# Project details

## Investigator details

| Chief Investigator for SHAREHD | Professor Martin Wilkie  
Sheffield Teaching Hospitals NHS Foundation Trust,  
Trust Headquarters  
8 Beech Hill Road,  
Sheffield.  
S10 2SB UK.  
martin.wilkie@sth.nhs.uk  
T +44 (0) 114 271 5326 |
|---|---|
| Study Sponsorship | R & D Contact  
Dr Dipak Patel,  
Research Manager, Clinical Research Office Sheffield  
Sheffield Teaching Hospitals NHS Foundation Trust  
D Floor, Royal Hallamshire Hospital  
Glossop Road, Sheffield S10 2JF  
Dipak.Patel@sth.nhs.uk  
T +44 (0) 114 2265941 Fax. +44 (0) 114 2265937  
http://www.sheffieldclinicalresearch.org |
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| STH Directorate affiliation | Academic Directorate of Renal Services |
| NIHR CRN number |  |

## Signatures

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<th>Chief Investigator</th>
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<td>Date</td>
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<tr>
<td>R &amp; D contact</td>
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<td>Date</td>
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2. Research question
A mixed methods pilot study to explore the impact of HHD on patient and carer experience, community integration and cost effectiveness with the objective of obtaining primary evidence to develop theories, identify mechanisms and quantify benefits that will support increased uptake across the NHS.

3. Abstract
This pilot study will provide information that will go towards the preparation of a competitive grant to support a detailed study. It will explore the experience of home haemodialysis from the perspective of service users and carers and will include a health economic component. The study will be in 2 phases: a 6 month cohort study with 20 patients to test the instruments and evaluate data returns; interviews with 10 patients and carers to explore individual experiences of care. In addition to this work we will also test the Social Return on Investment methodology to determine its utility in this context.

4. Aim of the study
Collaboratively with patients and their co-habitants, our work will test the best ways to explore the experience of and outcomes that matter to home haemodialysis (HHD) patients by piloting processes of information collection and identifying the instruments that are best suited to this patient group and these circumstances. At patient and carer interviews we will map the individual journey to HHD, understand achievement of competencies, barriers, facilitators and support mechanisms. We will aim to better understand carer burden. We will evaluate the use of Social Return on Investment methodologies to measure broader socio-economic outcomes, permitting the inclusion of the views of multiple stakeholders in a singular monetary ratio (1).

Our specific objectives will be to better understand -
1. the patient and carer (cohabitee) experience of home haemodialysis and wider support needs
2. community links (assets) and how these can be utilised to reduce social isolation
3. the educational experience that HHD patients receive to prepare them for the modality choice and uptake of the therapy
4. the health economics of HHD including the monetary and non-monetary costs using SROI methodologies
5. the technological challenges of HHD with a view to identifying practical solutions

The ultimate goal will be to use this pilot information to prepare a research grant that will allow us to develop an intervention (s) that enables better support for HHD from the patient perspective and therefore makes HHD a much more attractive option to patients.

5. Background
Effective management of chronic kidney disease requires considerable engagement of patients and their carers to navigate complex interventions including dietary modifications, medication schedules and shared decision making in modality choice, not to mention the supported self-management skills required to perform home dialysis. Individual self-management skills and confidence are impacted by self-efficacy (2) and health literacy. These subjects are receiving increasing attention since they are risk factors that are potentially modifiable to both improve outcome and to reduce demand on stretched health services. Low health literacy is common among CKD populations, is
associated with non-white ethnicity and low socioeconomic status (3) and is presumably one of the explanations why these factors impact on the uptake of home therapies.

In England approximately 20,000 people attend institutions three times (totalling approximately 16 hours) per week to receive haemodialysis (HD) treatment. Unfortunately, current institutionalised approaches to dialysis encourage patients to become passive recipients of their care, with limited engagement with their own treatment. This is despite considerable evidence of the benefits of supported self-care in long term conditions. Low health literacy amongst dialysis patients is associated with worse survival (4) whereas self-motivation and patient education results in better care (5). As with the broader NHS, dialysis services are experiencing considerable pressure to deliver high quality in the face of fiscal challenge. An important mechanism to ensure that quality of care is maintained is to engage service users as true partners in their own care. A key aim is for as much treatment as possible for long term conditions to be conducted in the community, in line with the objectives of the NHS sustainability and transformation plans.

Although HD is a technical treatment, it can be performed safely by patients themselves with suitable training and support. Patients who perform home haemodialysis (HHD) have better survival (6) and quality of life, and the treatment is more cost-effective than dialysis at hospital centres (7). Advantages of HHD from the patient perspective include greater flexibility of treatment, reduced treatment-related travel time and higher treatment quality as it is possible to dialyse more frequently at home and therefore avoid the adverse effects of the conventional 3 day inter-dialytic gap (8).

Our patient engagement work has shown us that access to this therapy remains too difficult and should be prioritised. On the other hand, patients and their carers can find dialysing at home stressful describing treatment related anxiety (needling of the arteriovenous fistula, problem solving), a sense of isolation from renal services (9) and practical problems (eg liaising with council services regarding waste management). It can place a considerable burden on carers, impacting on work and their financial situation. During patient and carer engagement work conducted in December 2017 and February 2018 (focus group of 7 HHD patients and 3 carers) topics for exploration were prioritised by participants in the following rank order: vascular access; symptom control; “managing your health”; carer burden; overall health; treatment satisfaction; illness intrusiveness; memory and cognition; generic dialysis survey; health literacy; social isolation; mood; Adult Carer Quality of Life Questionnaire. While we recognise that the priority was determined by the individuals who attended the group, we have used this information to identify the instruments that will be included in this cohort pilot study.

In 2002 a NICE Technology appraisal recommended that HHD should increase to 10 - 15% of prevalent renal replacement therapy (10). This has not been achieved in the UK where the current prevalence remains at 4.1% (UK Renal Registry report), with considerable variation between centres (0 to 11.5%) and compared with Australia where the average is 12.9% (11). Increasing HHD in the UK to that level would save approximately £16M for the NHS annually. Inequalities exist in access to HHD since it is more likely to be utilised by Caucasians, people on higher incomes or educated to a higher level (12). People who live alone are much less likely to take up this modality; age, comorbidity and cognitive impairment also impact on uptake. Evidence of unequal access to home therapies comes from the latest UK Renal Registry report (13). 17% of dialysis therapy is delivered as a home therapy (13% PD, 4% HHD) with wide variation between centres. 28% of in centre HD patients are from minority ethnic groups, whereas this figure is 22% for PD and 13% for HHD. The impact of deprivation on treatment modality is marked - PD was commenced in 22.1% of the least deprived quintile and 16.67% in most. This trend extends to pre-emptive transplantation that in the least deprived quintile was 12.9% compared with 7.0% in the most deprived. In the US, a similar discrepancy in access to home therapies was noted in African Americans and Hispanic patients (14).
Overcoming inequalities in access to high quality therapies is a major challenge. Part of the problem relates to the way information is given to support decision making for home dialysis and the confidence that patients have to make that choice, which is impacted by cultural, language, educational and economic issues. These factors have been explored in linked studies from New Zealand where the home dialysis rates are among the highest in the world. These include an exploration of patient and caregiver values, beliefs and experiences when considering home dialysis that identified themes including difficulty with decision making due to the complex nature of the information presented, lack of exposure to home dialysis, feelings of disempowerment, and pressure to make a choice. Impacting on decision making was the extent of family and community support, social isolation and confidence in clinical teams. Despite the presence of a pre-dialysis service, patients commonly reported sub-optimal preparation for dialysis and inadequate support (15). An interview study of Maori CKD patients found that marginalisation was contributed through delayed diagnosis, fear of dialysis and lack of awareness of cultural issues among clinical staff (9). Personal economic considerations influence modality choice, but are rarely reported. If HHD is to be promoted strategies to improvement employment retention, housing and out of pocket expenses need to be addressed (16).

Given this background, it is not surprising that the NICE target is far from being realised. Home therapies compete together with the complex challenges of low health literacy, socio-economic deprivation, isolation, late presentation and poor preparation for renal replacement therapy. To overcome these, educational programmes require to be prioritised, ensuring that they are responsive to individual requirements, supported where necessary by health coaching, greater involvement of peer support workers as well as approaches to provide assistance to allow people to dialyse in the community. Such programmes require to be co-designed with users so that they take account of the complex issues that have been highlighted in these studies and give the best opportunity to support self-management skills and decision making particularly among groups that have greater difficulty accessing health care. Indeed, both PD and HHD teams have extensive experience of the design of educational programmes that take account of variations in learning approaches and barriers such as impaired vision or cognition. That experience needs to be used more extensively across the CKD pathway so that pre-dialysis education, as well as training programmes for in centre HD patients are able address health literacy and focus on cultural and social values to reduce fear and build confidence around decisions to undertake home dialysis. Peer educators who have first-hand experience of kidney failure and its treatment, can help to improve the quality of information given, through presence in clinics and home visits. Such a programme has been established in the English West Midlands where Black, Asian and minority ethnic patients make up 40% of the population. A variety of languages are spoken by the educators including Urdu, Mirpuri, Punjabi and Bengali, allowing greater engagement, education and support (17). Until there is a better understanding of patient and provider barriers to the uptake of HHD it will not be possible to design a meaningful strategy to impact significantly on the under use of this important treatment option in the UK.

Methodology
The objective of this non-interventional study is to assess the patient and carer experience of HHD and to understand better the community context of the therapy. We aim to explore the confidence that patients and their cohabitees have to conduct HHD, and better understand patient costs and benefits. To achieve this we will –

- Conduct a cohort study in 20 home haemodialysis patients and 20 carers at 4 centres.

We will pilot selected 7 questionnaires with patients and a single questionnaire for their carers in order to better understand patient and carer experience of HHD. This will give us indicative data
that can be explored in more detail in the subsequent grant. We will test mechanisms to collect key data including quality of life and potentially treatment schedules.

Table 1 – instruments.

<table>
<thead>
<tr>
<th>Domain</th>
<th>Instrument</th>
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<tbody>
<tr>
<td>Patient details</td>
<td>Demographic form.</td>
</tr>
<tr>
<td>Vascular access</td>
<td>Short-form Vascular Access Questionnaire (SF-VAQ) (18)</td>
</tr>
<tr>
<td>Symptom burden</td>
<td>Renal Symptom Score (iPOS-S) (19)</td>
</tr>
<tr>
<td>Managing your health</td>
<td>Patient Activation Measure (20)</td>
</tr>
<tr>
<td>Carer burden</td>
<td>Cousineau Scale of perceived burden (21) and Adult Carer Quality of Life Questionnaire (22)</td>
</tr>
<tr>
<td>Overall health</td>
<td>EQ-5D-5L(23)</td>
</tr>
<tr>
<td>Treatment satisfaction</td>
<td>Renal treatment satisfaction questionnaire (RTSQ) (24)</td>
</tr>
<tr>
<td>Illness intrusiveness</td>
<td>Illness intrusive Ratings Scale (IIRS)(25)</td>
</tr>
</tbody>
</table>

- Exploratory qualitative information - interviews with 10 patients and 10 carers to establish themes to be explored in further study

Initial theories regarding the uptake and maintenance of HHD will be tested and refined through interviews with a small number of patients and carers in their home environments. Areas of interest will include time taken to perform treatment, stress related to the conduct of treatment, interaction with technology, support from the hospital and other sources, and linkages with community assets. These interviews will be conducted by Drs Jo Blackburn and Steven Ariss. We will also explore the use of the Social Return on Investment tool in this context (1).

Study design
A cohort questionnaire based study with additional qualitative evaluation by means of interviews with patients and their cohabitees.

Table 2 – study phases.

<table>
<thead>
<tr>
<th>Phase</th>
<th>Start point</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pilot cohort</td>
<td>Month 0</td>
<td>Commence data collection – 2 data collection points at baseline and 6 months</td>
</tr>
<tr>
<td>Patient and cohabitant</td>
<td>Month 0</td>
<td>Start implementation with first 4 centres</td>
</tr>
<tr>
<td>Evaluation</td>
<td>Month 9</td>
<td>Data analysis, report writing, start larger grant preparation</td>
</tr>
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</table>

Setting
The home environment or clinic attendances for patients and carers associated with dialysis centres in England selected on the basis of organisational characteristics and variation in demographics and utilisation of home dialysis.

Participants
Prevalent home dialysis patients

Inclusion
- Established on home haemodialysis
• Capacity to give written informed consent to participate in the study
• Able to speak and read English

Exclusion
• Patients who are too unwell to engage in the study, as judged by the clinical team
• Patients too distressed to participate, as judged by the clinical team
• Patients with impaired capacity who are unable to give informed consent
• Patients unable to understand written and verbal communication in English

Carers of prevalent home dialysis patients

Inclusion
• Carers of prevalent home dialysis patients
• Capacity to give written informed consent to participate in the study
• Able to speak and read English

Exclusion
• Individuals who are too unwell to engage in the study, as judged by the clinical team
• Individuals too distressed to participate, as judged by the clinical team
• Individuals with impaired capacity who are unable to give informed consent

Endpoints
Efficacy Endpoints
Descriptive information on patient experience will be analysed to explore trends and associations.

Recruitment
Cohort pilot-study
All prevalent HHD patients at 4 selected centres will be entered into a screening log and from this patients will be approached and given the opportunity to participate in the research with the intention of recruiting 5 patients and 5 carers at each site. Patients will be sent an information sheet in the post and at subsequent clinic appointments consent will be taken after giving the opportunity to ask questions based on the information sheet. Informed consent will be taken by trained members of staff who have appropriate Good Clinical Practice certification.

At the time that we recruit the patient, we will give them the carers’ information sheet and questionnaire so that they can pass it to their carer. Carer consent will be obtained by the carer completing the consent form and the questionnaire and returning them in a stamped addressed envelope to the sponsor site.

Interviews of patients and carers.
Information sheets will be posted out to home haemodialysis patients and their carers inviting them to participate in interviews that will be conducted at locations to suit the participant. Informed consent will be taken at the beginning of each interview.

Data Collection
Patient Questionnaires
Measures will be collected by asking patients to complete data forms which will be securely transferred to the Sponsor site (Sheffield Teaching Hospitals NHS Trust) to be entered into the research database. We will use the demography data collection form that was used in a previous study
of kidney patients (26). At the baseline visit patients and carers will be given the opportunity to complete the questionnaires at the time; however for the follow-up visit we will send questionnaires to subjects and ask them to return them to the sponsor in a stamped addressed envelope (SAE).

Baseline visit

- Patient consent
- Complete baseline questionnaires
- Take carer information sheet and consent form home if carer is not with them in clinic.
- Carer completes questionnaire and send to the sponsor in SAE.
- Interview information sheet is also taken home at this point and returned with the carer questionnaire if willing to be interviewed.

Follow-up visit (6 months)

- Sponsor sends out questionnaires in the post to be completed and returned to the sponsor in the SAE.

Table 3 – schedule of study activities

<table>
<thead>
<tr>
<th>Activity</th>
<th>Baseline</th>
<th>6 months*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informed consent</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Patient questionnaire document: Demography, Cousineau Scale, IIRS, RTSQ, SF-VAQ, Your Health Survey (contains iPOS-S, EQ-5D-5L, Patient Activation Measure).</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Adult Carer Quality of Life Questionnaire</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Patient / carer interviews</td>
<td>20 interviews with 10 patients &amp; 10 carers throughout the study period</td>
<td></td>
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</tbody>
</table>

Questionnaires will be sent to the participant by the sponsor.

Analysis including statistical methods

Statistical analysis:
We will use descriptive statistics to report means and distributions and explore simple associations between data items through correlations.

Economic Evaluation (Efficiency)

Economic analysis will be conducted using Social Return on Investment (SROI) methodology. We will be using ‘Sinzer’ software to create the SROI model and to generate electronic surveys for stakeholders. This work will consist of six stages:

Stage One: Identifying stakeholders

After establishing the preliminary scope of the project, the first stage of SROI, is identifying stakeholders to be included in the exercise. Stakeholders refer to any group of individuals or organisation that is affected by the service/ intervention and experience. Engagement activities should be organised to ensure inclusion of as many relevant stakeholders as possible. The participants should identify other key stakeholders and their contribution and impact on the programme and vice versa.

Stage Two: Mapping the full range of inputs, outputs and outcomes

An impact map sets out the programme theory of the intervention, and communicates how an intervention is expected to make a difference, and how inputs are expected to result in outputs which lead to outcomes. An SROI impact map is similar to a ‘theory of change’ or ‘logic model’; it
describes the overall rationale for the programme and sets out linked assumptions of the relationships between inputs, activities and outcomes.

**Identifying and Valuing Input**

Inputs are those things that stakeholders contribute in order to make activities possible. For example, finance used to pay for the staff salaries, running cost of the office premises etc. Other contributions from clients and other stakeholders, for instance in the form of their time, is considered as an input but not given a financial value in line with standard SROI approach. Similarly, the time of practitioners in other organisations has not been costed.

**Clarifying outputs and outcomes**

Outputs are quantitative summaries of activities. Sometimes outputs are repeated for several stakeholders at this stage because they form part of the theory of change.

Measuring outcomes is the only way to be sure that changes for stakeholders are taking place. It is important at this stage to consult stakeholders in order to check assumptions about outcomes that are included in the impact map. However, in deciding on outcomes other factors, such as the organisation’s objectives, as well as the views of your stakeholders should be considered. Stakeholders’ views are critical but are not the only factors in deciding which outcomes are significant. SROI is stakeholder-informed, rather than stakeholder-led.

Necessary assumptions are based on the most appropriate evidence, together with expert judgement. Following the ethos of SROI, these are conservative and transparent, such that these are open to challenge so that they are either improved or displaced in time by empirical evidence.

**Stage Three: Identifying and Measuring Key Outcome Indicators**

Indicators are ways of knowing that change has happened. They show both whether the outcome has occurred, and by how much. These indicators can be identified by consulting with key stakeholders and investigating current literature to ensure relevance. An important activity in this stage is to check that indicators are not only measurable but that you will be able to measure them within the scope and the resources of the study.

A basic principle of SROI is to measure and value the things that matter. Measurability does not mean finding an indicator that is easy to measure. If the outcome is important it is critical to find a way to measure it. More than one indicator per outcome will strengthen the findings and increased confidence that the outcome has occurred.

**Stage Four: Establishing Impact**

Establishing impact refers to determining how much of the outcome would have happened anyway in the absence of the programme/intervention. It also explores the proportion of the outcome can be isolated as being added by the programme activities(27, 28). Establishing impact is important as it reduces the risk of over-claiming and improves credibility of the analysis and reporting.

**Deadweight and displacement**

Deadweight is a measure of the amount of the outcome that would have happened anyway without the programme. This is measured as a percentage, which is deducted from the total quantity of the outcome. For instance, if 30% more people on a programme gain employment than would have without the programme the deadweight is calculated as 100%
(business as usual) expressed as a percentage of 130% (programme outcome) = 77% deadweight.

Displacement is an assessment of the extent to which the outcome measures have demonstrated a change, which has been absorbed elsewhere. For instance, reductions in DVA could change into other forms of violence to others. This would require an adjustment by either including the stakeholder now being affected or estimating the effect of double counting as a percentage to be deducted from the total.

**Attribution**

Attribution is an assessment of the extent to which outcomes were caused by other external influences (e.g. other programmes, organisations or people). Within this programme there are no similar voluntary interventions aimed at addressing the abusive behaviour of low-risk DVA perpetrators. However, there are other services that clients can approach to potentially address problematic behaviour (such as substance abuse), which is also addressed by elements of the programme. The extent to which outcomes are assessed at being attributable to other sources is deducted from the programme outputs.

**Drop-off**

Drop-off is concerned with how long the outcomes last. The amount of an outcome will be expected to reduce over time, or be influenced by other factors, so that attribution becomes lower. It is calculated for outcomes that last longer than one year, as a fixed percentage that is deducted year on year.

**Calculating impact**

Impact is calculated by multiplying the financial proxy by the quantity of an outcome to give a total. From this total, percentages are then deducted for deadweight, displacement and attribution. This is repeated for each outcome to give the impact for each. These individual impacts are then combined to give a figure for the total impact.

**Stage Five: Valuing Outcomes**

The purpose of valuation is to understand the value of outcomes and demonstrate how important they are relative to the value of other outcomes.

The process of valuation assigns a monetary value to things that do not have a market price. Prices that we use in our day-to-day lives are approximations (proxies) for the value that stakeholders gain and lose in the transaction. Therefore value will be different for different people in different situations.

In SROI financial proxies are used to estimate the social value of non-traded goods to different stakeholders. Just as two people may not agree on the value of a traded good, different stakeholders have different perceptions of the value they get from a wide range of transactions. By estimating and combining these valuations, we arrive at an estimate of the total social value created by an intervention.

A successful SROI analysis captures the different types of value relating to an activity, intervention or organisation, as seen from the perspective of those that are affected – i.e. the stakeholders.

**Stage Six: Calculating the SROI**

**Projecting into the future**
Projecting the value of outcomes into the future consists of setting out the value for each outcome for a determined time-period (e.g. five years), and copying across the number of time periods it will last. Any drop off calculated above is then deducted.

**Calculating the net present value**

The Net Present Value (NPV) is calculated by comparing costs and benefits over a time period. Discounting (of 3.5% per annum) over the projected time periods is used to account for money today having greater value than money in the future. This gives the present value of benefits. The value of investments is then deducted to calculate the NPV.

**Calculating the SROI ratio**

The SROI ratio is calculated by dividing the present value by the value of inputs.

**Sensitivity analysis**

After calculating the ratio, it is important to assess the extent to which this would be changed by altering some of the assumptions from previous stages. The sensitivity analysis assesses the importance of various elements of the model. It is therefore possible to explore which assumptions have the greatest effect on the model. The standard requirement is to check changes to:

- estimates of deadweight, attribution and drop-off
- financial proxies
- the quantity of the outcome
- the value of inputs, (where non-financial inputs have been valued).

To estimate the sensitivity, calculations are made to explore how much each estimate is needed to change in order to make the social return ratio to 1:1 (£1 value for £1 investment). By calculating this, the sensitivity of the analysis to changes in estimates can be shown. This allows reporting of the amount of change to the model necessary to make the ratio change from positive to negative or vice versa.

**Payback period**

The ‘payback period’ describes how long it would take for the investment to be paid off in terms of the accrual of social value. Specifically, it describes at what point in time the value of the social returns starts to exceed the investment. This can be used to determine risk in a project. While a short payback period may seem less risky, a longer payback period is often a feature of activities that are able to demonstrate significant long-term outcomes. For these types of interventions longer-term core funding is required.

6. **Statistical opinion**

   **Sample size: Power of the study.**

   This is a pilot study and the investigation is therefore exploratory – a power calculation has not been conducted.

7. **Project management**

   Study oversight will be from a project advisory board that will include patient representation.
8. Expertise

The study group has expertise in several areas –

Martin Wilkie has lead a previous quality improvement initiative relating to Shared Haemodialysis Care and is Chief Investigator for the UK Catheter Study (a questionnaire related cohort study of peritoneal dialysis access)

Steven Ariss has expertise in complex evaluation and a wide range of qualitative and quantitative methodologies. He is experienced in leading large multi-centre programmes. He holds influential posts in the health care innovation infrastructure including Evaluation Lead for the NIHR CLAHRC for Y&H. He is the Module lead for ‘Complex Evaluation Methods’ (Masters in Clinical Research). As the Innovation and Knowledge Translation Lead for Health Services Research at the University of Sheffield, he also provides evaluation consultancy services for a range of NHS, third sector and private organisations.

Tracey Young is a Health Economist with over 20 years’ experience in health service research; she has developed methodology for developing health economic outcome measures. Tracey has experience of economic evaluations in trials and observational studies (e.g. liver/small bowel transplantation and aphasia), and has worked with large datasets including TARN and HES. She is a Member of the Health Economics and Decision Modelling section in ScHARR, which has an international reputation in developing and application of methodology. Tracey is the Acting Lead for the health economic and outcome measurement theme in the NIHR CLAHRC for Y&H.

James Fotheringham has led previous data linkage programmes, data analysis and evaluation of cost in ESRD patients. He is a member of the NIHR Haemodialysis study group, and has ongoing collaboration in other projects with UKRR and KRUK. He will lead on clinical data linkage and provide specialist clinical advice and guidance.

Joanna Blackburn is a research fellow working in the Research and Development department at Barnsley Hospital and holds an honorary contract with the Public Health section in SCHARR. She has been involved in a number of service evaluations (e.g. Diabetes and Emergency Department) and has coordinated clinical trials. She has experience of conducting qualitative research and has worked as a researcher on several projects in the Healthy Weight theme in the NIHR CLAHRC for Y&H.

Tania Barnes has already established the Clinician Education programme for the successful Regional Shared Haemodialysis Care project, and delivered much of that education.

Sandip Mitra is a consultant nephrologist with particular experience in home haemodialysis and the analysis of gaps in unmet need in technology in SHC from a patient perspective; develop proof of concept on technology aids.

Claire Reid is a consultant nephrologist with experience in qualitative evaluation in people who receive dialysis treatment.

Rachel Gair Leads Transforming Participation in CKD Programme and has experience as Renal Network Manager for the South West. Her skills include programme management, quality improvement and communications.

Andy Henwood will provide patient leadership to the project.

Louese Dunn has detailed experience in clinical trial set-up and will be responsible for research governance.

Sonia Lee will provide programme management.
Sabine Van der Veer, research fellow, Farr Institute, University of Manchester brings electronic data collection expertise.

Charmaine Lok, Professor of Medicine at the Faculty of Medicine, University of Toronto and Senior Scientist at the Toronto General Hospital Research Institute.

9. Governance, ethics and confidentiality
Ethical review will be undertaken before the study proceeds. All participants in the core sample will sign informed consent after reviewing a patient information sheet and taking time to consider whether to participate.

Information Governance and Data Linkage
Paper questionnaires will be sent on from participating sites to the sponsor site (STH). These will then be input to a bespoke research database held on a secure server with limited access within the trust. Paper questionnaires will be retained at STH for audit purposes.

Patient information sheet and consent forms
These documents will describe the study and the uses that data is being put to.

10. Service users: involvement during the study design
Focus groups of patients and carers have actively contributed to the co-design of the study, and the best way of collecting required data. There will be patient representation on our project board.

11. Dissemination.
We produce a report at the end of the study and use the information to input into grant development.

12. Taking the work forward.
We will establish appropriate collaborations with key partners necessary to support a successful grant application – identifying suitable participating centres utilising a questionnaire to evaluate practices and technologies. We will seek funding for a multi-centred mixed methods study that will examine the place of HHD in UK communities including drivers of patient and carer experience, linkages with community support mechanisms and health economics. This will lead to the development a comprehensive business case in conjunction with service users that will support successful adoption of HHD at a level recommended by the 2002 NICE review. The project will be conducted in close collaboration with the NIHR Y & H CLAHRC and NHS England.

13. Funding arrangements
The funding is from a competitive Sheffield Hospitals Charity’s project grant award, supported by funding from Y & H CLAHRC and the Health Foundation (award reference 7664).

14. References
10. NICE. Guidance on home compared with hospital haemodialysis for patients with end-stage renal failure. 2002.

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