Malhotra K, Buraimoh O, Thornton J, Cullen N, Singh D, Goldberg AJ. Electronic capture of patient-reported and clinician-reported outcome measures in an elective orthopaedic setting : a retrospective cohort analysis. BMJ Open. 2016;6:e011975.

4. Schick-makaroff K, Molzahn AE. Evaluation of real-time use of electronic patient-reported outcome data by nurses with patients in home dialysis clinics. BMC Health Serv Res. BMC Health Services Research; 2017;17(439).

5. Snyder C, Blackford A, Wolff A, Carducci M, Herman J, Wu A. Feasibility and Value of PatientViewpoint: A Web System for Patient-Reported Outcomes Assessment in Clinical Practice. Psychooncology. 2013;22(4):895–901.

6. Devlin NJ, Appleby J. Getting the most out of PROMs. Putting health outcomes at the heart of NHS decision-making [Internet]. Available from: https://www.kingsfund.org.uk/sites/files/kf/Getting-the-most-out-of-PROMs-Nancy-Devlin-John-Appleby-Kings-Fund-March-2010.pdf

7. Greenhalgh J, Dalkin S, Gooding K, Gibbons E, Wright J, Meads D, et al. Functionality and feedback : a realist synthesis of the collation, interpretation and utilisation of patient-reported outcome measures to improve patient care. Heal Serv Deliv Res. 2017;5(2).

8. Department of Health (London). Guidance on the routine collection of Patient Reported Outcome Measures (PROMs). For the NHS in England [Internet]. 2008. Available from: http://webarchive.nationalarchives.gov.uk/20130105081711/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_092625.pdf

9. Health and Social Care Information Centre. Monthly Patient Reported Outcomes [Internet]. 2017. Available from: https://www.england.nhs.uk/statistics/statistical-work-areas/proms/

2.6 Research proposal

Please outline in detail your proposed programme of research.

This section does not have a character / word limit, but, we do ask that answers are no more than 2,500 words. *

BACKGROUND

Benefits of electronic patient-reported outcomes (PROs)
Routine PRO collection potentially benefits multiple stakeholders. For patients, it may improve detection of problems and monitoring disease progression; guide treatment plans; enhance communication with clinicians; and support shared decision-making (1–4). For healthcare providers, PRO data can inform improvements of the quality and person-centredness of services (2,5), while commissioners may use PROs as a performance indicator to assess value for money and incentivise better care (1,6). Disease registries can capture PROs to better understand patients' needs and evaluate how well these are met by healthcare organisations in audits (7), as well as using them as an outcome measure in registry-based observational research and pragmatic trials. For these benefits to take effect, PRO data need to be collected widely across patient groups and, in the case of long-term conditions (LTCs), repeatedly and sustainably over time. This requires a strategy that convinces and enables a broad range of patients to complete PROs routinely at scale.

Collection of PRO data in the UK Renal Registry (UKRR)
In 2015, the UKRR launched Transforming Participation in Chronic Kidney Disease (TP-CKD), a national programme funded by NHS England (https://www.thinkkidneys.nhs.uk/ckd). The programme aimed to support kidney patients to manage and make decisions about their health. As part of TP-CKD, PRO data have been collected for more than 3,000 people from fourteen renal units using paper questionnaires. These were returned to the UKRR and scanned into the database, after which results could be viewed in PatientView. This proposal builds on TP-CKD by using the same PRO instruments (i.e. EQ-5D-5L (8) and a kidney-specific symptom score (9)), which were selected in consultation with patients, clinicians and researchers.
TP-CKD demonstrated enthusiasm in the renal community for collecting PRO data; routine PRO collection into the UKRR will be part of the new service specifications for specialised renal services [personal communication, Dr Richard Baker, chair of the renal Clinical Reference Group for NHS England]. However, TP-CKD has also shown that paper-based collection is not sustainable as it is logistically complex and costly, and results in substantial time lags between data capture and feedback to patients and renal units.

Extending the UKRR infrastructure for electronic PRO (ePRO) collection at a national scale
Since 2007, the UKRR has routinely collected, analysed and reported clinical data for all dialysis and transplant patients in the UK using a national infrastructure. The infrastructure includes a data repository where renal patient-level data are stored, as well as facilitating communication and secure data transfer between renal unit IT systems, laboratories, the UKRR, other renal registries and a patient portal (PatientView). This project will extend the available infrastructure to facilitate collection of ePRO data at a national scale. It will make the UKRR the first national audit that can routinely and electronically collect PRO data alongside clinical data.

OBJECTIVES
1. Identify barriers to and facilitators for engaging in routine collection of ePROs for key stakeholders (kidney patients, clinicians, commissioners);
2. Using the findings from objective 1, develop a comprehensive strategy for the UKRR to optimise ePRO response rates across patient groups;
3. Implement, evaluate and further refine the engagement strategy in routine care;
4. Produce a blueprint to inform routine ePRO collection by other disease registries in the NHS.

We will address each objective in a separate work package (WP), described in more detail below.

THEORETICAL FRAMEWORK
We will use Normalisation Process Theory (NPT) (10,11) as the theoretical framework throughout the project to guide study design and synthesis of findings. NPT explains how new technologies and ways of working become routinely embedded in everyday contexts, and specifies mechanisms of importance in implementation processes. It has been widely used in studies to understand how eHealth and other complex interventions are routinely embedded and sustained in healthcare practice (12). The framework consists of four constructs: coherence (e.g. do users have a shared view of the intervention's purpose and potential benefits); cognitive participation (e.g. do users buy into the idea and can they sustain engagement); collective action (e.g. effect on roles and responsibilities); and reflexive monitoring (e.g. how do users appraise the intervention's value). These constructs are relevant to achieving our aim of embedding and sustaining a new way of working for renal services to engage key stakeholders in ePRO collection in routine care.

WP1: QUALITATIVE RESEARCH WITH KEY STAKEHOLDERS

General methodological approach
The design of the research in this WP (including interview guides, field note templates and coding framework) will be informed by our theoretical framework (10) and available literature on engagement in and implementation of (e)PROs and other IT interventions in healthcare settings (2,13–19).
Data collection will continue until thematic saturation is reached, and interviews and focus groups will be audio-recorded and transcribed verbatim. Transcripts and field notes will be imported and analysed using qualitative data analysis software. We will employ the constant comparative method to synthesise results across the different qualitative data sets, aiming to identify both commonalities and differences (20). This method enables an interplay of deduction and induction (21), allowing us to interrogate the data informed by the theoretical framework and previous research whilst remaining open to unexpected findings. It supports iterative analysis, and emerging findings can therefore inform ongoing data collection across WP1.1 to 1.3 (22).

WP1.1 – Interviews with kidney patients

We will conduct semi-structured interviews with kidney patients treated in the fourteen units that were part of the TP-CKD programme. We will strive for maximum variation in age, ethnicity, socio-economic status and treatment modality, which are patient characteristics associated with engagement in (e)PROs or health IT (17,23,24). Further, we aim to recruit patients who responded to the invitation to complete a paper-based PRO as part of TP-CKD, as well as those who did not. The UKRR will work with units to identify eligible patients, whom local research nurses will approach and consent to take part in the research.

WP1.2 – Observing workflows in renal units

We will observe workflows in renal units of our clinical partners (see section 2.8) to identify opportunities and barriers for clinical and administrative staff to engage patients in ePROs as part of their usual care pathway. Observational methods are recognised as essential to understanding how new digital ways of working operate in practice (25), providing insights into both formal and informal organisational/technical features that impact patient and professional experience (26). Researchers will make contemporaneous observational notes, and use these to complete field note templates (27). We will construct a guide to synchronise observations and ensure their comparability across clinical sites. Observations will be supplemented with staff interviews to confirm and refine findings. Data analysis will include identifying similarities and differences within and between sites and modalities (e.g. pre-dialysis, in-centre haemodialysis). This will help us understand to what extent we should allow flexibility to tailor the strategy to local settings and patient pathways.

WP1.3 – Interviews with commissioners

We will conduct semi-structured interviews with commissioners from NHS England's national, regional and local commissioning bodies, including members

and leads of: the renal Clinical Reference Group; specialised commissioning teams (i.e. hubs); regional teams; and Clinical Commissioning Groups affiliated with our clinical partners. Recruitment will be facilitated by Mr Jon Gulliver (study team) and Dr Richard Baker (advisory group).

Interviews will address topics such as commissioners' views on the importance of ePROs for incentivising better care, their role in promoting routine ePROs collection as part of LTC services, and tools (e.g. CQUINs, dashboards) and evidence (e.g. health economics evaluations) that could support commissioners in this role.

The findings of WP1.3 will inform a chapter in the blueprint (WP4).

WP1.4 – Co-designing the engagement strategy

We will conduct participatory co-design workshops with patients and professionals (28). Co-design enables "real time synthesis" with stakeholders to ensure outputs are acceptable, feasible and user-centred (29). Outputs will therefore be able to directly inform the blueprint (WP4). We will present participants with prototypes and products for critique (one workshop with patients, one with professionals), review and refine the outputs, and then conduct a final joint workshop with both groups to consider interactions between them. The initial design of workshop materials will be informed by results from WP1.1 and 1.2, and may include prototype screens for recording and viewing ePRO data, diagrams of ePRO workflows and supporting materials for patients and staff.

WP1.4 will deliver the prototype engagement strategy, which will serve as input for WP2.

WP2: DEVELOPMENT OF THE ENGAGEMENT STRATEGY FOR THE UK RENAL REGISTRY

We will develop the engagement strategy in the context of the UKRR. This includes an extension of the available national infrastructure to facilitate collection and direct transfer of ePRO data between patients, clinicians and the UKRR (see Figure). In particular, we anticipate development of:
a) Screens in PatientView where kidney patients can complete and view ePROs on a tablet or desktop computer, including support to aid access and interpretation. This will allow offering translations or simplified versions of PRO instruments to address language and literacy barriers (30,31). It will also enable patients to engage with ePROs at home, as well as in the hospital using a device provided by the unit. PatientView is now available in 68 of the 71 adult renal centres in the UK, with 60,000 patients registered as users;
b) Software interfaces and screens for the local renal IT systems of our clinical partners (see Table for Digital Maturity Assessment scores) to view ePRO results during outpatient clinics. Studies have shown that discussing ePROs in consultations is a facilitator for engagement (2,18), which was confirmed in feedback from PPI groups on our proposal;
c) Materials to support patients with, for example, registering for PatientView, completing ePROs in PatientView, and interpreting results;
d) Organisational procedures for renal units, such as reminders for ePRO collection in individual patients.

Alongside the development, we will create a technical implementation guide, as well as templates of all materials and procedures to be part of the blueprint (WP4).

WP2 will deliver an ePRO engagement strategy for implementation and evaluation in WP3.

WP3: MIXED-METHOD EVALUATION AND REFINEMENT OF THE STRATEGY IN ROUTINE CARE SETTINGS

We will implement the strategy developed in WP2 among 300 patients from at least three clinical sites. We will continuously monitor response rates, while conducting embedded qualitative research to understand engagement, identify challenges and barriers and address them as they arise. Frequency of ePRO completion will be informed by WP1, but we anticipate it to be monthly or quarterly, depending on the patient group.

Patient selection, recruitment and consent
Findings from WP1 will inform from which patient group(s) we will select participants (e.g. in-centre haemodialysis, pre-dialysis patients). All will be recruited in renal units from our three clinical partners, where they will be invited by staff members to complete ePROs at several data collection time points as part of a service evaluation. Consent will be assumed by patients submitting their ePRO data (see section 2.9), enabling evaluation of response rates in naturalistic settings. It will also minimise risk of non-engagement of patients who are willing to complete an ePRO as part of their care, but do not want to participate in research-related activities. Patient interviews will be conducted as research, for which we will obtain NHS REC approval.

Outcome measures
Our primary outcome measure is the difference in initial ePRO response rates between the first and last iteration of evaluating the strategy; the iterations are described below. Initial response rate is defined as the proportion of patients completing the ePROs when they get invited at their first data collection time point.
As a secondary outcome measure we will compare initial response rates between all iterations, as well as follow-up response rates, i.e. the proportion of patients completing ePROs at subsequent data collection time points.

Sample size for quantitative evaluation
Preliminary results from the TP-CKD programme showed an average initial response rate to paper PROs of 67%, with a difference of 25% between units with the highest and lowest rates. We used this information conservatively as input for our sample size calculation, which showed that we will need cohorts of at least 82 patients to identify an increase from 60% to 80% with a confidence level of 95% and 80% power (32). The primary outcome measure will thus be evaluated by comparing initial response rates for the first and last 82 invited patients.

Evaluation and further refinement of the strategy
We have designed our approach in line with methods successfully used for optimising recruitment into complex trials (33). The process is designed to produce insights into issues within relatively short time periods, with the aim to improve engagement iteratively over time. We anticipate our timelines to allow 3-4 iterations, with each iteration consisting of the following steps:
i) Implementation of the strategy in up to 75-100 patients across clinical sites;
ii) Understanding engagement through: monitoring of initial and follow-up response rates; and embedded qualitative research. We will use similar qualitative research methods as in WP1.1 and 1.2, and keep activity logs to document the effort required by patients and staff;
iii) Based on the findings from step 2, develop a plan of action to improve initial and follow-up engagement across patient groups and discuss this with clinical staff, the study team and our advisory group. The plan may include actions such as providing additional staff instructions; amending patient materials; or changing when patients are prompted to complete ePROs;
iv) Revise the strategy according to the plan of action.

The refined strategy and results from the mixed-methods evaluation will feed into the blueprint (WP4).

WP4: PRODUCING A BLUEPRINT FOR ROUTINE ePRO COLLECTION BY OTHER DISEASE REGISTRIES

The purpose of the blueprint is to inform implementation of ePRO collection by other national disease registries. It will also serve as a guide for the UKRR to roll-out ePRO collection across the UK.

We will synthesise findings across WPs guided by our theoretical framework (10). We will design the blueprint to provide guidance on achieving established implementation outcomes, such as acceptability, feasibility, implementation costs and sustainability (34). We will build on the blueprint expertise of Salford Royal as our clinical partner, who are leading nationally on blueprint development for the NHS' Global Digital Exemplars

(https://www.england.nhs.uk/digitaltechnology/info-revolution/exemplars).

In addition to a description of our approach and findings within the renal setting, chapters will contain a section with generalisable lessons learned, checklists and templates. Chapters may include recommendations for understanding and improving patient engagement in ePROs and for embedding collection in routine care settings; potential benefits and impacts; description of a technical infrastructure to facilitate ePRO collection and feedback; required financial and human resources; and potential models and tools for commissioning ePROs as part of health services for people with LTCs, including what is needed for implementing these in NHS settings.

The draft blueprint and an accompanying dissemination strategy will be developed by the study team with multiple rounds of feedback from our advisory group, clinical partners, the Health Foundation and other stakeholder groups (see section 2.8). We will also engage with a range of other disease registries in the UK to ensure that the blueprint fits their needs.

References

Complete reference list for section 2.6 uploaded as attachement

Maximum of three file attachments allowed. File types accepted: MS Excel (xls, xlsx), MS Word (doc, docx), MS Project (mpp) and PDF.

File upload	Figure_Diagram_of_UKRR_infrastructure.pdf
File upload	Table_-_Digital_maturity_assessment_scores_of_clinical_partners.pdf
File upload	2.6_Reference_list.pdf

Please select 'Save' or 'Save & Continue' to ensure file(s) are attached correctly. This can be found at the bottom of the page.

2.7 Project impact

How will your research support the development and use of audits and registries as a mechanism for improving health care quality in the UK? *

1850 character limit (approximately 300 words). The count box below indicates the number of characters remaining

This research aims to advance the routine collection of high quality ePRO data in the context of healthcare services for people with kidney disease and other LTCs by delivering: a strategy to optimise patient engagement; extension of the UKRR data infrastructure; blueprint to inform ePRO implementation in other registries; and pointers to use ePROs for commissioning of better care. We expect these deliverables to have impact via the following pathways:

1) The engagement strategy and extended infrastructure will provide the UKRR with a sustainable system for collecting ePROs. If the project is successful, they have indicated commitment to rolling out the system more widely across UK renal units. This will result in high quality patient-reported data to be added to the UK renal data landscape, which can be used for multiple purposes, e.g. within national audits of renal services; registry-based pragmatic trials; and quality improvement initiatives.

Wider implementation of the ePRO system in renal units aligns with the new service specifications (expected end 2018), which will dictate routine PRO collection. In the addition to the three renal units participating in the research, the project will enable the remaining 65 units in the UK to deploy PatientView as the portal for patients to submit ePROs to the UKRR. The blueprint will further support embedding of ePROs in care pathways across patient groups.

2) The input from other clinical audits and registries into the development and dissemination strategy of the blueprint will inform routine implementation of ePRO collection at scale in other disease areas.

3) As part of the research, we will actively engage with commissioners of renal and other LTC services to design ePRO-based commissioning models and tools that support wider implementation into the NHS.

References

2.8 Partnerships and stakeholder engagement

Please identify the partners and stakeholders for this project. How have you engaged with the partners / stakeholders already and how will you continue to do so during the lifetime of this project?

Please indicate the level of digital maturity of health care providers involved in the project.

3200 character limit (approximately 500 words). The character count box below indicates the number of characters remaining

All stakeholders and partners listed below have indicated a commitment to embedding routine ePRO collection in the UKRR and renal services. We have engaged with them prior to submission to ensure alignment with their ongoing activities and future plans. All will provide input on the blueprint (WP4) to support its development and dissemination.

Continued engagement is ensured through representation in our study team and/or advisory group. The latter will be chaired by Dr Graham Lipkin (president elect of the Renal Association; chair of the Kidney Quality Improvement Partnership); they will meet twice a year to advise the study team on design and delivery of the research, interpretation and dissemination of findings, and how to maximise impact. They will form a direct link between the project and the organisations they represent to ensure delivery according to timelines.

UK Renal Registry
Involved in project delivery throughout. Represented by Dr Fergus Caskey (medical director; study team) and Mr Ron Cullen (chief executive; advisory group).

Clinical partners
Renal services of three NHS Trusts across England to act as clinical sites in WP1.2 and 3:
- Salford Royal; local PI: Dr James Ritchie (advisory group; one of the Trust's chief clinical information officers);
- King's College London; local PI: Dr Rob Elias (advisory group);
- Lister hospital Stevenage; local PI: Prof Ken Farrington (study team).

Trusts' Digital Maturity Assessment scores are uploaded as a Table in section 2.6. All participating renal units have an electronic patient record system in place that is used either hospital-wide or in other units. The project's IT deliverables will thus have potential to be deployed in other clinical sites and settings beyond the development context.

Commissioners
Involved in WP1.3 and represented by Mr Jon Gulliver (NHS England specialised commissioner for renal; study team) and Dr Richard Baker (chair of the renal Clinical Reference Group (CRG); advisory group). We will present our proposal at the next renal CRG meeting in Oct 2017.

Collaboration for leadership in applied health research and care (CLAHRC)
CLAHRC Greater Manchester bring expertise relevant to the qualitative and implementation research throughout, and represented by Dr Sarah Knowles (study team) and Mr Paul Wilson (advisory group). CLAHRC West (Leila Rooshenas, advisory group) will additionally advise on the research in WP3.

UKRR Patient Council
The Council has representatives of two national kidney patient organisations (British Kidney Patient Association; National Kidney Foundation). We have engaged with Fiona Loud (Council chair) and agreed to meet with them regularly to update them on progress and gather their input. They will also be represented in our advisory group (Mr Guy Richards).

Kidney Disease@Farr collaboration
Initiative that aims to improve kidney patient outcomes through health informatics research while working towards a national renal learning health system, in which patient-reported data are currently missing. Represented by Prof Corri Black (advisory group) and Dr Sabine van der Veer (study team), co-chairs of the collaboration.

2.9 Data requirements for the proposed research

Please identify each data source you plan to use in this study and describe the information governance framework governing the dataset (or provide a reference to a published description). Please indicate what permissions and allowances are required to access the data and who from, and outline the estimated timeline for all required permissions to be obtained.

Please also provide details of the current coverage, reach and reporting of the audit/registry data included in the study (using the inclusion criteria given in the NHS England Quality Accounts list 2017/18).
3200 character limit (approximately 500 words). The character count box below indicates the number of characters remaining.

Data will come from three sources:
1. Qualitative research (interviews, focus groups and observations)
2. Electronic patient-completed questionnaires
3. The UK Renal Registry (UKRR) database

Written informed consent will be obtained from individuals participating in the qualitative research. To use data stored in the UKRR database individual patient consent will not be obtained - a legal basis to collect and analyse data is provided under section 251 support - 16/CAG/0153 for non-research and 16/CAG/0064 for research. In the written instructions provided for completing the ePRO questionnaires we will include a statement on consent being assumed by patient submitting their response.

The UKRR also has database research ethics approval that allows a range of observational studies and cluster randomised studies. It scored 94% in the Information Governance Toolkit (IGT) 2017 assessment and is registered under the Data Protection Act as follows: registration number Z8096557; organisation name: THE UK RENAL REGISTRY (next renewal due: 09/11/2017).

Following the establishment of the UKRR as a national audit in 1995, full coverage of all 84 renal centres in the UK was achieved in 2007, with the UKRR database now holding clinical data on all people in the UK who receive dialysis and those who are living with a kidney transplant.

The UKRR's activities have broadened significantly in recent years from its initial audit and benchmarking roles and now include the UK Registry for Rare Kidney Diseases (RaDaR), the hosting of the PatientView patient portal and the launch of three national programmes in collaboration with NHS England: acute kidney injury, Transforming Participation in Chronic Kidney Disease (TP-CKD) and the Kidney Quality Improvement Partnership (KQUIP).

The UKRR is increasingly getting involved in supporting efficient clinical trials. There are two individual level 'registry' RCTs recently funded by NIHR's Health Technology Assessment programme:
- The SIMPLIFIED trial led by Dr Thomas Hiemstra (Cambridge), NIHR HTA 14/49/127.
- The High-volume haemodiafiltration vs High-flux Haemodialysis Registry trial led by Dr Fergus Caskey (Bristol), NIHR HTA 15/80/52.

The Health Foundation is currently funding two ongoing stepped wedge cluster randomised trials with the UKRR as the analysis partner:
- ASSIST CKD led by Dr Hugh Gallagher, aimed at reducing late presentation with kidney failure
- Tackling AKI led by Dr Nick Selby, aimed at reducing death associated with AKI

The current project will allow patient-reported outcomes to be collected once into the Registry and used for multiple purposed, including clinical care, national audits of renal services, national and local quality improvement initiatives and registry-based observational and randomised studies.

References

2.10 Patient and public involvement

Please outline how the public, patients and service users have been involved in developing the project. How will these groups contribute to the day-to-day design, management, delivery and dissemination of the project?
1625 character limit (approximately 250 words). The character count box below indicates the number of characters remaining.

PPI groups of the Health eResearch Centre (University of Manchester) and the UK Renal Registry reviewed and provided feedback on the draft application. They suggested to more explicitly acknowledge that discussing ePROs in clinic is a facilitator for patient engagement, which we included in our proposal. Group members will act as moderators for the co-design workshops in WP1.4. We will meet regularly with both groups to gather their input throughout the project, and group representatives (Mr Anthony Albrow and Mr Guy Richards) will attend advisory group meetings to ensure a patient perspective remains central to our strategy. We have included PPI funds in our budget to reimburse them for their time.

Dr Michael Rees is a qualitative researcher, kidney patient, and co-investigator. He provided feedback on drafts of the application, and will continue to contribute to the design, delivery and dissemination of the research as a member of the study team. His main role will be to support linking the planned PPI work with the research itself, informed by his qualitative research expertise as well as his experience as a kidney patient. This dual role is similar to the one he currently fulfils within the Kidney Research UK User Group, where he is involved both as an academic and a patient.

3. 3. Milestones and Project management

Please ensure that you have read the notes for applicants and the AIMS user guide before completing this application form. You can access this information on the Health Foundation website.

3.1 Project plan

Please attach a project plan outlining the key stages of the project, including key milestones and deadlines for outputs.
Please include all key milestones such as meetings, and deadlines for outputs.
Please ensure that you include two advisory group meetings per year, submission of an annual and final award report, and submission of an end of project research report.

Add file attachment: eg plan / Gantt chart	3.1_Project_GANTT_chart.pdf

Please select 'Save' or 'Save & Continue' to ensure that the file is attached correctly. This can be found at the bottom of the page.

3.2 Project management

Please outline the project management/quality assurance system that you will be adopting to ensure the research is delivered on time and to a high standard.
1400 character limit (approximately 200 words). The count box below indicates the number of characters remaining.

The University of Manchester (UoM) has considerable experience and expertise in successful management of research programmes. The Health Informatics Domain, within which this research proposal sits, currently has more than 50 projects, and collaborates on grants worth of over £175 million across a range of funding sources (including the MRC funded Health eResearch Centre (HeRC) and the Office of Life Science funded Connected Health Cities).

The operations team at HeRC have skills in managing research delivery and finances, risks and communications. 0.4FTE is requested for a project manager (0.7 for 15 months of WP3; 0.2 for other WPs). Embedded in HeRC's operations team they will plan and control all activities, tasks and deliverables against the overall project plan. Working closely with the study team, UKRR, clinical partners and other stakeholders, they will support: practical and organisational elements of the research (e.g. coordinate implementation of strategy across sites, organise co-design workshops, coordinate capture of feedback from stakeholders on blueprint); organise 4-6 weekly study team and biannual advisory group meetings; communicate and report on progress (e.g. content updates for website; drafting progress reports for funder); and manage risks (using the project's risk register), budgets and resources.

3.3 Risk register

Please attach a risk register for the project including risk impact and mitigating actions. Please ensure you include any ethics approval and/or data access and collection considerations.

Add file attachment: eg: diagram / chart	Risk_Register.xlsx

Please select 'Save' or 'Save & Continue' to ensure that the file is attached correctly. This can be found at the bottom of the page.

3.4 Working with the Health Foundation:

Please outline how the research team will work with the Health Foundation throughout the project, and beyond. In particular, please highlight any support or input you anticipate you will need from the Health Foundation.
1625 character limit (approximately 250 words). The count box below indicates the number of character remaining.

We will update the Health Foundation on progress and delivery of outputs through annual and final grant reports. A Health Foundation representative is welcome to join our study team meetings, and we will explicitly invite them to attend if needed. We will also ask the Health Foundation to be represented in the project's advisory group, and we will share with them the minutes of our biannual advisory group meetings. Lastly, we will actively seek the Health Foundation's input on the development and dissemination of the blueprint (WP4), and explore opportunities to publish our findings as (part of) a Health Foundation report or white paper.

4. 4. Budget

Please ensure that you have read the notes for applicants and the AIMS user guide before completing this application form. You can access this information on the Health Foundation website.

4.1 Total amount requested for this application

Total	GBP399,574.00

4.2 Project budget

Click here to download the budget template that we would like you to use. Please upload once complete.

Upload completed budget here	Budget_template_submitted.xlsx

Please select 'Save' or 'Save & Continue' to ensure that the file is attached correctly. This can be found at the bottom of the page.

4.3 Budget justification

Please provide justification for items requested in the budget and the level of funding requested?
1400 character limit (approximately 200 words). The count box below indicates the number of characters remaining.

We apply for a large-scale award to deliver a 3-year project across multiple sites that will transform the national UKRR infrastructure to support collection of ePROs at scale, as well as guide similar initiatives by other disease registries.

Staff costs (£270,638)
We request £193,994 for appointing a full-time researcher to conduct and write up the qualitative research, and a project manager (0.4 FTE; see section 3.2) throughout the project. The remaining £76,644 covers time of study team members.

Running costs (total: £120,436)
£44,800 is requested for national (£15,800) and local (£29,000) IT developments (WP2), and £30,000 for supporting the three clinical sites with implementing the engagement strategy (e.g. tablets, human resources) and coordinating the related research (WP3). The remaining £45,636 is to cover costs related to UKRR statistical and administrative support (£15,850), co-design workshops (WP1), stakeholder interviews (WP1 and 3), blueprint development and dissemination (WP4), and PPI members' time to prepare and attend advisory group meetings over the course of the project.

Travel and subsistence (£8,500)
Lastly, we request funds for face-to-face meetings of the study team and advisory group (£4,500), and for study team members to attend national and international conferences to present research findings (£4,000).

4.4 Joint funding

Have you approached any other organisations to fund this research proposal or any significant component of it? What organisation(s) have you approached and when? What was the outcome?
1400 characters (approximately 200 words). The count box below indicates the number of characters remaining.

We have approached the UK Renal Registry, the Health eResearch Centre at the University of Manchester and NHS England for supporting the proposed research. They have agreed to the following in-kind contributions:

UK Renal Registry
- General hosting of the available infrastructure
- Data management of ePRO data collected as part of the project (WP3)
- Access to the UKRR Patient Council for input and advice throughout the project
- Ron Cullen's time to prepare and attend advisory group meetings

Health eResearch Centre
- Access to the PPI group
- Long-term loan of additional tablets to support data entry at clinical sites (WP3)

NHS England
- 2.5% of Mr Jon Gulliver's time throughout the project as a member of the study team

We will also submit the project to the Clinical Research Network portfolio, which –upon acceptance– will contribute towards research costs for clinical sites to

support identification, recruitment and consenting of eligible participants (WP1 and 3).

4.5 Previous funding from the Health Foundation

Have you received any funding from the Health Foundation in the last 5 years? If so please give details below.
1400 character limit (approximately 200 words). The count box below indicates the number of character remaining.

No

5. 5. The research team

Please ensure that you have read the notes for applicants and the AIMS user guide before completing this application form. You can access this information on the Health Foundation website.

5.1 Lead organisation

Please provide a brief description of the lead organisation in terms of its activities, organisational governance and management.
Please assume that the Health Foundation has no prior knowledge of your organisation or its activities.
1850 character limit (approximately 300 words). The character count box below indicates the number of characters remaining.

The Centre for Health Informatics (CHI) at the University of Manchester (UoM) is the lead organisation for this application.

The UoM is a member of the Manchester Academic Health Science Centre (MAHSC, www.mahsc.ac.uk). MAHSC is one of five Department of Health designated AHSCs in the UK. The designation is a mark of excellence across research, innovation and patient service, and recognition of potential to excel in translational medicine. MAHSC provides a strong link with Salford Royal, a clinical partner in our proposal and also a MAHSC partner.

CHI hosts the MRC Health eResearch Centre (HeRC, www.herc.ac.uk). HeRC conducts world-leading research in health informatics and forms a centre of excellence in digital health innovation for North England. The Centre has a national role in driving advanced methodological research to harness health data. HeRC is a founding partner of the national Farr Institute of Health Informatics Research (www.farrinstitute.org) which has been established to create a network of safe havens for analysis of electronic health records at UK-scale. The Centre runs a portfolio of research with over 20 projects with a value in excess of £60M. The Centre is actively involved in delivering major initiatives including one of the two NIHR-funded national Primary Care Safety Translational Research Centre, and the UK Government's "Connected Health Cities" pilot. The latter will seed a population-based learning health system in four city regions across North England, including Greater Manchester.

The proposed research feeds directly into HeRC's "Co-produced Health" theme which focuses on developing and testing methods to capture patient-generated data. This ensures availability of organisational support and methodological expertise to achieve the project's aim and objectives.

5.2 Principal Investigator details

Please note that the below information is pulled through from section 1.2. If this in incorrect please amend in section 1.2

Name	Sabine van der Veer
Job title	Research Fellow
Responsibility as related to this research proposal	Dr Van der Veer will act as the principal investigator for the study, overseeing and taking responsibility for all aspects of the study's design and its subsequent undertaking. This will include academic, financial, practical and governance elements. She will be the key contact for the study.
Expertise as related to this research proposal	Dr Van der Veer has been collaborating with the UKRR since 2013 to shape their PROM collection. She was involved in a UK-wide pilot on measuring kidney patients' experiences of shared decision-making in NHS settings. Currently, she chairs the Measurement workstream of the Transforming Participation in Chronic Kidney Disease programme. She holds a Kidney Research UK grant to develop a method using accelerometers to collect and report patient-generated data on itch as a kidney disease symptom.

5.3 Partner organisations:

Please provide details of partner organisations or collaborators you will be working with on the project.

Organisation and key contact	UK Renal Registry (Dr Fergus Caskey) University of Wolverhampton (Dr Michael Rees) NHS England (Mr Jon Gulliver) Clinical Reference Group for renal services (Dr Richard Baker) Salford Royal Renal unit (Dr James Ritchie) Lister hospital Stevenage renal unit (Prof Ken Farrington) King's College London renal unit (Dr Rob Elias)

	CLAHRC Greater Manchester (Dr Sarah Knowles) CLAHRC West (Dr Leila Rooshenas) Kidney Disease@Farr (Dr Sabine van der Veer)

5.4 Research team information

Please provide details of the individuals, who you are proposing will comprise the project team.Where there are subcontracting arrangements, please highlight them.
Please add a line per person
ADD is a multi-function button. You should click on ADD to save the data entered in each row. You will be left with a blank row when you have completed this question in order for the last row to be saved.

Name, job title and organisation of proposed research team members	Responsibility as related to this research project	Expertise as related to this research proposal
Dr Fergus Caskey Medical Director UK Renal Registry	Coordinate activities and tasks delivered by the UK Renal Registry; Establish link between relevant UKRR activities/plans and the research; Bring clinical domain expertise and knowledge on kidney disease and treatment, and renal unit workflows; Provide clinician's view on ePROs; Support dissemination of research findings by co-writing project publications, and presenting at (inter)national meetings.	As well as being a consultant nephrologist, Dr Caskey has 20 years of experience in renal registry and patient-reported outcomes research. More recently he has brought these together, leading to registry-based clinical trials for research and quality improvement. Several of his trials use the QuinteT model of embedded qualitative research to optimise recruitment to the trials and acceptability of the interventions, which is relevant to the research proposed here in WP3.
Dr Sarah Knowles NIHR Research Fellow Alliance Manchester Business School University of Manchester	Advise on design and conduct of qualitative and implementation research; Bring expertise and skills for interviews with commissioners; Advise on development of blueprint to ensure it supports implementation of ePROs; Advise on effective PPI and co-design activities; Support dissemination of research findings by co-writing project publications, and presenting at (inter)national meetings.	Dr Knowles currently holds an NIHR Knowledge Mobilisation Research Fellowship exploring data-driven improvement in Learning Health Systems, focusing on involving patients and professionals through co-design approaches. She has conducted multiple implementation evaluations as a senior qualitative researcher with the GM CLAHRC, and works directly with both clinicians and commissioners to design and evaluate improvement projects in routine care settings.
Prof Ken Farrington Consultant Nephrologist East and North Herts NHS Foundation Trust	Advise on effective planning and delivery of research and implementation activities at clinical sites; Act as local PI for one of the clinical partners; Bring clinical domain expertise and knowledge on kidney disease and treatment, and renal unit workflows; Provide clinician's view on ePROs; Support dissemination of research findings by co-writing project publications and presenting at (inter)national meetings.	Prof Farrington has extensive experience and expertise in clinical nephrology and dialysis. He has a leading role in patient-centred clinical research including NIHR-funded studies in self-management and depression in haemodialysis patients. He is the co-chair of the Intervention workstream in Transforming Participation in Chronic Kidney Disease (https://www.thinkkidneys.nhs.uk/ckd), a national programme funded by NHS England. The programme aims to support kidney patients with better managing and making decisions about their health.
Mr Jon Gulliver Specialised commissioner NHS England	Support design and delivery commissioners for interviews (e.g. input for topic guide; access to potential participants; interpretation of findings); Contribute to blueprint to ensure relevance and implementability for commissioning practice; Provide commissioner's view on ePROs; Establish link between relevant commissioning activities/plans and the research.	Mr Gulliver has worked for NHS England Specialised Commissioning for the last 3 years. He is the lead commissioner for the renal services Clinical Reference Group (CRG). His role is to lead on the development of commissioning policies, guidance and specifications. This includes working closely with the CRG, professional bodies, patient organisations and other stakeholders to identify priority areas for action. He is the co-chair of the Commissioning workstream in Transforming Participation in Chronic Kidney Disease programme.

Dr Michael Rees Lecturer Faculty of Social Sciences University of Wolverhampton	Advise on design and conduct of qualitative research; Conducting part of the interviews and observations; Bring patient's experience with kidney disease and treatment, and renal unit workflows; Provide patient's view on ePROs; Establish link between planned PPI and co-design activities and the research; Support dissemination of research findings by co-writing project publications, and presenting at (inter)national meetings.	Dr Rees is a lecturer with interests in the sociology of the body, including the sociology of health and illness. He holds a Masters in Social Research Methods through which he has gained qualitative research skills. As well as an academic, he is a kidney disease patient having been diagnosed with polycystic kidney disease in 2014. He is a member of the Kidney Research UK User Group and has been involved in developing several grant applications in a dual role as a researcher and patient.

5.5 About the research

Please attach the CVs of the primary members of the research team, detailing any relevant publications that support this application.
Maximum of six members

Please attach one document containing biographies / CVs of the research team members detailing any relevant publications that support this application.

File upload	5.5_CV_Van_der_Veer.pdf
File upload	5.5_CV_Caskey_2017.pdf
File upload	5.5_CV_Knowles.pdf
File upload:	5.5_CV_Rees.pdf
File upload	5.5_CV_Farrington_2017.pdf
File upload	5.5_CV_Gulliver_2017.pdf

Please select 'Save' or 'Save & Continue' to ensure file(s) are attached correctly.

6. 6. External peer reviewers

Please ensure that you have read the notes for applicants and the AIMS user guide before completing this application form. You can access this information on the Health Foundation website.

6.1 **If your proposal is short listed it will be reviewed by a number of external experts. Please provide us with two independent experts that would be suitable to peer review this proposal.** ***Please note: Please seek their permission before supplying their details. We will have in place a panel of peer reviewers, so we may or may not approach individuals listed below.***		
	Independent Reviewer 1	**Independent Reviewer 2**
Name	Prof Martin Wilkie	Dr Rachel Morton
Organisation	Consultant renal physician and honorary professor at Sheffield Teaching Hospitals NHS Foundation Trust; PI for the SHAREHD programme (funded by Health Foundation's Scaling Up Programme)	Director of Health Economics at the NHMRC Clinical Trials Centre (Australia); Convener of the PROMS Working Group of the Australian and New Zealand Dialysis and Transplant Registry
Email	Martin.Wilkie@sth.nhs.uk	rachael.morton@ctc.usyd.edu.au
Telephone no.	+44 114 2715326	+61 9562 5013
How do you know this person?	Prof Wilkie has an established track-record and interest in enhancing patient involvement in management of long-term conditions. We have met occasionally at national renal meetings over the last two years.	Dr Morton is a well-known renal researcher. We have met several times at international meetings. She attended the consensus meeting in 2013 on how to routinely collect PROMs in renal registries in Europe, which was hosted by the UKRR.

7. 7. Declaration

Data Protection Act 1998

To comply with this Act, we require your consent for the Health Foundation and their approved agents to use personal data supplied by you in the processing and review of this application and in any other legitimate activity of the Foundation. This includes transfer to and use by such individuals and organisations as the Foundation deems appropriate. The Health Foundation requires your further assurance that personal data about any other individual is supplied with his/her consent.

By submitting this completed application form you are confirming that the information you have supplied is, to the best of your belief, correct.

7.1 **Declaration**	
By applicant ***(Please note this is the contact who will receive all reminder emails.)***	Sabine van der Veer
Organisation name	University of Manchester
Date ***(Please enter the date you are submitting the form)***	25th July 2017
Authority to submit proposal	☑ I confirm that the organisation named on this proposal has given me authority to submit this proposal on its behalf.

8. 8. Marketing monitoring information

We request this information to help us monitor the effectiveness of our marketing activities for each of our programmes. This information is not used in the application review process.

8.1 **Please tell us how you first heard about this programme:***

- [x] Email from the Health Foundation
- [ ] Directly (face-to-face, verbal)
- [ ] Twitter
- [ ] Facebook
- [ ] LinkedIn
- [ ] Forwarded to me by a colleague
- [ ] The Health Foundation website
- [ ] The Health Foundation newsletter
- [ ] Other organisation website
- [ ] Other organisation newsletter/network
- [ ] I saw an advert online or in a journal
- [ ] I picked up/saw some information at an event
- [ ] I found out about the programme in another way