This protocol has regard for the HRA guidance

RESRARCH PROTOCOL

Study Title	Applying Systems Thinking to enhance recovery after acute kidney injury
Short Title	AsterAKI
Study Design	Mixed-methods
Planned Study Period	30 months (1st of May 2022 to 31st of October 2024)
Research Aim	To understand and target improvements in the quality of post-discharge care following AKI.
Chief Investigator	• Tom Blakeman, Clinical Senior Lecturer, University of Manchester
Co-Investigators	• Robbie Foy, Professor of Primary Care, University of Leeds • Holly Loughton, PPI co-I, Kidney Patient Involvement Network • Kirsty Samuel, PPI co-I, Leeds • Darren Ashcroft, Professor of Pharmacoepidemiology, University of Manchester • Pearl Mok, Research Fellow, University of Manchester • Caroline Sanders, Professor of Medical Sociology, University of Manchester • Stephen Campbell, Professor of Primary Care Research, University of Manchester • Simon Fraser, Associate Professor of Public Health, University of Southampton • Paul Roderick, Professor of Public Health, University of Southampton • Nicholas Selby, Professor of Nephrology, University of Nottingham • Andrew Lewington, Consultant Renal Physician/Hon Clinical Associate Prof, Leeds Teaching Hospitals Trust • Simon Sawhney, Senior Clinical Lecturer, University of Aberdeen • Duncan McNab, Assistant GP Director, NHS Education for Scotland • Kelly Howells, Research Fellow, University of Manchester

	• Mark Jeffries, Research Fellow, University of Manchester
Funder	HSDR NIHR131948
Study Sponsor	• Faculty Research Governance Team, The University of Manchester

LIST of CONTENTS

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RESEARCH REFERENCE NUMBERS

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The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature:

.....

Date:
...../...../.....

Name (please print):

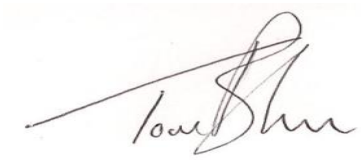
.....

Position:

.....

Chief Investigator:

Signature:



Date:
...../...../.....

Name: (please print):

Dr Tom Blakeman.

KEY STUDY CONTACTS

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Funder(s)	NIHR Health and Social Care Delivery Research (HSDR) Programme University of Southampton Alpha House, Enterprise Road Southampton, SO16 7NS

STUDY SUMMARY

BACKGROUND: 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 after AKI experience high rates of unplanned readmissions and poor long-term health outcomes. There is uncertainty around how patient, clinician and system factors contribute to these outcomes and, critically, how they can best be targeted to benefit patients.

AIM: To understand and target improvements in the quality of post-discharge care following AKI.

WORK PACKAGE 1 (WP1): This population-based cohort study will use linked electronic health records from the Clinical Practice Research Datalink (CPRD), Hospital Episode Statistics (HES) and Office for National Statistics (ONS) mortality records. We will identify patients with AKI-related hospitalisation and apply earlier-developed indicators of evidence-based, person-centred care. This work will determine the extent of variations in post-discharge care of people with AKI according to recommended evidence-based practice and identify patient and general practice characteristics associated with the implementation of recommended practice.

WORK PACKAGE 2 (WP2): Qualitative case studies in six integrated care systems with purposefully sampled organisations, patients and care providers. We will conduct longitudinal interviews with 24 patients and 12 carers following hospital discharge, interview 36 primary care and specialist staff, analyse local policies and protocols, and take field notes.

Our combined thematic and narrative analysis will enable cross case comparisons whilst also considering personal stories as holistic accounts. We will use Systems Thinking as a sensitising framework, contrasting 'work-as-imagined' with 'work-as-done' in analysing how patients, clinicians, practice teams and organisations manage post-discharge AKI care. This work will therefore understand patient, carer and healthcare staff experience of post-discharge AKI care pathways and identify patient, professional and organisational factors that support or inhibit the implementation of safe post-discharge AKI care.

WORK PACKAGE 3 (WP3): Our structured deliberations in participatory workshops will involve healthcare providers across the primary-specialist care interface and key patient and professional organisations. We will integrate WP 1&2 findings to define and iteratively refine an ideal care pathway. We will develop an improvement strategy defining actions needed at patient, clinician and organisational levels and explicitly consider impacts on affordability, practicability, effectiveness, acceptability, safety and equity.

OUTPUTS: We will produce a coherent logic model for service improvement which includes practical recommendations and a set of indicators based on routinely collected data for assessing progress. Our findings will articulate the patient voice in strengthening systems of care. Our strong partnerships with the UK Kidney Association and the Kidney Patient Involvement Network will enable the translation of our work into national policy and improvement programmes.

OUR COLLABORATION: We are an interdisciplinary group with strong policy links and expertise and experience in AKI, quality improvement and safety, organisation and delivery of care, patient and public involvement, analysis of large datasets, qualitative methodology, and clinical primary care.

PLAIN ENGLISH SUMMARY

Kidneys are essential for our health. They have a number of vital roles. These include filtering our blood and getting rid of waste and excess water by converting it into urine.

"Acute Kidney Injury" (AKI) refers to a circumstance when the kidneys suddenly stop working properly within hours or a few days. There are many reasons why AKI can occur. The most common cause is when our body becomes short of salt and water, such as when people become dehydrated from diarrhoea and/or vomiting. AKI is common, harmful and costly. It affects 1 in 7 people admitted to hospital unexpectedly. It is more common among people who are frail or who live with multiple health problems such as diabetes and heart failure.

We have shown that AKI remains an important and overlooked health problem for people even after they recover and go home from hospital. One in 5 people will need to be admitted to hospital again as an emergency within a month and 1 in 3 people within three months. If someone has had AKI, they are also more likely to develop lasting kidney damage known as chronic kidney disease (CKD). Over the past 10 years, tackling the harm related to AKI has been a major priority for the NHS. However, most research and quality improvement activities have taken place in hospitals. Research is now needed on how to ensure high-quality person-centred care for people affected by AKI following discharge from hospital.

As a starting point, we have already used robust research methods to develop national standards to improve care for people affected by AKI. These include: (1) helping people understand how to keep their kidneys healthy when they become unwell; (2) supporting people with their medicines, such as restarting important drugs for people with heart failure; (3) ensuring a timely review by a clinician; and (4) carrying out tests at the right time to ensure that we are quick to identify people with recurrent or lasting kidney problems.

Through the establishment of the Kidney Patient Involvement Network working group, the UK Standards for Public Involvement will provide a structure to ensure patient voice and experience are central to all stages of the study. First, we will analyse large numbers of medical records to assess the current state of care for people leaving hospital following AKI. We will check whether care is being delivered according to national standards, try to work out why care sometimes fails to meet these standards and identify areas where we can improve future care.

Second, we will talk with people to learn from their experiences of care following AKI. With people's permission, we will review their medical records and interview others involved in their care such as their GP, nurse, pharmacist or member of hospital staff. Where appropriate, we will also talk with family members who provide support.

Third, we will hold workshops with patients and care providers, where we will discuss findings from our analyses of the interviews and medical records. Through shared learning, we will develop practical recommendations to improve the quality of post-discharge care.

In partnership with patient and professional representatives, our research will: (1) strengthen national guidelines; (2) help improve resources that support person-centred care; (3) develop reliable ways of measuring high quality care for people leaving hospital after AKI; and (4) guide quality improvement across the health service.

FUNDING AND SUPPORT IN KIND

FUNDER(S)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
NIHR Health and Social Care Delivery Research (HSDR) Programme	£888,579.33
SUPPORT IN KIND	
UK Kidney Association NHS England Renal Services Transformation Programme Renal GIRFT Programme	'The kidney community is currently establishing a national AKI Special Interest Group, which involves all stakeholder organisations responsible for the care of patients with AKI. The group will commit to supporting the delivery of this application.'

ROLE OF STUDY SPONSOR AND FUNDER

The study will be conducted in accordance with the contractual requirements signed on the 24th of August 2021 between the Secretary of State for Health and Social Care and The University of Manchester.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITTEES/GROUPS & INDIVIDUALS

Study Steering Committee

We will establish a Study Steering Committee (SSC) in keeping with NIHR guidance (https://www.nihr.ac.uk/documents/research-governance-guidelines/12154). The SSC will provide supervision on behalf of the project sponsor and funder and will ensure that the study is conducted in accordance with governance standards. The SSC will include an Independent Chair, a member with statistical expertise, a member with qualitative expertise, and a PPI representative. It will also include representation from the UK Kidney Association AKI Special Interest Group. The Steering Committee will meet at least annually, with flexibility to meet quarterly if required, with WP leads to oversee progress, advise on methodology and interpretation of findings, and guide our engagement and dissemination planning.

Kidney Patient Involvement Network AKI Working Group

The planned research is grounded in Patient & Public Involvement and Engagement (PPIE) infrastructure developed through the Kidney Patient Involvement Network (KPIN). The study is aligned with the key objectives of KPIN, which include the embedding of patient and carer voice and experience into the planning, delivery and evaluation of health and care services. We will achieve this objective and support wider capacity building through our establishment of a PPIE working group that will meet on a flexible and regular basis throughout the study (See Study Flow Chart). Section 8 provides details regarding PPIE.

PROTOCOL CONTRIBUTORS

The study protocol has been developed through regular meetings with all co-investigators and through PPIE, leading to submission of an application for NIHR Health and Social Care Delivery Research (HSDR) Programme funding. The protocol was developed further in response to HSDR panel feedback.

Patient & Public Involvement/Engagement

Patient and public engagement is integral to our applied research. Kirsty Samuel and Holly Loughton are PPI co-applicants. The research builds on a platform of engagement developed through the award-winning Think Kidneys awareness raising campaign as well as resources developed in partnership between the Royal College of General Practitioners and Kidney Care UK.

The proposal has been informed by earlier discussions with PPI groups in Leeds (September 2019) and Manchester (Primary Care Research in Manchester Engagement Resource, September 2019) as well as with the RCGP Patient and Carer Participation Group (May 2019). Specifically, these meetings emphasised a need to: map variation in post-discharge AKI care (WP1); consider approaches to participant recruitment (WP2); and explore people's relationship with medicines following AKI (WP2).

Following discussions with the Policy Director at Kidney Care UK, the research was presented to the Kidney Care UK's Patient Advisory Group in December 2020. This stimulated debate, leading to interest in aligning the research with the Kidney Patient Involvement Network (KPIN; https://kpin.org.uk/). KPIN is a 'network of kidney organisations, charities and individuals committed to quality patient and public involvement and engagement (PPIE) who are willing to work collaboratively to improve standards and develop patient leaders of the future.'

Since January 2021, meetings with KPIN patient members led to a group meeting focused on understanding and improving post-discharge care for people affected by AKI. These discussions strengthened the research in terms of ensuring the KPIN-led PPIE working group is central to 'strategic co-design', particularly in terms of the development and outputs arising from Work Package 2 (WP2: qualitative case studies) and Work Package 3 (WP3: participatory workshops). In addition to shaping the plain English summary, specific points raised during our PPIE working group discussions have informed the further development of the research plan. These included a need to:

- Make explicit that 'co-design rooted in people's experiences' is an essential aspect of this research. (WP2) - Consider how this work fits into integrated care systems and takes into account 'pressures'/'tensions' in the system. (WP2)
- Consider how people can experience 'uncertainties' and a sense of insecurity/anxiety following discharge. (WP2)
- Consider development of a support package that enables 'confidence' building and helps people 'edge back to normality,' i.e. a programme to support care transitions, which includes support for people's mental health and social needs. (WP3)
- Consider strategic sampling of the organisations participating in the study. (WP2)
- Consider our approach to interviewing participants, with recognition that 'NHS language' and 'jargon' can get in the way of understanding (and improving) care. (WP2)
- For the research to move beyond an 'idealised process' of care, and instead, to understand how people's care in the community is often experienced as 'improvised' and felt to be lacking clear structure. (WP2)

- Consider the 'disconnect' often experienced in the coordination and timeliness of care (e.g. between the renal consultant and the GP) and seek to address this, particularly in light of the COVID-19 pandemic. E.g. 'Who is the go-to person?' (WPs 1, 2 & 3).

NIHR Health and Social Care Delivery Research (HSDR) Programme Funding Panel
The protocol was developed in response to feedback from the NIHR Health and Social Care Delivery Research (HSDR) Programme Panel.

KEY WORDS:

Acute Kidney Injury; Patient Safety; Primary Care; Patient Discharge; Quality of Health Care; Systems Thinking

MANCHESTER 1824
The University of Manchester

AsterAKI
Applying Systems Thinking to Enhance Recovery after Acute Kidney Injury

NIHR | National Institute for Health and Care Research

STUDY FLOW CHART

	Pre-funding Preparation					Year 1												Year 2												Year 3					
	-5	-4	-3	-2	-1	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6
WP1: Analysis of population-based linked electronic health records																																			
Finalise ISAC Advisory Committee protocol	■	■	■	■	■	■																													
Delineation of the linked study cohort							■	■	■	■																									
Data cleaning and analysis											■	■	■	■	■	■	■	■	■	■	■	■	■												
Writing and publishing of academic papers																							■	■	■	■	■	■	■						
WP2: Qualitative case studies in six integrated care systems																																			
Finalise ethics/R&D approvals	■	■	■	■	■																														
Recruitment/planning at each site												■	■	■																					
Conduct initial patient interviews & carers														■	■	■	■	■	■	■	■														
Conduct interviews with care providers															■	■	■	■	■	■	■	■	■	■	■	■									
Conduct follow-up patient interviews																■	■	■	■	■	■	■	■	■	■	■	■								
Data analysis															■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■				
Writing and publishing of academic papers																												■	■	■	■	■	■	■	■
WP3: Participatory workshops to integrate findings and develop practical recommendations for improvement																																			
Finalise ethics/R&D approvals	■	■	■	■	■																														
Conduct participatory workshops								■										■											■		■		■		
Writing and publishing recommendations																																	■	■	■
Management /PPI/Outputs for Dissemination																																			
Finalise collaboration agreements	■	■	■	■	■																														
Recruitment of staff for WP1 and WP2	■	■	■	■	■																														
Research Management Group meetings						■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
KPIN PPI working group meetings						■		■		■		■		■		■		■		■		■		■		■		■		■		■		■	
Whole team meetings	■					■						■						■						■						■				■	
Kidney Association stakeholder meetings	■		■			■			■			■			■			■			■			■			■			■			■	
Output: Updating national guidance																															■	■	■	■	■
Output: Kidney health resources																															■	■	■	■	■
Output: Post-discharge quality indicators																															■	■	■	■	■
Output: Model for quality improvement																															■	■	■	■	■
Writing and completing reports to HSDR											■					■	■						■					■	■				■	■	■

STUDY PROTOCOL

Applying Systems Thinking to enhance recovery after acute kidney injury (AsterAKI)

1 BACKGROUND

Acute kidney injury (AKI) is a common, harmful and costly clinical syndrome.(Liano and Pascual 1996, Group 2012, (NICE) 2013, Kerr, Bedford et al. 2014, Wonnacott, Meran et al. 2014) It is a marker of illness severity, characterised by sudden worsening in kidney function. Around half a million people in England sustain AKI each year, affecting 7 in every 100 unplanned hospital admissions.(Registry 2020) There are many causes for AKI, though it is most commonly associated with episodes of acute illness against the background of increased risk. AKI affects all ages, though older frail people living with multiple long-term conditions (multimorbidity) (MLTC-M) are especially vulnerable to AKI.(Abdel-Kader, Girard et al. 2018, Ortiz-Soriano and Neyra 2018, Registry 2020, Research 2020). Nearly 1 in 5 people who sustain AKI die within 30 days.(Registry 2020) AKI-related care costs around £1 billion per annum of the NHS budget.(Kerr, Bedford et al. 2014)

People affected by AKI experience potentially avoidable adverse outcomes following hospital discharge. These include high rates of unplanned readmissions (1 in 5 within 30 days and 1 in 3 within 90 days) and poor long-term health outcomes (1 in 5 sustain AKI again, 1 in 6 develop chronic kidney disease - CKD), and over the year following AKI, 1 in 4 sustain a major adverse cardiovascular event).(Silver, Harel et al. , Omotoso, Abdel-Rahman et al. 2016, Sawhney, Marks et al. 2017, See, Jayasinghe et al. 2019) Because AKI affects so many people each year, improved post-discharge care after AKI would lead to sizable overall benefits across the UK.

Tackling AKI has become a global priority to improve patient safety.(Mehta, Cerdá et al. , Siew, Liu et al. 2020) The emergence of AKI as a national driver of quality and safety stemmed from a 2009 National Confidential Enquiry into Patient Death and Outcome (NCEPOD) report, *Adding Insult to Injury*, which highlighted significant failings in 'basic care' for people who had an episode of illness complicated by AKI.(Stewart JFG 2009) These findings resonated with both the 2013 Francis Inquiry and the Berwick Review into Mid-Staffordshire NHS Foundation Trust, which highlighted a need for the NHS to become a learning organisation in order to improve patient safety.(England 2013, Francis 2013) The NCEPOD report directly led to the development of the 2013 NICE clinical guidelines as well as the establishment of the NHS England *Think Kidneys* Programme (2014-2017).((NICE) 2013, NHS England 2017) In doing so, the NHS became the world's first healthcare system to tackle AKI at a national level.(NHS England 2017)

Situated within NHS England's Patient Safety Domain, the *Think Kidneys* Programme entailed six multidisciplinary workstreams (education; risk; detection; intervention; measurement; and implementation) focused on tackling avoidable harm associated with AKI.(NHS England 2017) It resulted in two national patient safety directives: the first mandating the implementation of an AKI clinical decision support system within all acute NHS trusts; and the second requiring NHS providers in all settings to 'develop an action plan to ensure any relevant resources are used to improve local systems and processes for the care of patients with AKI.'((NICE) 2013, England 2014, NHS England 2016).(NHS England 2017) In addition, through the NHS Commissioning for Quality and Innovation (CQUIN) framework, hospitals were financially incentivised to improve discharge summaries for patients with AKI.(Team 2015) With the aim of improving the provision of information to GPs and to 'positively impact on readmissions rates', hospitals were paid for ensuring discharge summaries documented: the severity of an episode of AKI (stages 1, 2 and 3); evidence of a medicines review having been carried out; as well as the type and frequency of blood tests required following discharge.(Team 2015, NHS England 2017) However, to date, despite a decade of mainly hospital-focused policies and quality improvement initiatives, there remains limited progress on improving outcomes and the patient experience of post-discharge AKI care.(Siew, Liu et al. 2020)

As a starting point to address this gap, we led the development of NHS England *Think Kidneys* guidance for primary care, followed by the Royal College of General Practitioners' (RCGPs') AKI Quality Improvement Toolkit to support person-centred care (2018-2020).(NHS England 2017, Practitioners 2018) The 2020 NICE COVID-19 rapid guidelines for AKI specifically incorporate standards for care after hospital discharge that we (TB, SC) developed through the (NIHR and NHS funded) RCGP partnership using existing evidence and rigorous UCLA/RAND methodology.(Practitioners 2019, Excellence 2020, Selby, Forni et al. 2020, Tsang, Murray et al. 2020) Our research (NS), in conjunction with an evolving literature, highlights that AKI is a common complication of COVID-19.(Kolhe, Fluck et al. 2020, Nadim, Forni et al. 2020, Ronco C 2020)

As a clinical syndrome that is particularly relevant to care for people living with multiple long-term conditions (MLTC-M), AKI offers a lens to move away from a single disease framework to instead enable person-centred service delivery.(Guthrie, Payne et al. 2012, Blakeman, Harding et al. 2013) An important feature in our ongoing approach to the development of guidelines and resources is to help ensure that an AKI diagnosis is placed in context, enabling tailored and timely follow-up that takes into account an individual's existing co-morbidities, social circumstances and prognosis.(Silver, Adu et al. , Hounkpatin, Fraser et al. 2019, Tsang, Murray et al. 2020) Navigating the challenge of 'too much medicine' is central in our approach to support effective implementation of AKI as a new disease classification system to improve care and outcomes.(Glasziou, Moynihan et al. 2013, Blakeman, Griffith et al. 2016, Practitioners 2018, Moynihan, Brodersen et al. 2019, Tsang, Murray et al. 2020) As stated in the RCGP AKI toolkit, a key principle underpinning our programme of work is to 'maximise the clinical utility of AKI as a driver of quality and safety whilst minimise treatment burden for patients (and corresponding unnecessary clinician workload).'(Practitioners 2018) Based on consensus methodology that considers current best available evidence, RCGP guidance (https://www.rcgp.org.uk/aki) outlines what usual pathways of post-discharge AKI care should entail.(Practitioners 2019, Tsang, Murray et al. 2020) Key elements include: conducting timely clinical reviews (e.g. within 3 days for people with stage 3 AKI, heart failure and poor kidney recovery); optimising medicines management, including the secondary prevention of cardiovascular disease; promoting awareness of the diagnosis to enable effective self-management and reduce future risks, and; testing kidney function for both monitoring medicines and to identify new or worsening CKD.(Practitioners 2019) Aligned with NHS England discharge standards, the guidelines emphasise that 'appropriate systems and safety net arrangements should be in place in primary and secondary care.'(Domain 2016)

To date, through *Think Kidneys* and the RCGP QI partnership, we have led the development of standards, guidance and resources to improve post-discharge AKI care.(NHS England 2017, Practitioners 2019) In doing so, using consensus methodology and stakeholder engagement (i.e. shared learning events & feedback through a range of regional and national organisations including the British Society for Heart Failure, the UK Renal Association, Primary Care Cardiovascular Society and Academic Health Science Networks), we have ensured our approach to improving post-discharge AKI care is grounded in an understanding of routine practice. Furthermore, in single-centre research studies, we have identified gaps in the delivery of recommended care.(Elvey, Howard et al. 2020, Howard, Elvey et al. 2020, Tsang, Brown et al. 2021) Building on this platform, scaled-up research entailing a more granular analysis is now needed to inform targeted quality improvement. Aligned with a policy priority to develop integrated systems of care,(England 2019, Care 2021) next steps entail: (i) examining patterns and variations in the delivery of post-discharge AKI care; (ii) identifying patient, professional and organisational factors supporting or inhibiting the implementation of person-centred post-discharge care; (iii) identifying opportunities to strengthen service delivery to prevent unplanned hospital readmissions as well as improve kidney and cardiovascular outcomes; and (iv) developing practical recommendations for improvement.

2 RATIONALE

(i) Examining patterns and variations in the delivery of post-discharge AKI care. We (SS, PR) have demonstrated socioeconomic variation in AKI incidence and outcomes.(Hounkpatin, Fraser et al. 2019) However, while there are well-recognised variations in the quality and safety of primary care,(Panesar, deSilva et al. 2016, Willis, West et al. 2017) little rigorous, generalisable work has focused on pathways of care after AKI. Most research to date has highlighted the extents of high-risk prescribing, which increases vulnerability to AKI,(Guthrie, McCowan et al. 2011, Avery, Ghaleb et al. 2013, Camin, Cols et al. 2015) and surveillance of people with CKD.(Lusignan, Gallagher et al. 2013, Willis, West et al. 2017). Our process mining (SS) of hospital discharges in Grampian, Scotland, demonstrated a lack of any post-AKI monitoring following discharge in 42% of people who died or were readmitted within 30 days and in 39% of deaths/readmissions within 90 days after AKI.(Sawhney, Tan et al.) Our NIHR CLAHRC Greater Manchester quality improvement project (TB) focused on post-discharge AKI care across 31 general practices within a single clinical commissioning group.(Elvey, Howard et al. 2020, Howard, Elvey et al. 2020) Through NIHR School for Primary Care Research funding, we (TB, SC) have also user-tested a performance informatics dashboard to support AKI aftercare.(Brown, Gude et al. 2019, Tsang, Brown et al. 2021) These studies identified scope for improvement in recommended practice and involved general practices in developing reproducible operationalised definitions of post-discharge AKI processes.(Howard, Elvey et al. 2020, Tsang, Brown et al. 2021) We are now well positioned to scale up single-centre work to general practices across England by examining variations and guiding targeted improvements in post-discharge AKI care.

(ii) Identifying patient, professional and organisational factors supporting or inhibiting the implementation of person-centred post-discharge care. NICE guidance recommends increasing patient awareness of AKI to enable effective self-management.((NICE) 2014) Public awareness of kidney health is low; only around half surveyed know that kidneys make urine.(NHS England 2014) To date, there is limited understanding of how AKI is communicated, understood and managed following hospital discharge.(Silver, Saragosa et al. 2018) Our preliminary research suggests that implementing post-discharge AKI care is enabled through general practice action plans and delegation of responsibilities to staff, particularly practice pharmacists.(Elvey, Howard et al. 2020) We have shown that diagnostic coding of AKI in general practice is associated with significant improvements in downstream patient care (medicines reviews, kidney monitoring and provision of information).(Howard, Elvey et al. 2020) However, improved coding does not necessarily equate with person-centred care nor improved outcomes.(Bailey, Pierides et al. 2019, Bailey, Hunt et al. 2020, Howard, Elvey et al. 2020)

Relationship-based care is the top priority for the RCGP in the delivery of high quality services.(of and Practitioners) It reflects concerns that 'technocratic logic' has 'come to characterise' organisational and professional standards.(Greenhalgh, T. et al. 2010, Greenhalgh 2014, Salisbury 2020) This is evidenced in our previous ethnographic analysis of hospital management of AKI in which quality improvement initiatives, driven by financial incentives, led to an organisational focus on 'producing auditable accounts of care' at the expense of human agency and scope for adaption.(Bailey, Pierides et al. 2019, Bailey, Pierides et al. 2020) In addition, though we have demonstrated that it is possible to engage general practices in post-discharge AKI care processes, the implementation of post-discharge AKI improvement work may be largely transactional, with less emphasis being given to the relational qualities of the interaction.(Bailey, Pierides et al. 2020, Salisbury 2020) For instance, our single centre evaluation of a primary care Quality Improvement (QI) intervention showed significant improvements in the provision of written information to patients (NICE quality indicator),((NICE) 2014) yet our qualitative analysis of provider accounts was largely 'silent' on how AKI was being communicated.(Elvey, Howard et al. 2020, Howard, Elvey et al. 2020) One reason that general practices may struggle with this aspect of communication, suggested by our RCGP QI project and the international literature, is that patients and carers may have poor awareness and understanding of AKI and kidney health.(NHS England 2014, Practitioners 2018, Silver, Saragosa et al. 2018) This is not surprising given that many people with AKI also need to contend with multiple long-term conditions and the considerable 'work' needed to maintain their own health.(May, Montori et al. 2009) It is further compounded by a variable 'hit and miss' discharge

process that lacks context (e.g. discharge information limited to 'repeat U+Es in 1-2 weeks').(Practitioners 2018) Building on the award winning *Think Kidneys* awareness campaign (https://www.thinkkidneys.nhs.uk/), as well as resources developed in collaboration with Kidney Care UK, we will explore the relational issues around the communication and coordination of post-discharge AKI care by examining the experiences and perspectives of patients, carers and healthcare staff.(NHS England 2017) We will then consider and propose practical strategies for enhancing relational care in routine practice.

(iii) Identifying opportunities to strengthen service delivery to prevent unplanned hospital readmissions and improve cardiovascular outcomes. Studies across different healthcare systems suggest that around 30% of all readmissions are potentially avoidable (van Walraven, Bennett et al. 2011, Blunt, Bardsley et al. 2015, Auerbach, Kripalani et al. 2016) and two-thirds of adverse events during transitions from hospital to home could be prevented or minimised.(Forster, Murff et al. 2003) Though people affected by AKI face similar challenges to those discharged from hospital with ongoing care needs, they represent a population who tend to be sicker, experience more episodes of acute illness and need complex multi-speciality input.(Tonelli, Wiebe et al. 2018) Organisational responses appear to be highly variable and include AKI specialist nurse roles and post-AKI follow-up clinics.(Karsanji, Pannu et al. 2017) (Silver, Goldstein et al. 2015, Ebah, Hanumapura et al. 2017) The high rates of readmission for people with heart failure affected by AKI pose a particular concern; this group needs coordinated early clinical review and re-introduction of heart failure medicines following acute illness.(Silver, Harel et al. , Sawhney, Marks et al. 2017, Clark, Kalra et al. 2019, Parikh and Coca 2019) We (RF) are involved in work developing person-centred approaches, initiated during hospital stays, to improve such transitions of care.(Baxter, O'Hara et al. 2018) Through multidisciplinary stakeholder engagement, our focus on post-AKI care will enable us to identify omitted or mistimed care processes across interfaces (primary/secondary, health/social) to specifically target for improvement.(Michie and Johnston 2004)

(iv) Developing practical recommendations for improvement. Our work so far has identified and promoted best practices in the detection, management and aftercare of AKI.(NHS England 2017, Practitioners 2018) However, there is a need for a concerted programme of generalisable research to improve outcomes for people after AKI. Over the past year, there has been an increasing international focus on improving care for people following hospitalisation with AKI.(Siew, Liu et al. 2020) Through granular analysis in conjunction with multidisciplinary stakeholder engagement, our research addresses the challenge set by NHS Improvement leadership to 'maintain the momentum' established by the *Think Kidneys* programme to improve systems of safety within and across organisations.(NHS England 2017)

Through collaboration with the UK Kidney Association (which represents the merger of The Renal Association, The British Renal Society and Affiliates) and the Kidney Patient Involvement Network, we will integrate our findings and develop recommendations for improvement across organisational, clinical team and patient levels of care within a series of participatory workshops with key stakeholders. We will also deliver a coherent logic model for service improvement and a set of indicators based upon routinely collected data to assess progress. Our approach will ensure recommendations feed into the NHS England Renal Services Transformation Programme.

Our proposal fits with the aspirations set out in the 2021 White Paper, *Integration and innovation: working together to improve health and social care for all*, as we focus on collaboration within integrated care systems, promoting innovation and enhanced data sharing.(Care 2021) In particular, we are aware that our planned qualitative work and structured deliberations will examine and consider improvement of post AKI care within primary, secondary and social care, which is the responsibility of the evolving integrated care systems.(England 2019, Care 2021) In doing so, it builds on recognition that AKI is an important 'barometer of good basic clinical care' across NHS settings, particularly for vulnerable people living with complex health and social needs.(Blakeman, Harding et al. 2013, 2014, NHS England 2017)

3 THEORETICAL FRAMEWORK

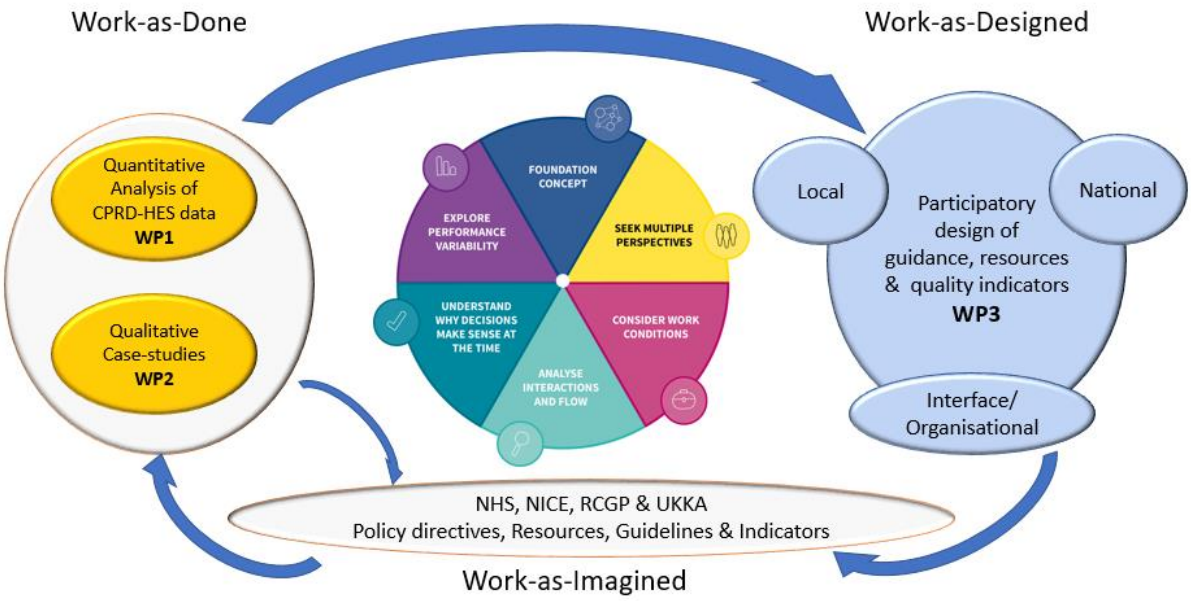
Our preliminary work conducted through the RCGP QI project and earlier collaboration (with DM) drew upon *Systems Thinking*.(Practitioners 2018, McNab, McKay et al. 2020) This framework is derived from the Human Factors approach to 'how safety is created in complex systems.'(McNab, McKay et al. 2020) It aligns with the complementary application of safety-I and safety-II perspectives to improve quality and safety in healthcare.(Holnagel E 2015) Recognising the emergence of AKI as a national priority to improve safety, through granular analysis and 'strategic co-design', Systems Thinking provides a relevant sensitising framework to align the study with the aims of the NHS Patient Safety Strategy: *Insight*; *Involvement;* and *Improvement*.(NHS and Improvement 2019)

We will draw upon the inter-related principles of Systems Thinking (Appendix E), founded on the basis that 'most healthcare problems and solutions belong to the system.'(McNab, McKay et al. 2020) As stated by Hollnagel (2018), Systems Thinking rejects the view that success and failure are fundamentally different in character.(Hollnagel 2018) Rather, it takes the perspective that 'individuals and organisations must adjust to the current conditions in everything they do.' These adjustments will always be approximate because 'information, resources and time always are finite.' Acceptable outcomes in terms of timeliness and precision of care are achieved through coordinated changes across different levels of healthcare (individuals, groups and organisations).(Ferlie and Shortell 2001) In contrast, unacceptable outcomes are 'due to a temporary or permanent inability to make those adjustments.'(Hollnagel 2018) We will be guided by the principles of Systems Thinking to strengthen the ability of patients, care providers and organisations to make adjustments to reduce unwanted variability in the delivery of post-AKI care.

A Systems Thinking framework recognises the need to seek multiple perspectives to understand system safety, consider the influence of prevailing work conditions (demand, capacity, resources and constraints), analyse interactions and work flow within the system, understand why professional decisions made sense at the time, and explore everyday work, including the adjustments made to achieve success in changing system conditions.(McNab, McKay et al. 2020)

We will apply the Systems Thinking principles to help integrate our quantitative (WP1) and qualitative (WP2) findings in examining the relationship between current recommended post-discharge AKI care ('work-as-imagined') and the everyday working practices undertaken by patients, care providers and organisations ('work-as-done').(Holnagel E 2015, McNab, McKay et al. 2020) Through multiple stakeholder (including patient and carer) participation (WP3), it will also provide a practical improvement framework for us to strengthen guidance, resources and quality indicators ('work-as-designed').(McNab, Freestone et al. 2018, Practitioners 2018, McNab, McKay et al. 2020) Both Figure 1 and Table 1 (pg.8) outline the linkage between the three work packages.

Figure 1. Systems Thinking to understand and improve post-discharge AKI care.



4 RESEARCH QUESTION/AIM(S)

Aim: To understand and target improvements in the quality of post-discharge care following AKI.

Research questions:

1. What factors are associated with variations in the implementation of recommended person-centred post-discharge AKI care?
2. How do patients, carers and healthcare staff experience post-discharge AKI care?
3. What opportunities exist to strengthen person-centred service delivery to prevent unplanned readmissions and improve cardiovascular outcomes following AKI?

4.1 Objectives

Work packages and objectives: We will address these questions through three linked work packages (WPs; Figure 1).

WP1. Analysis of population-based linked electronic health records (months 1-24) to address question 1 and objectives:

1a. To determine the extent of variations in post-discharge care of people with AKI according to recommended evidence-based practice.

1b. To identify patient and general practice characteristics associated with the implementation of post-discharge recommended care processes after AKI.

WP2. Qualitative case studies in six Integrated Care Systems (months 6-30) to address questions 1 and 2, and objectives:

2a. To understand patient, carer and healthcare staff experience of post-discharge AKI care pathways.

2b. To identify patient, professional and organisational factors that support or inhibit the implementation of person-centred, evidence-based post-discharge AKI care.

With linkage to WP1 findings, qualitative work will allow us to understand performance variability and assess aspects of care not amenable to measurement, using routinely collected data.

WP3. Participatory workshops (months 1-30) to address question 3 and objective:

3. To integrate findings from WPs 1&2 and develop practical recommendations for improvement at patient, clinician and organisational levels of care.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

5.1 WORK PACKAGE 1 (WP1). Analysis of population-based linked electronic health records (Months 1-24)

OBJECTIVES

1a. To determine the extent of variations in post-discharge care of people with AKI according to recommended evidence-based practice.

1b. Identify patient and general practice characteristics associated with the implementation of post-discharge recommended care processes after AKI.

DESIGN

This population-based cohort study will use linked electronic health records from the Clinical Practice Research Datalink (CPRD-Aurum), HES and ONS mortality records. CPRD Aurum contains anonymised health records covering 1375 GP practices from across England (March 2021 build) with over 13 million people currently registered with these practices. The cohort will cover a period from 3 years prior (1/1/17) until one year after (31/3/21) the onset of the COVID-19 pandemic and will enable an understanding of variation in post-discharge care following changes in health service design as a consequence of the pandemic.

Data include dates of clinical consultations, diagnoses, medicines prescribed and blood tests. Additional patient level linkages will be to HES for dates and diagnoses of hospital admissions and outpatient clinics, to ONS mortality records, and to small area measures of Index of Multiple Deprivation (IMD) based on patient residential postcodes.

Building on our earlier consensus studies and aligned with Systems Thinking methodology, WP1 will provide evidence on the variation in the delivery including timeliness of recommended post-discharge care processes.(Hollnagel 2018, Tsang, Murray et al. 2020) The findings will inform qualitative interviews conducted in WP2 to understand how patients, their carers and healthcare staff work to reduce unwanted variation as well as understand the boundaries to the everyday adjustments being made.(Hollnagel 2018)

METHODS

Study population: Study participants will be 18 years or over, with at least 1 year of continuous registration with the general practice before the study entry to ensure reliable measures of drug use and baseline covariates. Participants will be included in the study cohort based on a recorded hospital admission with AKI defined using International Classification of Diseases (ICD)-10 code, N17. N17 codes are highly specific covering the subset of AKI occurring among people in hospital which is recognised and diagnosed by healthcare professionals. We chose this approach because our analysis purposefully focuses on post-discharge care for people who have sustained AKI and that has been recognised in hospital, deemed clinically relevant and led to a clinical diagnostic code.(Health and (NCCID). 2017, Registry 2020) The study entry window will be from 1 January 2017 to 31 March 2021 (or the latest available data build), which includes a period during the COVID-19 pandemic.

AKI is a common complication of COVID-19, as we (NS) have shown in a retrospective cohort study in which AKI occurred in 26.2% of COVID-19 patients.(Kolhe, Fluck et al. 2020) The same study also demonstrated that AKI occurred in 12.4% of a contemporaneous cohort who did not have COIVD-19.(Kolhe, Fluck et al. 2020) As such, there is evidence that AKI is both a complicating factor of COVID-19 and that it also remains common in patients without COVID-19. The pandemic has had an impact on both kidney health and equitable continuity of health care such as limitations of access to post-hospital community blood test monitoring.(Chudasama, Gillies et al. 2020, Levene, Seidu et al. 2020) Accordingly, pre- and post-pandemic phases will be included within our analysis plan to evaluate the impact of COVID-19 for all people who have had a hospital admission complicated by AKI, with our analysis taking into account those who have and have not had COVID-19. Specifically, through analysis of population-based linked electronic health records, we will examine: i) changes to services delivery pre- and post-COVID-19 and ii) differences in post-discharge AKI care for patients hospitalised with and without COVID-19. A feasibility count of CPRD Aurum to inform our study plans has identified 340,917 adult patients (52.5% male, 47.5% female) with a record of AKI in HES Admitted Patient Care records during the period 01/01/2017- 31/12/2019. All of these patients were eligible for linkage to HES, ONS death data and IMD data.

Data collection-Indicators of evidence-based, person-centred care: Building on our leadership of national standards (Table 1; pg. 8) (NHS England 2016, Practitioners 2019, Tsang, Murray et al. 2020) and our NIHR CLAHRC-funded development of operational definitions,(Howard, Elvey et al. 2020) our post-AKI care indicators will include:

<u>For all people following discharge:</u>

- Clinical coding of AKI in the primary care electronic health record within 30 days.
- Consultation with healthcare professional within 30 and 90 days.
- Testing of blood pressure and essential blood and urine kidney tests to monitor for new onset CKD, CKD progression or kidney recovery.
- Avoidance of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs; known to be harmful to kidneys) on any prescriptions within 90 days.

<u>Subgroups:</u>

- Early consultation within 2 weeks for those with heart failure.
- Prescribing of ACE-inhibitor/ARB medication within 90 days where clinically indicated for heart failure, previous myocardial infarction, diabetes or hypertension with poorer kidney function, and CKD with proteinuria.
- Prescription of appropriate cardiovascular risk prevention medication (antiplatelet and lipid lowering) in accordance with NICE clinical guideline.(NICE 2014)
- Coding of CKD among those that have *de novo* CKD / non-recovery at 90 days.
- Long term monitoring of those who develop new onset CKD after AKI in accordance with NICE clinical guideline CG182: Additional monitoring of blood/urine/BP between 90-455 days among those without normal kidney structure/function.(National Institute for Health and Clinical Excellence (NICE) 2014)

Table 1. Summary of RCGP recommendations for post-discharge AKI care.(Practitioners 2019)

RCGP guidance **(Work-as-Imagined)**		Analysis **(Work-as-Done)**
Place AKI in clinical and social context	Before and after discharge, involve all patients (and where appropriate their carers) in planning follow-up care: ○ Timely clinical review of reason(s) for admission ○ Identify and address social needs ○ Understand AKI and the relevance of kidney health	WP2 WP1 WP2

	○ Ensure timely drugs review and kidney monitoring ○ Support during an acute illness	WP2 WPs 1&2 WP2
Tailored and timely review	Coordinate follow-up for all people following AKI with prompt and personalised care	WPs 1&2
Discharge hand over	Provide key information to support continuity & determine urgency of follow-up	WP2
AKI coding	Code AKI in general practice to manage future risk.	WP1
Optimise drugs management	Ensure clarity on why drugs were stopped/altered, e.g. avoid restarting NSAIDs	WPs 1&2
Drugs affecting renin-angiotension-aldosterone system	Identify patients with clinical indication for restarting inhibitors ACE-I/ARB (unless new contraindication): ○ Heart failure with reduced ejection fraction ○ History of myocardial infarction ○ Diabetes with albumin:creatinine (ACR) ratio >3 mg/mmol ○ Hypertension with ACR >30 mg/mmol ○ ACR > 70 mg/mmol irrespective of hypertension or cardiovascular disease	WPs 1&2 WP1 WP1 WP1 WP1 WP1
Heart failure	Ensure early post-discharge clinical review	WPs 1&2
Coordinate monitoring	Align kidney monitoring with existing long-term condition reviews	WP2
Urine ACR at three months	If albuminuria is present, development and/or progression of CKD should be monitored, coded, and communicated	WPs 1&2

We will also assess processes of care to inform care pathway analysis such as outpatient attendance, unscheduled A&E and repeat hospital admission within 90 days of discharge.

Data analysis: The care indicators cover different domains including clinical assessment, investigations and medicines management. These will be reported separately because levels of adherence may differ between domains. We will also describe adherence according to patient characteristics (age, sex, ethnicity, IMD quintile, COVID-19, evidence of multiple long-term conditions including key co-morbidities such as diabetes and heart failure).

We will calculate the proportion of patients meeting each indicator (with 95% confidence intervals) and variation in prevalence between practices will be quantified for each indicator using a mixed effects two level logistic regression model with patients nested within practices. We will derive intraclass correlation coefficients (ICCs) for each indicator. We will evaluate indicator achievement during phases before and after the COVID-19 pandemic to determine the impact of the pandemic on care among people leaving hospital. Overall N17 (hospital) coding is good, but there is variation; we may be able to specifically evaluate if there is a relationship between care and N17 coding rates. We further recognise there are likely to be missing data for our covariates of interest or processes of care. For the latter (processes of care), we are specifically focussed on recorded measures (e.g. blood pressure, renal function checks, etc.) so our outcome of interest is whether this is documented or not. That is, the presence or absence of recorded data in the primary care records for this patient population is of specific interest to us. The covariate which would be affected by missing data to a larger degree is ethnicity. However, we will be using a linked dataset from primary care and hospital records, with the latter greatly improving capture

of information on ethnicity.(Mathur, Bhaskaran et al. 2014) We have developed algorithms to categorise ethnicity from linked health records which have been applied in other studies.(Wright, Kontopantelis et al. 2017, Wright, Welsh et al. 2020) To inform WP2, we will use process mapping to identify patterns of care by providing a visual representation of healthcare utilisation and the most frequent journeys through a chain of events. It has previously been used to identify opportunities to improve cancer care.(Rinner, Helm et al. 2018) We will visualise the pathways of all care processes after discharge for those with and without AKI readmissions. From 12 months, these visualisations will feed into WP2 to inform areas of questioning to both help understand pathways and identify opportunities to improve care. Table 1 outlines recommended processes to be examined through WPs 1&2.

We are mindful that variation can be driven by artefacts within routine data; indeed, our team has developed a logic model approach to interrogating sources of variation.(Sawhney, Robinson et al. 2018) Our broad stakeholder input will further strengthen and contextualise our interpretation of findings. Through WP3, we will encourage robust debate of sources of variation identified in WP1.

5.2 WORK PACKAGE 2 (WP2). Qualitative case studies in six integrated care systems (Months 6-30)

OBJECTIVES

2a. To understand patient, carer and healthcare staff experience of post-discharge AKI care pathways.

2b. To identify patient, professional and organisational factors that support or inhibit the implementation of person-centred, evidence-based post-discharge AKI care.

DESIGN

We will conduct multi-perspective qualitative case studies in six integrated care systems (ICSs) in England. ICSs are 'partnerships that bring together providers and commissioners of NHS services across a geographical area with local authorities and other local partners, to collectively plan and integrate care to meet the needs of their population.'(Fund 2020) We plan to recruit one hospital trust within each ICS. We will also sample by primary care network (PCN). PCNs are key 'building blocks' in the NHS Long Term Plan to establish integrated systems of care.(England , England 2019, NHS England 2019, Fund 2020) They entail general practices in a geographical area, serving populations of 30-50,000, working together with other care providers including community, mental health, social care, pharmacy, hospitals and voluntary services.(Fund 2020) We recognise that PCNs are maturing in structure in their aim to 'enable greater provision of proactive, personalised, coordinated and more integrated health and social care.'(England , Checkland, Hammond et al. 2020, Fund 2020)

Informed by the principles of Systems Thinking, our approach will entail in-depth analysis of interviews with patients following an episode of AKI, their carers, and with care providers across primary and secondary care. Informed by findings from WP1, the qualitative case studies will illuminate relational mechanisms that influence the communication and coordination of timely and precise post-discharge AKI care. (Hollnagel 2018)

METHODS

Data sampling and recruitment:
We will recruit patients to participate in the research in one of two ways:

1. Via purposively sampling of organisations, patients and care providers.
2. Via the Kidney Patient Involvement Network (KPIN)

1.Organisations: Discussions with our UK Kidney Association AKI Special Interest Group (SIG) stakeholder panel, with linkage to the UK Renal Registry AKI Master Patient Index, will inform our sampling of hospital trusts and PCNs within a minimum of six integrated care systems. We plan to recruit

one hospital trust per ICS. We will sample hospital trusts according to: i) local initiatives to improve AKI care (AKI nurse specialists as 'change agents'; collaborative AKI QI with primary care) and ii) varying rates of emergency readmission within 30 days.(52) We will further purposively sample at PCN level for neighbourhood socioeconomic status and ethnic diversity.(Kidney and UK 2019) This approach takes into account our research findings (SF, PR) and the wider literature, which shows that AKI and CKD disproportionately affect people living in areas of high socio-economic deprivation.(Hounkpatin, Fraser et al. 2019, Hounkpatin, Fraser et al. 2020, Registry 2020, MacRae, Mercer et al. 2021) This disparity includes evidence of higher mortality rates within 30 days of AKI for people of working age.(Registry 2020)

Patients and carers: Clinical care teams at the selected hospitals will identify patients who meet the inclusion and exclusion criteria for the study (see Table 2). They will be asked to identify patients in hospital who have had an episode of care complicated by AKI or have a readmission within 30 days of a hospital admission complicated by AKI.

The study aims to consider AKI in the context of people living with multiple long-term conditions and social needs. Based on our previous research on multimorbidity, we will recruit an estimated 24 patients (about 6 per case study site) for qualitative longitudinal interviews (Daker-White, Hays et al. 2014, Morris, Kennedy et al. 2016, Hays, Daker-White et al. 2017) on their experiences of post-AKI discharge care. To achieve this, over the course of the study, hospital provider sites will be asked to identify patients who have a range of a) severities of AKI (i.e. AKI stages 1, 2 and 3), b) complex health needs (cardiovascular multimorbidity including heart failure and diabetes) and c) social needs (with and without family/carer support). In addition, recognising that the onset of multiple long-term conditions (multimorbidity) occurs 10-15 years earlier in highly deprived areas, to understand seek to address this NHS priority, we will ask hospital provider sites to purposively recruit patients of working age.(Sawhney, Tan et al. , Blakeman, Blickem et al. 2014, Practitioners 2018, Valtorta, Kanaan et al. 2018, Selby, Forni et al. 2020, Tsang, Murray et al. 2020) Our purposeful sampling of PCNs serving diverse and highly deprived areas (inner-city, post-industrial) will also help ensure that inclusion of people from underserved communities are reflected in samples of individuals within each site.(Research 2020) We will purposively recruit patients of working age living in deprived areas.

Table 2. Eligibility criteria for Qualitative Case Studies.

Inclusion criteria	**Exclusion criteria**
The main groups of people who will participate in Work Package 2 are: 1. Patients aged 18 or over who have had an episode of hospital care complicated by AKI or have had a readmission within 30 days of a hospital admission complicated by AKI and: b) who have been informed about their AKI by their hospital clinical team. 2. Healthcare professionals and carers connected with patients in Group 1.	1. People who do not fall within one of the two groups specified in A17-1. 2. People who are in receipt of palliative care. 3. People who lack capacity to consent. 4. Patients who have not been informed about their AKI. 5. Patients whose healthcare team deem the research would add distress/burden.

3. Recruitment of patients via KPIN

KPIN will help identify potential participants from established contacts they have in their network. This will involve emailing a study description to eligible participants in the network. Only eligible participants living in the ICS areas we have recruited will be eligible to participate.

Potential participants will be able to contact the researchers directly if are interested in participating via email or telephone. The research team will not have access to any personal information of participants contacted.

Health care professionals

We intend to recruit health professionals to be involved in interviews about their experiences of providing care for AKI patients.

We will do this in one of two ways:

1. With patient consent, we will contact the health professionals directly involved in their care (both in primary and secondary care) to participate in an interview;
2. We will contact health professionals across the ICSs recruited to participate in a focus group (or interview) about their experiences of AKI care. These interviews will not be directly linked to any patients recruited to interview.

Interviews with healthcare professionals

With participant consent, we will conduct interviews with health professionals involved in their care including those based in primary care (e.g. GPs, practice nurses, community matrons, pharmacists) and those in secondary care (e.g. doctors, AKI nurse specialists, pharmacists). With the patient participant's permission, local gatekeepers at the hospital provider site and the patient's registered general practice (e.g. Practice Manager) will help identify health professionals involved in their care. The research team will not have any other personal identifiable information of potential healthcare provider participants prior to direct contact from healthcare provider via a Consent to Contact reply slip.

Local gatekeepers at the hospital sites and the patient participant's general practice will identify potential healthcare professional participants from staff lists. The local gatekeepers will send an invitation letter (either via post or email) as well as copy of the participation information sheet and a Consent to Contact reply slip to potential professional interviewees. Consent will be sought to collect their: name; contact details; their role; place of work; gender; and age. The research team will correspond with the local gatekeepers. If the local gatekeepers do not receive a response within 10 days, a follow-up invitation via the local gatekeeper will be sent.

Focus groups across ICS

If patients do not consent to us approaching their GP or other health professionals OR their healthcare professionals do not consent to take part, we will approach other health professionals working across the ICS study sites to participate in a focus group to discuss their experiences of providing care for patients with an AKI. We will approach health professionals based within ICS areas already recruited so that we can compare experiences across different systems. We will work with the NHS trusts recruited to identify potential participants in the local area and they will continue to act as gatekeepers for recruitment. Once participants are recruited, we may also ask them to identify any other suitable participants in the local area and approach them to participate also (snowballing). If anyone wants to participate but does not to participate in a focus group or cannot attend the scheduled date, they will also be offered a one to one interview.

The total number of interviews and focus groups will depend on data saturation of emergent themes, though we estimate 1 to 2 care providers per patient and at least one focus group per ICS. Secondary care staff (e.g. AKI nurse specialists) are likely to be providing care for multiple patient participants. Where relevant we will conduct interviews with informal carers, mainly as patient-carer dyads. Informed by our PPIE discussions, patient accounts will be central to data collection and analysis.

In total, we anticipate conducting interviews with 24 patients (twice), 36 healthcare staff, and 12 carers. This equates to an anticipated 84-96 interviews (12 patient interviews; including 3 carer-dyads; and 9 healthcare staff at each of the six research sites).

Process of Consent:
Patients and carers: A member of the clinical care team at the hospital provider site will double check eligibility and determine an appropriate time to approach potential patient participants during their hospital admission.

With the patient's permission, a member of the clinical care team at the hospital provider site will present the study to the potential patient participant. The patient will be asked if they have a carer and if they wish their carer to be present a) during informed consent, and/or b) during the interview.

The member of the clinical care team will provide potential patient participants (and where necessary, carer participants) with the study information sheet, the consent form and a consent to contact form. With permission, the member of the clinical care team will then plan to revisit the patient (and carer where requested) at an agreed time the following day to discuss the study further. Again, they will double check timings before approaching the potential patient participant. The patient will have a minimum of 24 hours to decide whether or not to take part.

The member of the clinical care team will read through the participant information sheet with the patient (and carer where relevant) to ensure they have understood all the information. If interested in participating, the clinical care team at the hospital provider site will either a) then provide patient (and carer) contact details (via the consent to contact form) to the research team (via encrypted files sent via zendto.manchester.ac.uk) or b) if the research site has a GCP trained member of staff, they will take full consent and send the consent form and contact information to the research team. A copy of the consent form will be added to the patient's records.

For carer participants (where relevant), consent will be sought to collect their: name; contact details; and their relationship with the patient participant.

Patient and carer participants will be offered £25 in gift vouchers per hour as a token of thanks for participation in each qualitative interview. This is set out in the Participant Information Sheets for WP2.

The research team will not have any patient or carer details prior to receipt of a Consent to Contact reply slip provided separately by both the potential patient participant and (where relevant) the potential carer participant. At no time during the study will the research team have access to the patient participant's medical records.

A date will then be arranged for a first interview, which, is anticipated to take place within one month of hospital discharge. Pending patient participant consent, interviews with carers will be either conducted individually or as a patient-carer dyad.

On the day of the interview and before the interview takes place, the researcher will read through the consent form with the patient (and carer, where relevant) to ensure they have understood the relevant information and to ensure that consent is fully informed. As stated in the Patient Participant Information Sheet, consent will also be sought to obtain a copy of the patient's 'discharge summary record'. This will provide their: age; the reason(s) for their admission; a list of health conditions including details of your diagnosis of AKI; the name of their registered general practice; date of hospital admission (or readmission); and anticipated date of hospital discharge. This information will be requested directly from the clinical care team and will only be shared once consent has been taken from the patient. In accordance with University guidance provided by the Information Governance Team, all personal information will be shared via encrypted files shared via zendto (zendto.manchester.ac.uk).

Health professionals: We will conduct interviews or focus groups with health professionals including those based in primary care (e.g. GPs, practice nurses, community matrons, pharmacists) and those in secondary care (e.g. doctors, AKI nurse specialists, pharmacists).

We will recruit health professionals in one of two ways:

With the patient participant's permission, local gatekeepers at the hospital provider site and the patient's registered general practice (e.g. Practice Manager) will help identify health professionals involved in their care. The research team will not have any other personal identifiable information of potential healthcare provider participants prior to direct contact from healthcare provider via a Consent to Contact reply slip.Local gatekeepers at the hospital sites and the patient participant's general practice will identify potential healthcare professional participants from staff lists. The local gatekeepers will send an invitation letter (either via post or email) as well as copy of the participation information sheet and a Consent to Contact reply slip to potential professional interviewees. Consent will be sought to collect their: name; contact details; their role; place of work; gender; and age. The research team will correspond with the local gatekeepers. If the local gatekeepers do not receive a response within 10 days, a follow-up invitation via the local gatekeeper will be sent.

In keeping with NHS study support costs, GP and primary care staff will be reimbursed for their participation.

1. We will also work with local gatekeepers at hospital sites and the CRN to recruit health professionals across the ICS to participate in a focus group about their experiences of providing care for patients with an AKI. The local gatekeepers will send an invitation letter (either via post or email) as well as copy of the participation information sheet and a Consent to Contact reply slip to potential professional interviewees. Potential participants will be instructed to contact the research team if they are interested in participating. If interested in participating, the research team will send the PIS to the healthcare professionals via email and discuss the study over the phone with them. They will be invited to attend a focus group, however if this is not possible, they will be asked if they would prefer an interview. Audio recorded consent will be taken prior to the focus group/interview.

Focus groups will take place online using Zoom/Microsoft teams. Participants will be reminded that they should participate in a private space or use headphones if they are unable to. Specific patients will not be discussed in the focus groups and will instead follow a general approach to what happens in primary care when a patient is discharged with an AKI. No confidential information will be discussed. Participants will be reminded that although they can withdraw at any time, it may be difficult to withdraw their data up until that point from the recording.

In keeping with NHS study support costs, GP and primary care staff will be reimbursed for their participation.

Data collection:
We will generate a research archive for each case study site that enables qualitative comparative analysis of documents, interview transcripts and reflexive field notes.

Documents:
We will analyse integrated care system documents to familiarise ourselves with sites and to understand how they aim to translate AKI guidance into post-discharge pathways of care, particularly for those with multiple long-term conditions. These will include: organisational action plans developed in response to the NHS AKI Patient Safety Directive; policies focused on developing integrated systems of care; and local clinical guidance (e.g. AKI, heart failure, CKD, frailty, COVID-19).(NHS England 2016, Tsang,

Murray et al. 2020) We will develop summary documents, synthesising salient information to identify areas of disparity and alignment within and across the organisations for each case study site.

Interviews with patients and care providers:
To date, AKI research and quality improvement initiatives have largely examined organisational and provider working practices with little attention to exploring the everyday work undertaken by patients following hospital discharge. Our previous ethnographic research focused on hospital management of AKI and included eight patient interviews.(in and Manchester 2018) Informed by discussions with KPIN, WP2 is explicitly designed to address this gap with patient accounts central to data collection and analysis.

With consent, we plan to conduct two interviews with each patient participant. The first will aim to take place within 1 month of hospital discharge and the second within 3 to 6 months following discharge from hospital. On average, we anticipate interviews will last around 45-60 minutes and up to a maximum of 90 minutes. Where relevant we will conduct interviews with informal carers, with the option of patient-carer dyads.

Through an iterative process, we will map out the patient's journey with a particular focus on the discharge process and coordination of follow-up arrangements, communication of AKI in the context of living with other complex health and social needs (i.e. MLTC-M), medicine use (including stopping and restarting), dealing with episodes of acute illness, kidney care monitoring, and personal support networks including dealing with finances and employment.(Blakeman, Blickem et al. 2014, Practitioners 2019) The interviews will also enable consideration of a new primary care workforce (i.e. PCN pharmacists, social prescribing link workers, care coordinators) being introduced through the NHS Long Term Plan to support people living with complex health and social needs (MLTC-M).(England 2019, NHS England 2019) Recommended care processes (Table 1), findings from the RCGP Quality Improvement project(Practitioners 2018) and our emerging analysis of CPRD (WP1) will inform our areas of questioning. In particular, WP1 data, stratified according to pre- and post-COVID-19 time periods, will be presented to explore comparisons in the everyday work undertaken by patients and care providers to ensure timely and effective post-discharge care.

The interviews will either be conducted remotely via telephone or online (using Zoom or Teams), or face-to-face, in accordance to COVID-19 guidance. We will record reflexive notes throughout. We recognise that AKI is a marker of vulnerability and occurs more frequently in people with existing co-morbidities. This is reflected in our risk assessment forms, which will be used as dynamic documents to guide safe research practice. COVID-19 guidance will be discussed as a standing item at our regular research team meetings and our risk assessment and standard operating procedures will be updated accordingly.

Where available, to help ground the interviews in specific rather than general experiences, we will ask patients to refer to their hospital discharge summary. We will also ask participating GPs to re-familiarise themselves with the patient's care through a review of their medical records or by having the patient record open during interview. This will help direct areas of questioning to explore relevant mechanisms (e.g. care co-ordination) not readily captured through analysis of large-scale routine datasets such as CPRD (see Table 1). The research team will not have direct access to the patient's medical records.

Data analysis:
We will combine a thematic and narrative approach,(Riessman 1990, Morris, Kennedy et al. 2016) using complementary strategies that enable cross-case comparisons based on coding and segmenting of data to create themes, whilst also considering personal stories as holistic accounts.(Riessman 1990, Coffey A 1996)

To maintain a focus on strengthening service delivery, the Systems Thinking perspective will provide a relevant sensitising framework to guide our analysis of how patients, carers, clinicians, practice teams and organisations manage the quality and safety of post-discharge AKI care.(Holnagel E 2015, McNab, McKay et al. 2020) We will examine the relationship between current AKI aftercare guidance ('work-as-

imagined') and the everyday working practices ('work-as-done') surrounding care for people following a hospital admission complicated by AKI.(Holnagel E 2015, Bailey S 2019) Through constant comparison of patient, professional and organisational work, we will seek to understand the conditions that affect AKI care (demands, capacity, resources, and constraints), bottlenecks and blockages to effective AKI aftercare as well as efficiency-thoroughness trade-offs and workarounds that contribute to both successful and unsuccessful outcomes.(NHS and Scotland 2018, McNab, McKay et al. 2020)

In conjunction with WP1 findings, our Systems Thinking approach will enable us to better understand performance variability and its effects on outcomes. We will use the Functional Resonance Analysis Method (FRAM) to model the activities that people perform, the factors that influence these activities and how outcomes emerge from the performance variability of interacting activities.(Hollnagel and E 2012, Hollnagel 2018) We (DM) have previously used this approach in quality improvement work.(McNab, Freestone et al. 2018) The analysis will build on the process mapping exercise in WP1 to combine the understanding developed in WP2 of the relational factors that influence everyday work and the variability of key activities observed in WP1. In particular, we will consider the adjustments that patients, carers and care providers undertake to reduce unwanted variation concerning the timelines and precision of key functional activities (i.e. clinical review; medicines management; support daily living; monitoring of kidney health in context of living with multiple long-term conditions; support and care escalation during an acute illness).(O'Hara, Baxter et al. 2020) The FRAM will aid identification of contextual factors that influence these adjustments and, from this, we will identify strategies to improve AKI outcomes.

5.3 WORK PACKAGE 3 (WP3). Participatory workshops to integrate findings and develop practical recommendations for improvement (months 1-30)

OBJECTIVE

3. To integrate findings from WPs 1&2 and develop practical recommendations for improvement at patient, clinician and organisational levels of care.

DESIGN

WP3 will be aligned with the structure for the NHS Patient Safety Strategy: *Insight*; *Involvement;* and *Improvement*.(NHS and Improvement 2019) Our scaled-up research entailing granular analysis of quantitative (WP1) and qualitative (WP2) data will provide *insights* into current pathways of post-discharge AKI care. We will work through structured deliberations in participatory workshops to guide our work, interpret our findings and develop practical recommendations to improve relationship-based care for people following AKI. The participatory workshops will *involve* patients, healthcare staff and improvement partners representing organisations within and across the interfaces of care (primary/secondary; health/social). The workshops will take place on five occasions throughout the study, face-to-face and online, in accordance with COVID-19 guidance. We will leverage our collective experience in quality improvement in this field and build upon previous work, particularly the *Think Kidneys* programme, the RCGP AKI toolkit and the Kidney Care UK self-management resources. Our deliberations will draw upon Systems Thinking (Appendix 2) as we consider and set out recommendations for sustainable *improvement* across organisational, clinical team and patient levels of care.(McNab, Freestone et al. 2018) This will entail a focus on strengthening systems to support the everyday adjustments that patients, care providers and organisations undertake to ensure timely and precise care.(Hollnagel and E 2012, Hollnagel 2018) Critically, we envisage WP3 and our dissemination strategy as a means to feed in and integrate our work within existing improvement collaborations.

METHODS

Sampling Participants:
Table 3 details the eligibility criteria for the stakeholder participatory workshops. Recognising a need to place AKI in context of care for people with MLTC-M, we will work with our stakeholder representatives

from both UK Kidney Association AKI SIG and the Kidney Patient Involvement Network (KPIN), to recruit a range of healthcare staff and managers from primary (GPs, healthcare assistants, pharmacists) and secondary care (nephrologists and AKI nurse specialists, medicine for the elderly, heart failure teams, surgical teams) as well as patients and carers with lived experience of AKI. Building on our involvement (SF, TB) in ongoing work to develop a roadmap towards embedding electronic Patient Reported Outcomes (ePROs) into routine care that takes into account MLTC-M, we will also ensure representation of expertise in the development of ePROs.(British, Society. et al. 2020) In keeping with our previous AKI consensus studies, we plan to recruit 10-12 individuals to participate in the workshops.(Blakeman, Griffith et al. 2016, Tsang, Murray et al. 2020)

Table 3. Eligibility criteria for qualitative participatory workshops.

Inclusion criteria	**Exclusion criteria**
The main groups of people who will be invited to participate in the workshops are: 1. Patient Representatives aged 18 or over who have had an episode of hospital care complicated by AKI. 2. Carer Representatives connected with patients who have had an episode of hospital care complicated by AKI. 2. Health professionals from primary (GPs, Pharmacists, Nurses, Care coordinators) and secondary care (Hospital doctors, nurses including AKI nurse specialists, Pharmacists, Care coordinators) involved in the care of people affected by AKI. 3. Policy makers, Commissioners and Managers involved in design of Integrated care Systems. 4. Professionals with expertise in Quality Improvement. 5. Professionals with expertise in data development and Information Technology including the development quality indicators and electronic Patient Reported Outcome Measures.	1. People who lack capacity to consent.

Participant's invitation process:
Potential participants will be first approached by a local gatekeeper at the UK Kidney Association secretariat, NHS England Renal Services Transformation Programme and the Kidney Patient Involvement Network (KPIN). They will email potential participants a generic information sheet, an invitation letter, and Consent to Contact reply slip with contact details of the research team, should they be interested in participating. Though co-investigators are members of these Associations, Programmes and Networks (Loughton, Selby, Lewington, Blakeman), for the purposes of this study, they will not access contact lists of members of the UK Kidney Association, NHS Renal Services Transformation

Programme, Renal GIRFT Programme or the Kidney Patient Involvement Network. The research team will not have any personal identifiable information prior to receipt of a Consent to Contact reply slip.

For potential patient and carer representatives, consent will be sought to collect their name, contact details, gender and age. For potential health professional participants, consent will be sought to collect their name, contact details, job role, place of work, gender and age. Only the research team at The University of Manchester will have access to this personal identifiable information. It will not be shared with anybody else, except for The University of Manchester's research governance office if they need to check that proper processes have been followed.

Patient and carer representatives will be offered £25 in gift vouchers per hour, up to £75 for half-day or £150 for a full day of participation in each workshop. This is set out in the Participant Information Sheets for WP3.

Data collection:
We plan to conduct 5 participatory workshops with a range of stakeholders over the course of the 30-month study (1 within the first 6 months; 1 at around 13 months; and 3 in the last 6 months of the study). Our deliberations will follow a sequence of steps but also allow for moving back and forward between steps as we gain deeper insights and challenge prior assumptions.

As with Work Package 2, the location of the workshops will be guided by COVID-19 guidance and will either be conducted online (using Zoom or Teams) or face-to-face. Pending COVID-19 guidance, we anticipate conducting two face-to-face workshops that will last between 4 to 6 hours and 3 online workshops that will be shorter in duration (approximately 90-120 minutes). Rules will be set and agreed with the group of participants at the beginning of the workshops.

Workshop 1 will take place early on in the project (month 3) to help refine our data collection and analyses for WPs 1&2. We will first consider what an idealised pathway of care would look like, starting with the *Think Kidneys* guidance for primary care and the RCGP Toolkit to support person-centred care and drawing upon collective experience.(NHS England 2017, Practitioners 2018) We will also draw on wider evidence concerning care transitions for vulnerable patient groups including older people with MLTC-M as well as consider care for people of working age.(Leppin, Gionfriddo et al. 2014, Le Berre, Maimon et al. 2017, Naylor, Shaid et al. 2017, Baxter, O'Hara et al. 2018, Murray, Hardicre et al. 2019, O'Hara, Baxter et al. 2020)

We will align our goals with UK Kidney Association AKI SIG following a recent meeting (March 2021), which proposed a future AKI quality improvement dashboard. Dashboard outcomes to support targeted AKI improvement under consideration include: 30-day mortality; length of hospital stay; duration of AKI; progression of AKI; and follow-up after AKI.(Silver, Harel et al. , Silver, Goldstein et al. 2015, Siew, Liu et al. 2020) Informed by our discussions with PPI partners, emergency re-admission to hospital within 30 days of discharge following an AKI episode is another such goal. Emergency admissions typically signal a major health-related event for patients and carers, incur significant healthcare costs, and can be measured efficiently using routine data. They are a common outcome of relevance to key patient groups including those with heart failure or palliative care needs. However, we will need to consider a range of goals that variously reflect policy, clinician, patient and carer priorities, e.g. chronic kidney disease incidence and progression, recurrence of AKI, number of hospital bed days, and mortality.

Workshop 2 will review early and emerging findings from WPs 1&2 (month 13), including WP1 data pertaining to the COVID-19 pandemic. We will consider the quantitative and qualitative findings relevant to each indicator of evidence-based, person-centred care, recognising that our qualitative work will provide insights around indicators not amenable to measurement using routinely collected data. At this point, drawing upon a wider evidence base, we will also familiarise the panel with our prototypical logic model and suggestions for practical ways of promoting implementation of recommended practice (Appendix 3).(Leppin, Gionfriddo et al. 2014, Le Berre, Maimon et al. 2017, Naylor, Shaid et al. 2017, Murray, Hardicre et al. 2019, O'Hara, Baxter et al. 2020) The logic model will evolve as our deliberations

progress. The model currently addresses discharge planning in hospital as well as aftercare for patients managed solely in the community, e.g.:

- identification of patients with AKI by a community-based clinical nurse specialist or care co-ordinator who liaises with patients, general practices and hospital teams to ensure tailored follow-up;
- an AKI aftercare plan stratified for key patient groups, including advice for patients (e.g. coping with acute illness) and for clinicians on treatment (e.g. re-introducing heart failure treatment, avoiding nephrotoxic drugs), and monitoring (e.g. blood tests);
- integration of resources, such as ePROs, to support a biopsychosocial approach to post-discharge communication and support signposting to relevant health and social resources (e.g. social prescribing to address loneliness);
- an automated algorithmic prompt within the electronic health record to allow real-time identification and stratified management of patients following AKI; and
- education and performance feedback for general practice teams, including identification of patients who require further action and reviews.

Workshops 3-5 will take place over a shorter period of time towards the end of the project (months 24, 26 & 28). We will review later more definitive findings from WPs 1&2 as we explore influences on the delivery of recommended care and levers for change at patient, clinical team, and organisational levels. We will consider each of these levers according to their relative impacts, amenability to change, or how any improvement strategies need to take account of them. We will explicitly draw upon Systems Thinking to bridge the analysis of our findings and potential solutions ('work-as-designed').(McNab, McKay et al. 2020) Data from WPs 1&2 will enable consideration of opportunities to tailor post-discharge AKI care according to existing multimorbidity (MLTC-M) as well as specific requirements for individuals with a history of COVID-19 infection. In doing so, WP3 will seek to strengthen the updated NICE COVID-19 guideline [ng191], which specifically refers to the Royal College of General Practitioners AKI Toolkit to support follow up.(Practitioners 2018, Excellence 2021) Through our sampling strategies, the practical recommendations will be sensitive and relevant to supporting care for people living in highly deprived areas.

We will initially generate (but not jump to) solutions for improving care, based on WPs 1&2 findings, our earlier survey of models of care, Systems Thinking and existing systematic reviews of interventions to change practice (e.g. collaborative care models, audit and feedback).(Foy, Hempel et al. 2010, Ivers N 2012) We will review each proposed solution against the six APEASE criteria of affordability, practicability, effectiveness, acceptability, safety and equity.(Michie and S 2014) We will then consider how coherently the most promising candidate solutions fit together and revise our logic model (Appendix F).

We will draft a set of practical recommendations for improving post AKI care defining actions required at patient, clinical team and organisational levels, and a suggested suite of indicators based on routinely collected data to assess progress towards defined goals.

We will share our penultimate logic model, draft recommendations and proposed suite of indicators with a wider group of stakeholders (e.g. RCGP, British Society for Heart Failure; wider membership of UK Kidney Association, British Geriatrics Society) and seek feedback, again using the APEASE criteria.(Michie and S 2014) We will finalise our logic model, recommendations and indicators in Workshop 5.

End of Study

The end of study will be when the analysis of data for all three Work Packages is complete, leading to a finalised logic model and recommendations. As stated in contractual agreements, a draft Final Report will be prepared within fourteen days of the completion date. The draft Final Report will be sent for external peer review with a Final Report and Final Report Summary, submitted within four weeks of receiving the reviewers' comments, unless otherwise agreed with the Authority. The end of study notification will be submitted to the HRA within 90 days of the end of study.

6 ETHICAL AND REGULATORY CONSIDERATIONS

The planned study entails 3 work packages focused on identifying, understanding and targeting variation in post-discharge care for people affected by acute kidney injury (AKI). Work Package 1 has been approved by the CPRD Independent Scientific Advisory Committee (Ref: 22_001760; 14.04.2022) Work Packages 2&3 require both HRA and NHS Research Ethics Committee review. An application for Work Packages 2&3 is being submitted via the Integrated Research Application System (IRAS).

Before the start of the study, favourable opinions will be obtained from the UK Health Department's Research Ethics Service (NHS REC) as well as via the Clinical Practice Research Datalink. Once approved:

- Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.
- Before any site can enrol patients into the study, the Principal Investigators will ensure that appropriate approvals from participating organisations are in place.
- All correspondence with the REC will be retained.
- It is the Principal Investigators' responsibility to produce the annual reports as required.
- The Principal Investigators will notify the REC of the end of the study.
- An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.
- If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.
- Within one year after the end of the study, the Chief Investigator will submit to the REC a final report with the results, including any publications/abstracts.

Summary of risks and burdens for consideration

Our planned approach to the research aims to ensure patient voice and experience are central to understanding and improving care for people following acute kidney injury. To achieve this, the study entails close collaboration with Patient and Public Involvement & Engagement (PPIE) partners as co-applicants (Loughton and Samuel) and the establishment of a PPIE working group through the Kidney Patient Involvement Network (https://kpin.org.uk/). Informed by discussions at PPIE meetings, the study design for Work Packages 2&3 take into account and seek to address risks and burdens to participants and researchers.

Risks and burdens to participants

Potential for distress:

We have established a PPIE working group to inform the design and conduct of the research. The PPIE working group will meet on a flexible basis every two months. This will provide an opportunity to iteratively inform interview questions and the design of workshops, helping to ensure that they minimise participant distress.

Awareness of AKI remains low and as such, information about acute kidney injury may cause distress for patients. We are aware that there are likely to be a range of approaches to communicating a diagnosis of AKI with a spectrum of understanding. Exploring communication and coordination of care for people affected by AKI is an important aspect of the study. However, this needs to be balanced against the risk of causing distress through disclosure of the diagnosis arising through the research rather via healthcare staff. Therefore, to reduce this risk, in keeping with our previous interventional (NRES Committee North West Greater Manchester Central reference: 11/NW/0855) and ethnographic (Wales REC 7 15/WA/0400) research focused on kidney care, we will only select and recruit patients who have already had the AKI diagnosis communicated to them by a healthcare professional during

their hospital admission. To minimise this risk, we will identify and approach potential patient participants during their hospital admission.

We recognise that AKI is a common clinical syndrome relevant to a range of patients, particularly those with multiple co-morbidities and potential complex health and social needs. With that, we recognise that potential patient participants are likely to be in the process of recovering from an episode of acute illness. As such, we need to balance sampling for diversity of need against the potential for research burden. Therefore, informed consent will be a staged process, providing multiple opportunities for potential patient and carer participants to consider participation in the study.

During recruitment and again, prior to interviews, potential patient participants will be asked if they have a carer and if they want their carer to be present during the interview. During interviews, the researcher will remain sensitive to the potential complex health and care needs experienced by patient participants. Building on our previous ethnographic research (Wales REC 7 15/WA/0400), the structure of the interviews supported by a topic guide is designed to be sensitive to these complexities and support a safe discussion about the patient's reflections (and carer's when relevant) concerning their episode of care.

A distress protocol will aid the interviews. It is the role of the researcher to minimise distress. If a patient becomes upset or distressed during an interview, the researcher will pause the interview. If the participant's emotional response is prolonged, the researcher will ask the patient if they would like to stop the interview and continue at another time.

Potential for inconvenience:
Informed by discussions with the Kidney Patient Involvement Network working group, a key objective is to ensure patient voice and experience are central to the research. However, this wider benefit must be balanced against our need to be sensitive to demands placed on individual patient participants. Patient participants may have experienced a severe episode of illness and researchers will remain aware that they could find interview participation exhausting. At all stages, interviewees will be reminded that participation is voluntary.

Risk of COVID-19:
To reduce risks to participants and researchers, we will ensure the study is conducted in accordance with Health Research Authority and The University of Manchester COVID-19 guidance. Recognising the changing nature of guidance, this will be a standing governance item for discussion at regular research meetings. A risk assessment form and a standard operating procedure will be used as dynamic documents to guide research practice.

Each consenting participant will be interviewed at a time of their choosing. Mode of interview will be informed by up-to-date COVID-19 guidance, which if available will include offering a telephone, online or face-to-face interview at a place of their choosing. Pending COVID-19 guidance, this could be at a university office or at the patient's home.

Confidentiality, privacy and disclosure:
We will adhere to Health Research Authority, The University of Manchester, GCP guidelines, data protection regulations and GDPR regulations. HRA guidance and the UK Data Service (https://www.ukdataservice.ac.uk/) guidance will provide a framework for balancing anonymisation whilst ensuring the qualitative data is beneficial. Steps have been considered and will be taken to ensure and monitor pseudonymisation, data minimisation, and anonymisation of direct and indirect personal identifiers (details outlined in the 'Data protection and patient confidentiality' section below). Members of the researcher team will not have access to patients' medical records and researchers will only have access to contact details for potential participants after they have given consent to be contacted by the research team. The research aims to identify, understand and target variation in post-discharge care for people affected by AKI. Through a Systems Thinking perspective, we are interested in how people and systems work to create safety, reduce unwanted variability and the factors that enable or hinder this being achieved. Most saliently, the interviews focus on specific clinical practices concerning post-

discharge care for people affected by AKI, where we already know there is scope for improvement. In doing so, the focus of the interviews and workshops are to support the development of service delivery, not to assess the performance of the individual practitioner/lay provider. However, there is a risk that participants may disclose instances of unsafe practice that put themselves or others at risk. We will discuss the boundaries to confidentiality with potential participants as part of informed consent.

If a patient discloses something that might put them at risk or someone else at risk, or if the researcher is concerned about the patient for any other reason, then the interviewer will discuss this with the research team which includes GPs, or contact another appropriate person directly (e.g. a relevant healthcare practitioner). The researcher will inform the patient and/or carer of the actions taken.

In deciding what action to take, we will use an 'escalator' system. The researcher will initially discuss any concerns with a clinical member of the research team. In all cases where we have any serious concerns, these will be communicated to patients' own GP or to another relevant health practitioner, by the senior clinical member of the team.

Risks to researchers

Health Research Authority and The University of Manchester health and safety guidelines, including lone work policies, COVID-19 guidance, and travel risk assessment will be followed by members of the research team. A risk assessment form has been developed which will act as a dynamic document for discussion at regular research team meetings. Researchers conducting the interviews and the workshops will be made aware of any health and safety risks involved in visiting other premises. Where possible, interviews will be arranged during normal working hours and researchers will travel to and from these meetings at reasonable times. In extremis, if an individual researcher perceives an immediate threat to their safety or wellbeing, they will withdraw from the study setting. In accordance with The University of Manchester guidance, travel risk assessments will be carried out in advance of visits to workshops or subsequent conferences to disseminate findings.

Lone working:

https://documents.manchester.ac.uk/display.aspx?DocID=13644

A lone working risk assessment will be carried out and included in the dynamic risk assessment document. In accordance with university guidance, measures will be put in place to ensure effective communication. These include:

- Establishment of a buddy system with a nominated buddy within the research team who is fully aware of the movements of the lone worker, having all necessary contact details for the lone worker, attempt to contact the lone worker if they do not contact the buddy as agreed, follow the agreed local escalation procedures for alerting their senior manager and Security if the lone worker cannot be contacted or if they fail to contact their buddy within agreed and reasonable timescales.
- Details of location and anticipated time of return left with a manager or colleague.
- Details of vehicles used by lone workers left with a manager or colleague, for example, registration number, make, model and colour.
- Regular contact with a manager or relevant colleague, particularly if they are delayed or have to cancel an appointment.
- Use of a mobile phone with GPS tracking.

Relevant members of the research team will undertake online training provided by The University of Manchester: Lone working training for Researchers (online).

Research governance issues will be a standing agenda item at regular research team meetings and will including monitoring implementation of a Lone worker action plan.

COVID-19:

https://www.hra.nhs.uk/covid-19-research/covid-19-guidance-sponsors-sites-and-researchers/#patients
To ensure the research team remain up-to-date, COVID-19 guidance for research will be a standing governance item at regular meetings.

HRA guidance will be followed to reduce the risk of potential exposure to COVID-19 for participants and researchers at the time of interview or workshop. For example, as necessary, changing from phone calls or online interviews to face-to-face meetings with appropriate infection prevention control measures. As with Work Package 2, the location of the workshops will be guided by COVID-19 guidance and will either be conducted online (using Zoom or Teams) or face-to-face.

Recognising that AKI is a marker of vulnerability and occurs more frequently in people with existing co-morbidities, to support inclusivity and reduce COVID-19 risks for members of KPIN AKI PPIE working group, we currently plan to hold PPIE meetings online. This is reflected in our risk assessment forms, which will be used as dynamic documents to guide safe research practice for participants, researchers and PPIE partners. COVID-19 guidance will be discussed as a standing item at our regular research team and PPIE meetings and our risk assessment and standard operating procedures will be updated accordingly.

Travel-risk:
The University of Manchester travel guidance will be followed when planning and conducting fieldwork as well as attending meetings and conferences to disseminate findings:

- Generic Risk Assessment for Low-risk fieldwork in the UK https://documents.manchester.ac.uk/DocuInfo.aspx?DocID=46071
- UK and Overseas travel to conferences to disseminate findings https://www.staffnet.manchester.ac.uk/compliance-and-risk/travel/flowchart/

Data protection and patient confidentiality

All investigators and study site staff will comply with the requirements of the Data Protection Act 2018 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

Work Package 1
This population-based cohort study will use linked electronic health records from the Clinical Practice Research Datalink (CPRD-Aurum), HES and ONS mortality records. Work Package 1 has been approved by the CPRD Independent Scientific Advisory Committee and is not a subject of the current application (Ref: 22_001760; 14.04.2022).

CPRD details how patient data is protected (https://cprd.com/safeguarding-patient-data). CPRD states (last reviewed 08/03/2022):

Collecting data from GP practices

- GP practices choose to share patient data (primary care data) with CPRD for public health research purposes.
- The Royal College of GPs and the British Medical Association are supportive of GP practices, sharing their data with CPRD.
- No information that can identify a patient is ever sent to CPRD.
- CPRD never receives any patient identifiers from a GP practice such as patient name, address, NHS number, full date of birth or medical notes.
- Because the patient cannot be identified from the data a GP practice sends to CPRD, the GP practice does not need to seek a patient's consent to share data with CPRD.

- The anonymised data CPRD receives includes clinical information such as diagnoses, symptoms, prescriptions and laboratory tests.
- Individual patients can opt-out of sharing their data for research. CPRD does not collect data for these patients.

Providing data for public health and medical research

- CPRD has ethics approval from the Health Research Authority to support research using anonymised patient data.
- CPRD must complete an annual NHS Data Security and Protection Toolkit assessment to demonstrate that it meets the required standard for holding data securely.
- Once CPRD receives anonymised data from a GP practice, we ensure the data is fully compliant with the Information Commissioner's Office (ICO) anonymisation code of practice and that patient privacy is protected.
- The identity of GP practices that have contributed data is concealed.
- The data CPRD holds can only be used for public health research.
- Only bona fide researchers can receive the data.
- Checks are conducted on organisations carrying out and funding the research to assess whether they are suitable to receive CPRD data.
- Requests by researchers to access the data are reviewed via the CPRD Research Data Governance (RDG) Process to ensure that the proposed research is of benefit to patients and public health.
- Researchers must adhere to robust terms and conditions governing how the anonymised data is used.

CPRD links data from GP practices in England to other datasets

The ability to link primary care data to other health datasets enables researchers to have a more complete picture of a patient's medical history. This information is used to support vital public health research such as studies into the safety of medicines, causes of disease or improving delivery of care.

The datasets that are linked to CPRD primary care data include hospital data and data from disease registries such as the Cancer Registry. When CPRD receives these datasets, they have already been anonymised. The linkage process involves the following:

- Each year CPRD must obtain Section 251 regulatory support through the Health Research Authority Confidentiality Advisory Group to enable data linkage to take place.
- A GP practice must give permission for primary care data from their practice to be linked to other datasets.
- Linkage is carried out via NHS Digital, the statutory body in England legally permitted to receive identifiable patient data.
- NHS Digital receives and processes identifiable patient data on behalf of CPRD and only sends anonymised data to CPRD.
- For NHS Digital to be able to link the data, a patient's NHS number, full date of birth, postcode and gender, together with a pseudonym for each patient, are sent from the GP practice directly to NHS Digital. No clinical primary care patient data is sent to NHS Digital.
- NHS Digital receives a similar set of patient identifiable data for the other datasets to be linked.
- The patient identifiers from the two datasets are matched to generate a de-identified linkage file that does not contain any of the original patient identifiable information.
- NHS Digital sends the de-identified linkage file to CPRD which allows CPRD to link the two datasets without needing any patient identifiable data.
- CPRD never receives patient-identifiable data from GP practices or from NHS Digital or from any other source.

- All requests from researchers to gain access to linked data must be approved via the CPRD Research Data Governance (RDG) Process.
- The anonymised linked data can only be used for public health research by bona fide researchers.

Data storage and processing

The data will be stored in The University of Manchester Research Data Storage Service. This is an access-restricted data share on The University of Manchester network storage infrastructure, which is the recommended location for storing sensitive or critical university data. The data will be processed on The University of Manchester interactive Computational Shared Facility (iCSF), which is a service designed specifically for interactive computationally-intensive work. The iCSF is only accessible on campus and exists on a private network. All data processing is done on the iCSF and no raw data will be transferred out. The workstations used for accessing the iCSF environment do not directly access the data. Access is via Virtual Desktop Infrastructure (VDI) technology to ensure the data is only processed within and never leaves the virtual environment. No remnants of the data are ever stored on the user device through mechanisms such as temporary files or browser caches. A valid university IT account is required to login to the iCSF. Account credentials are unique to each member of staff and only the account owner knows the password.

Work Packages 2 & 3

Informed by Health Research Authority (HRA) guidance, we will implement safeguards to ensure personal data is processed securely and accurately. We will adhere to the research data management plan and policies of The University of Manchester, GCP guidelines, data protection regulations and GDPR.

Only members of the research team at The University of Manchester will have routine access to participants' personal data. 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.

Personal data will be held in locked filing cabinets and on secure university computer servers that will be password protected at both computer and file level. This data will be held separately from the primary research data stored on the Research Data Storage system.

Safeguards:

Confidentiality of personal data will be considered at all stages of the research:

1) Recruitment:

Potential patient participants for WP2:

Only members of the clinical care team at the hospital provider sites will have access to patient records to identify and conduct an eligibility check on potential patient participants. The research team will not have access to personal identifiable information of potential patient participant prior to informed consent or receipt of a Consent to Contact reply slip.

Potential carer participants for WP2:

Potential carer participants will be identified at time of consent by the clinical care team during the patient's hospital admission and/or during interview with a member of the research team. Potential carer participants will be provided Patient Information Sheet and a Consent to Contact reply slip. Members of the research team will not have access to potential carer participant's personal identifiable information prior to receipt of a Consent to Contact reply slip.

Potential healthcare professional participants for WP2:

With patient participant consent, in addition to carers, we will conduct interviews with health professionals involved in their care including those based in primary care (e.g. GPs, practice nurses,

community matrons, pharmacists) and those in secondary care (e.g. doctors, AKI nurse specialists, pharmacists). Local gatekeepers at the hospital sites will be in place to identify potential healthcare professional participants from staff lists, including lists of general practices. The local gatekeepers will send an invitation letter (either via post or email) as well as copy of the participation information sheet and a Consent to Contact reply slip. Members of the research team will not have access to potential participant's personal identifiable information prior to receipt of a Consent to Contact reply slip.

Potential participants for WP3:
Potential patient, carer and health professional workshop participants will be identified and approached by local gatekeepers from key stakeholder organisations including the UK Kidney Association AKI Special Interest Group, the Kidney Patient Involvement Network (KPIN), the Renal GIRFT Programme and NHS England's Renal Services Transformation Programme (see Appendices 26 & 27). The research team includes members of the Kidney Patient Involvement Network (Loughton), UK Kidney Association (Selby, Lewington) and NHS England Renal Services Transformation AKI Workstream (Blakeman). Whilst this helps ensure patient, public and professional engagement in the study, this needs to be balanced with a maintenance of confidentiality. To achieve this, for the purposes of the study, named individuals (Loughton, Selby, Lewington and Blakeman) will not access registers containing personal information of members of the Kidney Patient Involvement Network (KPIN), the UK Kidney Association or NHS England Renal Services Transformation Programme. Instead, other members of the Kidney Patient Involvement Network, the secretariat of the UK Kidney Association and Leads for both NHS England Renal Services Transformation and Renal GIRFT Programmes will act as local gatekeepers and will be responsible for accessing and sending expressions of interest to potential stakeholder participants. Members of the research team will only have access to personal information on receipt of email or reply slip from potential stakeholder participants.

For both Work Packages 2&3, electronic personal identifying information will be encrypted and stored on a password-protected secure shared areas of The University of Manchester servers (Research Data Storage System). Databases will be password protected at both computer and file level. Personal identifying information will be held separately from the primary research data and will only be accessible to members of the research team at The University of Manchester.

Identifiable paper-based personal data listed above will be stored in a locked filing cabinet at the Centre for Primary Care and Health Services Research at The University of Manchester.

2) Data collection:

a) Qualitative interviews and Participatory Workshops
In line with The University of Manchester guidance, should verbal consent need to be audio recorded, then the researcher encrypted digital recording will be generated as a separate file to the interview data. This consent file will be stored separately from the rest of the data generated for the study. (https://www.staffnet.manchester.ac.uk/rbe/ethics-integrity/ethics/app-prep/),

Following informed consent, interviews and workshops will be audio-recorded onto an encrypted university-provided device or use of secure online platforms (Zoom, Teams) in accordance with university guidance (https://documents.manchester.ac.uk/display.aspx?DocID=48888). Members of the research team will:

- Set up Zoom and Teams accounts using their staff email address and will not use a personal Zoom or Teams account.
- Apply the following settings before they commence meetings: use a password when scheduling new meetings, which will be sent to the interviewees in an email separate to the meeting invite; use Waiting room so that Zoom or Teams participants cannot join unless admitted by the researcher conducting the interview; and use a randomly generated link for each meeting and not use a Personal meeting ID.
- Seek consent to audio-record the interview.
- Ensure that only the researcher can make an audio-recording of the interview.

- Switch on the setting where only the host researcher can view the recordings.
- Look to save the audio-recordings to the cloud where possible rather than recording locally.
- Recordings saved to the cloud will be deleted after 30 days so we will ensure that the recording is downloaded and saved onto allocated The University of Manchester Research Data Storage.

Devices used to make the recording will never be left unattended and will be locked away securely when not in use. Recordings will be transferred from the recording device to university storage as soon as possible to ensure that a master copy is backed up and the file is encrypted. Recordings will be checked once transferred and before deleting from the recording device. Audio-recordings that contain personal data will not be shared with other organisations.

The encrypted digital recordings will be labelled with a participant/study identification code (study ID) so the individual cannot be identified.

The encrypted audio-files will be sent for verbatim transcription via The University of Manchester Dropbox service (or alternative secure data management systems used by the selected The University of Manchester approved transcribing agency).

- Pseudonymisation of data: For both interviews and workshops, all participants will be allocated reference numbers, which will be applied to all data including field notes, audio-recordings, interview transcripts and analytic notes. Only university desktop computers and university laptops will be used. Data will be encrypted and uploaded onto a secure university server. The data will be managed within NVivo QR within our allocated The University of Manchester Research Data Storage.

- Data minimisation: During audio-recordings of interviews and in keeping with The University of Manchester's 'Procedure for the security of voice recordings', we will take steps to reduce the collection of unnecessary direct (e.g. names, postcode) and indirect personal identifiers (e.g. workplace, name of hospital setting). During interviews, the member of the research team will refer to the reference number of the participant at the start of the interview. Interview and Workshops participants will be informed not to refer to people's or places' names. However, as stated above, in instances when this occurs, interview transcripts will be checked and anonymised with removal of direct and indirect identifiers.

  Demographic data, including a list of health conditions, is important to place the findings in the context of understanding and improving care for people with complex health and care needs affected by AKI. With that there is also a need to only collect information relevant to the research questions and avoid unnecessary data collection (e.g. data minimisation in collecting Age instead of Date of Birth). Balancing these benefits and risks, personal data relevant to the study includes: contact details, age, gender, details of registered general practice, name of hospital consultant, date of hospital admission (or readmission), date of hospital discharge, reason(s) for admission, AKI severity, list of existing health conditions. With informed consent, the hospital clinical care team will provide this personal data or, if consent takes place following discharge, will be collected prior to the audio-recording of the interview by the researcher.

- Anonymisation of data: Interview and workshop transcripts will be checked and any direct or indirect personal identifiers will be removed.

Completed consent to contact forms, consent forms and the patient's discharge summary record (which includes admissions and discharge dates, AKI diagnosis and list of other long term conditions) will be shared between University and NHS sites via encrypted files uploaded to zendto only. Once received, the information will be downloaded, pseudonymised and saved to RDS. The original files will be deleted. Only personal data will be shared following patient consent.

Only data that has been pseudonymised will be transferred to co-investigators external to The University of Manchester. The University of Manchester Dropbox Service or Zendto service (https://zendto.manchester.ac.uk/) will be used to transfer data to co-investigators external to The University of Manchester. Data will be encrypted before storing on the service.
http://www.itservices.manchester.ac.uk/ourservices/catalogue/commscollab/sec/

b) Documents: To gain greater familiarity with each study site (4 integrated care systems) and to understand how organisations are translating AKI guidance into post-discharge pathways of care, we will analyse hospital and primary care organisational action plans and guidance documents developed in response to the NHS AKI Patient Safety alert. Only publicly available policies and guidance documents will be accessed for analysis.

3) *Dissemination:*
Published results will refer only to participants by code or pseudonym. Direct and indirect personal identifiers will be removed from transcripts and will not be presented when publishing results.

For all participants, consent will be sought as to whether they are willing for their contact details to be retained by the research team, in order to provide them with a summary of the findings of this study.

Consent and Transparency:
In accordance with university guidance, the personal information collected is listed in the Participant Information Sheets.

The UK Data Service (https://www.ukdataservice.ac.uk/manage-data/legal-ethical/anonymisation/qualitative.aspx) - guidance on best practice - will provide a framework for balancing anonymisation whilst ensuring the qualitative data is beneficial. During the consent process, we will plan and agree with participants our approach to data collection, data storage and data sharing.

With consent and where available, to help ground the interviews in specific rather than general experiences, if available, we will ask patient participants to refer to their hospital discharge summary. We will ask participating GPs to re-familiarise themselves with the patient's care through a review of their medical records or by having the patient record open during interview. We will also encourage participating GPs to use the Royal College of General Practitioners' (RCGP) AKI case note review templates to aid their reflection in advance of the interview (https://www.rcgp.org.uk/clinical-and-research/resources/toolkits/acute-kidney-injury-toolkit.aspx and see also summary of topic guide). Participant reference to the discharge summary and their medical records will help direct areas of questioning to explore relevant mechanisms (e.g. care co-ordination). However, the research team will not have access to the patient's medical records and will not collect RCGP AKI case note review forms generated by participating GPs. As stated, we will anonymise the transcripts to remove direct and indirect identifiers.

***Data protection impact assessments*:**
In keeping with The University of Manchester guidance, we will adhere to The University of Manchester's Standard Operating Procedure for 'Taking recordings of participants for research projects.' This will inform a safeguard checklist log to ensure a secure process for each individual participant. We will also keep an audit trail of all study documentation relating to the research process and the management of the research process within our allocated Research Data Storage. We will ensure that the safeguard checklist is a standing governance item during regular research team meetings.

We will follow The University of Manchester's Standard Operating Procedure for incident reporting (https://documents.manchester.ac.uk/display.aspxDocID=15678).

Incidents where audio-recordings or transcripts have not been anonymised, are lost, stolen, corrupted, or disclosed to or accessed by unauthorised persons, will be reported to the Head of Information Governance at the University of Manchester (infosec@listserv.manchester.ac.uk; 0161 275 7789) as soon as possible in order that appropriate measures can be taken to contain any damage and minimise the harm which might arise.

Data storage
Dr Tom Blakeman (Principal Investigator) at The University of Manchester will act as data custodian.

Personal data will be stored in accordance with The University of Manchester Information Governance Office Records Retention Schedule. We are required to keep copies of consent forms for this study for a period of 5 years from the end of the study. Audio consent recordings will be retained for the same period as the hard copy consent forms. Once retention is reached, we will securely delete the person identifying information.

Contact details will be destroyed as soon as they are no longer needed. For all participants, consent will be sought as to whether they are willing for their contact details to be retained, in order to provide them with a summary of the findings for this study.

Storage of research data will be managed in line with The University of Manchester's Research Data Management Policy including the Information Governance Office Records Retention Schedule (last modified 27/08/2020):

- Research data will be stored for a minimum of 5 years after publication of the study. Informed consent will be sought from potential participants for research data to be stored for this period.
- Research management documentation will be stored for 6 years after closure of the project account.
- Research outputs, including final versions of publications and presentations arising from research, will be stored for 6 years after closure of the project.

The dataset will be stored within the Research Data Management Service at The University of Manchester. We will seek informed consent for anonymised data to be used to support other research in the future and that it may be shared anonymously with other researchers. This will be made explicit on the consent form.

Indemnity
The University of Manchester has insurance available in respect of research involving human subjects that provides cover for legal liabilities arising from its actions or those of its staff or supervised students. The university also has insurance available that provides compensation for non-negligent harm to research subjects occasioned in circumstances that are under the control of the university.

Access to the study dataset
Only members of the study team will have routine access to participants' personal data. 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.

Though the research team will carry out data minimisation, interview and workshop data are still likely to include direct and indirect personal identifiers. This data will exist as digitally recorded audio-files and as electronic transcript files. The audio-files will be transferred to a university approved professional transcribing agency via The University of Manchester Dropbox service (or alternative secure data management systems used by the selected university approved transcribing agency).

Members of the research team at The University of Manchester will access the files for the purposes of data management and analysis. To support data analysis, only anonymised encrypted versions of the interview and workshop transcripts will be made available to other members of the research team, external to The University of Manchester, including members of the Kidney Patient Involvement Network AKI PPIE working group.

7 PEER REVIEW

The research was submitted for NIHR Health and Social Care Delivery Research (HSDR) Programme funding. HSDR NIHR peer review entails a staged process with the protocol strengthened in response to feedback from the funding panel.

The study was approved for NIHR HSDR funding on the 21st of July 2021.

8 PATIENT & PUBLIC INVOLVEMENT/ENGAGEMENT

We will establish a Kidney Patient Involvement Network AKI Working Group (KPIN), which will meet on a regular and flexible basis (see Study Flow Chart). The study is aligned with the key objectives of KPIN, which include the embedding of patient and carer voice and experience into the planning, delivery and evaluation of health and care services. KPIN was one of 10 Test Bed Projects to support implementation of the UK Standards for Public Involvement. Building on experiences gained, the standards will provide a structure for our strategic approach to PPIE:

- Our governance framework for working together will entail a small working group comprising KPIN patient members and members of the research team (Loughton, Samuel, Blakeman, Sanders & Foy). Through distributed PPI leadership, the working group will provide a safe space that encourages and respects all participating voices. Minutes of meetings with agreed actions will enable shared accountability.
- As PPI co-investigators, Loughton (KPIN) and Samuel (PPI Leeds) will help ensure inclusive opportunities for both kidney care specific and generic 'system' experiences to be considered throughout the study. Recognising AKI affects a range of people with complex health and social needs, the group will consider sampling strategies to include people from diverse populations with high levels of patient need. We will also work to ensure use of venues for meetings are accessible and COVID-19 safe as well as assist with teleconferencing to ensure inclusivity.
- The working group will be supported by established KPIN training resources. This will ensure support and learning for members of the working group as well as future participants involved in the stakeholder workshops (WP3).
- KPIN is a network of organisations, charities and individuals. Embedding the study within existing KPIN infrastructure will enable us to engage with a range of stakeholders, enabling communication of planned workshops and development of key recommendations. In doing so, the study will strengthen reciprocity and help cement the centrality of patient and carer voice.
- The Guidance for Reporting Involvement of Patients and the Public (GRIPP2) template will support reflective practice and help us evaluate the impact of our approach to embedding PPIE into research designed to understand and improve service delivery.

The PPIE working group will meet on a flexible basis, every two months throughout the course of the study, with agreements for the PPIE group to:

- Determine a final set of relevant process and quality indicators to examine during our analysis of electronic health records (WP1).
- Inform sampling and recruitment of organisations and participants (WP2) - iteratively inform interview questions and discuss emergent findings (WP2).
- Interpret findings from WPs 1&2 to inform participatory workshops (WP3).
- Participate and support wider engagement in the participatory workshops (WP3).

- Shape the development, integration and dissemination of person-centred guidelines and resources into routine practice as well as inform AKI improvement strategies including the development of an AKI quality improvement dashboard (WP3).

Guided by NIHR INVOLVE guidance, we have costed PPIE activities:

- PPIE Activity #1: Steering/Management Group - Co-facilitated by Loughton and Samuel, we have costed for up to six members of the KPIN AKI working group to meet every two months over the course of the 30-month study. Pending COVID-19 guidance, we have costed for a blend of online and face-to-face meetings.
- PPIE Activity #2: We have costed for PPIE representation at the five participatory workshops (WP3) over the study duration, which, pending COVID-19 guidance, will entail 3 one-day online and 2 face-to-face meetings.
- PPIE Activity #3: We have costed PPI roles in the dissemination at 4 local events and 4 national conferences including UK Kidney Week, Royal College of General Practitioners, Society for Academic Primary Care Annual Scientific meetings and Health Services Research UK annual conference. We have also costed production of PPIE outputs entailing creative engagement.

9 PROJECT MANAGEMENT

Blakeman will be the overall strategic lead but will work closely with Foy as the co-lead. Through joint responsibility and mentoring, Blakeman will continue developing his leadership abilities and capitalise upon Foy's experience. Blakeman will secure the required ethical and research governance approvals prior to the project start and then coordinate with Leads and the research fellow for WP1, the research associate for WP2, and the research fellow for WPs 2&3. Administrative and communications support will be provided within the Centre for Primary Care and Health Services Research at The University of Manchester.

The Project Management Team, comprising all applicants, the research fellows and research associates, will meet monthly. Work package teams will meet regularly according to project needs and comprise:

- *WP1. Analysis of population-based linked electronic health records*. Ashcroft will lead and manage the WP1 research fellow with further data science, epidemiological and clinical input from Fraser, Sawhney, Roderick and Selby.
- *WP2. Qualitative case studies in six integrated care systems*. Blakeman and Sanders will co-lead and manage the qualitative research associate and fellow, with Samuel and Loughton guiding our focus on patient and carer perspectives, McNab on organisational aspects, and Lewington, Selby, Fraser and Roderick supporting recruitment at sites.
- *WP3. Participatory workshops to integrate findings and develop practical recommendations for improvement.* Foy will lead with support from the qualitative research fellow, with WP1 input from Ashcroft and WP2 inputs from Blakeman, Sanders, Loughton and Samuel. Campbell will support stakeholder engagement and the development of AKI quality indicators. McNab will lead on considering 'Systems Thinking' and Lewington and Selby on enabling national networking with input from other clinical team members.

As outlined under our PPI plans, we will convene a working group which will meet every two months and include KPIN patient members and members of the research team (Loughton, Samuels, Blakeman, Sanders and Foy).

A Steering Group including leads for UK Kidney Association AKI SIG (Murray) will meet quarterly with WP leads to oversee progress, advise on methodology and interpretation of findings, and guide our engagement and dissemination planning.

We will monitor progress and achievement of milestones and deliverables at the Project Management Team and Steering Group meetings.

10 DISSEMINATION POLICY

10.1 Dissemination policy

We will publish interim and final reports in accordance with the contractual requirements between the Secretary of State for Health and Social Care and The University of Manchester.

What do we intend to produce from our research? We will ensure dissemination of findings from each of the linked work packages throughout the duration of the study. Key outputs include:

Work Package 1 Outputs:
Work Package 1 (WP1) findings will: (i) explain variations in adherence to care indicators between practices using intraclass correlation coefficients; (ii) inform qualitative interviews (WP2) to help identify modifiable factors affecting implementation and vulnerable groups of people disproportionately affected by the COVID-19 pandemic; and (iii) inform participatory workshops (WP3) by demonstrating post-discharge AKI care quality indicators that can be widely harvested from routine electronic health record data to monitor and drive quality improvement.

Work Package 2 Outputs:
Our methodological approach to WP2 addresses current gaps in AKI research and will enrich understanding of relational mechanisms around the communication and coordination of post-discharge AKI care. WP2 will: (i) articulate the patient voice in care following AKI and strengthen the development and integration of kidney health resources developed by Kidney Care UK into routine practice; (ii) identify relational factors than enable or constrain implementation of recommended practice; and (iii) identify emergent quality and safety strategies across different levels of healthcare (I.e. individual, practice, system) to strengthen delivery of post-discharge AKI care ('work-as-designed').(McNab, Freestone et al. 2018, NHS and Scotland 2018, Practitioners 2018)

Work Package 3 Outputs:
Our plan is consistent with current policy directions set out in the 2021 White Paper, *Integration and innovation: working together to improve health and social care for all*, with its focus on collaboration within integrated care systems, promoting innovation, and enhanced data sharing. We will produce a coherent logic model for service improvement, which includes practical recommendations and a set of measures for assessing progress.

Working in partnership with the UK Kidney Association AKI SIG and with the Kidney Patient Involvement Network, our recommendations will further strengthen: (i) national guidelines including post-discharge care for people affected by COVID-19 complicated by AKI; (ii) the RCGP AKI toolkit and dissemination of Kidney Care UK self-management support resources; (iii) the development of a workforce designed to support the needs of people living with complex health and social needs (MLTC-M);(England 2019) and (iv) AKI quality improvement strategies to improve patient outcomes and reduce NHS costs. Our proposed suite of quality indicators will be fit for integration into the NHS Renal Services Transformation Programme, the development of the *Getting it Right First Time* (GIRFT) AKI Dashboard and the Quality Improvement Domain of the GP contract.(England 2019, NHS England 2019)

We will generate at least one open access, peer-reviewed output from each WP and tailor presentations for different audiences, e.g. the RCGP and Society for Academic Primary Care (for primary care), the UK Kidney Week and the American Society for Nephrology (for nephrology), and the Health Services Research UK (for service delivery and organisation).

How will we inform and engage patients/service user, carers, NHS, social care organisations and the wider population about our work? Our overall approach is based upon a 'push, pull, and linkage & exchange' framework:(Tetroe, Graham et al. 2008)

- Push, typically one-way dissemination of knowledge to research users. This includes our above outputs.
- Pull, stimulating a demand for knowledge amongst potential users. We have already started this process through discussions with various stakeholders (e.g. UK Kidney Association, Kidney Patients Involvement Network) in developing this proposal; our discussions suggest a strong appetite for rigorous research addressing how to improve post-AKI care.
- Linkage & exchange activities that bring researchers and interested parties together to discuss research needs, findings and plans. Our whole research team, our KPIN PPIE working group, proposed Steering Group and WP3 workshops will all enable interpersonal knowledge exchange. We deliberated on whether to develop a further professional reference group for this study but, rather than develop another 'new entity', we decided that we would have a greater impact with sustainable reach if we worked within existing networks (e.g. through participation in the UK Kidney Association AKI Special Interest Group).

How will our outputs enter the health and/or social care system or society as a whole? Building on our previous programmes of research and quality improvement, we have established collaborations with the UK Kidney Association AKI SIG and KPIN. Through ongoing regular working group meetings (see Flowchart), we will work with our collaborators to align and embed the research and its findings into routine health and social care.

What further funding or support will be required if this research is successful? Through support from the UK Kidney Association, we intend to maximise impact by feeding the findings into GIRFT and the NHS Renal Services Transformation Programme. We have also costed PPI resource to support the development of patient-centred resources. We will work with KPIN to further support dissemination.

What are the possible barriers for further research, development, adoption and implementation? We anticipate that we will face a number of challenges, despite our above knowledge exchange approach and plans to make our outputs freely accessible. We will mitigate key challenges as follows:

- Perceived lack of relevance of research – we will work with KPIN and with the UK Kidney Association AKI SIG to ensure we address their key questions and refine our messages;
- Poor fit of recommendations with NHS ways of working and resources – by drawing upon the APEASE principles to develop our recommendations;
- Competing priorities of service planners – by demonstrating the potential service and patient benefits of tackling post-AKI care and highlighting that we are offering solutions for the highlighted problems; and
- Competing priorities of research team members – by integrating protected time for knowledge exchange within our programme (e.g. WP3).

What do we think the impact of our research will be and for whom? We realistically understand that our research outputs need to be harnessed by national programmes (e.g. GIRFT) and local integrated care systems to improve patient care and outcomes at scale. We anticipate that our research will lead to:

- More patient-centred care at and beyond the point of discharge following AKI;
- Wider implementation of standards for best practice; and

- Improved short- and long-term patient outcomes, e.g. unplanned re-admissions associated with AKI, CKD progression and cardiovascular health.

How will we share with study participants the progress and findings of our research? We will produce summaries of key findings and suggestions for improvement tailored to each of the six integrated care systems taking part in WP2. We will make plain English summaries of our work available through our patient partner organisations.

10.2 Authorship eligibility guidelines

All co-investigators will be responsible for the final study reports. The International Committee of Medical Journal Editors (ICMJE) will guide authorship of peer-reviewed publications. The ICMJE recommends that authorship is based on the following 4 criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

11 REFERENCES

(2014). Donal O'Donoghue: Being a doctor is "a ball", BMJ. **349:** *g5497*

(NICE), N. I. f. H. a. C. E. (2013). Acute Kidney Injury: prevention, detection and management (CG169), NICE.

(NICE), N. I. f. H. a. C. E. (2014). Acute kidney injury Quality standard nice.org.uk/guidance/qs76, NICE.

Abdel-Kader, K., et al. (2018). "Acute Kidney Injury and Subsequent Frailty Status in Survivors of Critical Illness: A Secondary Analysis." Critical care medicine **46**(5): e380-e388.

Auerbach, A. D., et al. (2016). "Preventability and Causes of Readmissions in a National Cohort of General Medicine Patients." JAMA Intern Med **176**(4): 484-493.

Avery, A. J., et al. (2013). "The prevalence and nature of prescribing and monitoring errors in English general practice: a retrospective case note review." Br J Gen Pract **63**(613): e543-553.

Bailey S, H. C., Brisley A, Howard SJ, Sykes L, Blakeman T. (2019). "Implementation of clinical decision support to manage acute kidney injury in secondary care: an ethnographic study." BMJ Quality & Safety. Manuscript ID bmjqs-2019-009932.R2 [Accepted for publication 06 November 2019].

Bailey, S., et al. (2020). "Implementation of clinical decision support to manage acute kidney injury in secondary care: an ethnographic study." BMJ Qual Saf **29**(5): 382-389.

Bailey, S., et al. (2019). "Financialising acute kidney injury: from the practices of care to the numbers of improvement." Sociology of Health & Illness **41**(5): 882-899.

Bailey, S., et al. (2020). "Dismembering organisation: The coordination of algorithmic work in healthcare." Current Sociology **68**(4): 546-571.

Baxter, R., et al. (2018). "Partners at Care Transitions: exploring healthcare professionals' perspectives of excellence at care transitions for older people." BMJ Open **8**(9): e022468.

Blakeman, T., et al. (2014). "Effect of information and telephone-guided access to community support for people with chronic kidney disease: Randomised controlled trial." PLoS ONE **9**(10).

Blakeman, T., et al. (2016). "Development of guidance on the timeliness in response to acute kidney injury warning stage test results for adults in primary care: an appropriateness ratings evaluation." BMJ Open **6**(10): e012865.

Blakeman, T., et al. (2013). "Acute kidney injury in the community: why primary care has an important role." British Journal of General Practice **63**(609): 173-174.

Blunt, I., et al. (2015). "Classifying emergency 30-day readmissions in England using routine hospital data 2004-2010: what is the scope for reduction?" Emergency medicine journal : EMJ **32**(1): 44-50.

British, et al. (2020). Electronic

Patient-Reported Outcomes (ePROs) for the kidney patient community Online summit.

Brown, B., et al. (2019). "Clinical Performance Feedback Intervention Theory (CP-FIT): a new theory for designing, implementing, and evaluating feedback in health care based on a systematic review and meta-synthesis of qualitative research." Implementation Science **14**(1): 40.

Camin, R. M., et al. (2015). "Acute kidney injury secondary to a combination of renin-angiotensin system inhibitors, diuretics and NSAIDS: "The Triple Whammy"." Nefrologia **35**(2): 197-206.

Care, D. o. H. a. S. (2021). Integration and

Innovation: working together to improve health and social care for all.

Checkland, K., et al. (2020). "Exploring the multiple policy objectives for primary care networks: a qualitative interview study with national policy stakeholders." BMJ Open **10**(7): e038398.

Chudasama, Y. V., et al. (2020). "Impact of COVID-19 on routine care for chronic diseases: A global survey of views from healthcare professionals." Diabetes & metabolic syndrome **14**(5): 965-967.

Clark, A. L., et al. (2019). "Change in renal function associated with drug treatment in heart failure: national guidance." Heart **105**(12): 904.

Coffey A, A. P. (1996). Mak*ing*

sense of qualitative data: Complementary research strategies , Sage, London.

Daker-White, G., et al. (2014). "MAXimising Involvement in MUltiMorbidity (MAXIMUM) in primary care: protocol for an observation and interview study of patients, GPs and other care providers to identify ways of reducing patient safety failures." BMJ Open **4**(8): e005493.

Domain, N. E. P. S. (2016). Standards for the communication of patient diagnostic test results on discharge from hospital.

Ebah, L., et al. (2017). "A Multifaceted Quality Improvement Programme to Improve Acute Kidney Injury Care and Outcomes in a Large Teaching Hospital." BMJ Quality Improvement Reports **6**(1).

Elvey, R., et al. (2020). "Implementing post-discharge care following acute kidney injury in England: a single-centre qualitative evaluation." BMJ Open **10**(8): e036077.

England, N. Primary Care Networks.

England, N. (2014). Patient Safety Alert: Stage 3 Directive: Standardising the early identification of Acute Kidney Injury, NHS England.

England, N. (2019). The NHS Long Term Plan.

England, N. A. G. o. t. S. o. P. i. (2013). A promise to learn – a commitment to act. Improving the Safety of Patients in England, Department of Health.

Excellence, N. I. f. H. a. C. (2020). COVID-19 rapid guideline: acute kidney injury in hospital. NICE Guideline [NG175].

Excellence, N. I. f. H. a. C. (2021). COVID-19 rapid guideline: managing COVID-19. NICE Guideline [NG191], NICE.

Ferlie, E. B. and S. M. Shortell (2001). "Improving the quality of health care in the United Kingdom and the United States: a framework for change." Milbank Q **79**(2): 281-315.

Forster, A. J., et al. (2003). "The incidence and severity of adverse events affecting patients after discharge from the hospital." Ann Intern Med **138**(3): 161-167.

Foy, R., et al. (2010). "Meta-analysis: effect of interactive communication between collaborating primary care physicians and specialists." Ann Intern Med **152**(4): 247-258.

Francis, R. (2013). Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry. London, The Stationery Office.

Fund, T. K. s. (2020). Integrated

care systems explained: making sense of systems, places and neighbourhoods.

Fund, T. K. s. (2020). Primary Care Networks explained.

Glasziou, P., et al. (2013). "Too much medicine; too little care." BMJ : British Medical Journal **347**: f4247.

Greenhalgh, et al. (2010). Measuring

quality in the therapeutic relationship. London, The King's Fund.

Greenhalgh, T. (2014). "Future-proofing relationship-based care: a priority for general practice." British Journal of General Practice **64**(628): 580.

Group, K. D. I. G. O. K. A. K. I. W. (2012). KDIGO Clinical Practice Guideline for Acute Kidney Injury, Kidney International Supplement. **2:** 1-138.

Guthrie, B., et al. (2011). "High risk prescribing in primary care patients particularly vulnerable to adverse drug events: cross sectional population database analysis in Scottish general practice." Bmj **342**: d3514.

Guthrie, B., et al. (2012). "Adapting clinical guidelines to take account of multimorbidity." BMJ **345**.

Hays, R., et al. (2017). "Threats to patient safety in primary care reported by older people with multimorbidity: baseline findings from a longitudinal qualitative study and implications for intervention." BMC health services research **17**(1): 754-754.

Health, U. o. B. a. U. o. Y. and E. C. (NCCID). (2017). Development feedback report on piloted indicators

1st October 2016 – 28th February 2017

Hollnagel and E (2012). FRAM,

the Functional Resonance Analysis Method: Modelling Complex Socio-Technical

Systems. Farnham,

Surrey. Ashgate, UK England.

Hollnagel, E. (2018). The

Functional Resonance Analysis Method.

Holnagel E, W. R., Braithwaite J (2015). From Safety-I to Safety-II: A White Paper, Published simultaneously by the University of Southern

Denmark, University of Florida, USA, and Macquarie University, Australia.

Hounkpatin, H. O., et al. (2019). "The association of socioeconomic status with incidence and outcomes of acute kidney injury." Clinical Kidney Journal.

Hounkpatin, H. O., et al. (2020). "The association of socioeconomic status with incidence and outcomes of acute kidney injury." Clinical Kidney Journal **13**(2): 245-252.

Howard, S. J., et al. (2020). "Post-discharge care following acute kidney injury: quality improvement in primary care." BMJ Open Quality **9**(4): e000891.

in, N. I. f. H. R. C. f. L. and A. H. R. a. C. N. C. G. Manchester (2018). Improvement in context: An ethnographic study of quality improvement programmes for Acute Kidney Injury, NIHR CLAHRC GM.

Ivers N, J. G., Flottorp S, Young JM, Odgaard-Jensen J, French SD, O'Brien MA, Johansen M, Grimshaw J, Oxman AD. (2012). "Audit and feedback: effects on professional practice and healthcare outcomes." Cochrane Database of Systematic Reviews(Issue 6. Art. No.: CD000259.).

Karsanji, D. J., et al. (2017). "Disparity between Nephrologists' Opinions and Contemporary Practices for Community Follow-Up after AKI Hospitalization." Clinical journal of the American Society of Nephrology : CJASN **12**(11): 1753-1761.

Kerr, M., et al. (2014). "The economic impact of acute kidney injury in England." Nephrology Dialysis Transplantation **29**(7): 1362-1368.

Kidney and R. UK (2019). Kidney

health inequalities in the UK: An agenda for change. Peterborugh, Kidney Research Uk.

Kolhe, N. V., et al. (2020). "Acute kidney injury associated with COVID-19: A retrospective cohort study." PLoS Med **17**(10): e1003406.

Le Berre, M., et al. (2017). "Impact of Transitional Care Services for Chronically Ill Older Patients: A Systematic Evidence Review." J Am Geriatr Soc **65**(7): 1597-1608.

Le Berre, M., et al. (2017). "Impact of Transitional Care Services for Chronically Ill Older Patients: A Systematic Evidence Review." Journal of the American Geriatrics Society **65**(7): 1597-1608.

Leppin, A. L., et al. (2014). "Preventing 30-day hospital readmissions: a systematic review and meta-analysis of randomized trials." JAMA Intern Med **174**(7): 1095-1107.

Leppin, A. L., et al. (2014). "Preventing 30-day hospital readmissions: A systematic review and meta-analysis of randomized trials." JAMA Internal Medicine **174**(7): 1095-1107.

Levene, L. S., et al. (2020). "Pandemic threatens primary care for long term conditions." BMJ **371**: m3793.

Liano, F. and J. Pascual (1996). "Epidemiology of acute renal failure: A prospective, multicenter, community-based study." Kidney Int **50**(3): 811-818.

Lusignan, S., et al. (2013). "Audit-based education lowers systolic blood pressure in chronic kidney disease: the quality improvement in CKD (QICKD) trial results." Kidney Int **84**.

MacRae, C., et al. (2021). "Comorbidity in chronic kidney disease: a large cross-sectional study of prevalence in Scottish primary care." British Journal of General Practice **71**(704): e243.

Mathur, R., et al. (2014). "Completeness and usability of ethnicity data in UK-based primary care and hospital databases." J Public Health (Oxf) **36**(4): 684-692.

May, C., et al. (2009). "We need minimally disruptive medicine." BMJ **339**: b2803.

McNab, D., et al. (2018). "Participatory design of an improvement intervention for the primary care management of possible sepsis using the Functional Resonance Analysis Method." BMC Medicine **16**(1): 174.

McNab, D., et al. (2020). "Development and application of 'systems thinking' principles for quality improvement." BMJ Open Qual **9**(1).

Mehta, R. L., et al. "International Society of Nephrology's 0by25 initiative for acute kidney injury (zero preventable deaths by 2025): a human rights case for nephrology." The Lancet(0).

Michie and A. L. S, West R (2014). The

APEASE criteria for designing and evaluating interventions. In: The Behaviour

Change Wheel: A Guide to Designing Interventions. London, Silverback Publishing.

Michie, S. and M. Johnston (2004). "Changing clinical behaviour by making guidelines specific." Bmj **328**(7435): 343-345.

Morris, R. L., et al. (2016). "Evolving 'self'-management: exploring the role of social network typologies on individual long-term condition management." Health Expect **19**(5): 1044-1061.

Moynihan, R., et al. (2019). "Reforming disease definitions: a new primary care led, people-centred approach." BMJ Evidence-Based Medicine: bmjebm-2018-111148.

Murray, J., et al. (2019). "How older people enact care involvement during transition from hospital to home: A systematic review and model." Health Expect.

Nadim, M. K., et al. (2020). "COVID-19-associated acute kidney injury: consensus report of the 25th Acute Disease Quality Initiative (ADQI) Workgroup." Nature Reviews Nephrology **16**(12): 747-764.

National Institute for Health and Clinical Excellence (NICE) (2014). Chronic kidney disease. Early identification and management of chronic kidney disease in adults in primary and secondary care (CG182). London, NICE.

Naylor, M. D., et al. (2017). "Components of Comprehensive and Effective Transitional Care." J Am Geriatr Soc **65**(6): 1119-1125.

NHS and Improvement (2019). The

NHS Patient Safety Strategy: Safer culture, safer systems, safer patients.

NHS and E. f. Scotland (2018). Systems

Thinking for Everyday Work (STEW): A Safety & Improvement Model for

Healthcare.

NHS England, B. (2019). Investment and evolution:

A five-year framework for GP contract reform to

implement The NHS Long Term Plan.

NHS England, N. I., Think Kidneys (2016). Resources to support the care of patients with acute kidney injury, NHS England.

NHS England, U. R. R., Think Kidneys (2014). Understanding what the public know about their kidneys and what they do. Findings from Ipsos MORI survey – July 2014, Think Kidneys.

NHS England, U. R. R., Think Kidneys (2016). When or if to re-start ACEI, ARB, diuretics and other antihypertensive drugs after an episode of Acute Kidney Injury, Think Kidneys.

NHS England, U. R. R., Think Kidneys (2017). Think Kidneys National AKI Programme: Review and Evaluation Report, Think Kidneys.

NICE (2014). Cardiovascular

disease: risk assessment and reduction, including lipid modification [cg191].

O'Hara, J. K., et al. (2020). "'Handing over to the patient': A FRAM analysis of transitional care combining multiple stakeholder perspectives." Appl Ergon **85**: 103060.

of, R. C. and G. Practitioners Policy and

campaigning priorities 2020-23.

Omotoso, B. A., et al. (2016). "Acute kidney injury (AKI) outcome, a predictor of long-term major adverse cardiovascular events (MACE)." Clin Nephrol **85**(1): 1-11.

Ortiz-Soriano, V. and J. A. Neyra (2018). "The impact of acute kidney injury on frailty status in critical illness survivors-is there enough evidence?" Journal of emergency and critical care medicine (Hong Kong, China) **2**: 93.

Panesar, S. S., et al. (2016). "How safe is primary care? A systematic review." BMJ Qual Saf **25**(7): 544-553.

Parikh, C. R. and S. G. Coca (2019). ""Permissive AKI" with treatment of heart failure." Kidney Int **96**(5): 1066-1068.

Practitioners, R. C. o. G. (2018). Acute Kidney Injury Toolkit, RCGP.

Practitioners, R. C. o. G. (2019). Guidance
on the timeliness of post-discharge care for adults following acute kidney
injury.

Registry, U. R. (2020). Acute kidney injury (AKI) in England – a report on the nationwide collection of AKI warning test scores from 2018., UK Renal Registry.

Research, N. I. f. H. (2020). Improving inclusion of under served groups in clinical
research. Guidance from INCLUDE project, NIHR.

Research, N. I. f. H. (2020). NIHR strategic framework for multiple long-term
conditions (Multimorbidity) MLTC-M Research, NIHR.

Riessman, C. K. (1990). "Strategic uses of narrative in the presentation of self and illness: a research note." Soc Sci Med **30**(11): 1195-1200.

Rinner, C., et al. (2018). "Process Mining and Conformance Checking of Long Running Processes in the Context of Melanoma Surveillance." International journal of environmental research and public health **15**(12): 2809.

Ronco C, R. T., Husain-Syed F (2020). "Management of acute kidney injury in patients with COVID-19." Lancet Respir Med.

Salisbury, H. (2020). "Helen Salisbury: Is transactional care enough?" BMJ **368**: m226.

Sawhney, S., et al. (2017). "Acute kidney injury as an independent risk factor for unplanned 90-day hospital readmissions." BMC Nephrology **18**: 9.

Sawhney, S., et al. (2018). "Acute kidney injury in the UK: a replication cohort study of the variation across three regional populations." BMJ Open **8**(6): e019435.

Sawhney, S., et al. "Validation of Risk Prediction Models to Inform Clinical Decisions After Acute Kidney Injury." American Journal of Kidney Diseases.

See, E. J., et al. (2019). "Long-term risk of adverse outcomes after acute kidney injury: a systematic review and meta-analysis of cohort studies using consensus definitions of exposure." Kidney International **95**(1): 160-172.

Selby, N. M., et al. (2020). "Covid-19 and acute kidney injury in hospital: summary of NICE guidelines." BMJ **369**: m1963.

Siew, E. D., et al. (2020). "Improving Care for Patients after Hospitalization with AKI." Journal of the American Society of Nephrology **31**(10): 2237.

Silver, S. A., et al. "Strategies to Enhance Rehabilitation After Acute Kidney Injury in the Developing World." Kidney International Reports **2**(4): 579-593.

Silver, S. A., et al. (2015). "Ambulatory care after acute kidney injury: an opportunity to improve patient outcomes." Canadian Journal of Kidney Health and Disease **2**: 36.

Silver, S. A., et al. "30-Day Readmissions After an Acute Kidney Injury Hospitalization." The American Journal of Medicine **130**(2): 163-172.e164.

Silver, S. A., et al. (2018). "What insights do patients and caregivers have on acute kidney injury and posthospitalisation care? A single-centre qualitative study from Toronto, Canada." BMJ Open **8**(6): e021418.

Stewart JFG, S. N., Kelly K, Mason M. (2009). Adding insult to injury: a review of the care of patients who died in hospital with a primary diagnosis of acute kidney injury (acute renal failure), A report by the National Confidential Enquiry into Patient Outcome and Death.

Team, N. E. C. a. I. (2015). Commissioning for Quality and Inovation Guidance for 2015/16. Leeds, NHS England.

Tetroe, J. M., et al. (2008). "Health research funding agencies' support and promotion of knowledge translation: an international study." Milbank Q **86**(1): 125-155.

Tonelli, M., et al. (2018). "Comparison of the Complexity of Patients Seen by Different Medical Subspecialists in a Universal Health Care System." JAMA Network Open **1**(7): e184852-e184852.

Tsang, J. Y., et al. (2021). "Mixed methods evaluation of a computerised audit and feedback dashboard to improve patient safety through targeting acute kidney injury (AKI) in primary care." Int J Med Inform **145**: 104299.

Tsang, J. Y., et al. (2020). "Guidance for post-discharge care following acute kidney injury: an appropriateness ratings evaluation." BJGP Open: bjgpopen20X101054.

Valtorta, N. K., et al. (2018). "Loneliness, social isolation and risk of cardiovascular disease in the English Longitudinal Study of Ageing." Eur J Prev Cardiol **25**(13): 1387-1396.

van Walraven, C., et al. (2011). "Proportion of hospital readmissions deemed avoidable: a systematic review." Cmaj **183**(7): E391-402.

Willis, T. A., et al. (2017). "Variations in achievement of evidence-based, high-impact quality indicators in general practice: An observational study." PLoS One **12**(7): e0177949.

Wonnacott, A., et al. (2014). "Epidemiology and outcomes in community-acquired versus hospital-acquired AKI." Clin J Am Soc Nephrol **9**.

Wright, A. K., et al. (2017). "Life Expectancy and Cause-Specific Mortality in Type 2 Diabetes: A Population-Based Cohort Study Quantifying Relationships in Ethnic Subgroups." Diabetes Care **40**(3): 338-345.

Wright, A. K., et al. (2020). "Age-, sex- and ethnicity-related differences in body weight, blood pressure, HbA(1c) and lipid levels at the diagnosis of type 2 diabetes relative to people without diabetes." Diabetologia **63**(8): 1542-1553.

12 APPENDICIES

Appendix A. RCGP QI Project: Illustrative application of Systems Thinking to post AKI care (Practitioners 2018)

Principle	***Relevance –Examples based on analysis of professional accounts***
Foundational concept: 'Most healthcare problems and solutions belong to the system'	AKI work is largely in the context of caring for people with complex health and social needs. AKI is an acute problem but which informs future management. Work towards becoming a 'kidney conscious' practice: safer prescribing; better communication; better response to crises.
Principle 1: Seek multiple perspectives to understand system safety	The RCGP QI Project largely examined AKI at the organisational and professional level. 24 general practices across England and Scotland conducted and reflected on case note reviews. These include practices located in: Greater Manchester (10); Kent Surrey & Sussex (4); North East & Cumbria (6); and Scotland (4).
Principle 2: Consider the influence of prevailing work conditions—demand, capacity, resources and constraints	Post AKI care occurs within a system contending with competing clinical priorities. ○ Demand: Anxieties over opening up a 'Pandora's box' of new work v formalising existing work that has been part of practice for 'decades'; ○ Capacity: Aligned with skillset of practice pharmacists – but caution to ensure a realistic medicine approach rather than protocol driven care; ○ Resources: Think Kidneys; Incentives enable buy-in; ○ Constraints: Lack of structure to post-AKI care.
Principle 3: Analyse interactions and work flow within the system	Safe and effective post-AKI care depends on effective 'handovers' between teams in primary and secondary care and between healthcare professionals and patients and carers. Bottlenecks occur: variable discharge documentation with lack of clarity. Can be 'Beholden to what the junior doctor was writing'. AKI nurse specialists communicate AKI diagnosis with patients but usually at a time of critical illness and not then involved in care at time of discharge.
Principle 4: Understand why professional decisions made sense at the time	Identify opportunities for better information exchange – prepare patients that might get an out of hours call.
Principle 5: Explore everyday work including the adjustments made to achieve success in changing system conditions	Suggested workarounds: better hand over required to reduce uncertainty and help determine the urgency of response. Post-AKI care process and outcome data: Potential low numbers of patients at practice level – benefit from aggregate data (e.g. CCG, Cluster (Scotland), PCN (England) to understand impact.

See also https://www.rcgp.org.uk/aki

The University of Manchester
AsterAKI Applying Systems Thinking to Enhance Recovery after Acute Kidney Injury
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Appendix B. Prototypical logic model for improving post-AKI care

Levels of action	Timing			Mechanisms	Outcomes
	At discharge	*Within first 30 days*	*Continuing care*		
Organisational	Informatics tool guides real-time identification and management tailored to individual need Electronic Patient Reported Outcomes assess performance and guide ICS improvement.		Provides monthly feedback to practices on performance (including lists of patients with action pending and lessons from re-admissions).	Identification of at-risk population. Reinforcement and facilitation of good practice. Patient and/or carer awareness of plans for kidney health. Patient understanding and confidence in use of medicines. Patient-centred assessment of needs Coordination to ensure offer and receipt of recommended care. Active monitoring tailored to patient need to identify early signs of deteriorating kidney function.	*Early* Increased clinician adherence to recommended practice. Reduced potentially harmful kidney prescribing. Reduced prescribing related adverse kidney events. Reduced likelihood of acute heart failure or recurrence of AKI. Reduced 30-day hospital re-admission. *Late* Prevention or reduced progression of chronic kidney disease. Reduced mortality.
Clinical nurse specialist or clinical pharmacist	Identifies patients with a new episode of AKI from hospital ('in-reach') or community electronic health records. Tailors & agrees individual action plans with patients, carers and primary care team, e.g. prioritising palliative care Checks receipt of action plans by primary care team; includes advice on medicines (e.g. re-introducing heart failure treatment) and monitoring.	Calls or visits patients for review of medicines and monitoring. Advises patients (e.g. coping with future acute illness, medicines to avoid). Reviews actions & monitoring with primary care team. Checks enactment of action plans by primary care team Liaises with specialist services (including AKI).	Calls selected (higher risk) patients to review monitoring and medicines. Follows up monthly feedback to practices by reinforcing and checking adherence to recommended actions.		
Patient and/or carer	Consider and agree action plan.	Engage with medicines advice and monitoring.	Initiates action as needed (e.g. checking medicine use during acute illness).		
Primary care team	Code AKI. Review and act on individual patient action plans.	Check test results and optimise medicines. Liaise with nurse specialist.	Receive monthly feedback with recommended actions.		
Wider system considerations	Our approach will need to be sufficiently flexible to fit with and build upon an evolving health and social care landscape as well as variations in local service configurations. This includes changes to primary care (e.g. wider roles of team pharmacists, networks, social prescribing) and secondary and social care (e.g. other clinical nurse specialist roles, frailty initiatives).				

11.1 Appendix 1- Required documentation

A1 Study Protocol	*Version 2: 19/05/2022*
A3 Distress protocol	*Version 2: 19/05/2022*
A4 Risk Assessment Form	*Version 2: 19/05/2022*
A5 SOP	*Version 2: 19/05/2022*
A6 Disclosure of unsafe practice protocol	*Version 2: 19/05/2022*
A7 Copy of Letter of Support	*Version 2: 19/05/2022*
A8 Patient Participant Information Sheet interviews	*Version 2: 19/05/2022*
A9 Patient Participant Consent Form Interviews	*Version 2: 19/05/2022*
A10 Carer Participant Information Sheet Interviews	*Version 2: 19/05/2022*
A11 Carer Participant Consent Form Interviews	*Version 2: 19/05/2022*
A12 Health Professional Participant Information Sheet Interviews	*Version 2: 19/05/2022*
A13 Health Professional Participant Consent Form Interviews	*Version 2: 19/05/2022*
A14 Patient & Carer Participant Information Sheet Workshops	*Version 2: 19/05/2022*
A15 Patient & Carer Consent Form Workshops	*Version 2: 19/05/2022*
A16 Professional Participant Information Sheet Workshops	*Version 2: 19/05/2022*
A17 Professional Consent Form Workshops	*Version 2: 19/05/2022*
A18 Summary of Topic Guide for Patient & Carer Interviews	*Version 2: 19/05/2022*
A19 Summary of Topic Guide for Health Professional Interviews	*Version 2: 19/05/2022*
A20 Work Package 2 Flow Chart	*Version 2: 19/05/2022*
A21 Copy of SoECAT NIHR131984	*Version 2: 19/05/2022*
A22 GP Information Letter	*Version 2: 19/05/2022*

A23 GP Information & Invitation letter	*Version 2: 19/05/2022*
A26 Patient and carer invitation letter	*Version 2: 19/05/2022*
A27 Professional invitation letter workshop	*Version 2: 19/05/2022*
A28 Consent to contact: workshop	*Version 2: 19/05/2022*
A29 Consent to contact interviews	*Version 2: 19/05/2022*
A30 Health professionals invitation letter interviews	*Version 2: 19/05/2022*
A33 CV Blakeman	*Version 2: 19/05/2022*
A34 Insurance Assessment	*Version 2: 19/05/2022*
A35 Study document checklist	*Version 2: 19/05/2022*
A36 Easy Access PIS	*Version 1: 19/05/2022*