# Applying Systems Thinking to enhance recovery after acute kidney injury

**Health Professional Participant Information Sheet (PIS) for Interviews and Focus Groups**

You are being invited to take part in a major new research study funded by the National Institute of Health Research. The study is focused on improving the quality of care post-discharge for people who have had a hospital admission affected by acute kidney injury (AKI). This information sheet outlines its purpose and what participation involves.

Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part, and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

## About the research

- **Who will conduct the research?**

The research is being led by The University of Manchester. Researchers based at the Universities of Leeds, Southampton, Nottingham and Aberdeen as well as at NHS Education for Scotland, Leeds Teaching Hospitals Trust and the Kidney Patient Involvement Network are also involved in this study.

The research will be led by Dr Tom Blakeman (GP and Clinical Senior Lecturer) and Professor Caroline Sanders (Professor of Medical Sociology) at the Division of Population Health, Health Services Research and Primary Care, School of Health Sciences, The University of Manchester.

- **What is the purpose of the research?**

Acute kidney injury (AKI) is a common, harmful and costly clinical syndrome, characterised by sudden worsening in kidney function. It affects around half a million people in England each year, contributing to 7 in 100 unplanned hospital admissions. Older frail people living with multimorbidity are especially vulnerable to AKI.

People discharged from hospital following AKI experience high rates of unplanned readmissions (1 in 5 within 30 days) and poor long-term health outcomes (1 in 5 sustain AKI again, 1 in 6 develop chronic kidney disease, and 1 in 4 sustain a major cardiovascular event).

This study aims to help improve outcomes for people following AKI. As part of this study, it is important that we understand the experiences and opinions of healthcare professionals from both hospitals and primary care who are involved in caring for people after AKI.

**Will the outcomes of the research be published?**

We will publish a report of the findings as well as publish results in peer-reviewed journals. Working in partnership with key stakeholders, the findings will inform participatory workshops to strengthen national guidelines and resources to support people who have been affected by acute kidney injury.

- **Who has reviewed the research project?**

All research in the NHS is looked at by Research Ethics Committees to protect your interests. This study has been reviewed and given a favourable opinion by Greater Manchester East Research Ethics Committee, REC Reference 22/NW/0222

- **Who is funding the research project?**

The study is funded be the NIHR Health Services & Delivery Research Programme (Reference: NIHR131948)

## What would my involvement be?

- **What would I be asked to do if I took part?**

If you consent to take part in the study, a member of our research team will contact you to arrange an interview at a reasonable time and place of your choice. Alternatively, you may wish to participate in a focus group with other healthcare professionals to share your experiences. We will follow COVID-19 guidance, which will inform whether we are able to offer face-to-face and/or online or telephone interviews. Most likely, interviews will take place on the phone or on Zoom/Microsoft teams. Focus groups will also most likely take place online.

We take it for granted that healthcare professionals often work in very challenging circumstances to deliver the best care for their patients. It is often difficult to deliver best care, especially across primary-secondary care boundaries for patients who may have complex health and social care needs and within the limited time and resources typically available in clinical practice. The interview will explore events (e.g. communications, consultations) around and after discharge from hospital for the consenting patient. It may be useful to have the patient record open at the time of the interview.

We expect most interviews/focus groups to take around 30-45 minutes and no longer than one hour; interview duration will depend on your level of involvement in the care of your consenting patient and your own time constraints. With your prior agreement, the interview will be audio-recorded. You will not be identifiable from the subsequent analysis.

- **Will I be compensated for taking part?**

Funding is provided to compensate general practice staff time for their involvement in the study.

- **What happens if I do not want to take part or if I change my mind?**

It is up to you to decide whether or not to take part. Please contact the research team via email Kelly.howells@manchester.ac.uk or by telephone 0161 275 0324 whether you want to take part or not. If you do decide to take part you will be given this information sheet to keep and will be asked to sign a consent form or will be asked to provide verbal consent to confirm consent. If you decide to take part, you are still free to withdraw at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove your data from the project once it has been anonymised as we will not be able to identify your specific data. This does not affect your data protection rights. If you decide not to take part, you do not need to do anything further.

With your prior agreement, to enhance the analysis the interviews/focus group will be audio-recorded. However, you are free to decline the recording. You should be comfortable with the recording process at all times and you are free to stop the recording at any time.

## Data Protection and Confidentiality

- **What information will you collect about me?**

In order to participate in this research project we will need to collect information that could identify you, called "personal identifiable information". Specifically we will need to collect:

- Your name and contact details;
- Your job role and where you work;
- Your gender and age;
- Either a signed consent form from you, or an audio recording of you giving consent to take part in the study. Recordings will consist of your voice only.

Only the research team at The University of Manchester will have access to this personal identifiable information. Study data and material may also be looked at by individuals from The University of Manchester, from regulatory authorities or from the NHS Trust, for monitoring and auditing purposes, and this may well include access to personal information.

- **Under what legal basis are you collecting this information?**

We are collecting and storing this personal identifiable information in accordance with UK data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is "a public interest task" and "a process necessary for research purposes".

- **What are my rights in relation to the information you will collect about me?**

You have a number of rights under data protection law regarding your personal information. For example, you can request a copy of the information we hold about you, including audio recordings.

If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our Privacy Notice for Research (https://documents.manchester.ac.uk/display.aspx?DocID=37095)

- **Will my participation in the study be confidential and my personal identifiable information be protected?**

In accordance with data protection law, The University of Manchester is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following way:

The study team at The University of Manchester (UoM) will have access to your personal information and they will anonymise it as soon as possible. Your name and any other identifying information will be removed and replaced with a random ID number. The research team will have access to the key that links this ID number to your personal information. Your consent form will be retained for 5 years in a locked cabinet on UoM premises for audit purposes. Audio consent

recordings will be retained for as long as hard copy consent forms. Your consent recordings will not be linked by an ID number. With your consent, we would also like to retain your contact details for 5 years in order to provide you with a summary of the findings for this study and also to inform you about future studies that you may be interested in. If you provide consent for this, your details will be safely stored on UoM servers in a digital folder only accessible to the study team and used only for the purposes described above.

In order to ensure that we have an accurate record of our conversation, we need to record it using Zoom or Microsoft Teams software. This may mean that your personal data is transferred to a country outside of the European Economic Area, some of which have not yet been determined by the United Kingdom to have an adequate level of data protection. Appropriate legal mechanisms to ensure these transfers are compliant with the Data Protection Act 2018 and the UK General Data Protection Regulation are in place. The recordings will be removed from the above third-party platform and stored on The University of Manchester managed file storage as soon as possible following the completion of data collection.

The recording will only include your voice (audio). We will use the recording of our conversation to make a transcript and once we have checked that the transcript is correct, the recording will be deleted. The recording will be sent securely to a UoM approved supplier for transcription. We will then remove any information from the transcript that might identify you. Only anonymised transcripts will be shared with collaborating researchers and members of the patient and public involvement working group based in the named institutions.

In accordance with the UK Policy Framework for Health and Social Care Research and with your consent, we would like to be able to share your anonymised data with other UoM researchers who are doing studies similar to ours. This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of research focused on understanding and improving delivery of health services, and cannot be used to contact you regarding any other matter. It will not be used to make decisions about future services available to you. (https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/)

At the end of the project, we would like to deposit a fully anonymised dataset in an open data repository where it will be permanently stored. We will use Figshare at The University of Manchester Library. Researchers at other institutions and others can access the anonymised data directly from the repository and use it for further research or to check our analysis and results.

## Potential Disclosures

Please also note that individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

The study is interested in how people and systems work to create safety and understand factors that enable or hinder this being achieved. In doing so, the focus of the interviews are to support the development of service delivery and not to assess the performance of the individual practitioners. However, there is a small risk that participants may disclose instances of unsafe practice that put themselves or others at risk. If, during the study, you disclose information about misconduct/poor practice, we have a professional obligation to report this and will therefore need to inform your employer/professional body.

**What if I have a complaint?**

If you have a complaint that you wish to direct to members of the research team, please contact **TOM BLAKEMAN** (tom.blakeman@manchester.ac.uk;) or **CAROLINE SANDERS** (caroline.sanders@manchester.ac.uk;)

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researcher in the first instance, then please contact:

The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the Information Commissioner's Office about complaints relating to your personal identifiable information Tel 0303 123 1113. (https://ico.org.uk/make-a-complaint/)

## Contact Details

If you have any queries about the study or if you are interested in taking part then please contact the researchers:

**Kelly Howells, Research Fellow, Centre for Primary Care and Health Services Research, Faculty of Biology, Medicine & Health, The University of Manchester**

Kelly.howells@manchester.ac.uk

**Mark Jeffries mark.jefferies@manchester.ac.uk Centre for Primary Care and Health Services Research, Faculty of Biology, Medicine & Health, The University of Manchester**

**Thank you for your time**

## Additional information in relation to COVID-19 (if applicable)

**Are there any additional considerations that I need to know about before deciding whether I should take part?**

When taking part in a face-to-face interview or group workshop there may be additional risks to yourself, including possible infection through travelling to and from the interview venue, coming into contact with the researcher and/or other research participants, or through the handling of any research equipment.

We cannot guarantee that researchers or research participants will be fully vaccinated against COVID-19. You should not participate in a face-to-face interview or group discussion if you are in a vulnerable or high-risk group, or if you have any symptoms of COVID-19 and should therefore, opt for a telephone or online meeting.

**What additional steps will you take to keep me safe while I take part?**

The research team will wear face masks at all times and ask other research participants to do the same. The researcher will ensure steps are taken to reduce contact between you, the researcher, and other participants (if present), through maintaining social distancing, disinfecting chairs and tables and other equipment. The research team will adhere to the latest government guidelines relating to COVID-19, and, should the guidance change so that face-to-face research is no longer permitted under the current guidelines, the interview or workshop will be postponed and re-arranged, or, if possible, the research team will try to find another way to conduct the interview or group workshop (e.g. a telephone call or online) that is in-line with the COVID-19 guidance at that present time.

**Is there any additional information that I need to know?**

Personal protective equipment (PPE), such as masks, may be mandatory within a research venue (unless exempt). This is for the protection of yourself, the research team, and other participants (if in a discussion group setting). Please arrive on time to avoid participants gathering in the same area.