UNIVERSITY OF BIRMINGHAM

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Participant Information Sheet

RePROM Qualitative Sub-study

Full study title: The use of an electronic Patient-Reported Outcome Measure in the Management of Patients with Advanced Chronic Kidney Disease – The RePROM Pilot Trial

Version 1.1 – 07/02/18

UNIVERSITY OF BIRMINGHAM | CPROR
CENTRE FOR PATIENT REPORTED OUTCOMES RESEARCH

1. Invitation and brief summary

We would like to invite you to take part in our research study. Joining the study is entirely up to you. Before you decide we would like you to understand why the research is being done and what it will involve for you. Please feel free to talk to others about the study if you wish. Please do take the opportunity to ask any questions you have using the contact details at the end of the form and to ask for more information if anything is unclear. If you do take part, you can still withdraw at any time up to the point of data analysis (5 working days following the interview), without having to give a reason.

2. Purpose and background to the research

Chronic Kidney Disease (CKD) affects around 1 in 7 people in the UK. Some patients with advanced CKD may go on to need demanding treatments, such as dialysis, for the rest of their lives. These patients often experience a poorer quality of life.

Existing research in oncology suggests it can be helpful for patients to provide reports about their symptoms and quality of life in between their regular hospital appointments by completing a questionnaire on their computer or smartphone. We call these questionnaires 'electronic Patient-Reported Outcome Measures' or ePROMs.

Clinical teams can use ePROM reports to find out if a patient needs urgent care, so they can take action straight away – rather than waiting until the next clinic appointment. This methodology could help prevent emergency hospital admissions, reduce or delay the need for life-altering renal replacement therapy, and improve patient quality of life.

However, we do not yet know whether ePROM reporting in the NHS is possible and if it would lead to improved patient outcomes. Therefore, the RePROM study will test

the feasibility of an ePROM reporting system in a small group of patients with CKD, who are being treated at the Queen Elizabeth Hospital in Birmingham.

We will use the findings to plan a much larger clinical trial, which will help determine if eRPOM reporting in the NHS actually leads to patient benefit.

3. Why have I been invited?

You have been involved in the delivery of the RePROM pilot/feasibility trial at the host site.

4. What would taking part involve?

We would like to interview you about your experiences during the study. The interview would last approximately 30-45 minutes and can be conducted at a time and place of your choosing (including over the phone if this is your preference).

5. What are the possible benefits of taking part?

There are no direct benefits to you. However, your insights will help us refine the design of our planned ePROM Randomised Controlled Trial (RCT). If the ePROM reporting system is shown to be helpful in this large clinical trial, future patients with advanced CKD may benefit from its use across the NHS.

6. What are the possible disadvantages and risks of taking part?

We do not believe there are any disadvantages or risks associated with taking part in this aspect of the study, only the use of your time: around 30-45 minutes. Your

interview data will be treated as confidential and only anonymised data will be included in any arising publication/report.

7. Who is organising and funding the research?

This study is being sponsored by the University of Birmingham (Study number: RG_16-141). It is funded by the UK National Institute for Health Research, which is part of the Department of Health (funder's reference: PDF-2016-09-009).

8. How have patients and the public been involved in this study?

A group of patients and members of the public helped to develop this research topic and the research questions that should be asked. The group helped to design the study and develop this leaflet. They will continue to be involved throughout the study.

9. Who has reviewed the study?

This study has been reviewed and given favourable opinion by <insert REC details> Research Ethics Committee. The REC reference number is <insert ref>.

10. Will my taking part in this study be kept confidential?

All information about you will be handled in confidence. All information provided throughout this research is protected under the *UK Data Protection Act (1998)* and will only be used by those on the research team at the University of Birmingham and at the Queen Elizabeth Hospital, Birmingham.

Information sent from the Queen Elizabeth Hospital to the University of Birmingham will be securely stored and only used for this research project. The study will do its

utmost to keep your information confidential, therefore your name will not be mentioned in any report of this research.

We will ask your permission to record the study interview using a secure digital recorder. We will then ask a reputable company to produce a written version of the recording called a transcript. The company will need to sign a confidentiality agreement before they do so. We will then remove all identifying information from the transcript. After this, we will delete the original recording. We will only use anonymised quotes from the transcript in any publication or report.

11. Involvement of General Practitioner

We will not notify your GP if you decide to take part in this study, but you should feel free to discuss this with them if you would like.

12. What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to a member of the research team who will do their best to answer your questions <*insert site contact number*>. If you are harmed in any way, insurance is in place to deal with any negligence. If you remain unhappy and wish to complain formally, you can do this by contacting the NHS Patient Advisory and Liaison Service (PALS). Details can be obtained at the end of this information sheet.

13. What if I do not want to take part?

The decision to take part in this study is entirely voluntary and you can change your mind at any stage up to the point of data analysis (5 working days following the interview). After this, it will not be possible for the research team to withdraw your anonymised data from the analysis.

If you wish to withdraw, you may do so by contacting <insert site contact> using the details at the end of this information sheet.

14. Will my travel expenses be reimbursed?

We will reimburse interview travel expenses where required.

15. What will happen to the results of the research study?

We plan to publish the results in a leading scientific journal and present at international scientific conferences. You will not be identifiable in any published report or presentation. You will be sent a summary of the results (unless you tell us that you do not want one). The ePROM reporting system will be tested further in future research conducted by the study team.

16. Do you have any further questions?

General information about the study is available on the study website, here: www.birmingham.ac.uk/RePROM
For specific information about this research study, please use the contact details below.

Contact Information

If you would like to speak to someone about the study please contact:

< Contact Name > <Job Title>

<Telephone and/or E-mail>

Support can also be found through the NHS Patient Advisory and Liaison Service (PALS)

Tel: *<insert local PALS contact number(s)>* Email: *<insert local PALS email address>*