Kidney Services

Improving at Scale

Abstract

Overall purpose of the report

Kidney services have been actively leading on quality improvement for over 20 years. This report presents the collected learning from three Health Foundation funded programmes that scaled-up interventions. These were 1) Tackling acute kidney injury, 2) ASSIST-CKD a programme to spread eGFR graph surveillance for the early identification, support and treatment of people with progressive chronic kidney disease, 3) SHAREHD enabling self-management and shared haemodialysis care in hospital-based dialysis. In addition, the report draws on learning about patient co-production from the NHS England funded transforming participation in chronic kidney disease.

Basic design of the report

Individual programme reports were compared to see what common themes emerged and these were then prioritised through interviews with key stakeholders. The report was produced by working with each of the contributory teams supported closely by quality improvement experts and was completed in conjunction with the Kidney Quality Improvement Partnership.

Major findings

The report identifies five factors which are key to the successful scaling up of an intervention:

- *Defining the intervention by determining which aspects should be fixed and which could be adapted as part of local adoption. This requires a clear understanding of why each aspect is important and how best to implement them.*
- *Assessing teams' level of quality improvement expertise and readiness and selecting a quality improvement method that is consistent with their experience, knowledge and ways of working.*
- *Developing a clear evaluation plan at the outset and mechanisms to feed the learning into the programme as it progresses.*
- *Involving patients from the design stage and providing clear role descriptions and adaptable mechanisms to maximise opportunities for engagement.*
- *Ensuring that there is expert programme management capacity in place to hold the programme to account to ensure delivery to time and target. Equally important is a readiness within the team to listen, learn and adapt in order to allow problems to be anticipated and overcome.*

Conclusion

For spread to be successful it is critical to convince hearts and minds of potential adopters within multiple contexts. The message has to be clear, concise, well-rehearsed and easily shared. Scaling up requires a professional and coordinated approach with clear objectives, a support plan and stated deliverables. As other teams get involved and invest their time, resources and energy they will expect the core team to deliver the components that were set out in the invitation to join. At the heart is a committed and flexible team that values diversity and recognises strength in one another.

Kidney Service Improving at Scale (2020) Published by the Renal Association, Bristol, UK for the Kidney Quality Improvement Partnership (KQuIP) with support from the Health Foundation.

Available from https://www.renalreg.org/publications-reports/

KQuIP is the QI infrastructure of the UK renal community, supported by the Renal Association, British Renal Society, and Kidney Care UK.

Contents

This Learning Report explores the experience of what worked well and how the inevitable challenges were overcome in scaling up recent quality improvement programmes for kidney disease. It is hoped that this information will be of help to those planning to take a locally developed, tested intervention to the next stage of wider deployment.

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List of Key Abbreviations

CKD	Chronic Kidney Disease	ESKD	End Stage Kidney Disease
AKI	Acute Kidney Injury	ASSIST-CKD	‘**A** programme to **S**pread eGFR graph **S**urveillance for the early **I**dentification, **S**upport and **T**reatment of people with progressive **C**hronic **K**idney **D**isease’
TAKI	Tackling Acute Kidney Injury		
SHAREHD	Shared Haemodialysis Care programme	TP-CKD	Transforming Participation in Chronic Kidney Disease

List of Abbreviations

ACP	Action Period Call	LIMS	Laboratory Information Management System
ADB	Advisory and Dissemination Board	LNA	Learning Needs Analysis
AHSN	Academic Health Science Networks	MDT	Multi-Disciplinary Team
BRS	British Renal Society	NHSE	NHS England
CCG	Clinical Commissioning Group	NICE	National Institute for Health and Care Excellence
CJSN	Clinical Journal of the American Society of Nephrology	NIHR	National Institute Health Research
CLAHRC	NIHR Collaborations for Leadership in Applied Health Research and Care to be replaced in Oct 2019 by ARC (Applied Research Collaborations)	NKF	National Kidney Federation
CMOC	Context, Mechanism, Outcome Conjectures	NRES	National Research Ethics
CPD	Continuous Personal Development	PAG	Patient Advisory Group
CQUIN	Commissioning for Quality and Innovation	PAM	Patient Activation Measure
CRN	Clinical Research Network	PDSA	Plan Do Study Act
CS-PAM	Clinician Support for Patient Activation Measure	PI	Principal Investigator
DARS	Data Access Request Service	PID	Project Initiation Document
eGFR	Estimated Glomerular Filtration Rate	PKD	Polycystic Kidney Disease
GIRFT	Get it Right First Time	PM	Project Manager
GP	General Practitioner	PPT	Patient Project Team
HCA	Health Care Assistant	PREM	Patient Reported Experience Measure
HES	Hospital Episode Statistics	PROM	Patient Reported Outcome Measure
HQIP	Healthcare Quality Improvement Partnership	QALY	Quality Adjusted Life Year
HRA	Health Research Authority	QI	Quality Improvement
ICMJE	International Committee of Medical Journal Editors	RA	Renal Association
IHI	Institute for Healthcare Improvement	RRT	Renal Replacement Therapy
ISRCTN	International Standard Registered Clinical/ soCial sTudy Number.	ScHaRR	School of Health and Related Research
IT	Information Technology	SWCRT	Stepped Wedge Cluster Randomised Trial
KCUK	Kidney Care UK	TP2	Transforming Participation in CKD Phase 2
KPI	Key Performance Indicator	UKRR	UK Renal Registry
KPIN	Kidney Patient Involvement Network	UoS	University of Sheffield
KQuIP	Kidney Quality Improvement Partnership	WHO	World Health Organisation
KRUK	Kidney Research UK		

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2.2 Report contributors

The report production team acknowledge the efforts of all members of the programmes and organisations considered in the writing of this report. Without their support and active engagement, it would not have been possible to prepare it. The following individuals are specifically recognised for their contributions.

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2.3 Recognition and thanks

We would like to recognise the successes and progress made by each of the programmes that we report in advancing the drive towards delivering excellence in the kidney community.

The delivery of each programme was only possible due to the dedicated support of many contributors both directly within each project, such as work-stream members and participant trusts, but also more widely from staff, patients and leaders from multiple disciplines and supporting organisations, including renal charities and the commercial sector. A list of the specific trusts involved across all the programmes is included in appendix 12.3.

This report was funded by the Health Foundation.


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Foreword

In the last two decades there has been a steady growth in the numbers and scope of multicentre quality improvement (QI) projects in the UK renal community. This is a challenging area; in my view these projects can be at least as difficult in their development, implementation, and reporting as multicentre clinical research. They usually originate from work done in one centre which reports promising initial results. The project is then scaled up to assess if the approach can be generalised to produce outcomes that are of benefit to patients across several sites. And here is the challenge, as each renal service is complex, and there is much local variation in how care is delivered, and in available resources and staff skill mix, delivering a project in multiple centres requires care and expertise, particularly as these projects embed directly into the clinical service.

However, the value of this work is unquestionable. QI is often (and rightly) patient co-designed and can address multiple practical questions, including how to generalise QI and increase expertise and capacity in QI in clinical services. The current context for clinical renal care in the UK is major variance in outcomes, large inequalities, and services with different structures and expertise. This demands of us that we engage and support each other through the development and implementation of QI projects that are generalisable, as well as support individual units to increase their capability for local QI. These two areas are profoundly interlinked.

This Health Foundation commissioned report is a unique detailed learning analysis of three national improvement programmes for renal services that were funded by the Foundation, plus an NHS England funded programme. The Health Foundation has a strong track-record of supporting renal QI, both independently and in collaboration with other organisations. The four projects that are a focus for this report, ASSIST-CKD (co-supported by Kidney Research UK), Tackling AKI, SHAREHD and TP-CKD (NHSE funded), stand as major achievements. These achievements are detailed in this report and are a testimony to the hard work of healthcare professionals and support and involvement by patients in renal services across the UK.

The report is focused on the programmes experiences and learning that can help future QI projects. This is truly important as insufficient time and effort for reflection and structured critique is a common shortfall in major QI projects, leading to a failure to properly implement what works and to adapt or discard what does not work. Reflection, and reporting on that reflection, ensures that the main lessons from the projects are captured and can be used to inform the development and delivery of future QI projects in renal care and beyond. Great projects often learn more from what did not work as anticipated and why that was, than from what worked.

This report is detailed and intelligent. It rewards careful reading and will be used by all of us who are involved in development and delivery of QI in renal care. Successful project teams identify and embed those areas that are required for success, and carefully and openly deal with those areas that do not work. The report reinforces this principle and will therefore inform future QI project and programme design. A central message in the report is that project adaptation and delivery is about local teams; how these teams are supported to work within a project so that they can deliver within their unit whilst maintaining fidelity (integrity of the project design and objectives) is crucial. Over the next 12 months learning around these and other areas captured in the report will be rolled out through the renal community so that we can extract maximum value from this work.

We have a debt of gratitude to the many individuals who were involved in these projects, they are acknowledged in the document. This is courageous work that our colleagues have delivered. It requires great skills, both inherent and learned. Hugh Gallagher (ASSIST-CKD), Nick Selby (Tackling-AKI), Martin Wilkie (SHAREHD) and Richard Fluck (TP-CKD) were the overall clinical leads for the projects; Martin Wilkie and Sonia Lee (SHAREHD programme manager) have led on the writing of this report. Thank you for this leadership and for all those participating in this work.

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Executive Summary

Introduction

Chronic kidney disease (CKD) together with acute kidney injury (AKI) have a major impact on the health and wellbeing of people in the UK. Around three million people live with moderate to severe CKD, while AKI affects up to half a million people per year who are subject to an emergency hospital admission. Therefore, improving the quality of care, the patient experience and the clinical outcomes for kidney care represents a major opportunity for the NHS.

Kidney services have been actively leading on quality improvement for over 20 years. There have been major national developments which have supported this engagement with quality improvement, such as the establishment of the Renal Registry in 1995 and the early development of clinical practice guidelines by the Renal Association, first published in the same year. In addition, the emphasis in kidney services on multi-professional working and the existence of longstanding patient support charities, which have evolved over the years, has created a context which tends to support quality improvement work. Alongside national initiatives, local teams have developed, tested and delivered interventions to improve the quality of care and lived experience for people with kidney disease.

This report presents the collected learning from three programmes, grant funded by the Health Foundation, to scale-up their interventions. (1) Tackling Acute Kidney Injury (TAKI): a multi-centre quality improvement programme, led by University Hospitals of Derby and Burton NHS Foundation Trust; (2) A programme to spread eGFR graph Surveillance for the early Identification, Support and Treatment of people with progressive Chronic Kidney Disease (ASSIST-CKD), led by Kidney Research UK; (3) Enabling self-management and shared haemodialysis care (SHAREHD) in hospital-based dialysis, led by Sheffield Teaching Hospital NHS Foundation Trust. These programmes advanced from the stage of local implementation and were funded to scale up their efforts by getting other kidney services to adopt their intervention, with programme support to aid wider adoption.

The process of moving from a local ‘successful’ project, to enabling the intervention to grow into a programme with wide take up among other geographically dispersed services, which are then able to achieve similar results from applying the intervention is one of the key challenges for quality improvement in health care. What each of the teams discovered was that the focus and attention to detail that enabled the initial successful development was still needed. Scaling-up the work required a depth of management expertise, together with a raft of other skills: to ‘sell’ the concept, inspire others, offer distance support and negotiate numerous organisational and professional boundaries, while at the same time accepting that adopters will introduce different approaches and adaptations to the intervention that can be equally successful.

In addition, the report includes aspects of learning on programme delivery including patient co-production and project management from a fourth programme: (4) Transforming Participation in Chronic Kidney Disease (TP-CKD), funded by NHS England and delivered in collaboration with the UK Renal Registry.

The learning report aims to capture the experience of what worked well and how the inevitable challenges were overcome. The exercise of collating the learning from the programmes has been a quality improvement exercise itself, to try a different, more expansive approach to reporting and dissemination of the work. The evidence used for the report is drawn from reported data and results of the programmes, together with experiential evidence from participants. The authors have aimed to synthesise findings in a way that will be helpful to others aiming to scale up their improvement interventions, while remaining true to the spirit and core of each of the programmes.

It is important to note that each of these programmes had access to external funding, or other resources, to cover project management, administration and evaluation. While it may not always be possible to access grant funding, any attempt to scale up local project work will need to identify how staff time and other resources to support the development and wider take up of the intervention will be covered, whether by secondment arrangements or as fees from participating sites.

Summary of each of the quality improvement programmes

Tackling AKI (TAKI) aimed to improve the standards of care for Acute Kidney Injury (AKI), which is a sudden reduction in kidney function, often as a result of an underlying condition. It is harmful, associated with increased mortality, morbidity and length of hospital stay and is often preventable. AKI represents a major patient safety challenge for health care. The programme aimed to understand whether a complex, multi-component hospital-based intervention was able to improve AKI recognition and the delivery of basic elements of patient care. The intervention had three components: an electronic detection and alerting system; a care bundle covering assessment, investigation and basic management; and an educational programme to raise awareness and knowledge of AKI in healthcare.

TAKI built on work at Royal Derby Hospital that had shown improved patient outcomes. The hospital partnered with the UK Renal Registry and Bradford University to implement the programme across five hospitals in England. A key component, and critical to the programme timing, was the national rollout of the AKI Patient Safety alert. The primary quality improvement method adopted was peer review / peer assist between the participating services, with local project management support.

The notes audit of 1,048 patients found that AKI care bundle usage increased from 0% to 40.2% between the control and intervention periods. There was also increased AKI recognition (69.4% versus 88.8%), medication review (60.1% versus 71.3%), fluid assessment (74.4% versus 91.2%) and urine analysis (37.4% versus 64.7%), with no change in rates of specialist referral, renal imaging and urinary catheterization, which were important balancing measures.

The impact of TAKI was shown to improve care pathways but did not demonstrate a change in the primary outcome measure of all-cause mortality. The incidence of AKI increased, probably because of better recognition, together with a modest decrease in hospital length of stay of approximately one day, as well as the decreased duration of AKI episodes themselves. The programme demonstrated that a systematic approach to better delivery of person-centred AKI care across acute specialities can improve outcomes. The reduction in hospital length of stay, although modest on an individual patient basis, translates into a significant health economic benefit across the thousands of patients who sustain hospital-acquired AKI each year.

ASSIST-CKD aimed to spread estimated glomerular filtration rate (eGFR) graph surveillance for the early identification, support and treatment of people with progressive chronic kidney disease (CKD), which for the most part can be managed in primary care. As the condition progresses, the increased complexity requires management by a specialist renal centre to limit the impact of the condition and to plan for timely initiation of renal replacement therapy (dialysis and transplantation). Patients who present late with advanced CKD have poorer outcomes, including higher mortality. They are less likely to be transplanted or to receive home dialysis therapy. Late presentation usually results in an overall higher cost of treatment as well as being a marker for poorer outcomes and a cause of avoidable harm.

In 2004, the Heart of England NHS Foundation Trust renal and diabetes services developed a system to generate cumulative graphs charting the change in kidney function (estimated glomerular filtration rate: eGFR) over time, in patients with diabetes. Reviewing the graphs enabled the identification of patients with rapidly deteriorating kidney function. The impact of this intervention was a reduction in the rate of late referral for dialysis.

Software was developed to extract data for patients with low kidney function directly from the laboratory database, compiling and displaying the cumulative eGFR graphs. Graph surveillance was extended across all patients at risk of deteriorating kidney function. This demonstrated the potential improvement in outcomes if this intervention were to be scaled up across the health service.

The ASSIST-CKD programme intervention aimed to spread the software to hospital laboratory services around the country, to enable early identification of deteriorating kidney function. The programme trained laboratory staff and CKD renal nurses to read eGFR graphs, flagging those showing intermediate or high risk of kidney function deterioration to the GP, with a prompt that further review and action may be needed.

Training and staff costs for one year were provided for local staff to review and forward the flagged graphs to GPs for further action. The quality improvement approach centred on learning events for the participating sites. Early in the implementation phase, it was apparent that the software needed redesign to be supportable across laboratory systems. This impacted on the implementation timeline, which in turn meant that the planned stepped wedge cluster randomised controlled trial was not workable, necessitating a change of study design to ‘controlled before and after’.

ASSIST-CKD has been implemented at over 20 laboratories across the UK, serving approximately 11 - 12 million people. The intervention has been sustained past the initial subsidised year at most sites and two laboratories have now been reporting for over four years, with the intervention embedded in day to day practice.

SHAREHD is a programme for shared haemodialysis (HD) care, supporting people to self-manage elements of their dialysis. HD uses a machine to pass the patient’s blood through a filter to remove toxins. In England alone, approximately 20,000 people attend an institution three times a week to receive HD for around four hours at every visit. The opportunity to self-manage this care has tended to be limited to those who are able to dialyse at home. Despite evidence of the benefits of patients being engaged in their own care, such as feeling more ‘in control’, the institutional environment has not supported self-management. To achieve this change, health care professionals need to become educators and facilitators, supporting patients to take a greater role in their care.

The shared haemodialysis care programme was developed in Yorkshire and the Humber in 2010 through coproduction with patient partners, who were clear that this was “shared” rather than “self” care, with patients supported to make a choice about the level of engagement that they wish to undertake. It was funded through the Health Foundation Closing the Gap through Changing Relationships Programme, enabling shared haemodialysis care to be tested, iterated and spread to the six dialysis centres (26 units) in the Yorkshire & Humber region. More than 500 nurses from across the UK have subsequently been trained in a skills development programme currently funded by Kidney Care UK to enable them to support patients. SHAREHD offers choice to patients to participate in the tasks related to their haemodialysis treatment, tailored to the extent that the individual wishes to get involved.

The Scaling Up programme spread SHAREHD to 12 dialysis centres in England, through a Breakthrough Series Collaborative. Six centres were randomly allocated to start in wave one, with the remaining six starting six months later in wave two. The intervention was supported through learning events, where teams tested different ways of increasing patient engagement in their dialysis care using PDSA cycles and compared their results through the collaborative. A third wave of seven trusts from England, Scotland and Ireland participated in a collaborative, with additional peer assist support from the wave one and two teams. The opportunity to collaborate and share ideas enabled a more consistent approach between the 19 dialysis centres and accelerated programme implementation. Within the timeframe of the programme an estimated 2,000 centre-based haemodialysis patients were offered partnership in their care through SHAREHD and this choice continues for all dialysis patients past the programme end. Overall there was an increase in the percentage of people undertaking five or more tasks and the number of those dialysing independently in centre or at home also increased.

Transforming participation in chronic kidney disease (TP-CKD) had as its objective the development of new ways of working that support patients to take greater control of their health and wellbeing, and enable them to be more involved in the design and delivery of services that achieve their personal and clinical goals. Clinical outcome measures, traditionally considered important by healthcare professionals may not capture the priorities that matter more to patients such as symptom burden, quality of life and readiness to take a role in their care.

TP-CKD commenced in 2015 and completed in 2017 and tested whether it was feasible for units to routinely collect patient reported measures from kidney patients, return them to the UK Renal Registry for processing and return results to the units and patients. This provided the basis to further explore the knowledge, skills and confidence of people with kidney disease to self-manage their health and the association between these attributes, symptom burden and quality of life. A further objective was to understand the capacity of health care professionals to support such involvement, and develop a toolkit of targeted interventions for patients and clinical teams to support patients' active participation in their care. The programme used the NHS Change model and the peer assist approach, alongside learning events for teams of clinicians and patients from participating units. By using a structured approach, with strong leadership, wider team engagement and support, it was found to be feasible to routinely collect patient reported measures, from patients in haemodialysis centres and out patients. The focus on co-production and co-design meant that patients were included alongside health professionals in the leadership, design and implementation of the programme at national and local level and this enhanced the delivery of the programme. 14 renal centres participated in the programme, with 3,325 patients completing at least one survey. The measurement programme developed two survey tools: 'Your Health Survey' (YHS) and a 'Patient Reported Experience Measure' (PREM) which is now a UK wide annual survey. Results of YHS are uploaded to Patient View, enabling patients to access their own results to potentially aid discussion with their health care professionals.

Approach to synthesising learning from the programmes

The individual programme reports were compared to see what common themes emerged and these were then prioritised through interviews with key stakeholders. Five key themes emerged which then fed into the structure for this report.

Defining the intervention

Preparing a locally developed intervention for scaling up requires acknowledgement of its complexity. A clear definition with itemised components will help potential adopters to understand what is likely to be involved and whether they are ready to take it on. The process of itemising the core elements helps to inform the discussion about the extent of local adaptability that is desirable and necessary for the intervention to work in different contexts and the core essential components which must be retained.

Fidelity refers to the degree to which an intervention or programme is delivered as intended by the originators of the intervention.

All four programmes faced tensions between wanting to secure the fidelity of the intervention and the opportunities for local adaption, taking account of contextual issues and enabling adopter teams to develop a sense of ownership. It is important to strike a balance between top-down dissemination of a fixed intervention, versus each team deciding for themselves how to implement and what to include. It is one of the keys to success for scale-up to get this balance right.

Within the Tackling AKI programme the key components of the intervention were clearly defined as the AKI electronic detection and alerting system, the AKI care bundle and an educational program to raise awareness and knowledge of AKI with health care workers. The electronic detection system was uniform across all sites, conforming with a nationally mandated specification. However, each site evolved local mechanisms for communicating the alerts for action.

At SHAREHD learning events it was recognised that the core components of shared care should be consistent. More clarity was needed in the definition of the intervention and the components were subsequently identified as a patient competency handbook, a unit intervention roadmap (local implementation plan template), a patient awareness leaflet and patient / staff questionnaires. Defining these core components has facilitated wider spread, while maintaining the fidelity of the concept of shared care.

ASSIST-CKD was based on consistent software to produce patient data graphs. This method of implementation ensured a high degree of fidelity in graph preparation while it was recognized that there would be inter-operator variation in adherence to the quality standard for graph review. For example, those new to the process were likely to over report graphs as being significant when compared with more experienced graph readers. To achieve the appropriate level, staff reading graphs were given a training manual and required to achieve a minimum score of 80% in a mandatory test. Checks were undertaken every three months to ensure data reporting was maintained and this helped the new system to be embedded into day to day practice. Despite these steps, there was still a degree of variation between operators.

	Key learning points on defining the intervention ***- Define your intervention clearly*** ***- Indentify what are fixed and variable components***
Itemise the intervention	Any intervention intending to scale up or spread through a formal process requires a clear description that itemises its components.
Define the fixed components	Itemise the components which must be part of the intervention to retain fidelity. Test this during the programme and use the resulting learning to ensure a robust intervention for adoption by new teams once the programme has ended.
Balance between strict adherence and local adaption	Taking into account local contextual issues, determine the balance between the requirement for fidelity to the original components (and style) of implementation and the scope for local adaptation.
Measure adherence as part of the evaluation	Plan how the measurement of fidelity fits into the evaluation of programme effectiveness taking into account the nature of the intervention and the context of its delivery. Consider the domains against which it is to be measured and plan mechanisms to collect and review relevant data (Carroll et al.[1]). If it is available, use data that is collected nationally.
Don't become a slave to fidelity	Monitoring intervention fidelity exclusively runs the risk of overlooking other measures. Build in a mechanism to understand and share the contextual variation. Wider benefits and implications should be identified from the start and re-visited throughout the programme. (Mary Dixon-Woods[2]). Identification of barriers and enablers to an intervention inform its future iterations.
Is "how" the intervention delivered important?	Fidelity may not only refer to the "what", but also the "how and why" the intervention is delivered taking account of context. For example, how patients were offered the choice of shared care in SHAREHD, rather than the exact shared tasks or number of tasks they undertook was a core component. This human element is critical to influence hearts and minds and prevent a box ticking approach. Discuss the programme design and intervention with a 'non-partisan' reviewer who is familiar with the intervention type. This is to build awareness of risks and implications in deployment of the activity at scale, but also to identify gaps in the project teams' skills and understanding that need to be filled before commencement and whether sufficient piloting has been undertaken to be ready to scale.
Obtain objective review of the planned intervention and project	Discuss the programme design and intervention with an objective reviewer who is familiar with the intervention type. This is to build awareness of risks and implications in deployment of the activity at scale, but also to identify gaps in the project teams' skills and understanding that need to be filled before commencement and whether sufficient piloting has been undertaken to be ready to scale.

Findings 1 : Defining and Implementing the Intervention with Fidelity

Quality improvement

Quality improvement activity has been described as 80% relational and 20% technical. This is reflected in the reports from the scaling up programmes, which focus more on the planning, management and challenges of implementation than on the technical QI tools and methods used. The core enablers for successful implementation were found to be:

- *Clarifying the aims*
- *Choosing the most appropriate QI tools*
- *Understanding the resources that are available for the work*
- *Learning through practical experience.*

Logic models and driver diagrams are typically used in QI to help clarify the project aims. Within Tackling AKI an overall logic model was developed. The evaluators encouraged the individual teams to complete the models before and after the intervention, to explore their planned implementation mechanism and how it was delivered. Some teams required a lot of support from the evaluators to design their model, so the intended benefits of working through the ideas were partly lost.

A similar situation occurred in SHAREHD. It was initially assumed that each team would establish their own driver diagram to develop their local aims, using the IHI Model for Improvement. This did not happen, due to limited time or lack of understanding of how the tool should be developed and used. Instead, teams concentrated on their aims for PDSA cycles which were limited to tackling single points of intervention. These nevertheless had value to plan delivery of discrete elements, such as increasing the number of dialysis patients who were performing their own observations.

ASSIST-CKD used a logic model at the programme level, which focused mainly on the activities that were required after the eGFR software was installed in the lab. The complexities of deploying software into labs became a major component of the implementation but the logic model was not updated to reflect this.

The experience of these programmes was that logic models and driver diagrams are not easy to use by people unfamiliar with the concepts. It is therefore recommended that the aims and objectives of using the tools are clear and that the core team has the skills available to use them effectively and to teach developing and using them.

One technical aspect of QI which teams on the ground struggled with was data collection for measurement. In the SHAREHD PDSAs most teams did not follow through to identifying appropriate measures and then producing sequential run charts that documented the changes that had been made. Data collection was not seen to be of value and therefore not worth the time investment. Implementing small changes was preferred to analysis and measuring. However, where teams kept this simple and saw a direct link with the objective and displayed the results, there was more incentive to collect and analyse the information.

Likewise, in the TAKI programme, teams planned to manually measure care bundle uptake after implementation but this did not happen. The most common reason reported for not doing this was lack of time to collect the data and then do something with it. The learning for future programmes is that technical support is required by front line staff, particularly around the analysis approach, once data is collected. When these data were analysed and fed back to the teams it was found to be useful.

When scaling up an intervention that has been developed in a single setting, it is inevitable that local adopter teams will vary considerably in their characteristics and approach. The core programme teams need to consider the priorities and context of the adopter teams, so that the approach can be adapted to suit those requirements. Each participating site will have different expectations from the programme and different levels of experience of QI work, so support requires a degree of individualisation. Understanding what motivates sites to participate will enable these goals to be realised. The programmes found it helpful to obtain information regarding site preparedness, motivating factors, the level of QI experience and understanding, as well as key contextual characteristics in advance of engaging the site in the programme.

For SHAREHD, site initiation visits were used as an opportunity to cover both the research and QI implementation approaches in a joint meeting. TP-CKD undertook a detailed learning needs analysis asking teams questions such as ‘how effective are you at leading service change?’ and ‘how good are you at involving patients?’. These questions helped the team shape the programme but also understand why certain units were cautious and others appeared more able to deliver.

Within ASSIST-CKD the complexities and variance of the IT landscape from site to site was a challenge to implementation. Each Trust had separate IT teams dedicated to the laboratory systems, database management and networks and they mostly worked in isolation. It took considerable tenacity from teams on the ground to establish the linkage, management processes and requirements between IT, laboratories and GP practices. Some initially interested sites did not proceed as it was too complex to manage alongside other daily pressures. The level of skills needed to negotiate the internal management was unexpected.

TAKI undertook learning needs assessments to identify which elements of the education package would be appropriate for each team. The initial training materials grew into a 'pick-list' of education elements, supported by the peer to peer learning, as locally created materials were tried and tested from one unit to the next. Initially it was mainly factual, but evolved to encompass a 'hearts and minds' message, recognising the importance of this to promote uptake. Interventions such as TAKI are implemented to a large extent by doctors in training who rotate periodically to other roles, therefore educating nursing staff is more important for sustainability.

All the programmes used learning events and workshops to educate the adopter sites on the interventions and the approaches to implementation. In SHAREHD, learning events were central to the quality improvement collaborative. They evolved over the course of the programme, to become more intentional as to the education to be delivered, with the team planning the content and delivery of each session, with post-event evaluation of whether the goals had been achieved or not.

TAKI used several styles including a central kick-off event, locally focused education programmes, and peer review /assist events. Within ASSIST-CKD, three learning events were held towards the end of the programme to allow the participating teams to build a 'dynamic project community' specifically to share experiences, examples of good practice and challenges. Key to the success of the learning events was having clear objectives to maximise benefit for the time invested by the participating teams. Without this, teams might lose interest in the programme and pull out of later sessions.

Local team leadership is a key determinant to the successful implementation and ownership of the programme by adopter sites. The local "2nd leaders" will inevitably have a much more detailed understanding of local priorities. The TP-CKD programme report highlighted that for programme success, senior leaders had to act as advocates of the key messages of the programme and respond to staff concerns. The SHAREHD programme actively encouraged teams to present and share their work at learning events and local launches and to submit abstracts to academic meetings and conferences. The programme was promoted as a culture change 'movement' that anyone can join, at any level of the organisation, not just senior staff. Motivated individuals from junior roles were able to shine as second leaders for SHAREHD.

	Key learning points related to quality improvement *- Agree and document your QI aims and methods* *- Understand the QI skills of your adaptors and plan accordingly* *- Create an environment where you can share experiences - embrace 2nd leaders* *Focus on the spirit of WHY*
Agree and document your chosen QI aims and methods	Decide what your QI aims, methods and adoption approaches are. Explicitly describe these in the protocol so that the adherence to the methodology during implementation can be formally evaluated.
Assess adopter QI capability and capacity	Assess whether adopter sites have the skills, understanding and time to use the chosen QI method necessary to implement the intervention. Offer appropriate training and external expertise to build necessary skills.
Build a collaborative to enable sharing	Create opportunities to share between the adopter teams' experiences and learning, both positive and negative. Build a supportive, educational environment where there is no fear of declaring failures, which is where much of the learning arises. Methods include QI Collaborative, Peer Assist and Developmental Evaluation.
Be open to learning from adopter sites	The originators of the intervention need to be open to learning from adopters. Consider how adaptations that adopter sites have made to the intervention have worked and how these can be taken forward within the next iterations of the work.
Embrace 2nd leaders	Beware of reliance on a temporary project team. Encourage 2nd leaders and create an ongoing improvement faculty that can sustain past the programme end.
Reuse existing resources	Learn from previous work and use existing resources, rather than reinventing. Consider making your resources available for others to use also. The programmes highlighted have produced resources that are accessible from the Think Kidneys website.
Focus on the spirit of why	Focus on education and exploring the spirit of the intervention as well as processes and technicalities. To achieve sustainability a tipping point of changing hearts and minds is required.

Findings 2 : Quality Improvement Methods and Mechanics

Evaluation

Evaluation was prioritised in the Health Foundation scaling up programmes reviewed in this report, but this is relatively unusual in QI programmes. This is because it is time consuming and expensive when externally commissioned. There is a preference to spend resources on direct improvement work. However, evaluation is critical to know whether the intervention works as expected in the new contexts, and to understand the mechanics for scaling up. It needs to be built into the design of the programme wherever possible. The programmes in this report used a combination of qualitative, quantitative and economic evaluation to gain insight on how the intervention was implemented in adopter sites and the results that were achieved.

The development and publication of an evaluation protocol was a key step for the programmes, setting out key research questions and data through which results would be measured. Developing the protocol requires detailed understanding of the techniques that are intended to be used. The benefit of working with an experienced research evaluation team to lead on this cannot be over-stated. SHAREHD registered their evaluation study on a trials register. While this is an accepted step for clinical research trials, it is not always done for quality improvement evaluation studies. The advantage is a greater acceptability for publication, with access to support through the Clinical Research Networks if the study is adopted onto the NIHR portfolio.

The decision whether to submit an evaluation study for ethics review is complex. Although QI is often considered to be service review and therefore not requiring ethical approval, if there is a desire to collect patient-related data, ask patients to complete questionnaires or conduct interviews with patients or staff, then it is necessary to have the appropriate permissions. In SHAREHD the realist evaluation was based on observations of learning events and interviews with trust teams and patient users. Getting the necessary research passports at participating trusts and patient consent forms for interview completed required tenacity to accomplish. ASSIST-CKD, TP-CKD and TAKI decided not to seek National Research Ethics Service (NRES) approval after taking advice and receiving the opinion that the programme did not require it. ASSIST-CKD notes in the evaluation report that it did however limit “our scope to work directly with patients so the ability to explore the impact of the programme on patient experience was reduced”.

It takes considerable time and know-how to work through the steps of applying for ethics approval, particularly when the programme will run at multiple sites. It is important to check the latest advice on the national research ethics service website at the outset and to start the application process as soon as possible, as it can take several months. It helps enormously to work with an experienced research co-ordinator - and SHAREHD had access to such an individual.

Within the TAKI programme the qualitative team sought to understand the perspectives of key stakeholders involved in the design, implementation and delivery of the package of AKI interventions in each of the five hospitals. The evaluation findings and insights were fed back to sites at key points using developmental evaluation that helped to frame and test theories and models. The objective was to provide on-going insights to the implementation team about factors which could be influencing the fidelity of the intervention, so that they were able to adjust their approach.

Part of the ASSIST-CKD programme evaluation was a fidelity assessment which determined the extent by which teams adapted the intervention for local use. Teams signed up to the programme objective and were provided with the eGFR graph software. They were then encouraged to determine the best way to deliver the intervention in their local context. Variations were described in the form of case studies that helped teams to understand the local ‘storyline’ of delivering the intervention while attempting to maintain core fidelity. This helped teams to plan the work for their environment and to make necessary adaptations.

In the quantitative evaluation, three of the programmes set out to use a stepped wedge cluster randomised controlled trial (SWCRT) design. In this method, the intervention is delivered in a staggered fashion to clusters of sites at fixed time periods. The SWCRT is an appropriate method to study the routine implementation of an intervention for which there is existing evidence, in an ethical approach, as all the sites are able to implement the intervention by the end of the study. It is more robust than ‘before and after’ studies at each site and is a cost-effective way of evaluating complex interventions. However, complex statistical approaches are required and the study has to be sufficiently powered for the results to be meaningful, and appropriate statistical expertise is essential. Complications can arise if clusters of sites are not ready to implement the intervention in their allotted time period.

The SWCRT worked for TAKI and SHAREHD, but for ASSIST-CKD it was confounded by the delay required to redevelop the software, which meant that the intervention could not be tested within the predetermined timeframe and those timelines could not simply be extended whilst maintaining the fidelity of the method. A key learning point from the use of the SWCRT design is that careful consideration needs to be given to the size and cohort type required, the timing of the steps and whether they can realistically be maintained, along with a reflection on of the potential impact of time on the uptake of the intervention during the course of the study.

SHAREHD delivered a complex intervention that involved learning events within a SWCRT, with [3][4]the challenge inherent in delaying the start of the intervention for second wave teams and then getting them up to speed quickly, during the appropriate time window within the collaborative. First wave teams took part in four learning events as a group, after which the second wave commenced a single 'catch up' quality improvement learning event, following which all teams attended the remainder of the learning events. The study results demonstrated that patients in the second wave had started to increase the number of dialysis related tasks they undertook before their teams attended the learning events. This may have been a consequence of completing questionnaires on how many dialysis related tasks they were performing and is an example of the "Hawthorne effect" that the very act of studying something changes it. While the structure of the SWCRT was known, it was not possible to prevent centres randomised to the second wave of the study from engaging in the intervention before their allotted time.

	Key learning points related to evaluation ***- Plan early including evaluation endpoints and ethics implications*** ***- Publish the protocol and register your trial*** ***- Establish effective feedback links***
Consider the appropriate study design	Several QI scale-up projects have found the stepped wedge cluster randomised trial design useful. It means that all participating sites benefit from an intervention for which there is already some evidence, over the course of a planned programme, with data comparison available between the early adopters and those yet to adopt the intervention. SWCRT is not appropriate for all interventions however.
Determine plausible and meaningful endpoints for the evaluation	For evaluation of the effect of the intervention it is necessary to set a primary outcome measure for the evaluation hypothesis, such as, reduction in 30-day mortality, with a rationale for how the intervention will impact on the measure. This needs to be achievable and able to be robustly measured throughout the study using a consistent methodology.
Plan how to understand user experience and context	Consider how and when patients/service users, carers and staff will participate in the evaluation, for example, plans to interview or carry out surveys. The approach adopted will be a key factor in what ethical approval for the evaluation study is required. Involve patient partners in the design and governance to be sure the evaluation is not misdirected or that the surveys are over burdensome.
Consider the place of ethics review	Carefully consider if ethics approval is going to benefit the resultant evaluation and dissemination of the findings, even if the project is deemed to be service improvement. It is necessary in order to assess the experience of users. Allow plenty of time for the process to gain the ethics approval, so that implementation is not delayed, or the evaluation team do not miss the opportunity to study the early stages of the programme.
Define the protocol early and publish it	Invest time early in the work to define the evaluation protocol, statistical analysis plan and data requirements by balancing the requirements of qualitative, quantitative and economic evaluation in as much detail as possible. Use framework guidelines to structure the protocol according to best practice. Publish it to formally document the programme's intentions as well as increasing the validity of subsequent publications.
Consider registration if appropriate	Register the study on the NIHR portfolio and a clinical trials register, before the first patient is recruited even if is deemed to be service improvement, as this will increase the provenance of the study results.
Decide what key documents are appropriate for your programme	Identify what key documents are needed or appropriate for your programme (see Figure 7 and Table 15) and the dissemination of results.

Link the evaluation to the programme real time	There is great value in the evaluation research team feeding back to the implementation teams via some form of developmental evaluation, to enable the emerging findings to inform the implementation during the programme period. Within realist evaluation this is a key part of the approach as it helps inform the learning of what works, in what circumstances and why.
Build in regular catch-ups between intervention and evaluation	Ensure the evaluation is distinct from the intervention but with close communication between the teams so that learning can be shared. Plan regular ‘catch-up meetings’ and hold them even if it is thought there is not much to update, sometimes these informal conversations that have the greatest relevance.
Specialised resources and funding may be available	It may be appropriate to look wider than the immediate study funding for additional sources and skills to enhance the programme learning in specific areas.
Non-achievement of end points in scaling-up is not failure	If the primary outcome measure is not achieved that does not detract from the value of the work or reduce the important learning that can come from it.

Findings 3 : Evaluation Methods and Mechanics

Patient involvement

The quality improvement programmes reported here all included different components of patient involvement, from patient experience, to patient representation, to co-production of care. To a large extent the engagement level and approaches were driven by the different clinical contexts and the nature of the interventions.

A common factor across the programmes was the participation of patients as service user representatives on advisory groups or committees, recognising the importance of having the patient voice on these groups. Patients informed the development and direction of the work from a non-clinical perspective to ensure it was focused on outcomes and processes that were important to them.

It is important to involve sufficient patients in a programme in order to gain wide representation and skills to enable continued participation for the full duration of the programme. ASSIST-CKD initially recruited ten patients onto the steering and advisory groups. Due to illness or change in circumstances and also because of the nature of the programme (technical, IT, at some distance from direct patient interaction) it was at times difficult to meaningfully involve patients and therefore to maintain motivation through to the end of the programme.

TP-CKD achieved a high level of patient participation with an appointment of an expert patient as a co-chair and patient co-chairs for the work-streams. It was also expected that all renal unit teams involved in the programme would bring patient members to the events and include them in working groups locally. This was a successful approach although it required effort to promote and maintain both nationally and locally. It radically changed the way patients were involved in a programme and enabled clinical teams and patients to work collaboratively to deliver agreed aims and objectives that were co-produced[4].

From the start of SHAREHD there was the intent to have the patient at the heart of everything that was done within the intervention and throughout the organisation of the programme at every level. This built upon the experience of the original intervention and how the patient engagement evolved during its development. There was patient engagement throughout the discussion and planning for the programme and this involvement continued to be built into in all the work-streams as it moved into the delivery phase.

Healthcare professionals need to take an objective look at how they work with involved patients on advisory groups and as partners in the implementation of improvement and consider the extent to which ‘normalised’ working practices need to change, to enable the full partnership working with patients. A programme seeking to promote patient involvement needs to work in a co-production mode throughout, to promote and model the culture change.

	Key learning points related to patient involvement ***- Involve patients early*** ***- Be clear about their role and set expectations. Don't be tokenistic.*** ***- Engage several patients and be prepared to be flexible in how you engage.***
Aim to involve more than one patient representative	Try to avoid a situation of having lone patient representation: where there is a planning or steering group of six to 12 people, aim for two or three patient/ service user or carer participants. For some interventions and approaches, it may be appropriate to aim for a 50:50 ratio of patients to healthcare professionals.
Involve patients early	Try to involve patients before there is a project, get input and ideas for what to improve and involve the patient voice throughout the scoping, development, funding/ contracting stages.
Describe the patient role clearly	Prepare a written brief for patient roles on committees, planning groups or in carrying out aspects of the intervention/ research. Give a personal briefing on the remit and expectations for those involved when they initially start.
Aim to be genuinely representative	Recognise the demographic of the intervention and try to match at least some of the patient involvement to that demographic.
Develop review mechanisms	Build in review mechanisms with patient partners to check experiences from both sides. This will facilitate the discussion of any issues that need to be addressed.
Match involvement to motivation	Understand the motivations for patients to get involved and try to give them activities that are relevant. All patients do not have to be involved in everything from start to finish - specific actions or timeframes may work better for some so be prepared to be flexible.
Be clear about expenses and remuneration	Consider what expenses remuneration will be provided and budget for this accordingly. Ensure this is transparent to all involved. An NHS England policy paper gives generic role descriptions and the level of expenses and remuneration linked to these, which is a useful guide.[78]
Consider accessibility of meetings	Consider the timing and venue for all activities involving patients, including teleconference options, to ensure maximum accessibility.
Develop peer support	Establish peer support between patients involved in the improvement work. For a scale up programme it is helpful to have a cross-programme patient support and communication mechanism.
Foster patient co-production more broadly	Consider how to support healthcare professionals to become more mindful of patient involvement and their care experience throughout all their interactions with patients and carers. Foster ongoing co-production, not just when in 'improvement project' mode.
Consider the longer term patient role	Maintain a level of communication and links with involved patients beyond a specific project and signpost organisations such as Kidney Patient Involvement Network https://kpin.org.uk/ and NIHR INVOLVE https://www.invo.org.uk/

Findings 4 : Patient Involvement and Experience

Managing the programme

During discussions in the preparation of this report, programme managers and team members universally commented how it had been exceptionally rewarding but harder work than they had anticipated and only possible to achieve with the relevant leadership and energy.

The initial planning stages were seen as vitally important for a successful programme. It was important to consider patient representation at this stage, to be sure that the work was relevant and focussed on issues that were important to quality of care and patient experience. It was equally important to get expert advice on all key aspects such as evaluation, management and costing to produce proposals that were meaningful and understandable to stakeholders.

These large-scale QI programmes required sophisticated structures to underpin implementation and evaluation, as well as ensuring governance of these functions. The programmes had quite different structures, depending on:

- *where they were situated - a joint approach between several organisations, or led by one NHS trust*
- *how centrally controlled implementation was, or delegated to adopter sites*
- *whether evaluation was integrated or separately commissioned.*

The programmes adopted different programme management approaches. For TP-CKD a patient centred care facilitator acted both as programme manager and a coach travelling to sites to support teams' progression against set plans, present site-specific data and share knowledge. This was efficient for participating teams but a significant burden for a single individual to carry. Within TAKI local team building and empowerment to define the mechanisms for local delivery was seen as a critical component to drive the intervention locally, and to do this, regional project managers were recruited to work directly with the local teams. Thus, in contrast to ASSIST-CKD, TP-CKD and SHAREHD which all had a single coordinating programme manager, TAKI had distributed programme management across the sites.

Each of the implementation teams had a principal investigator/ clinical lead with a programme manager role and other core team members. The constitution of the team depended on the intervention and the delivery methods, but each core team needed to be cohesive, with a mix of all the necessary professional, clinical and research knowledge and expertise to run the programme. Clear expectations of what was required from team members both in terms of time and input was critical, as were regular planned and structured meetings. These meetings maintained momentum, built trust and facilitated team cohesion, which was invaluable when challenges arose. When setting up multiple groups, a written purpose and terms of reference were needed for each group, with clarity on whether its function was primarily managerial, advisory or governance oversight, to avoid blurring of remit or overlap of responsibilities and to help avoid 'mission creep'.

Each core team needed to engage and support adopter sites. The involvement of front-line staff in these sites was essential for successful implementation. In a scaling up programme, it is particularly important to consider how staff are introduced to an intervention that has been developed elsewhere and which they are expected to adopt, with limited scope for local adaptation.

All the programmes set out a broad 'call' for renal services to get involved and selected participant teams from those who responded. TAKI identified the number of teams they planned to work with, and stuck to those teams originally engaged, to enable the planned stepped wedge evaluation. ASSIST-CKD, TP-CKD and SHAREHD all tried to accommodate additional teams who wanted to get involved, as the programmes progressed. It was reported by all the programmes that local teams found it hard to get together as a team as often as they needed to, which could have hampered progress. Teams were supported in these opportunities through launch events, local site visits, or teams attending learning events and creating 'team time' to work on their implementation.

Scaling up programmes need a formalised communication plan which requires time, specialised skills and multiple dissemination routes to get the messages to different stakeholders. A range of communication channels and methods need to be incorporated, such as using programme newsletters, existing communication routes for professional associations and patient groups and developing a social media presence. Each programme started with a short descriptor and went on to develop a clear brand and a set of communication tools.

As with all improvement work in healthcare, these four programmes were not working in isolation. While each had specific objectives and a timeline to achieve, they were also subject to the wider culture of shifting priorities and system change. Tackling AKI for example built into the programme the implementation of a national patient safety alert for AKI detection, which required specific actions to align programme timescales with the national deadlines. ASSIST-CKD did not talk to teams in terms of a project that had an 'end', rather as a way of working that once in place would remain the norm, with establishing local funding as part of the implementation process. The sustainability work stream in SHAREHD documented a shared care 'strategy' that defined specific elements that the programme would focus on delivering such as the inclusion in Renal Association haemodialysis guidelines. TP-CKD worked closely with NHSE to align achievements in embedding patient activation measures and patient reported outcomes across Trusts with the wider programme of self management.

The learning from the programmes is to acknowledge the significant time and effort required at the start. If setting aspirational aims, be clear about managing the expectations to match the scope that funding and timescales allow.

	Key learning points related to managing the programme ***- Recruit early experienced programme management, QI and evaluation team members*** ***- Setup formal governance to support implementation reslience*** ***- Recognise and understand the context of the programme as it is not working in isolation.***
Identify suitable project management to get the project started	If possible, engage the project manager from the start-up period, or bring in experienced advice to ensure initial activities are appropriate and are creating a sound base.
Consider specific QI expertise	Be aware that project and quality improvement management are different fields and the expertise is not interchangeable. The expertise that is required may change at different stages of implementation. Consider having a QI 'director' if the PM does not have the necessary experience to give the relevant direction and support.
Plan sustainability from the beginning of the programme	Be mindful of what happens to the intervention when the project finishes and the programme team is no longer in place. CQUINs are beneficial in the short term but can promote a temporary tick-box culture rather than changing practice sustainably.
Ensure a balanced financial profile	Consider the financial plan for the programme and whether the balance between different elements such as evaluation, programme management, patient involvement and so forth are appropriate.
Plan required data collection in detail	Plan in detail what data items are needed, where they will come from and what the quality, data completeness etc. is likely to be. Consider implications for analysis if the data is not available on time, or to the quality required so that early mitigations can be put in place.
Plan and hold regular programme board meetings	Regular planned and structured meetings, including face to face, will maintain programme momentum and build team cohesion.
Develop lean and responsive meeting structures	Facilitate an environment for active and effective steering committees as this allows for quick and decisive actions when problems arise. Ensure terms of reference and expectations are in place but not onerous.
Review progress against the plan	Have a robust structured plan which includes any formal research protocol or bid. Regularly report progress against the plan and hold team members to account.
Actively manage risks	Review and put in mitigations for all risks - Be prepared specifically regarding implications for analysis if the data is not available on time, or to the quality required so that early mitigations can be put in place.
Link with existing networks	Harness the power of networks, linking with related projects and interested individuals but be mindful how robust their structures are and what will happen if they dissolve during your project.

Findings 5 : Management Methods and Mechanics

Conclusion

Delivering an initiative at scale is different to creating and implementing an intervention in a local health care environment. For spread to be successful it is critical to convince the hearts and minds of potential adopters within multiple contexts. The message has to be clear, concise, well-rehearsed and easily shared. The scaling up process needs to have a professional and coordinated approach with clear objectives, a support plan and stated deliverables. As an intervention spreads and other teams, organisations and bodies invest their time, resources and energy they will expect the core team to deliver the components that were set out in the invitation to join. The mechanisms for delivery need to be robust, while flexible to respond to the different needs of adopter sites and responsive to contingencies that arise.

The programmes all benefitted from seeing their work as part of a bigger picture, in terms of the 'movement' to which the programme linked such as patient involvement, self management policy focus on prevention, or delaying progression of disease. The TAKI programme linked their intervention with similar SEPSIS interventions via Patient Safety Link Nurses and SHAREHD was able to link with TP-CKD as they built on work using the “Your Health Survey” and PAM® instruments.

Within the team, expertise is required from a range of disciplines including patient experience, quality improvement, education, statistics, study design, qualitative research, as well as clinical leadership. The team needs to be diverse and to include patient partners from the development of the concept to implementation of the programme, through to sustainability plans and ongoing peer support.

Finally, essential to the success of these complex programmes is resilient teams who have a strong sense of networking across the renal community. All of the programmes were part of, or linked closely with, these wider networks without which their success would have been significantly harder. It is important to acknowledge the role of organisations such as NIHR, AHSN, KQuIP, KPIN, RA,UKRR,BRS, KRUK, Kidney Care UK, NKF, as well as the substantial funding from NHS England and the Health Foundation without which these programmes and this report would not have been possible.

5. The Kidney Community Context and Direction

Over the last two decades there has been considerable growth in the use of quality improvement (QI) methodologies in health care in order to tackle key challenges. Renal medicine has contributed to this trend, as enthusiastic teams have developed, tested and delivered interventions at scale intending to improve the quality of care and lived experience for people with kidney disease. This report examines four such programmes, three of which were funded by the Health Foundation, and the fourth a collaboration between NHSE and the UK Renal Registry, where interventions that had been developed and tested within a particular healthcare organisation were scaled up and implemented across several organisations. It aims to capture learning on what worked well, areas that were challenging and what could have been done better so that this information can strengthen future programmes of this nature.

5.1 The impact of renal failure on individuals and the NHS

It is estimated that in the UK three million lives are at risk as a result of moderate to severe chronic kidney disease (CKD). Advanced CKD impacts quality of life and is associated with high levels of morbidity and mortality. These burdens are considerably greater when kidney function declines to a point at which dialysis or transplantation is considered. Improving prevention and early detection, as well as ensuring that those who require it are enabled to be actively involved in choosing their treatment options are key objectives[5]. AKI affects 1 in 5 people admitted to hospital as an emergency and may be more deadly than a heart attack.

The health economic impact of chronic kidney disease is substantial, and was estimated at £1.45 billion in 2009-10 for the English NHS which is approximately 1.3% of its total budget[6]. Dialysis alone is estimated to cost over £30,000 per year per patient[7]. Reducing health inequalities in preventing the development and progression of kidney disease in all UK populations may help alleviate the burden of kidney care to the NHS. AKI extends hospitalisation and generates an annual cost in England of more than £1 billion or approximately 1% of the NHS budget [8].

5.2 History and context of renal QI activity

It is relevant to consider the history and development of QI in UK renal services, since this provides the context in which these programmes operated. Central to this culture was the establishment of the Renal Registry in 1995 and the development of Renal Association Clinical Practice Guidelines which were first published in the same year. In the ensuing years, both these agencies, in conjunction with others such as British Transplantation Society and the British Renal Society, have contributed considerably to underpin the quality of kidney care in the UK such that the specialty is in the strong position of having annual comparative data reports to support regularly updated, NICE accredited, guideline documents.

National bodies, networks and programmes that influenced the development of these initiatives

- *NHS Kidney Care - 2008-2012*
- *Academic Health Scientific Networks and Patient Safety collaboratives - 2018 onwards*
- *Kidney Quality Improvement Partnership (KQuiP) - 2016 onwards*
- *NHS Cardiovascular Strategic Clinical Network - 2013 onwards*
- *Acute Kidney Injury programme (including NHSE approved AKI detection algorithm) -Think Kidneys - 2014-2017*
- *Kidney Awareness Campaign - Think Kidneys - 2014-2017*
- *Kidney Patient Reported Experience Measure (PREM) - RA and KCUK - 2016 onwards*
- *Getting It Right First Time (GIRFT) renal medicine work stream - 2017 onwards*
- *NHS Right Care / Public health England: High value intervention in Chronic Kidney Disease - 2016*

National guidelines and frameworks that influenced the development of these programmes

- *Department of Health - National Service Framework for Renal Services -2004*
- *NICE AKI prevention detection and management guideline - 2013 onwards*
- *NICE CKD in adults: assessment and management guideline - 2014 onwards*

Figure 1 : Timeline of key national developments in England

Figure 1 shows an overview of relevant national developments during this period. The four nations, Scotland, Northern Ireland, Wales and England, also have evolved their respective health commissioning structures, research governance and QI approaches, such as Health Improvement Scotland and the Welsh Clinical Renal Network.

National and international annual conferences organised by the healthcare professional, clinical research and patient support organisations provide a forum for sharing research and improvement work and stimulate vigorous debate in the sector. Professional meetings dedicated to kidney medicine were established by the Renal Association (RA) when it was founded as a specialist medical society in 1950. The British Renal Symposium, (later known as the British Renal Society (BRS), was established in 1989 with the clear aim of promoting dialogue and collaboration across the multidisciplinary team, as it had become clear that such an approach would be beneficial to the development of renal care. Important partners have included the renal charities - both patient-facing such as Kidney Care UK (previously BKPA) and the National Kidney Federation and research focused such as Kidney Research UK, as well the commercial sector. In recent years the RA and BRS have held joint meetings under the banner of UK Kidney Week.

NHS Kidney Care was established in 2008 with the stated objectives to improve patient outcomes, and to enable equitable, effective and efficient kidney services. Its work-streams included quality and safety, patient experience and service development, with themes that focused on acute kidney injury, peritoneal dialysis, shared decision making, transition from childhood to adult care, end of life care and patient reported outcome measures. It established the renal networks, with regional remit to provide a co-ordinating function and leadership for clinical and quality improvement initiatives. An example was the establishment of a home therapies lead for the Yorkshire and Humber Renal Network which triggered the development of the shared haemodialysis care programme. In 2009, the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) report “Adding Insult to Injury” reviewed the care of patients who died in hospital with a primary diagnosis of acute kidney injury (acute renal failure) and highlighted a number of recommendations for improvement. The Think Kidneys campaign responded with the aims being to reduce avoidable harm and death for people with acute kidney injury, and to improve care for patients whether in hospital or at home. The campaign continues to drive improvement even though it formally ended in 2017.

As a result of reorganisation under the Health and Social Care Act 2012, NHS Kidney Care and the renal networks were disbanded and a national clinical director for renal was appointed with a revised role up till 2016 which was instrumental in setting up Think Kidneys, facilitating NHS E support for KQUIP and funding for TP CKD as well as supporting the national CKD audit.

In order to ensure that renal disease continued to advance standards of care, the Kidney Quality Improvement Partnership (KQuIP) mentioned above was established in 2016 with the intention of creating a “dynamic network of kidney health professionals, patients and carers committed to developing, supporting and sharing quality improvement in kidney services”. The goal was to enhance outcomes and quality of life for patients with kidney disease by co-ordinating quality improvement efforts across the sector, bringing together the professional renal societies, the Renal Registry, patient group charities and commercial enterprises. At first KQuIP was an informal partnership that did not come with dedicated funding or a national mandate for improvement across renal care services but it acted as a catalyst to stimulate project development.

Since 2017, with the support of Kidney Care UK and the Renal Association (RA), an annual national survey of patient reported experience measures has contributed new information that is steering the debate in the direction of outcomes that matter to patients. This work demonstrates the value of medical staff, patients and allied professions forming networks through which trust and collaboration facilitate efficient exchange of practical experience[2]. The combative academic style of early RA meetings contrasts with the facilitative and engaging culture that has come with engagement of the wider Multi diciplinary Team. Evidence of the robust nature of those early meetings comes from J Stewart Cameron’s “History of the first half century of the Renal Association” 1950-2000:

> ***The meetings in the small meeting room of the Ciba foundation were intimate and lively. The front row was full with all the heavy artillery on the subject of renal function and disease, and giving a paper as a young supplicant member could be an intimidating affair. Robert Heptinstall remembers: “Attendance at these meetings instantly dispelled the notion that the British are a polite and gentle race. Not only were the presenters of papers likely to be abused verbally, as Jo [Joekes] and I were by Clifford Wilson when we first put forward the concept of focal glomerulonephritis, but physically as well, such as when Robert McCance of Cambridge quite literally threw me off the platform for exceeding my time”. It should be added that McCance probably weighed only two-thirds as much as even the rather lean Heptinstall.***

This reflects the evolution of the profession from a culture where clinicians acted with autonomy, subject to limited external objective evaluation of the quality of the care they were delivering, to the modern environment, where it is recognised that openness and co-operation are essential to underpin safety and quality in health care. The recent NHS England “Getting it right first time programme” builds on this approach utilising objective metrics from a range of renal domains to assess the quality of individual renal services. These are presented to teams at site visits with the intention of highlighting areas for improvement and thereby improving the overall quality of care.

The “Delivering Kidney Excellence” report, written in 2013 by the ‘Kidney Alliance’, identified a number of key domains and ambitions including AKI, preparation and choice, self-management, person centred care and lifestyle on dialysis[9]. Each programme covered in this report was known to the wider kidney community and went some way to fill one of the ‘gaps’ identified therein.

5.3 Report objectives and analytical approach

KQUIP highlighted limited sharing of good practice and lack of QI resources specific to renal care as barriers to delivering QI, which the ongoing KQuIP initiatives intend to correct[10]. The objective of this work is to support this process by producing a combined learning report that can be used in the development, delivery and deployment of future improvement initiatives both within the kidney community and other disciplines. It is hoped that the report will be built on in the future, as new information comes in from subsequent programmes as they take place.

The report primarily focuses on three Health Foundation funded renal Scaling Up programmes, plus additional references to the wider context of projects and programmes within renal services. The evidence used is drawn from data, results, objective reports and other outputs provided by the contributing programmes.

Experiential evidence was gathered from meetings, taking the form of discussion, informal questioning and more structured workshops with the objective of gaining a greater understanding of the themes that lay behind information presented in the programme documentation. Comparison tables were developed to summarise the interventions, any management documentation that was produced, and the QI and evaluation methods used.

The aim was to prepare the report in a transparent, factual and constructive manner, covering both successes and challenges and basing the commentary on the available objective evidence. Learning comes from the response taken to overcome problems that were identified during the course of these projects and we have used these where possible to highlight key lessons from this rich experience. During the initial phases of feasibility planning and data gathering against the programme themes, key areas of overlap emerged that represented consistent lessons. These areas were confirmed with the key project leads and further elaboration undertaken that lead to the detailed chapters in sections 7 - 10.

5.4 Funding of programmes studied in this report

A stated objective of the Health Foundation is to support health care improvement and strengthen the collective understanding of the place of QI methodologies to reduce unwarranted variations in outcome that are evident from the multiple data sources that underpin the modern NHS. They have contributed strongly to the development of QI in renal medicine through their support for a series of programmes in the area of kidney disease, both in primary and secondary care. In particular, the Scaling Up programme supported teams that had developed approaches or interventions that when successfully tested at a single location were shown to improve care and were now ready to be implemented more widely.

For improvement interventions to have the greatest impact they require to be funded appropriately, conducted to a high standard and carefully evaluated [2]. Small quality improvement projects are necessary to allow individuals to pursue improvement ideas and to develop concepts that might be later scaled and spread. If they are to lead to sustainable benefit, a degree of methodological rigour is required as that enables the learning to be documented and shared. Sufficient investment is therefore required in the management and evaluation of improvement programmes so that the evidence base of appropriate methodologies and their application is developed and subjected to scrutiny, similar to other disciplines of health care delivery and research.

- *The Health Foundation funded programmes examined in this report are identified below. Each programme went through a competitive bid submission and evaluation process in order to gain places on the relevant Health Foundation initiatives during 2014, 2015 and 2016.*
- *Tackling acute kidney injury (TAKI): a multi-centre quality improvement programme, led by University Hospitals of Derby and Burton NHS Foundation Trust*
- *A programme to spread eGFR graph Surveillance for the early Identification, Support and Treatment of people with progressive Chronic Kidney Disease (ASSIST-CKD), led by Kidney Research UK*
- *Enabling self-management and shared haemodialysis care (SHAREHD) in hospital-based dialysis, led by Sheffield Teaching Hospital NHS Foundation Trust*

In addition, we also include aspects of the Transforming Participation in Chronic Kidney Disease (TP-CKD) that was funded by NHS England and delivered in collaboration with the UK Renal Registry, to provide further insights into particular aspects of programme delivery including patient co-production and project management.

5.5 Project abstract summaries

The programmes included in this report tackle different points in the patient pathway, from acute kidney injury to chronic kidney disease and renal replacement therapy. The following diagram shows where each programme fits in the spectrum of kidney care:

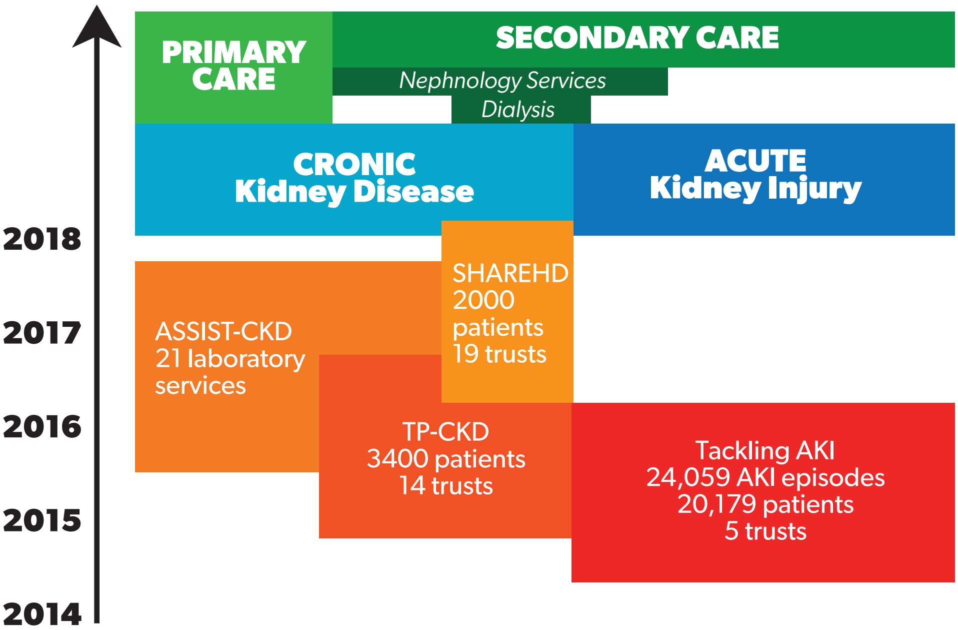


Figure 2 : The context of the programme within the health care setting

5.5.1 Tackling AKI

Aimed to test whether a complex intervention for Acute Kidney Injury delivered at organisational level led to improvements in the standards of care delivery and better patient outcomes

What problem was addressed?

Acute Kidney Injury (AKI) describes a sudden reduction in kidney function. Risk factors for AKI include greater age and long term conditions (such as heart failure, lung disease, diabetes and chronic kidney disease) and it is often precipitated by inter current illness such as an infection or volume depletion. AKI is common (half a million people per year in the UK experience AKI), harmful and often preventable. It is seen in 5 - 15% of those admitted to hospital and is associated with dramatic increases in mortality (having an associated death rate of 20-33%), morbidity and hospital length of stay. There are an estimated 100,000 excess deaths associated with AKI in UK hospitals per year. In addition to the personal impact for the patients and their families, AKI extends hospitalisation and generates an annual cost in England of more than £1 billion or approximately 1% of the NHS budget[8]. For those who survive AKI, recovery is often incomplete, exacerbating long term conditions, reducing quality of life and accelerating the progression of chronic kidney disease[11]. AKI therefore represents a major patient safety challenge for health care.

Previous initiatives leading to this programme

There is evidence that health care processes for patients with AKI are variable and that the quality of care delivered contributes to poor patient outcomes. These issues were highlighted in the 2009 National Confidential Enquiry into Patient Outcome and Death (NCEPOD) Report, which demonstrated that a significant component of harm arises from poor standards of AKI management [6]. This led to variety of initiatives, and in 2012 the Royal College of Physicians of Edinburgh convened a consensus conference that made some key recommendations around fluid therapy, e-alerts and biomarkers[12]. In March 2013, World Kidney Day focussed on AKI, and The National Institute for Health and Care Excellence (NICE) issued AKI guidelines in August 2013.

In October 2013, the Think Kidneys programme commenced, which was a major initiative from NHS England and the UK Renal Registry. Think Kidneys was the NHS's campaign programme for AKI, with the overall aims of reducing avoidable harm and death for people with AKI and improving care for patients whether in hospital or at home. Over its initial three year period, Think Kidneys delivered a number of major outputs, summarised in its Review and Evaluation report, published in February 2017[13]. Of particular relevance to the Tackling AKI project was the national standardisation of electronic detection for AKI across all laboratories in England, which was enacted via a Patient Safety Alert that required compliance by March 2015[14].

Underneath and in parallel to the Think Kidneys national campaign, a large number of local and regional AKI projects developed. One example of this was a patient safety collaborative led by Kent, Surrey and Sussex AHSN.

What this project did

Tackling AKI was launched in 2014 with the specific aim of understanding whether a complex, multi-component hospital-based intervention was able to improve AKI recognition and the delivery of basic elements of patient care. The intervention had three components: an electronic detection and alerting system; a care bundle covering assessment, investigation and basic management; and an educational programme to raise awareness and knowledge of AKI in healthcare. Tackling AKI built on a programme that had started at Royal Derby Hospital in 2010 and was associated with improved patient outcomes [15, 16].

Led by a team at Royal Derby Hospital, partnering with the UK Renal Registry and Bradford University, Tackling AKI was implemented over a 27 month period between 2014 and 2017 across five hospitals in England. It used, as a key component of the intervention, the national rollout of the AKI alert. The sites were Leeds General Infirmary, Leeds St James' Hospital, Bradford Royal Infirmary, Ashford and St Peter's Hospital, and Frimley Park Hospital. The intervention was rolled out across the five hospitals within a stepped wedge cluster randomised controlled trial (SWCRT) design. Over 24,000 cases of AKI in hospitalised patients were assessed. Data collection included patient outcomes, process measures and a qualitative assessment of barriers and enablers to implementation. The intervention was adapted to meet the needs of the specific centres but always included a national AKI alert with an associated care bundle to follow. The staff education to support the alert and care bundle was adapted by each site. The primary quality improvement method adopted was peer review / peer assist between the participating services, with local project management support.

What was the impact?

The project improved the care pathways that are important to the care of AKI patients, but did not demonstrate a change in the primary outcome measure of all-cause mortality. The incidence of AKI increased, probably because of better recognition, together with a decrease (approx. 1 day) in hospital length of stay, as well as a decrease in the duration of AKI episodes themselves. The programme demonstrated that a systematic approach to better delivery of person-centred AKI care across acute specialities can improve outcomes. The reduction in hospital length of stay, although modest on an individual patient basis, translates into a significant health economic benefit across the thousands of patients who sustain hospital-acquired AKI each year.

In addition, there was significant learning about the practicalities of undertaking large pragmatic trials in AKI as well as the complex interplay of local contextual factors that facilitate or impede hospital-wide AKI interventions. For example in such interventions, it is likely that there was variable uptake of the intervention across the participating sites. But with outcomes being measured on a hospital-wide basis it was important to understand whether any reduced impact of the intervention was due to its uptake rather than its effectiveness.

The notes audit of 1048 patients found that AKI care bundle usage increased from 0% to 40.2% between the control and intervention periods. There were also increases in AKI recognition (69.4% versus 88.8%), medication review (60.1% versus 71.3%), fluid assessment (74.4% versus 91.2%) and urinalysis (37.4% versus 64.7%), with no change in rates of specialist referral, renal imaging and urinary catheterization, which were important balancing measures. A full description of the Tackling AKI study and its primary results are published [17].

5.5.2 ASSIST-CKD

A programme to spread eGFR graph surveillance for the early identification, support and treatment of people with progressive chronic kidney disease (ASSIST-CKD)

What problem was addressed?

CKD is a common condition affecting 5% of people aged 70 and older, which for the most part can be managed in primary care. However, as the condition progresses, the increased complexity of care requires management by a specialist renal centre, to limit the impact of the condition and to plan for timely initiation of renal replacement therapy (dialysis and transplantation). Patients who present late with advanced CKD have poorer outcomes, including higher mortality, less likelihood to be transplanted and to receive home dialysis therapy as well as being significantly more costly to treat than those who present in a timely fashion. Therefore, late presentation is considered an important marker for poor outcomes and a cause of avoidable harm [18]. Tools to facilitate appropriate identification and timing of referral from primary to secondary care have the potential to increase confidence for appropriate management of patients in primary care. Risk stratification is particularly valuable for the management of patients at greatest risk of developing end-stage kidney disease (ESRD) [19], such as those with diabetes.

Previous initiatives leading to this programme

In 2004, the Heart of England NHS Foundation Trust (HEFT) renal and diabetes services developed a database that collated biochemical data to generate cumulative graphs charting the change in kidney function (estimated glomerular filtration rate: eGFR) over time in patients with diabetes. Reviewing the graphs enabled the identification of patients with more rapidly deteriorating kidney function that required particular attention. Primary care services were then alerted to those particular patients, facilitating early referral to the nephrology service. At the time when the graphs were first developed and used, approximately one-third of patients starting dialysis at HEFT had diabetes.

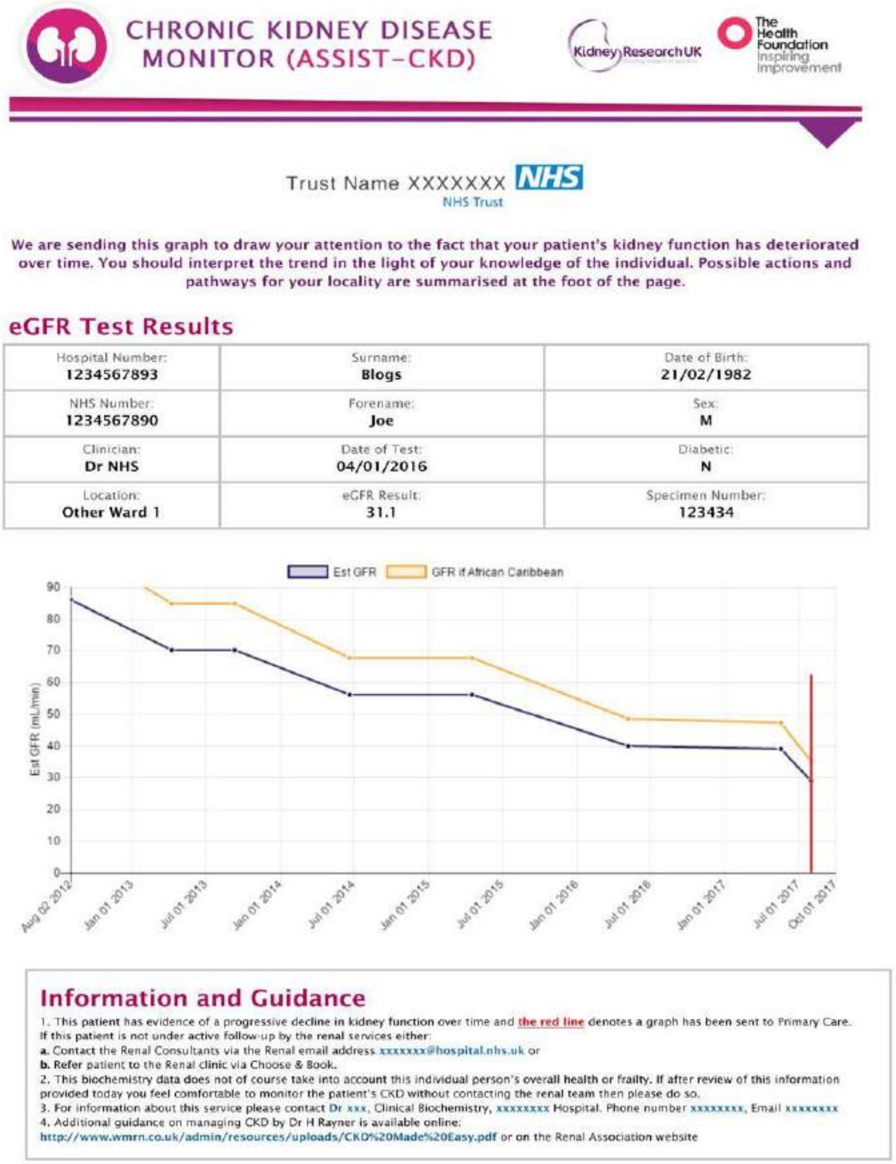
The impact of this intervention at HEFT was a reduction in the rate of late referral for dialysis (defined as referral/presentation within 90 days of commencing dialysis) to the lowest in the UKRR for 2009 [20]. Further evidence of the effectiveness of the approach was that since 2005, the number of patients starting dialysis per year at HEFT had fallen by 16%, compared to an increase of 8% in England as a whole [21]. However, it was unclear whether the impact on late presentation was due to the use of the eGFR curves or due to other aspects of management at HEFT.

A Health Foundation funded Shine project in 2011 extended the work beyond the diabetes service by developing and implementing software to extract data for patients with low eGFR directly from the laboratory database, compiling and displaying the cumulative eGFR graphs. This enabled the surveillance service to be extended across all patients who were at risk of deteriorating kidney function. Patients were classified as low, intermediate or high risk. For intermediate and high risk cases, the requesting primary care clinician was sent a paper copy of the cumulative eGFR graph with a prompt that further action might be needed. This project demonstrated the potential improvement in outcomes that could be made if this intervention were to be scaled up across the health service.

What this programme did

The overarching aim of the ASSIST-CKD programme was to drive large-scale measurable and sustainable change to reduce the burden of chronic kidney disease across the UK and in particular, reduce late presentation for renal replacement therapy (RRT). The intervention was to spread the software that had been developed for the HEFT laboratory service to hospital laboratory services around the country, with the aim of enabling early identification of those with deteriorating kidney function. The programme trained laboratory staff and CKD renal nurses in some sites to read eGFR graphs, with those showing intermediate or high risk of kidney function deterioration being flagged so that details could be sent to the GP with a prompt that further review and action may be needed.

It was intended for the intervention to be rolled out sequentially. Renal centre clusters would receive the intervention at staggered points as part of a stepped wedge cluster randomised controlled trial (SWCRT) with the primary outcome measure being the incidence of late presentation for RRT[22]. Initial support was provided to laboratories to link their pathology systems to a newly installed SQL database and then install the ASSIST-CKD software. Training and staff costs for one year were provided for local staff to review and forward the flagged graphs to GPs for further action. The intervention package included learning events for the participating sites. Early in the implementation phase, a significant change had to be made to redevelop the software since it became clear that the existing HEFT version could not be supported, nor be sustainable for set up, in various IT laboratories that planned to join the programme. This change impacted on the implementation timeline and meant it was no longer possible to run the SWCRT necessitating a change of study design to a quasi-experimental ‘before and after’ approach.



CHRONIC KIDNEY DISEASE
MONITOR (ASSIST-CKD)

Trust Name XXXXXXX NHS
NHS Trust

We are sending this graph to draw your attention to the fact that your patient's kidney function has deteriorated over time. You should interpret the trend in the light of your knowledge of the individual. Possible actions and pathways for your locality are summarised at the foot of the page.

eGFR Test Results

Hospital Number: **1234567893**	Surname: **Blogs**	Date of Birth: **21/02/1982**
NHS Number: **1234567890**	Forename: **Joe**	Sex: **M**
Clinician: **Dr NHS**	Date of Test: **04/01/2016**	Diabetic: **N**
Location: **Other Ward 1**	eGFR Result: **31.1**	Specimen Number: **123434**

Information and Guidance

1. This patient has evidence of a progressive decline in kidney function over time and the red line denotes a graph has been sent to Primary Care.
If this patient is not under active follow-up by the renal services either:
a. Contact the Renal Consultants via the Renal email address xxxxxxx@hospital.nhs.uk or
b. Refer patient to the Renal clinic via Choose & Book.
2. This biochemistry data does not of course take into account this individual person's overall health or frailty. If after review of this information provided today you feel comfortable to monitor the patient's CKD without contacting the renal team then please do so.
3. For information about this service please contact Dr xxx, Clinical Biochemistry, xxxxxxxx Hospital. Phone number xxxxxxxx, Email xxxxxxxx
4. Additional guidance on managing CKD by Dr H Rayner is available online:
http://www.wmrn.co.uk/admin/resources/uploads/CKD%20Made%20Easy.pdf or on the Renal Association website

Figure 3 : Sample eGFR result output

What was the impact?

The surveillance software was implemented at over 20 laboratories across the UK, serving approximately 11 - 12 million people. Local ownership and evidence of sustainability has been demonstrated where sites maintained the intervention past the initial subsidised year. Two laboratories have now been reporting for over four years - evidence that the intervention can be absorbed and embedded into day to day practice.

At the time of writing the qualitative evaluation had been completed but the quantitative assessment of the primary endpoint of late presentation for renal replacement therapy was not available due to the programme delays outlined and the timing of the UK Renal Registry's reporting cycle. This is due Autumn 2020. However, early indications from the first site show an encouraging trend.

5.5.3 SHAREHD

Aimed to implement and evaluate a programme of shared haemodialysis care (Dialysis Self-Management Support)

What problem was addressed?

Haemodialysis (HD) is the most common form of dialysis treatment and involves using a machine to pass the patient's blood through a filter to remove toxins. In England alone, approximately 20,000 people each attend an institution three times a week, to received HD for around four hours at every visit. However, since dialysis was first developed in the 1950s, it has been clear that people are able to manage their own care to a high standard [23-25]. The opportunity to self-manage has been, in general, limited to those who are able to dialyse at home. For those who dialyse at centres, the environment does not systematically support people to be engaged in their own treatment. This is despite evidence from a range of long-term conditions of the benefits of patients being engaged in their own care [26]. Such engagement can improve health literacy and facilitate patients to feel 'more in control' of their health. This is important since low health literacy amongst dialysis patients is associated with worse survival [27] whereas self-motivation and patient education result in better care, e.g. with phosphate control [28] and fluid balance [29]. As with the broader NHS, dialysis services are experiencing considerable pressure to deliver high quality care in the face of fiscal challenge. Engaging service users as true partners in their own care can be an important mechanism to maintain quality of care and is recognised as an ambition in "Kidney Health: Delivering Excellence" [9].

To achieve this change, health care professionals need to enhance their roles, becoming educators and facilitators, supporting patients to take a greater role in their own care, and increasing their opportunities of dialysing at home.

Previous initiatives leading to this programme

The shared haemodialysis care programme was developed in Yorkshire and the Humber in 2010 through coproduction with patient partners who strongly articulated the value of the experience of being able to learn about and take a greater role in their own treatment [30]. Those patient partners were clear that this was "shared" rather than "self" care - since it was important that the patient should be supported to make a choice about the level of engagement that they wish to undertake. This development was supported by the Yorkshire and Humber local renal network and was funded through the Health Foundation 'Closing the Gap through Changing Relationships' Programme. This underpinned team building between patients, managers, commissioners and health care professionals with shared goals. It enabled shared haemodialysis care to be tested, iterated and spread to the 26 dialysis units in the region. A training programme was developed that gave nurses the skills necessary to support patients in their own dialysis care. This has been continued with funding support from several sources, including most recently Kidney Care UK, and has trained more than 500 nurses over the intervening period.

In the shared haemodialysis care intervention, choice to participate in the tasks related to their haemodialysis treatment is offered to a patient by the health care team. Support and relevant training is tailored to the extent that the individual wishes to get involved and work towards their personal goals. HD is broken down into approximately 14 component tasks and the progress of training is documented from novice to expert using a competency record underpinned by bespoke educational materials [31].

Small steps (tasks) within shared care provide a framework to unlock potential. The shared care framework shown in Figure 4 illustrates the stepwise approach that can be taken to Shared Hemodialysis Care [32]. Patients can start with small tasks and do as much or as little as they feel able. As they learn, confidence is built.

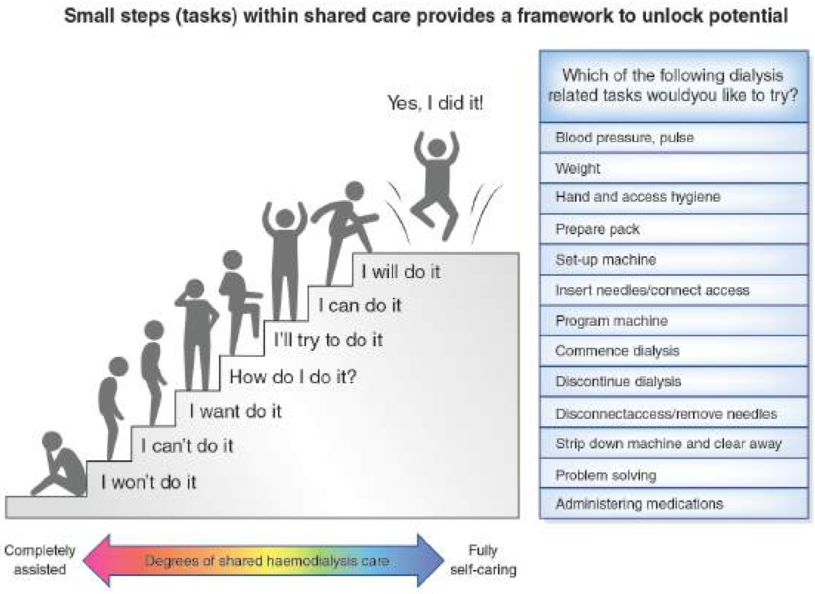


Figure 4 : Shared care framework [32]

What this programme did

The programme undertook a 24-month stepped wedge cluster randomised controlled trial (SWCRT) of the intervention at 12 dialysis centres in England. The quality improvement intervention was delivered by means of a Breakthrough Series Collaborative where six centres were randomly allocated to start in Wave 1, with the remaining six starting six months later in Wave 2. Objectives were to scale-up and sustain the established shared care approach via learning events, where teams tested different ways of increasing patient engagement in their dialysis care using PDSA cycles and compared their results through the collaborative. Wave 1 teams had four learning events followed by a single learning event for Wave 2 teams only, followed by four further learning events involving all teams. A third wave of an additional seven trusts from England, Scotland and Ireland participated in a collaborative of three learning events, with additional peer assist support from Wave 1 and 2 teams.

What was the impact?

SHAREHD provided a framework to articulate the shared care intervention. The opportunity to collaborate and share ideas has helped to draw together the 19 trusts involved in the programme and give a more consistent approach to shared care, accelerating its implementation. The resulting learning and materials are available for other renal services that are considering implementing this patient centred approach. We estimate that more than 2000 centre-based haemodialysis patients are now offered partnership in their care as a consequence of this work. Overall there was an increase in the percentage of people undertaking five or more tasks and the number of those dialysing independently in centre or at home also increased. The formal findings are currently being published.

5.5.4 Transforming participation in chronic kidney disease (TP-CKD)

What problem was addressed?

A person's knowledge, skills and confidence to make effective decisions and take action to maintain or improve their own health is known as 'patient activation'. This can be measured using a validated tool, known as the Patient Activation Measure (PAM® Insignia Health)[33]. Licences to use the PAM® tool were provided by NHS England to several organisations in 2016 including five Clinical Commissioning Groups, working with their GPs on innovative ways to support person-centred care for long term conditions and the UK Renal Registry. Assessment of care for renal patients has historically been based on clinical outcome measures, considered important by healthcare professionals. However, these measures often do not capture the priorities that may matter more to patients such as symptom burden, quality of life and readiness to take a role in care.

As stated by Jonathan Hope (patient co-chair TP-CKD board), "The current approach to renal failure is highly medicalised. The holy grail for most people with a chronic disease is to reclaim what is often lost in the face of a long-term condition;

hope, empowerment, independence, control and well-being".

Previous initiatives leading to this programme

As with Tacking AKI above the Think Kidneys programme, which started in 2013, was a major initiative to reducing avoidable harm and death for people with AKI and improving care for patients whether in hospital or at home. Over its initial three year period, Think Kidneys delivered a number of major outputs, summarised in its 'Review and Evaluation report', published in February 2017[13].

The NHS England initiative to develop the use of patient activation measures (PAM® Insignia Health) dovetailed nicely with the work the UK Renal Registry had been undertaking for several years with international partners on patient reported outcome measures (PROM). They were interested to explore mechanisms for collecting this routinely.

The TP-CKD programme provided an opportunity to explore these mechansims as well as build on and utilise the broader resources and recognisable brand that the National Think Kidneys campaign had established.

What this programme did

The overarching objective of the TP-CKD programme was to find ways to empower patients and health care professionals to develop new ways of working that support patients to take greater control of their health and wellbeing, and to be more involved in the design and delivery of services that achieve their personal and clinical goals [34]. It was a collaboration between NHS England and the Renal Association, with a primary aim of determining whether it was possible for units to routinely collect patient reported measures from kidney patients and return them to the UK Renal Registry. These measures included symptom burden (IPOS-S-Renal), quality of life (EQ5D-5L) and information on the person's ability to self-manage (Patient Activation Measure PAM[35]). This information was then used to explore the knowledge, skills and confidence of people with kidney disease to self-manage their health and the association between these attributes, symptom burden and quality of life. A further objective was to understand the capacity of health care professionals to support such involvement, and mechanisms that might enhance this [36]. The ultimate objective was to develop an intervention toolkit and test the efficacy of targeted interventions to improve activation.

The programme took place between Jan 2015 and Dec 2017 with two key workstreams:

1. *Measurement - agreeing a set of patient-reported measures suitable for routine collection.*
2. *Intervention - to develop and agree targeted interventions for patients and clinical teams to support patients active participation in their own health care (see the intervention tool kit[37].*

The QI methods adopted by the programme were the NHS Change model and the peer assist approach, which were used alongside learning events. A person centred facilitator supported local intervention activities.

Led by Richard Fluck, the programme started from engagement with the NHS England (NHSE) PAM learning set where the feasibility of using the PAM® tool in the NHS was tested[38]. Building on that theme and with the support of NHSE, the UK Renal Registry / RA aimed to extend the scope to explore the feasibility of collecting and reporting on wider patient reported outcomes and measures, beyond the aspects explored in the 13 point PAM® tool.

What was the impact?

The programme acknowledged that collecting patient reported measures routinely in renal services was challenging, but by using a structured approach, with good leadership, engagement and support, it was possible to achieve it, albeit primarily with patients with end stage renal failure (ESRF) on in-centre haemodialysis. The focus on co-production and co-design meant that patients were included alongside health professionals in the leadership, design and implementation of the programme at national and local level and this enhanced the delivery of the programme. 14 kidney units participated in the programme, with 3,325 patients from across the care pathway completing at least one survey. Co-produced outputs from the measurement workstream included the development of two survey tools: 'Your Health Survey' (YHS) and a 'Patient Reported Experience Measure' (Kidney PREM) which is now reported annually in the UK. In addition, the means were established for the results of YHS to be uploaded to Patient View so that patients can access their own results to potentially aid discussion with their health care professionals.

Another output from the programme was an Intervention Toolkit that recommends evidence-based interventions based on the premise that the likelihood of achieving full involvement of patients in their own care is dependent on both their own level of activation and the level of activation of the people who are looking after them [37].

5.6 Key project comparison themes

As part of initial preparation for this report a range of themes were highlighted in section 12.1. These were prioritised through the interviews with key stakeholders (principal investigators, project managers, patient leads). Five key themes emerged that were consistently relevant to any project and therefore merited deeper investigation and analysis. The following sections explore how the programmes approached these areas and overcame the challenges.

The key themes are:

a. 'The improvement idea' - the intervention and how it can be implemented across a range of healthcare environments

b. 'Change Management' - understanding the theory of change and what the appropriate QI mechanisms to deliver it are

c. 'Evaluators' - lessons for research teams and the importance of processes being in place to feedback to improve the delivery

d. 'Service Users' - the impact on front line staff and patients including co-production approaches

e. 'Delivery Team' - creating a learning environment that supports engagement and management to deliver to time quality cost including the celebration of second leaders.

These themes appeared and reappeared, with many examples, in the programme reports and from the interviews and workshops which explored stakeholder perspectives. They also speak to common areas of tension experienced during the design and implementation of improvement work (Table 1) and are confirmed in the wider improvement literature as referenced in the reading list at section 12.5.

Discussing and understanding such tensions and differences of opinion within the multi-disciplinary core programme team can begin to allow either the formulation of solutions, or at least a shared understanding of tensions, providing a more solid foundation on which to proceed. This was confirmed by Steve Ariss (SHAREHD Evaluation lead) reflecting on the initial kick-off meeting in which "frank and open disagreements to the approach of research versus improvement created an environment within the project where such issues and tensions could be debated in a mature manner. As a result participants could anticipate, and appreciate the reasons for, alternative perspectives. Disagreements were noted but decisions on a course of action to best support the programme were agreed and supported by the whole team".

PROJECT TENSION TABLE		
Purist Stick to the tool absolutely otherwise it is invalidated	**Technical Method or Tool**	***Pragmatic*** Use the tool as far as possible but make adaptions for the local circumstances
Attain full research ethics, clinical trials registration/ approvals and publish the study protocol in a timely manner	**Formal Registration**	'Service improvement' local management and governance
Top down dissemination	**Fidelity of the intervention**	Local adaption or reinvention
Agree 3 messages, reiterate at every opportunity throughout the project	**Communication Approaches (example - messages)**	Different stakeholders or audience have different messages tailored to their motivations
Centralised	**Management**	Distributed
Practicalities of involving patients (co-production)	**Patient involvement**	Desire to involve patients

Table 1 : Tensions that need to be considered in the planning of improvement programmes

6. Defining the Intervention and Implementing with Fidelity

Why is it important to define what you plan to do?

Fidelity refers to the degree to which an intervention or programme is delivered as intended by its originators. An assessment of fidelity contributes to understanding the effectiveness of that intervention and may provide an explanation for why outcomes were not as expected in any new context. In complex interventions it is often difficult to clearly define what exactly the intervention is and how it is expected to be implemented, however increasing that clarity will build the effectiveness of the evaluation and validity of the results.

Each of the Scaling Up programmes were required by the Health Foundation to invest considerably in an evaluation work stream, which included an assessment of how well both the programme and the intervention were delivered against the design or plan. These experiences are drawn on in this chapter to support future projects as part of their preparations for spread and to scale up.

Monitoring intervention fidelity is just one aspect of assessing complex interventions. Building in a mechanism to understand and share the contextual variation, wider benefits and implications should be identified from the start and re-visited throughout the programme. As stated by Mary Dixon-Woods[2], “solutions can be agreed at the level of principle and left up to local customisation at implementation, and which should be locally developed”. This requires an acknowledgement of the complexity of the intervention and the extent to which adaptations within local unique systems are required or can be accommodated. A detailed understanding of the local context for improvement, such as barriers and enablers, is also important to influence the hearts and minds of others who will sustain the implementation after the specific programme’s formal end.

It should be acknowledged that a natural tension may exist between the fidelity of the intervention and the opportunities that there are for local adaption, taking account of contextual issues and enabling adopter teams to develop a sense of ownership. This is essentially the balance between top-down dissemination of a fixed intervention versus each team deciding for themselves what an intervention should look like and how it should be actioned - which may diverge to the point of not actually being the same intervention. The absolute rigour with which fidelity of the intervention needs to be maintained, or the level at which it is defined, depends on the nature of that intervention and it should be recognised that it may take time to get the balance right. Tim Horton et al in ‘Against the Odds’ puts it as: “balancing fidelity, quality and adaptability - as an innovation scales, it must be flexible enough to be adapted to new contexts while continuing to achieve the same impact. Here adopters and evaluators are critical partners in identifying the core components of the innovation that must stay the same and those aspect that can be adapted to new settings”[39]. The three renal improvement programmes took different approaches to fidelity due to their very different natures.

6.1 Adherence to the defined intervention

Within the TAKI project, the key components of the intervention were clearly defined as follows:

- *an AKI electronic detection and alerting system*
- *an AKI care bundle*
- *an educational programme to raise awareness and knowledge of AKI in health care workers*

The electronic detection system was uniform across all sites, conforming with a nationally mandated specification, so this component was rigid. However, each site evolved local mechanisms for communicating the alerts for action. It is important to note that the timing of the TAKI programme was critical in order to align with the national rollout of the AKI detection system, creating a unique opportunity for this programme to be delivered. This highlights the importance of ensuring that if there is a plan to roll out a national programme that the opportunity should not be missed for it to become part of the intervention within a QI programme.

The AKI Care Bundle contained individual elements that covered the assessment, investigation, and basic management of AKI (summarised in Table 2). The core elements of the care bundles were intended to be consistent, but sites were encouraged to adapt other aspects of the bundle to account for local factors. These included the appearance of care bundles and additional non-core elements that might be included such as investigations into the cause of AKI, management of hyperkalemia and information for patients.

Core elements of Tackling AKI Care Bundles common across all sites	
Assess volume status and optimize blood pressure	Renal imaging
Treat sepsis	Medication review
Perform urinalysis	Referral (to nephrology or critical care outreach) for AKI stage 3 or AKI with complications

Table 2 : Core elements of Tackling AKI Care Bundles

Supporting this was an educational programme to raise awareness and knowledge of AKI among health care workers (summarised in Table 3). This was delivered organically across a range of meetings at the participating sites - some of which were designed by the programme (e.g. launch events) and some that made use of existing educational activities (e.g. grand rounds, departmental governance meetings, staff induction). Attendees included members from across the whole health care team including doctors, nurses and pharmacists. Effectiveness was influenced by multiple factors including whether staff who were actually implementing the intervention were available to attend.

TAKI - Educational Programme Activities				
Type of Education Session	**No. of Sessions per centre**	**Target audience**	**Audience Size**	**Duration**
Launch event	1	All members of staff welcome; hospital chief exec, medical director, chief nurse attended	30-50	1 h
Hospital grand rounds	2	Departmental teaching to a range of specialities (e.g. emergency medicine, acute medicine, elderly care, surgery, urology)	40-80	1 h
Department education or clinical governance meetings	3-6	All grades of physicians, doctors in training and open to those in other specialities who wish to attend	10-20	1 h
Teaching				
Post graduate doctors	3/yr (one for each grade of doctor)	AKI teaching as part of curriculum (essential teaching) for doctors in training, attendance often mandatory	20-40	1-2 h
Induction of new staff	1-3	Shorter sessions, more focused on process rather than education per se	20-40	15min
Nursing, pharmacy/ advanced practitioner	2-3	Varied between centres from small group teaching to formal AKI study day for large groups	5-70	1 h to whole day
Ward-based sessions	5-10	Formal teaching at ward level	1-10	5-10 min
Ad-hoc teaching sessions	20+	Informal teaching delivered by various members of the AKI team including reminders of resources, patient based teaching	1-3	Varied, usually only minutes

Table 3 : Description of education programme activities that were delivered across sites

A key tenet of the TAKI programme was to test the concept of the local implementation of a clinical intervention to support the diagnosis of and reduce the consequences of AKI on patient outcomes. It was not intended to mandate the adoption of a specific version of the intervention that had been developed in the Derby pilot, thus avoiding a top-down approach.

No specific fidelity measurements were built into the evaluation. However, the quality of AKI care was assessed through a series of process measures that were audited from an ongoing survey during the programme of 1,048 patient notes. In this way, the evaluation team covered three main areas: the effect on processes of care, the effect on patient outcomes, and a qualitative aspect to capture barriers and enablers of the intervention.

Assessment of the fidelity of engagement between the nurse and the patient to support patient choice to participate in dialysis-related tasks in the SHAREHD programme was limited to the information that was collected as part of the formal research programme. There was limited measurement for improvement conducted by the clinical teams themselves.

Prior to the Scaling Up Programme, the use of a Commissioning for Quality and Innovation (CQUIN) that had an “arbitrary 5 task benchmark” had resulted in unintended consequences, since it focussed on task numbers rather than whether a real choice was offered to undertake ‘as little or as much as each individual wanted to learn’. Further, once the CQUIN initiative was discontinued, the focus on shared care was lost as there had not been cultural change and the supported choice for patients stopped in several locations.

Direct comparisons between sites of the numbers of tasks that patients were engaged in was problematic since teams were at different stages in their programme. The implementation team had concerns that such comparisons might make some teams feel they were 'failing' or a long way behind other teams and so disengage. Indeed, one team stopped attending the collaborative because they were "uncomfortable that following the CQUIN, where they had been very successful things had dropped away dramatically". Also, for this intervention, the number of tasks is relevant from the perspective of an individual patient, to document changes in their individual progress over time, not as a measure of 'success' for the unit or nationally.

Since routine task data was being collected in the research cohort, the implementation teams were free to focus on quality improvement cycles and locally designed measures to demonstrate change. The core intervention focused on the motivation (why choice should be offered consistently) and the necessary culture change to achieve it. Focusing on the "why" enabled the team members to consider their individual motivation and how could they make it a reality within their local context.

As a consequence of discussions at the learning events it was recognised that the core components of shared care should be consistent and needed to be more obviously identified so there was clarity in the definition of the intervention. As a result, the team established the components as:

- *a patient competency handbook*
- *a unit intervention roadmap (local implementation plan template)*
- *a patient awareness leaflet*
- *patient / staff questionnaires*

Defining these core components has facilitated wider spread after the Scaling-Up programme completed, while maintaining the fidelity of the core components of shared care.

In contrast to SHAREHD and TAKI, the ASSIST-CKD intervention employed developmental evaluation and formally assessed fidelity from site to site using the framework approach such as that developed by Carroll C et al, based on the following domains [1, 40]:

- *adherence to an intervention - whether an intervention is being delivered as designed*
- *exposure or dose - the amount of an intervention received by participants*
- *quality of delivery*
- *participant responsiveness - how far participants respond to, or are engaged by, an intervention*
- *programme differentiation - elements of the intervention that are essential for its success*

As the intervention was based on the assessment of patient data graphs prepared through the deployment of a consistent IT software package, the repeatability of the method naturally implied a high degree of fidelity to be maintained through the spread and sustainability phases. Close adherence to the quality standard for graph review was important, however it was recognized that the human factors involved would lead to variation both in time taken and whether the patient would be referred to the GP or not. To ensure consistent quality, those reading graphs were given a training manual and required to obtain a score of at least 80% in a mandatory test of their ability to read the graphs to the required standard. Every three months, checks were undertaken to ensure data reporting was maintained and this also ensured that the new system was embedded in day to day practice. Despite these steps, there was still a degree of variation between operators, especially from those that were brand new to the process (over-reporting) versus graph readers that had been reporting for several months who were more experienced and confident. Like in TAKI, there were several steps outside the core intervention that were subject to variation, including the mechanisms of graph delivery to primary care (electronic or paper) and education pathways that surrounded their use.

ASSIST-CKD had key similar objectives to the London Renal Learning project that engaged with a cohort of CCGs where primary care physicians reviewed eGFR values to identify patients who would benefit from early intervention[41]. In that project, all the practices involved used the primary care IT system EMIS Web which includes a built-in trigger tool to identify eGFR trends, thus prompting the GP to review the patient. This version of the intervention automates part of the process, so there is a high degree of fidelity with no requirement for human intervention. However, the downside of such automation was evident when it was necessary to 'fine tune' the trigger tool, for a specific demographic of the local population. This local correction component then reduced the fidelity across the board and introduced some inconsistency. This once again demonstrated the trade-off between local iteration and broader fidelity.

6.2 Adherence to the implementation plan

Once plans (timeline, financial model protocol etc.) have been devised it is important to track progress against the plan and identify why variance has arisen, devising steps to bring the programme back on track if possible. This is important, firstly to deliver what has been 'promised' especially where other teams are expecting things to be in place for them to take forward (research nurses, local implementation teams etc.), but also because it can provide an early warning of issues and risks that need to be addressed early to minimise impact and avoid potential larger problems. In addition, by adhering to what was planned, this increases the replicability of the approach i.e. the possibility of reusing the plan, building on what worked and changing what did not.

Both SHAREHD and TAKI tracked project progress against their plans and research protocols closely.

For the SHAREHD cohort study, 587 of the 600 intended patients were recruited, all data collection points were completed and NHS digital data was received to enable hospitalisation analysis to be verified at the end of the programme. Nine learning events were planned and took place around the planned times with over 200 different staff and patients attending the events, resulting in 461 attendances in total (Figure 5). Over 55 PDSA cycles were planned and followed up within the learning events and 17 action period calls were run for the teams. Of the 19 teams involved, only 2 stopped attending the learning events, although they did continue to gather research data which was a result of the engagement of NIHR clinical research nurses to underpin the research component of the study.

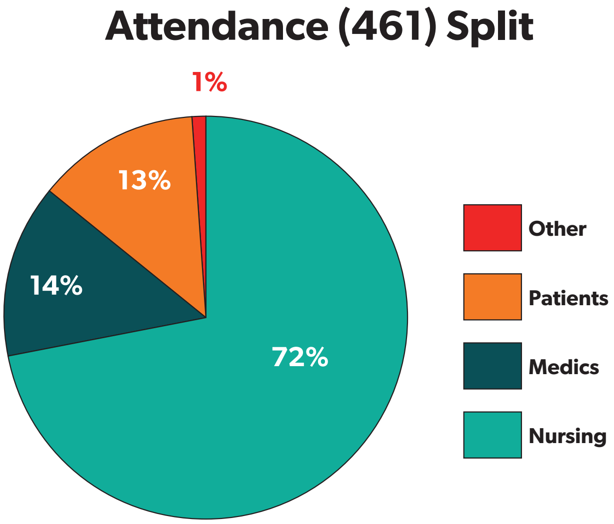


Figure 5 : Total SHAREHD learning event attendance split

Timescales for delivery of the learning events and research elements all were on target apart from the acquisition of NHS Digital hospitalisation data. The request was submitted in April 2018 and the data finally received in June 2019, taking 14 months rather than the 6 planned for and resulting in a delay in delivery of the final evaluation report to the Health Foundation and the preparation of academic papers. The learning from this experience is that projects need to start the process for requesting data from the NHS Data Access and Request Service as soon as it is clear which data fields are required and to carefully select who makes the submission, since that individual will be responsible for answering all questions and queries that arise during the review process.

Likewise, for TAKI the protocol and plans set out at the start of the project were delivered to target. Patient outcome data from 24,059 AKI episodes were analysed, with qualitative data arising from 128 questionnaires and 26 key informant interviews. A 'break' in the timeline was experienced when a Leeds laboratory IT system failure prevented reporting of laboratory results or linkage with hospital outcome data for two months. The decision was made to exclude this particular period from all sites with an additional three-month analysis period being added to end of the stepped wedge. This event in Leeds was completely unprecedented and could not have been predicted. It is an example of something completely unexpected happening that could have had a major impact on the project and required a prompt and bespoke solution that was only possible because of the robust reporting mechanisms and pragmatic structure of the TAKI implementation team.

The ASSIST-CKD project required sufficient technical support to be deployed consistently by Trust IT departments in order to implement the necessary software into laboratory services. When it became clear that the support for the original software that was going to be provided on an unfunded basis by the IT department at Heartlands was not going to be sufficient to support the roll-out of the intervention nationally, the intended approach had to be reviewed and radically changed to maintain the intervention. This was a major decision taken by the programme board resulting in a three way tender process that resulted in a 3rd party software house ('Tidy Design') being brought on board to redevelop the software and provide the required support to IT departments, laboratory and renal staff. This was achieved relatively quickly (within 8 months). Furthermore, the complexities of getting the lab data into the software and integrating with Trust IT represented a significant delay to the original implementation timetable which impacted on the timing of the collection of quantitative data and meant that the planned SWCRT methodology was no longer feasible necessitating change to a controlled before and after design.

The delay in deployment of the new software did not hinder the achievement of other key performance indicators as documented in the table below and resulted in a solid IT solution being available **https://www.kidneyresearchuk.org/research/assist-ckd** for any trust to take on and use beyond the conclusion of the formal programme.

Measure of Success - KPIs	Achievements
Uptake of intervention in at least 12-15 labs serving 8-12 renal units in Home Nations	20 of 23 sites live and reporting in UK
First randomised group in step wedge to start July 2015 - all sites to be implemented in 19 months	Step wedge methodology unsuccessful due to unexpected NHS LIMS delays adapted to a new methodology
Adopt and install version 2.1 of the software	Total redevelopment and deployment of eGFR software
Pilot in Wales to assess Pan Wales option	Pan Wales - 2 sites and 1 spread site
Evaluation plan fully implemented	Plan successful
Business case development	Infographic well received - embedded practice
Intervention becomes self-sustaining before the end of the project	11 sites still running > 1 year

Table 4 : ASSIST-CKD measures of success

During the TP-CKD project set-up, the processing of the Your Health Surveys (YHS) into the Renal Registry database and Patient View, took longer than had been anticipated which delayed the reporting of data back to sites. However, the issues were overcome which has provided the basis for the future expansion of the use of this patient reported outcome measure tool.

At its start, the project had a wide-ranging set of aspirations as set out in the Project Initiation Document[42]. It was part of the NHS England-supported Learning Set across six healthcare organisations (five Clinical Commissioning Groups and one disease registry) to test the use of the PAM®[38]. However, the project aspirations for TP-CKD were wider ranging than the PAM® alone and included Patient Reported Outcome and Experience measures, as well as running the programme in full co-production with patients. Though this additional scope was initially supported by NHS England, as the programme developed, the complexity of delivery became apparent, alongside organisational restructures within NHS England. This reduced the level of oversight and support available from NHS England and it became clear that many of the aspirations would have to be scaled back.

Despite this, TP-CKD exceeded its initial scope which was of testing the use of the PAM®. It demonstrated the practicality of co-production as part of a large project of work and also established whether it was possible for patient reported outcomes to be collected[4]. Most importantly, it enabled the infrastructure to support of the routine collection of Patient Reported Experience Measures from renal units in England, via the UK Renal Registry.

6.3 Key learnings and recommendations

	Key learning points related to defining and implementing the intervention
Itemise the intervention	Any intervention intending to scale up or spread through a formal process requires a clear description that itemises its components.
Define the fixed components	Describe the components which must be part of the intervention to retain fidelity. Test this during the programme and use the resulting learning to ensure a robust intervention for adoption by new teams once the programme has ended.
Balance between strict adherence and local adaption	Taking into account local contextual issues, determine the balance between the requirement for fidelity to the original components (and style) of implementation and the scope for local adaptation.
Measure adherence as part of the evaluation	Plan how the measurement of fidelity fits into the evaluation of programme effectiveness taking into account the nature of the intervention and the context of its delivery. Consider the domains against which it is to be measured and plan mechanisms to collect and review relevant data (Carroll et al.[1]). If it is available, use data that is collected nationally.
Is "How" the intervention delivered important?	Fidelity may not only refer to the "what", but also the "how and why" it is delivered taking account of context. For example, how patients were offered the choice of shared care in SHAREHD, rather than the exact shared tasks or number of tasks they undertook was a core component. This human element is critical to influence hearts and minds and prevent a box ticking approach.
Obtain objective review of the planned intervention and project	Discuss the programme design and intervention with an objective reviewer who is familiar with the intervention type. This is to build awareness of risks and implications in deployment of the activity at scale, but also to identify gaps in the project team's skills and understanding that need to be filled before commencement and whether sufficient piloting has been undertaken to be ready to scale.

Findings 1 : Defining and Implementing the Intervention with Fidelity

7. Quality Improvement Methods and Mechanics

The Dartmouth Institute identifies that quality improvement is 80% relational and 20% technical [43]. Therefore if we were to focus exclusively on the QI tools that were used by these projects we would only be tackling a small part of the mechanisms that contributed to the successful delivery of the health improvement programmes. With this in mind, this section will focus on the following core enablers to QI. Based on the experiences of the projects, we will explore not simply what tools were used but rather how and why approaches were taken, highlighting the difficulties and benefits that arose. These key components are:

- *Clarifying the project aims*
- *Understanding the resources that are available for the work*
- *Choosing and planning to use the most appropriate QI tools*
- *Learning through practical experience in the context of particular health environments.*

It should also be noted that the broader relational contexts of management and patient involvement are integral components to the success of any QI initiative and are covered in later sections.

7.1 Clarifying the aims

In section 6 we explored the importance of defining the intervention and the extent to which the programmes adhered to that definition. Framing the over-arching objective of the improvement programme is a consistent message at all levels of delivery i.e. “you have to know what you are trying to do in order to know if you have actually done it”. Formal research projects have clearly defined hypotheses and end points determined before the start and that are unlikely to change much during the programme of work. The paradox is that although QI is supposed to be unpredictable by its nature, the reality is that the clarity of intent is also needed when using QI methods.

Formal models or diagrams

Logic models or driver diagrams are widely used techniques to define this in QI terms. These tools differ in their intended purposes, with the driver diagram identifying the changes that will be needed to be made in order to deliver the intended improved outcomes, whereas the logic model identifies the execution theories that lie behind approaches that will be used [44]. For example, what will the improvement initiative do that will lead teams to adopt the change processes? It is critical that the aim and approach that is being adopted is clear and consistent.

Within TAKI, an overall logic diagram was developed and individual participating teams were encouraged by the evaluation team to complete logic models before and after the intervention in order to explore what their planned mechanism of intervention was and how it was delivered in reality. In some cases, the local teams did not really understand how to produce these so they required strong support from the evaluation team in their development. This limited their local benefit as an effective QI tool since a large part of that benefit comes from the thought processes that go into the creation of the output, rather than the output itself.

A similar situation occurred within SHAREHD where it was initially assumed that each team would establish their own driver diagram to develop their local aims using the IHI Model for Improvement. In reality this did not happen, either due to the limited time the teams had together or a lack of understanding of how tool should be used to this depth. Instead, teams concentrated on their aims for PDSA cycles that were more limited in scope and rationale and tackled single points of intervention. These nevertheless had value since they enabled teams to plan approaches to delivering specific discrete aims such as increasing the number of dialysis patients who were performing their observations.

By Wave 2 of SHAREHD, the QI teaching had been significantly simplified and made more meaningful by describing its application in a renal context. In addition, a generic driver diagram was prepared for teams to get them started. Of course this meant - as happened in TAKI with logic models - that teams did not design these diagrams themselves and therefore missed an opportunity for understanding the aim and delivery mechanics. The benefit however was that it was significantly easier for teams to get started quickly with initial tests of change and therefore see impact from their efforts which in turn built momentum and confidence.

ASSIST-CKD used a logic model at the programme level, which focused mainly on the activities that were required after the eGFR software was installed in the lab. In reality, the complexities of deploying into lab/trust IT departments became a major component of the work and the logic model was not updated to reflect this. Rather, developmental evaluation was used to feed this learning back directly back to teams while simultaneously evaluating their progress.

TP-CKD was a pilot project to identify how and if patient reported outcomes could be collected from clinical settings. They used the NHS Change Model framework identifying specific criteria against each element which allowed a broad perspective enabling teams to interpret locally.

Helen Crisp commented that logic models and driver diagrams should be ‘used if they are helpful, but not imposed if teams find them unhelpful’. They can provide a useful way of visualising the project and complement a business case very well. However, they are less relevant when the majority of the iterative development has already been done.

Figure 6 : NHS Change Model

The London Renal Learning Project used the Kotter theoretical approach to change management in its implementation process of the East London community kidney service[45]. A particularly useful element being the "create short term wins" concept which encourages people to keep going when implementation is hitting difficulties.

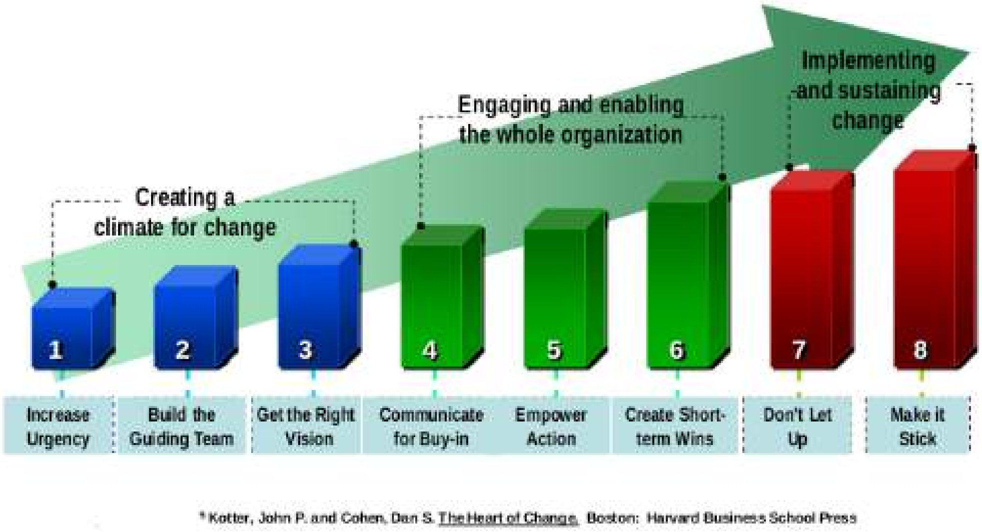


Figure 7 : Kotter theoretical approach to change management

It is clear from these programmes that logic models are not 'easy' to use, especially when teams are inexperienced in their use. It is therefore recommended that the aims and objectives of using the tool are clear and that the team has the skills available to use it effectively.

Testing and measuring changes

Plan Do Study Act (PDSA) cycles were used by SHAREHD teams to test a range of small initiatives, however there were practical difficulties in their delivery. Though most teams in SHAREHD identified aims of the test, only a limited number followed the process through to identifying appropriate measures and then producing sequential run charts that documented the changes that had been made. Commonly teams did not see that the data collection was of value to them and therefore worth the investment in time to deliver it – they preferred the doing, but less so the analysis and the measuring. Where teams kept this simple, saw a direct link with the objective and displayed the results then there was more incentive to collect and analyse the information (see Figure 8 for an example). The market place at learning events also provided an opportunity to do this.

Figure 8 : Omagh patient notice board including ladder of Shared Care activity

For TAKI, care-bundles were refined locally with cycles of iteration based on feedback from testing locally and from the dress rehearsals. Manual measurement was planned to be used to monitor and encourage the uptake and sustainability of the usage of the care bundle after it had been implemented. Unfortunately, this did not occur as hoped, with the most common reason reported being lack of time to both collect the data and do something with it. In hindsight, having some technical support for this monitoring and analysis was necessary and should be considered for future programmes. When these data were analysed and fed back to the teams it was found to be useful.

Structured events

All the projects used workshops and/or learning events at various time points throughout their programmes. In SHAREHD they were the central to the quality improvement collaborative (QIC). TAKI used several styles including a central kick-off event, locally focused education programmes, and peer review /assist events. Within ASSIST-CKD there were three learning events to encourage the participating teams to build a 'dynamic project community' specifically to share experiences, examples of good practice and challenges. They used a systematic approach to identify who would be the most appropriate delegates to attend their events and incentivised attendance by providing continuing professional development (CPD) points (see case study in section 12).

SHAREHD's learning events evolved over the course of the programme. By Wave 3 the Kirkpatrick education model [46] was being used to plan in detail exactly what the implementation teams and core team intended to achieve in the learning events which was then validated via evaluation forms. The evaluation forms were designed to confirm whether individual session objectives had been met with space for explanation if they were not. This technique has similarities to educational lesson planning and forced the core team to focus on exactly what, why and how each session was going to work, providing clear evidence after the event of whether goals had been achieved or not. Approaching the learning events in this way required considerable time to be allocated to their design. An iterative approach was adopted to ensure the maximum impact could be achieved from the time available.

TP-CKD used a peer assist model throughout the programme planning each event based on the learning from the previous event. Patients and key clinicians worked closely together both in the planning and the facilitation of the events on the day. Patients were encouraged to attend as part of unit teams and present alongside. The power of collaborative working will be discussed later, but key to the success of these learning events was that they had clear aims and objectives to ensure appropriate focus and to maximise benefit in return for the time invested by the participating teams. Without that clarity, the risk was that teams would lose interest in the programme, not be willing to invest the time and pull out of later sessions.

Impact and consequences of CQUINs

For both TAKI and SHAREHD, Commissioning for Quality and Innovation (CQUIN) that had been developed prior to the Scaling Up programmes, with the intention of supporting sustainability, resulted in unintended consequences. For shared haemodialysis care, a 'Closing the Gap' programme that was the precursor to the SHAREHD programme created a CQUIN that could be adopted by trusts to measure the number of patients undertaking five or more treatment related tasks. This was initially successful, but some trusts had found that once the CQUIN no longer applied and the associated funding was no longer available, that focus was lost and that cultural change had not been sustained. Within TAKI, a related CQUIN concerning discharge summaries for AKI patients was in place and actually helped the local project teams to raise AKI awareness, even though it wasn't directly related to the intervention which was aimed at early AKI treatment. So overall, this was a beneficial effect, but the withdrawal of the CQUIN then led to concerns regarding funding of posts and reduced prioritisation of AKI. The lesson is that the practice or cultural change that is being advocated by the CQUIN is everyone's responsibility to deliver and sustain - not just the responsibility of an individual who may be funded on a temporary basis, since this will only lead to a short-lived change. It should be recognised that a CQUIN that is linked to external policy and appropriate financial levers may help with spread, but needs to be very carefully designed to mitigate unintended 'box-ticking' consequences.

7.2 Understanding the available resources and how best to use them

Unlike research studies, QI projects do not use formal inclusion and exclusion criteria to select participants since they are intended to impact on "real world" clinical practice. For programmes where the aim is to scale up an intervention that has been developed in a single setting across a range of health care settings, it is inevitable that local implementation teams will vary considerably in their characteristics and approach. Given this landscape, the more the core team can understand about the priorities of the contributing teams the better, so that approaches can be adapted to suit those requirements. In addition, it is helpful to understand the individual skills and working styles of core team members so that these can be used to the advantage of the programme and also to reduce difficulties than can arise when expectations do not align to working styles.

Understanding and assessing learning needs

It is important to recognise that each participating site will have different expectations from the programme and previous experiences of QI work, therefore requiring that training and support should be individualised. Understanding what motivates sites to participate will enable these goals to be realised. Some teams will get more out of a particular approach than others, such as being able to fully benefit from QI training that is provided through the programme to develop their skills and delivery. Identifying and mitigating these risks and tensions is important for success. It is helpful to obtain information regarding site preparedness, the level of QI experience and understanding, and motivating factors, as well as key contextual characteristics. To this end, learning needs assessments were used to some extent by all the reviewed programmes. By analysing these assessments it became clear that the implementation teams had limited awareness of QI methods and this allowed the learning events to be pitched at the right level. Getting the pitch of the learning events right was essential to maintain enthusiasm and interest. This was enabled in TAKI by appointing local programme managers.

For SHAREHD, site initiation visits were a necessary part of setting up the cohort study and the opportunity was taken to invite implementation teams to these meetings. These visits were used as an opportunity to cover both the research and QI implementation approaches in a joint meeting.

For TP-CKD a detailed learning needs analysis was undertaken at the start of the project. Questions were asked such as 'how effective are you at leading service change' and 'how good are you at involving patients'. These questions helped the team shape the programme but also understand why certain units were cautious and others appeared more able to deliver.

Within TAKI, learning needs assessments were done locally within each trust as a way to identify which elements of the education package would be appropriate for that team to implement the AKI trigger and care bundle. An initial set of materials was provided to the first site from the pilot site. This grew into a 'pick-list' of education elements that was supported by the peer to peer learning, as initiatives including locally created materials were tried and tested from one unit to the next. After specific study days, follow-up was undertaken to confirm that the learning had been successful. Initially this education was mainly factual, but evolved to encompass a 'hearts and minds' message in recognition that "why" the intervention mattered was important to promote its uptake. TAKI also recognised that many staff who undertook the intervention (medical registrars, for example) would frequently rotate to other roles. Though their education was key, it was also important to ensure the education of those who were more 'permanent' (nurses, for example) for sustainability. TAKI tackled the conundrum of providing significant educational opportunities, but despite their considerable efforts there was feedback of it not being 'right'. For some, too much education took place and for others it was not enough, which is inevitable when the implementation involves a wide group of personnel (such as a whole hospital in the case of TAKI). It is key to have a plan and listen to the learning needs on the ground while adopting flexible training techniques, such as ward walks which worked well when staff were not able to attend set events. These also served to take training to staff at the time they needed it most i.e. when an AKI alert has occurred.

ASSIST-CKD did not specifically use a learning needs analysis but provided generic training on the website that included graph-reading validation tests. This gave consistency to training and meant that new sites got the same learning package. The Developmental Evaluation provided local awareness for the core team.

Understanding the team

Within TAKI, local team building and empowerment to define the mechanisms for local delivery was seen as a critical component to drive the intervention locally. To do this, regional project managers were recruited to work directly with the local teams. This meant the core project team was in effect distributed over a wide geographic region. To pull this "operating team" together regular teleconferences were held so that practical decisions to support the teams on the ground could be made. Thus, in contrast to ASSIST-CKD, TP-CKD and SHAREHD which all had a single coordinating programme manager, TAKI had distributed programme management across the sites.

For TP-CKD, a person centred care facilitator acted both as programme manager and a coach, travelling to sites to support teams' progression against set plans, present site-specific data and share knowledge. This approach was a significant burden for a single individual to carry and ran the risk of being a single point of failure. Against that, there was efficiency inherent in the facilitator visiting the site for a team meeting that could take 2 - 3 hours rather than the whole team having to travel to a learning event for the whole day thereby, reducing time away from clinical duties. However, by providing the support for teams to travel together and spend a day out on the programme at the central events this also facilitated teams to focus on the core themes of the project and enable greater commitment.

Local team leadership is a key determinant to the successful implementation and ownership of the project. As identified by Derek Sivers in his TED.com talk on "How to start a movement", the importance of second leaders cannot be underestimated since these individuals will build the momentum, especially where a culture change is needed for sustainability. The core team will not be able to select those local leaders who will inevitably have a much more detailed understanding of local priorities of their individual trusts. The TP-CKD programme report has highlighted that "successful units required senior leaders to act as advocates of the key messages of the programme and respond to staff concerns"[47]. The SHAREHD programme actively encouraged teams to present their work at the learning events and local launches and to submit abstracts to academic meetings. It was recognised early on that the programme was a culture change 'movement' that anyone can join at any level of the organisation not just senior staff. Motivated individuals frequently were from junior roles within the organisation and being a second leader for SHAREHD was an opportunity for those people to shine in their own environment. An example was seen at UK Kidney Week 2019, where a team of nurses from Hull presented their work on SHAREHD in a pop-up session and another team from Salford presented in a QI session.

In one TAKI implementation team, the lead implementers were intensive care consultants rather than acute physicians and they encountered more resistance to the change than at other sites. A common response was that 'we do that already', and there were difficulties in engaging senior clinicians in other directorates, especially medicine where a large proportion of the AKI case load resides. This resulted in it being much harder to encourage junior doctors to adopt the intervention, who took the lead from seniors when they were not supportive.

Within ASSIST-CKD, the complexities and variance of IT landscape from site to site was a challenge to implementation. Each Trust had separate IT teams dedicated to either the laboratory systems, database management or networks and in most cases, they worked in isolation. It took considerable tenacity from teams on the ground to establish the linkage, management processes and requirements between IT, laboratories and GP practices - a problem that teams were not expecting. For some sites who had initially expressed interest in the project, this meant that they did not in fact proceed as it was too complex a system to manage alongside other daily pressures, whereas others took a long time to get started, putting pressure on the evaluation of the validity of the intervention itself. Though the ASSIST-CKD project understood and identified upfront the requirement of local teams to identify laboratory staff to review the graphs, the additional skills needed to implement the software and negotiate the internal management for access to sensitive database systems were unexpected.

Managing time within the chosen methodology

TAKI found that teams randomised to the earlier components of the SWCRT had less time available for planning than those randomised later. Also, where peer review meetings identified potential developments to the plans unless these were minor in nature there was insufficient time for teams to incorporate them into their work. Because of the need to adhere to the timeframe as set-out in the SWCRT protocol, as well as the national rollout timescales for the AKI alert, there was limited flexibility for teams to delay implementation if they felt they were not ready. This represented a challenge to the QI principle of testing local implementations sufficiently before introduction, but since the intervention had been developed and tested to a high standard at Derby prior to the scaling up programme this was not a problem. Clearly it is important that the intervention is well developed before planning a SWCRT.

Such time constraints existed but were not quite so marked for SHAREHD, possibly because central programme management made it logistically easier to organise the learning events. At the start of the programme the number and dates of learning events were set out in advance to co-ordinate with the sequence of the randomisation for the 'stepped wedge' evaluation and did not substantially change thereafter. Letters were written to all the participating trust chief executives to confirm their participation and request support. By identifying the dates of learning events and action period calls for the whole programme in advance, it helped to maximise attendance by facilitating planning for off duty rotas, that are usually arranged months in advance. This worked in general for the learning events but was less successful for action period calls which were poorly attended although they were paradoxically easier to attend. Teams often struggled to find time to work together to progress tests of change between events. There are several conclusions that can be drawn from these observations. It may be that teams gave priority to planning time out together to attend a learning event - whereas including a teleconference as part of the working day is more subject to the competing pressures of the clinical environment.

Handling spread

There was significant interest in the ASSIST-CKD programme when the call was originally made for adopter sites. Thus, although the original plan was to recruit 12- 15 laboratories in fact the intervention was deployed at over 20 sites. As the primary motive of the programme was spread, variations were made to the original contract including a time extension to increase the coverage and reach of the project. Once the IT had been rewritten it was made available to be downloaded from the ASSIST-CKD web portal [31], supported with comprehensive documentation and an online help-desk. Formal education for laboratory staff is also available on the portal. Had the SWCRT design been retained, it is unclear whether spread would have occurred in the same way since a key challenge is maintaining the enthusiasm of sites randomised to participate later in the programme. The ASSIST-CKD team stated in its final report that "with plans to implement in over 20 NHS sites and with usually more than a dozen individuals involved at each site, local ownership in particular has been a critical factor". The core programme team needed friendly negotiating skills and patience to obtain buy-in and overcome local challenges to implementation. Processes needed to be in place also to monitor progress and the actual delivery of the intervention.

Conversely, an additional Wave 3 for SHAREHD was also agreed which had to sit outside the formal SWCRT cohort. The opportunity was offered to all renal centres in the UK to apply via the clinical directors' forum. This provided an excellent opportunity for the programme to select candidate teams to participate. A 'bid process' took place which articulated specific joining requirements or 'team readiness' and generated a degree of competition driven by the perceived value that the programme had developed. Teams were required to include at least one individual experienced with QI so that they could (a) select appropriate QI tools for use by their team, (b) teach QI methods to the rest of the team if needed and (c) link with the local trust QI teams. Tests of change were still the primary QI tool that was used but now within each team there was an individual who had understanding of the principles of a structured, experimental learning approach, some experience in carrying it out, and a willingness to accept that if in the event it did not result in improvement that the learning developed through the process was of value.

TP-CKD planned to recruit 10 units to participate in the programme but the response to the expression of interest was greater than anticipated. As a result two cohorts were agreed with ten units commencing at the beginning of the programme and a further thirteen planned for the second cohort a year later. The challenge during this time was to maintain engagement with the units 'in waiting' and as a result only four units participated in the second wave.

The Kidney Quality Improvement Partnership (KQuIP) has the clear aim of increasing QI capability and leadership across the multi-professional renal team. This has been done via three national projects (Hometherapies (DAYLiFE), Transplantation and Vascular Access MAGIC where each region selects one of the projects and teams identify Quality Improvement leads to receive training on leadership skills and QI tools and techniques. These are then put into practice to drive forward the chosen project via a regional collaborative with the dual benefit of developing improvement around project themes in that region, while at the same time building a faculty of QI capability for future project work. For the programmes included in this report, the focus and measures were aimed at the specific intervention that was being scaled rather than aiming to build a faculty of individuals with QI skills. To some extent, the expectation was that local teams would 'bring in' necessary QI skills. It is important when setting up a project to understand what QI skills are realistically available to both the core programme and the local implementation teams since this will influence to what extent particular tools can be realistically used and guide the amount of training required.

7.3 Choosing and planning the right tools

Quality improvement work is unlikely to be successful unless sufficient time and resources are allocated to selecting and applying the most appropriate tools.

Chosen approaches

The introduction of the TAKI intervention at the participating sites was supported by a "structured approach to change management" (Health Foundation project Tackling AKI protocol) v5.1[48]) intended to enable those caring for patients with AKI to understand the objectives of the work and motivate them to deliver it. The ease of the intervention - the electronic alert combined with the care bundle - was an overriding principle, supported by appropriate education. There were several key objectives that worked with varying levels of success including:

- *senior/executive engagement - achieved*
- *peer review/assist from preceding teams in the stepped wedge sequence - successful*
- *measurement for improvement - didn't work due to the volume of data making this impossible to maintain manually*
- *tailoring resources for local context - was done with variable success.*

For SHAREHD, the central QI approach was to adopt the IHI "Breakthrough Series Quality Improvement Collaborative" model which is specifically designed to help organisations learn both from each other and from recognised experts in topic areas where they want to make improvements.

Collaboratives in practice

The SHAREHD programme faced an inherent challenge in combining the SWCRT methodology with the Breakthrough Series Collaborative, which traditionally requires teams to start and finish the work together. The two problems were how to a) prevent teams in the second wave from starting the intervention at the beginning of the programme rather than delaying to the point planned in the stepped wedge design, and b) the challenge of bringing teams in the second phase up to speed quickly when required. There was also concern that there would be insufficient time during the learning events to provide sufficient teaching in QI methodologies. The compromise was for the Wave 2 teams to have a single initiation event to 'bring them up to speed' with the initial learning from Wave 1 and thereafter the full 12 teams continued as a single collaborative.

Although all teams engaged with the SHAREHD cohort research study (supported by NIHR research nursing teams) not all delivery teams engaged fully with the collaborative. Of the 12 original teams, only ten attended all the events. Reasons for non-attendance included time availability for the teams to be away from clinical work, distance to the learning events and concerns that earlier attempts to introduce SHAREHD had initially been successful and then had lost focus when the CQUIN no longer applied. It was clear that a 'fear of failure' was an underlying concern as well as insufficient senior managerial commitment to the intervention. It has to be recognised that for at least one site the distance required to travel to the events was significant.

Table 5 summarises key learning relating to successful delivery of the quality improvement collaborative (QIC)[49]. The account of the Stroke 90:10 QIC in the North West England provides an example of the challenges of delivering a QIC effectively[50].

Theme	Detail
Site preparedness and commitment	Sites need to want to be there - therefore the collaborative requires to have value which can only be achieved once impact has been demonstrated. For best effectiveness, sites need to be required to prepare including what their goals of attending are, the support that they have (including senior management and QI support), who the team are that are planning to attend and how time has been allocated for their engagement, a clear agreement to commit to the learning events, calls and between event work, baseline data of where they are up to with the objective.
Belief	Teams need to be clear about the goal and value it.
Ready to learn and share	Teams require to be ready to engage, test and share their successes and failures.
Leadership style	A leadership style that is open, inquisitive, collaborative, and supportive celebrating diverse contributions from the broader team.
Data	Data needs to be available real time to demonstrate improvement.

The intervention	The intervention needs to be clearly understood - for example an accepted, locally adapted checklist.
Programme management	Programme management that is dynamic, supportive and checks progress against milestones.

Table 5 : Ingredients for a successful quality improvement collaborative

The experiential nature of SHAREHD was particularly suited to learning events as part of a collaborative and strong patient engagement [46]. Although it was not strictly a breakthrough series collaborative, the approach was considered by participants to have real impact strengthened by patient involvement influencing the agenda.

Use of PDSAs and iterative development

SHAREHD selected Plan Do Study Act cycles (PDSAs) as a common approach that local implementation teams could use to test ways of introducing the intervention. However their use was not as straight forward as expected and it became clear that PDSAs are not easy to get right despite their apparent simplicity. This is made harder still if there is only lukewarm commitment to the method and limited expertise available to train and support teams[51].

At times, key concepts of the PDSA cycles had not been grasped, such as starting with small easily achievable objectives, developing plans in co-production with patient champions and not being afraid of failure. For SHAREHD this was important since the objective was to build the confidence of the teams to increase the patient choice for and uptake of shared care, rather than to run a perfect PDSA. The lesson is to make the teaching relevant and to be based around practical examples while providing plenty of encouragement and support.

There are clearly challenges around the way that PDSA cycles in particular are understood and used as they are not always the right tool to use. This has been described in detail in other publications [51] which readers are referred to for more explanation.

TAKI did not adopt PDSAs but instead used iterative design with the value being that it also provided a structured approach that would allow the care bundles to be refined for local use. In both TAKI and SHAREHD, the approach was to give teams constructive support that aimed to celebrate what and how far they had managed to get, rather than being critical of weaknesses in data presentation (for example in the form of run charts).

TP-CKD did not use a formal PDSA approach although teams were encouraged to start small and test ways of working building incrementally. This approach wasn't necessarily successful as the learning from each cycle was not then applied to the next to build and develop a sustainable model.

Formal Testing

A specific QI method that was used in ASSIST-CKD was to check the fidelity of the intervention by testing the ability of individuals to read the eGFR graphs. This was a necessary to ensure quality and that triggers would not be missed. Testing the delivery of a clinical checklist is much more challenging, but has been successfully implemented in the North American SCOPE Collaborative which checks the compliance against three clinical checklists relevant to peritoneal infection [52]. This initiative has resulted in marked improvement in peritonitis rates among children treated with peritoneal dialysis. It requires a validation process that checks compliance against the checklists and commitment from participating teams to that approach.

Status reporting

TAKI had project managers (PM) embedded within the local teams which not only ensured local plans were tailored but also that the core team had a clear understanding of the status of the improvement journey. By regularly discussing progress and highlighting concerns via core team telephone conference calls, issues could be discussed and potential solutions suggested that the local PM could try. Within Wave 3 of SHAREHD, teams were asked to complete monthly reports that reported local measurement, as well as documenting what had been achieved over the previous month, the plans for the following months and communication strategies. The aim of these reports was to enable local teams to work together and reflect on their own progress, as well as generating their own local sustainability plans that could continue beyond the timescale of the programme. ASSIST-CKD also monitored the progress on a regular basis that local teams were making with the implementation and reporting of data to the UKRR. This was primarily to ensure that the support provided was appropriate and timely. That support included providing advice on adapting a graph report for a specific Trust's branding, organising paperwork for finance or accreditation, acting as the co-ordinator between the laboratory/ renal team and IT teams for any software related issues as well as building site knowledge, self-reliance and ultimately, sustainability of the programme

Action period calls and teleconferences

All four programmes had wide geographic spread so teleconferences with teams seemed to form a sensible part of delivery plans. However, these were found in reality to be difficult to arrange with health care staff, poorly attended and experienced attendance drop off. It was realised that where staff are 'on the front line' getting away for a call at a set time was often challenging irrespective of when the meeting was scheduled. Face to face meetings require greater commitment - but paradoxically were easier to deliver. The reality is that clinical work will take priority when health care teams are at their own site.

In light of this, ASSIST-CKD arranged calls for smaller groups which worked better but also recognised that face to face learning events were required to develop the collaboration both within and between teams that the initial action period calls had hoped to provide. Three learning events were set up in response.

SHAREHD was alerted to these potential issues by the TP-CKD team and also the experiences of its quality lead who had previously tried to undertake action period calls using video conferencing. This had proven extremely frustrating due to technology constraints, even though the teams had been provided with the equipment. SHAREHD therefore choose to hold tele rather than video conferences and had clear agendas for the meeting as would be the case for face to face meetings. Even so, after the first few calls attendance diminished and so the sessions were reduced in time and the teaching element removed. In essence, the focus shifted to providing an opportunity for the teams to share their progress and discuss issues that had come up so that they could try to resolve problems together with support from the programme board.

TP-CKD used monthly action calls as a check-in opportunity for teams to share progress, maintain momentum and discuss relevant topics all the way through and beyond the formal end of the programme.

Patient stories

Patient stories that support the rationale for an intervention that is being undertaken are an important tool in any QI initiative. These had a particular role in both TP-CKD and SHAREHD possibly because the interventions were more experiential. However, unique bridges were created by TAKI and ASSIST-CKD who were able to engage clinicians who had personal experience of CKD or AKI to talk at a learning events. Patient stories are powerful since they give meaning and purpose to the intervention. They help teams to understand that the procedures they are undertaking (eg AKI checklist) are not just 'a paper exercise' but are relevant to patient experience and help to gain their ongoing support and commitment. More about engaging patients is discussed in section 10.

Sustainability approaches

The ASSIST-CKD team was clear that the terminology used should not frame the programme as having a defined end. The programme view was that sustainability would be born out of belief, local ownership and the availability of a business case. Initial funding for a laboratory technician or renal nurse to read the eGFR graphs was provided by the project only for the first year and the business case for it continuing past the first year was expected to be developed by the participating teams and included in their work plans. To support this, a generic business case was created that could be shared and adapted by sites. As a result, the sustainability approach was part of the intervention and the continuity of eGFR graph production and review was 'expected'. This was termed 'Invest to disinvest' - the learning being that sustainability should not be left to chance but should be a conscious part of planning and a clear aim of the intervention execution.

Similarly, the TAKI goal was to embed the intervention so that it would sustain after the programme completed. The national AKI alert was permanent and therefore the trigger was already sustained by policy - but mechanisms to ensure the awareness of what this meant and taking effective action in light of a trigger still required sustaining mechanisms.

Within SHAREHD, sustainability was a specific work stream throughout the programme. Section 14.2 discusses the multi-faceted approach and mind-map tool that emerged as a mechanism for recognising the various elements that could or should be progressed.

Each team developed online materials that could be used be teams planning to adopt their interventions. ASSIST-CKD developed robust and generically deployable IT solutions. SHAREHD and TAKI have made available tools produced by their teams stored in the national QI project archive[53]. The lesson here is to ensure that outputs from the programme are, wherever possible, generically usable by others.

What has become clear from all the programmes is that there is no single element or tool that delivers sustainability on its own - indeed the timescales required for sustained quality improvement will almost certainly be longer that any project timescale or available funding. Far from meaning that sustainability tools are ignored, the opposite happened where each project recognised they were part of a wider journey of which they could influence specific components.

7.3.1 Examples

Each programme chose methodologies that suited their purposes most appropriately which was influenced by the nature of each programme. Some examples are highlighted below.

QI methodology	Example	Project
Iterations / model for improvement (inc. PDSAs)	KI care bundle adaption - BRADFORD Locally chosen 'Test of change' to increase uptake of particular Shared Care tasks See 12.2.5 and 12.2.6 for additional case study detail	TAKI SHAREHD
Peer assist / peer review	AKI teaching / plans validation	TAKI
Create short term wins	Used by the east London community kidney service to encourage people to keep going when implementation is hitting difficulties.	London Renal Learning Project
Adoption	A financial argument considered to be a "no brainer" by East Midlands CCG led to the approach being adopted in Kettering and Leicester. This was in addition to the main programme teams.	ASSIST-CKD
QI collaborative	Learning events - marketplace Iterated though 2 waves and confirmed in the 3rd wave	SHAREHD
Patient co-production / involvement / stories	Patient break-out sessions in learning events and presentations to the whole group - Lisa and self-needling - the patient story	SHAREHD
Structured sharing within collaborative	Team presentations from SHAREHD - e.g. Nottingham	SHAREHD
CPD credited learning events	Three learning events with CPD credits to share and pass on learning / updates See 12.2.7 for additional case study detail	ASSIST-CKD
Testing fidelity through training	Testing the skills of reading eGFR graphs	ASSIST-CKD
Learning Needs Analysis (LNA)	Various LNA activities were undertaken across the programmes. TAKI looked at the needs of the local trusts and determined the education activities to support it, TP-CKD undertook a LNA to determine the learning events and SHAREHD used it specifically to identify levels of QI knowledge through questioning during the site initiation visit	SHAREHD TAKI TP-CKD

Table 6 : Examples and case studies

7.4 Learning by doing and sharing lessons

When teaching any improvement tool or technique, giving people the opportunity to learn by doing - preferably as part of the intervention to which they are committed, engaged and interested - is vitally important to set that tool in the right context. If teams were simply to teach or talk about the technical aspects of QI tools, this would be to ignore the critical relational aspects of the work. These include building a network of supportive stakeholders, the development of a cohesive team and involving patients in meaningful ways to make the integrated 'whole system' approach to improvement. For example see p10 of Radnor and Waring's discussion of lean in the UK [54].

Teaching methods

The initial SHAREHD learning event included a session that reviewed over 12 QI techniques. The teams were asked to note down during the session if they felt a specific tool would be useful to them, with the intention that the core team would build that into future teaching sessions. The problem with this was that it was over theoretical, included an excessive amount of material and did not use examples that were relevant to attending teams. The practical use of "Mr Potato head" to understand how the IHI Model for Improvement worked with Plan Do Study Act cycles was more active and engaging for teams but still lacked the renal context in terms of defining the objective and measurements. Some teams and individuals (including a patient champion) stated in their feedback that they felt overwhelmed by this and nervous about what was being expected of them during the programme. The team reflected on this learning and in subsequent events changed the approach so that when QI teaching was necessary, for example on understanding measurement, then the examples within the session were changed to have a renal context with renal data.

Central to the TAKI programme was a highly localised education approach. Training methods were selected from the available options dependent on the context of the local implementation with the aim that stakeholders should know what the intervention was and what they could do to progress and promote its delivery. An example of this was that the project managers used “ward walks”. This technique emerged because of the large number of staff that the intervention touched and the short ‘time bites’ that they had available. By taking education to day to day operations, rather than asking the staff on the ground to be taught at a separate time and place, real time support and advice could be provided directly where the intervention was needed. This is a technique often used in the first days after a new IT system is deployed, for example where floor walkers are asked immediate questions until the confidence of users in the new application grows.

Therefore, a good understanding of learning needs enables the most appropriate teaching methods to be selected, whether that is highly localised as with TAKI or generic learning to the precise level of quality as with the eGFR graph assessment validation.

Co-production

A key component of the ASSIST-CKD programme became focussed around IT development as the robustness and scalability of the software became a problem. Though this was not the original intent of the project, it provided an opportunity for the teams to get involved in the coproduction of the software as it was re-developed by the software house. Improvements, suggestions and enhancements were identified by participating teams so that they could be built into future releases of the software. One example was changing the wording on the graph to encourage doctors to act on it and not just file it away. Involving the teams in this redevelopment enabled an iterative approach that included small tests of change which increased local ownership of the final result by participating teams.

TP-CKD practiced co-production from the inception of the programme with patients as co-chairs on board and work-streams. Patients were involved as active members of the unit teams and planned, presented at and facilitated peer assist events. In partnership, they developed survey tools and the Patient View screens to enable the return of survey data to patients.

Co-production with the whole MDT, including patient partners, was an underlying objective for each of the projects which brought in a range of ideas and enabled consideration from several angles. It is essential to value all input as equal especially those from patients who may have to be encouraged or facilitated to contribute their ideas. See section 10 for a more detailed discussion on this.

Marketplaces

Although using a generic QI approach such as PDSAs or 30/60/90 day plans as used by TP-CKD may require experience to execute to the fullest degree, the approach provides a means for all teams have something to share - both within learning events but also in peer reviews. A good example of this are “market places” at learning events, where successes and challenges can be discussed on an equal footing. This places value on the learning that comes from facing and overcoming problems and hence avoiding ‘failure’ being seen as a reason to stop and not proceed with the intervention.

Towards the end of the SHAREHD programme, market places were held where teams were encouraged to prepare posters explaining their achievements. They were asked well in advance if they would be happy to present on a specific topic, sending their slides to the project manager at least a week before the event so that support could be provided, if needed. Teams really benefited from preparing these examples of their progress and sharing them with others. These market place events had considerable buzz and delegates learned considerably from each other and from themselves.

Peer assist

Within TP-CKD, a peer assist model provided support to the participating units and was used as a framework for change. Peer assist is also known as ‘learning before doing’ and describes a team asking for help through the following process:

- *Inviting people with previous experience to share their experiences, insights and knowledge with the team*
- *Checking whether others have faced similar problems/issues and solved them*
- *Holding problem solving/sharing sessions involving teams working together and presenting learning and recommendations back to the team.*

Participating teams were encouraged to:

- *Attend and participate in the peer assist events during the life of the programme*

- *Share lessons learned with other participating units to support implementation plans and potential challenges*
- *Attend monthly calls with other participating units to share the successes and challenges of their implementation plans*
- *Write blogs and case studies for the website to support sharing and learning*

Within TAKI, peer assist was also used as the central mechanism for sharing learning between those teams with experience of the intervention and those who were getting started. This allowed open and honest discussion and gave the opportunity for tests of change to be planned to refine components such as the care bundle. In addition, a peer review event took place after the intervention had been delivered that focussed on capturing the learning of what had actually happened, what worked, what didn't. The next team in the stepped wedge sequence was invited to the peer review as a means to support the planning and preparation stage for their peer assist meeting. These meetings were also effective in 'softer' aspects such as strengthening team building and interpersonal relationships.

SHAREHD did not formally employ peer assist, however aspects were used, such as the collaborative working, as well as inviting experienced teams to present on specific topics that they had become accomplished at. This worked very successfully as the new teams drew encouragement from teams that had overcome similar barriers to those that they were experiencing. Importantly, the presenting teams built their confidence as second leaders and so contributed to the growing movement. What was less successful, however, was an attempt at informal peer assist. Teams filled in forms to identify their strengths and weaknesses so that they could be paired and work together on key areas. In the event, few requests were made for such pairing and this informal approach did not have the impact that was hoped.

7.5 Key learnings and recommendations

	Key learning points related to quality improvement mechanics
Agree and document your chosen QI aims and methods	Decide what your QI aims, methods and adoption approaches are. Explicitly describe these in the protocol so that the adherence to the methodology during implementation can be formally evaluated.
Assess adopter QI capability and capacity	Assess whether adopter sites have the skills, understanding and time to use the chosen QI method necessary to implement the intervention. Offer appropriate training and external expertise to build necessary skills.
Build a collaborative to enable sharing	Create opportunities to share between the adopter teams' experiences and learning, both positive and negative. Build a supportive, educational environment where there is no fear of declaring failures, which is where much of the learning arises. Methods include QI Collaborative, Peer Assist and Developmental Evaluation.
Be open to learning from adopter sites	The originators of the intervention need to be open to learning from adopters. Consider how adaptations that adopter sites have made to the intervention have worked and how these can be taken forward within the next iterations of the work.
Embrace 2nd leaders	Beware of reliance on a temporary project team. Encourage 2nd leaders and create an ongoing improvement faculty that can sustain past the programme end.
Reuse existing resources	Learn from previous work and use existing resources, rather than reinventing. Consider making your resources available for others to use also. The programmes highlighted have produced resources that are accessible from the Think Kidneys website.
Focus on the spirit of why	Focus on education and exploring the spirit of the intervention as well as processes and technicalities. To achieve sustainability a tipping point of changing hearts and minds is required.

8

8. Evaluation Methods and Mechanics

Successfully achieving change for improvement at scale requires a detailed understanding of contextual issues combined with the determination to overcome the many problems that will be encountered along the way. To lead such work needs team building and negotiation skills, and if it is to be successful, many second leaders. The rationale for making the change should be compelling and the intervention clearly understood and evidence-based. Without thorough evaluation, the opportunity to learn from the experience will be missed. This is important to consider with the plethora of QI initiatives that are replicating across the NHS, since there is a risk that without building the learning into new projects, they could be falling into the same traps. These issues were highlighted in the Health Foundation report - "Against the odds: Successfully scaling innovation in the NHS"[39].

The evaluation was prioritised in the three Health Foundation funded programmes reviewed in this report, but this is relatively unusual in QI programmes. It has been observed that evaluation is commonly perceived "as unnecessarily frivolous or a diversion from resource that could and should be spent on the improvement[2]." Getting the evaluation of a project right requires planning, discussion and clarity of objectives; if possible it should be built into the design of the programme to ensure that the outcome is meaningful. It is also important that the outputs from the evaluation are delivered in a timely manner as close to the end of the project as possible so as to maintain momentum.

Central to planning is the design of the data collection and information gathering - including the selection of the instruments that will be used based on evidence of their validity and acceptability to the population that is being included in the work. Data collected through existing registry or NHS collection mechanisms will require appropriate permissions and time being built into the schedule, especially if the programme is to gain ethics and Health Research Authority (HRA) approvals.

The renal Scaling Up programmes in this report used a combination of qualitative, quantitative and economic evaluations in order to achieve their objectives. We summarise the key messages that can be applied to future projects and will hopefully save time, costs and heartache. We describe aspects of protocol design as well as considerations that went into determining endpoints and the choice of methodologies.

The table below presents the various evaluation reports and publications the programmes produced (or are producing) which provide a rich pool of data and information for others to build upon.

	Project Status	**Programme Reports**	**Publications**
TAKI	**Complete** *Dec 14 - Feb 17*	Final report to the Health Foundation Aug 2017 Quantitative and qualitative issued to the Health Foundation Dec 2017	Protocol (Nephron Clinical Practice - 05/2016) Primary Endpoint Paper (JASN 2019) Qualitative Paper (PLoS ONE, 2019 vol 14 (9))
TAKI - in progress		Cost benefit analysis	
ASSIST-CKD	**Complete** *July 15 - Nov 18*	Final report to the Health Foundation Nov 2018 Qualitative issued to the Health Foundation Nov 18	Protocol (BMC Nephrology - 2017)
ASSIST-CKD - in progress		Quantitative in progress - Due to the Health Foundation Spring 2020	
TP-CKD	**Complete** *Jan 15 - Dec 17*	Programme review issued Jan 2019	Programme report (BJRM - 03/2019) Co-production lessons Think Kidneys website

SHAREHD	**Complete** *08/2016 -12/2018*	Final report to the Health Foundation Dec 2018	Protocol (BMC Nephrology - 12/2017)
SHAREHD - in progress		Qualitative, quantitative and economic report issued to Health Foundation Sept 2019	Primary end point paper (targeted - 12/2019)

Table 7 : Programme outputs

Outcome
• *The quantitative evaluation of the outcome of the programme: Did the intervention impact on something important that can be measured?*
• *The qualitative evaluation of the outcome of the programme: What was the experiential impact of the intervention?*
Process
• *What measures can be used to assess the clinical pathways that contribute to the outcome?*
• *What can be understood about the experience of participants, such as: barriers that they experienced; impact on aspects of care; impact of the educational processes?*
Balancing measures
• *Were there quantifiable harms that resulted from the intervention?*
• *Were there additional burdens for patients or staff such as increased administration, or worry about the intervention?*

Table 8 : Evaluation plan outcome measures

8.1 Evaluation planning and protocols

The Medical Research Council document “developing and evaluating complex interventions”[55] provides valuable guidance. It asks key questions that will stimulate teams to think through their evaluation approach as they are planning the work, even though that document is directed towards research rather than improvement science. In simple terms, a successful evaluation plan requires components to determine the effect of the intervention on outcome, process and balancing measures. These can be summarised as follows:

Protocol

Developing the protocol requires detailed understanding of the techniques that are intended to be used. Each of the three programmes had the benefit of working with an experienced evaluation team that was able to contribute to this. The study design requires statistical planning, including appropriate power calculations, together with consideration of the components defined in the relevant checklist (e.g. the STROBE checklist for cohort studies or CONSORT guidelines for randomised controlled trials [55, 56]). For these reasons it is important that an appropriately skilled evaluation partner is selected who will be able to meet the necessary requirements. It is important to maintain sufficient separation between delivery and evaluation teams as was noted by James Fotheringham from SHAREHD who stated that “the interplay between the intervention and evaluation teams needs to be carefully balanced so that the enthusiasm of the intervention team does not ‘infect’ the objectivity of the evaluation”. Table 9 presents the three protocols that were published for these programmes (TP-CKD did not publish a protocol).

Project	**Published protocol**	**HRA/NRES**	**Trial website or NIHR portfolio registrations**
TAKI	Design and Rationale of 'Tackling Acute Kidney Injury', A multicentre Quality Improvement Study [17].	Advice from ethics committee programme deemed service improvement	Protocol published
Evaluation partners	UK Renal Registry (UKRR) The University of Bradford Health Studies		
ASSIST-CKD	A programme to spread eGFR graph surveillance for the early identification, support and treatment of people with progressive chronic kidney disease (ASSIST-CKD): protocol for the stepped wedge implementation and evaluation of an intervention to reduce late presentation for renal replacement therapy [22].	Advice from ethics committee programme deemed service improvement	ISRCTN - 13701669
Evaluation partners	University of Sheffield School of Health Research (ScHaRR) School of Health and Social Care London South Bank University		
SHAREHD	Rationale and design for SHAREHD: a quality improvement collaborative to scale up Shared Haemodialysis Care for patients on centre based haemodialysis[3]	HRA Ethics	IRAS ID: 212395 REC ID:16/LO/1558
Evaluation partners	University of Sheffield School of Health Research (ScHaRR)		

Table 9 : Programme protocols and evaluation partners for the three scaling up programmes.

Health Research Authority

There are many forms that QI can take, and some overlap with research methodology more than others. If relevant, then the process of Health Research Authority approval provides an established framework through which to conduct the evaluation as well as potentially providing the benefit of support from Clinical Research Network nurses if the study is adopted onto the NIHR portfolio. A further advantage of embracing the processes of a research study is the value that structured site set up meetings provide since they are an opportunity to familiarise local teams with the goals and practicalities of the work. SHAREHD used this to inform simultaneously the research and local implementation teams with both aspects of the programme aims.

Ethics

Preparing the protocol is not only the first step in planning the evaluation, it is also essential for obtaining National Research Ethics (NRES) approval. The application of the research ethics process to QI however can be challenging. Documentation by the Healthcare Quality Improvement Partnership (HQIP) discusses this in some detail, highlighting that this is an area that needs early careful consideration in any future project as the decision whether to submit the work for ethics review is complex[57, 58]. Although QI is considered to be service review, and therefore may not require ethics approval, if there is a desire to collect patient related data, ask patients to complete questionnaires or for the evaluation to conduct interviews with them then it is going to be necessary to have the appropriate permissions. This clearly depends on what is being proposed and what is hoped to be achieved. (See HQIP papers above).

An additional and important consideration is the requirements for publication of the work. For example, the Journal of the American Medical Association in its instructions to authors states the following - “For all manuscripts reporting data from studies involving human participants, formal review and approval, or formal review and waiver, by an appropriate institutional review board or ethics committee is required and should be described in the Methods section”. It is worth noting that the advice in this area changes over time and currently it is not possible to establish governance mechanisms retrospectively.

Of the programmes within this report, ethics approval was only obtained for SHAREHD. The protocol was very clear and defined for the structured collection of data for the quantitative evaluation but the qualitative and economic evaluation approaches were less well defined initially, becoming clearer as the work progressed and the evaluators gained more granular experience with the intervention. This meant that amendments were required to the protocol and the associated ethics approvals which led to unplanned delays in those aspects of the evaluation.

ASSIST-CKD, TP-CKD and TAKI decided not to seek NRES approval after taking advice. ASSIST-CKD submitted the project to a National Research Ethics Service Chair and received the opinion that the project did not require ethical approval. Though this may not have compromised the quantitative evaluation, it was noted specifically in the evaluation report that it “limited our scope to work directly with patients” since interviews with patients require such approval, and as a consequence the ability to explore the impact of the programme on patient experience was reduced.

Trials registration

There is considerable value in submitting the protocol for publication in a peer reviewed medical journal early during the programme. This lays out clearly in advance the intervention and it increases the likelihood of the results of the work being accepted for publication once it has been completed.

Registration is important as it can determine the types of journals that the results can be published in. There are currently two different approaches to registration, but it should be recognised that this area is rapidly changing so the latest advice should be identified. The International Committee of Medical Journal Editors (ICMJE) requirement is that clinical trials are registered in a WHO-approved public trials registry at, or before, the time of first patient enrolment. The Alltrials campaign does allow for retrospectively registered trials to be considered if the justification for late registration is acceptable [59, 60]. However, this may be a risky approach if thinking about peer reviewed publication, as many journals now state explicitly that they don’t accept this.

Provided this is appropriate for the project, registering is a strong recommendation from the projects within this report because a key aim of registration, as stated on the International Standard Registered Clinical/soCial sTudy Number registry (ISRCTN) website “is to ensure that healthcare decisions are informed by all of the available evidence, thus overcoming publication bias”.

Research Planning Flow - Research Documents

DECIDE ON YOUR STUDY DOCUMENTS

- Protocool
- Research instruments
- Statistical analysis plan
- Data management plan
- Reference CONSORT guidelines or STOBE checklist

DEALING WITH ETHICS

- University ethics (for staff questionnaires)
- NRES approvals (mandatory for patient interviews) - IRAS is the online form used to apply for NHS ethics and HRA approvals

REGISTER YOUR STUDY

- ICMJE requirements http://www.icmje.org/about-icmje/faqs/clinical-trails-registration/

OR

- All trials approach http://www.alltrials.net/news/alltrials-registered-and-results-reported/

PUBLISH THE PROTOCOL AND RESEARCH PAPERS

- Decide on appropriate journals

Figure 9 : Research planning flow and research documents

To help summarise this section, Figure 9 above shows a summary of research documents and activities suggested to be considered and undertaken during the evaluation planning of the programme. Not everything will be essential and is dependent on the type and approach of the programme.

8.2 Qualitative evaluation

The goal of the evaluations was broadly to gain understanding of the enablers and barriers that impacted on the delivery of the intervention that lay at the heart of the particular quality improvement programme. Mechanisms included a combination of observing learning events, as well as conducting surveys and interviews with team members and health care personnel and, where possible, patients. The methods are summarised in Table 10 below.

	Tackling AKI	**ASSIST-CKD**	**SHAREHD**
Method	Realist evaluation	Developmental evaluation	Realist evaluation
Evaluation question	In what circumstances, and in what ways does the package of AKI interventions impact on outcomes (or not)	To what degree has the original intervention been perceived and replicated What has been the impact?	In terms of encouraging patient involvement in haemodialysis, what works, for whom, in what circumstances and why?
Theories Used	Theory of change to understand how the interventions and implementation activities were connected to the outcomes Supported by framework analysis of the frontline staff questionnaires local logic models and other data sources	Fidelity elements - adherence, exposure, quality of delivery, participant responsiveness and programme differentiation Thematic analysis of interview responses groups by: effectiveness, impacts, unintended consequences, outcomes, sustainability	Programme theory-led element of the evaluation was focused on uncovering relevant Contexts, Mechanisms and Outcome Conjectures (CMOCs)
Methods	• *Key informant interviews (health care professionals)* • *Peer assist notes* • *Peer review transcripts* • *Barriers / enablers to implementation staff questionnaires* • *Logic model prepared by participating teams* • *Project minutes*	• *Audit of graphs interpreted and reported* • *Interview with graph interpreters* • *Interviews with lead nephrologists* • *GP survey* • *Focus groups with GPs*	• *Questions to programme team* • *Social media engagement with nurses and team members* • *Patients interviewed at participating sites* • *Staff interviewed at participating sites*

Table 10 : Qualitative outcome questions and mechanisms for the Scaling Up programmes

Within the TAKI project, the qualitative team sought to understand the perspectives of key stakeholders involved in the design, implementation and delivery of the package of AKI interventions in each of the five hospitals. This provided the implementation teams with on-going insights into factors which may have influenced fidelity.

Importantly, the evaluation findings and insights were fed back to sites at key points during the course of the project via peer reviews and at the end during the 'results day' event, with a collective look back at the common themes across all hospitals. This utilised 'developmental evaluation' which supports the progress of innovation and adaptation in complex, dynamic environments by helping to frame and test theories and models[61]. The objective was to provide on-going insights to the implementation team about factors which may influence the fidelity of the intervention so that they were able to adjust their approach.

Four enquiry questions were posed:

- *What are the key contextual characteristics of each of the five hospitals which may facilitate or impede the implementation of AKI interventions?*
- *What is the package of AKI interventions in each hospital and who are the key stakeholders involved in its design, implementation and delivery?*
- *What are the key stakeholders' perceptions of the barriers and enablers to implementation of the package of AKI interventions (three individual components and as a whole)?*
- *What is the theory of change in each of the five hospitals of how the AKI interventions and implementation activities are connected to the outcomes?*

Key conclusions from the TAKI qualitative review were:

- *Although core aspects of the three components of the interventions were maintained, aspects of all three components were adapted at each site*
- *Four key barrier and enabler themes were identified that related to: (i) practical and contextual factors; (ii) the TAKI team; (iii) the design, development and implementation approach; and (iv) hospital staff knowledge, attitudes, behaviours and support*

- *Perception of the AKI package as helping patients and preventing harm was reported by staff as the greatest motivation for its use. Staff reported "heavy workload/time pressures" and "difficult to use or attend" most commonly as the main barriers to adhering to the three components of the intervention*
- *Staff at the hospitals did not perceive the theory of change models to be useful for their implementation process and completion had to be supported by the qualitative evaluation team*

These themes were explored through questionnaires to all frontline staff in two wards at each of the five hospitals to explore behavioural determinants, barriers and enablers to the intervention. Though this provided rich findings that have been fully evaluated, the questionnaires were seen as 'heavy' to complete with participants perceiving them as repetitive and confusing [62]. Piloting the questionnaires would have been advantageous but was not possible due to the delay in the TAKI evaluation team coming on board to the project and the need to maintain the stepped wedge timeline.

ASSIST-CKD had initially planned that the qualitative and quantitative evaluations would be undertaken in parallel, but the software rewrite delayed the quantitative analysis and therefore the timescales became separated. The qualitative evaluation was based on a site by site assessment of the degree to which the original intervention had been replicated. Interviews and focus groups were conducted with clinical scientists reviewing the graphs on a day to day basis and the GPs who received them. Themes that were explored were effectiveness, impact, unintended consequences, outcomes and sustainability of the intervention.

One of the purposes of the fidelity assessment was to determine the extent by which teams adapted the intervention for local use. They had been given the programme objective and provided with the software and were then encouraged to determine the best way to deliver that intervention considering their local circumstances. Variations were described in the form of case studies that helped teams to understand the local 'storyline' of delivering the intervention in a particular context while attempting to maintain core fidelity. This information helped teams to plan the work for their own environment and to make necessary adaptations.

In SHAREHD, the realist evaluation was based on observations of learning events as well as interviews with trust teams and patient users. Although recruiting a predefined number of patients for the research cohort was relatively straight forward, it was much more complicated to identify patients for interview since this was based on the option of returning an additional document that was part of the cohort study consent form. The mechanism for evaluators to gain permission to interview patients and carers at participating trusts was complicated. "Research passports" are required to undertake research and to interview patients at NHS sites; the process of obtaining these is lengthy and requires tenacity to achieve. This needs to be built into the planning and management of the work, ensuring the right support is provided to obtain the passports without undue delay to the evaluation. Support for the process is available through the local clinical research networks. In the event, there were sufficient patients for interview but few carers.

Central to the exploration was the development of a programme theory to explain the mechanisms behind the intervention. The work on this started through discussions with the delivery team, enhanced through a WhatsApp group on social media. Through the course of the programme, the theory was further developed based on experiences of patients and staff, as well as materials and learning events. In this way it gained authenticity as it was tested against experience.

The programme theory then provided a structure in which to place themes that came from patient and staff interviews, leading to the development of patient involvement and staff involvement models which mapped to the likelihood of successfully delivering the intervention (shared haemodialysis care) or not. This became a meaningful and practical output from the information that had been obtained from those interviews - taking the work beyond listing barriers and enablers through to the practical incorporation into effective models of delivery (see the case study in section 12.2 for more details).

8.3 Quantitative evaluation

This section reviews the end points that were selected to assess the impact of each programme and the study designs that were adopted.

Determining the endpoints

Important to the design of the quantitative evaluation is the selection of study endpoints, which require being meaningful as well as mechanistically plausible. The identification of the most appropriate endpoints requires synthesis of evidence from pilot work including relevant literature. For the three scaling up programmes the case required to be sufficiently compelling for selection through the rigorous Health Foundation grant award process. A key component of the Scaling Up programme was that interventions had to have been tested extensively locally prior to submission, which included the examination of suitable end points.

	Primary outcome measure	**Secondary outcome measure**
TAKI	30-day mortality in people with AKI, measured in all contributing hospitals	- *Incidence of AKI* - *Incidence of AKI progression* - *Length of stay in hospital for admissions in patients with AKI* - *Number of critical care bed days used by patients with AKI* - *Achievement of complete renal recovery by hospital discharge in AKI patients* - *Process measures were evaluated using a notes audit of 1048 cases* - *AKI duration (post-hoc analysis)*
SHAREHD	Number of centre-based haemodialysis patients undertaking 5 or more treatment related tasks as part of a cohort study	- *Number of individuals dialysing independently in centre or moving to home* - *Health utility, patient activation and symptom scores* - *Hospitalisation*
ASSIST-CKD **From UK Renal Registry data**	Incidence of late presentation for RRT, defined as any patient first seen by renal services within 90 days of starting RRT	- *The use of temporary vascular access for starting dialysis* - *Latest eGFR measurement, within two weeks before start of RRT* - *Mortality at 6 months from start of RRT in new RRT patients* - *The incident rate of End Stage Kidney Disease (ESKD), measured annually.*

Table 11 : Quantitative outcome measures for the Scaling Up programmes

For TAKI, the electronic AKI alert with educational support and a care bundle had been developed and tested at Derby where it demonstrated a reduction in AKI related mortality from 24.4% before the care bundle was introduced to 20.4% after it had been [16]. This was sufficient justification for adoption of 30 day mortality for hospital-acquired AKI identified through the electronic alert mechanisms as the primary endpoint. It is standard research procedure to reflect on the endpoints on completion of a study and this is should be no different for QI initiatives. Two points can be made in respect of TAKI: (a) mortality is affected by many multiple factors including the co-morbidities of included patients, whereas renal specific endpoints (such as AKI duration, recovery of renal function) are more directly related to the intervention; and (b) mortality was measured on a hospital wide basis, but it was ambitious to expect spread of the intervention across the whole hospital during the period of the intervention. Had TAKI measured outcomes only in those areas where the intervention was directly delivered, there may have been a larger effect.

This highlights that in complex interventions it is often difficult to see tangible outcomes that are both meaningful to the wider audiences, yet actually can be influenced by the intervention. In the context of TAKI, mortality was a clearly measured outcome but complex to actually influence.

The rationale behind the ASSIST-CKD endpoint is that timely referral to nephrology is important for people who may ultimately require renal replacement therapy - allowing time for information giving, shared decision making and preparation for renal replacement therapy. Wide variations exist in late presentation rates across the UK - defined as being referred to nephrology services at least 90 days prior to commencing renal replacement therapy. The evidence for using this as a primary outcome measure came from the pilot site at Heart of England Foundation Trust where it was considered that the use of eGFR graphs to flag patients with progressive CKD had contributed to the lowest late presentation rate for renal replacement therapy in the UK in 2013-14 at 4.9%, where the range from UKRR extended up to 33%[63]. For this reason, and also the fact that it is a key quality marker, late presentation was taken as the primary outcome measure for the stepped-wedge evaluation [22]. Importantly, UKRR collected this data routinely so historical comparisons would be straight forward. It is important to reflect that a variety of factors influence late presentation rates, from the relationship between the nephrology centre and the local primary care practices to the socio-economic characteristics of the served population.

For SHAREHD, the primary endpoint was defined as a combination of the increase of 30% above baseline in patients participating in 5/14 dialysis related tasks by 6 months and an increase in those dialysing independently of 50% by programme end. These data were based on experience from earlier work conducted in Yorkshire and the Humber (Y & H) as part of a "Closing the Gap" Health Foundation funded programme. The evidence was that this increase in tasks was achievable and that across Y & H during the five years following the start of that programme, home haemodialysis had increased by 68%. Using the number of treatment related tasks as an outcome measure was questionable since evidence has not been demonstrated of its objective value - indeed it is more a process measure. The more commonly used outcome measure - impact on hospitalisation - was included as a secondary outcome measure principally as there was no prior information upon which to base an estimate of effect size.

A strength of TAKI was that data collection was remote to the study team and was collected by the UK Renal Registry through a process that enabled all cases of AKI at the contributing hospitals to be included. The primary outcome measure was determined in just over 24,000 cases of AKI from the five contributing hospitals accounting for 7.6% of admissions at those hospitals. This gave TAKI adequate statistical power to detect any planned difference and made the findings more robust. For ASSIST-CKD, the design also utilised the UK Renal Registry to collect the primary outcome data but that had to be delayed because of the IT issues described above. For SHAREHD, the intention had been for task data to be collected through UK Renal Registry, however it was not possible to do this, and therefore data was collected in paper form and inputted into a data base in Sheffield. This resulted in a "closed" rather than an "open" SWCRT, required ethics approval and patient level consent, and as a result the study was adopted onto the NIHR portfolio [3].

In the event, the TAKI primary outcome was not met, but despite that the study had considerable value. The study was pragmatic since it examined real-life clinical practice in a large number of patients against the UK Renal Registry data to measure the endpoint. This allowed considerable study power at a significantly lower cost than it would be for a conventional trial with patient level randomisation. It demonstrated improvements in quality of care - based on the notes audit - as well as a reduction in the duration of AKI and in the length of hospital stay. Coded AKI increased during the study which may have been due to better recognition. The value of demonstrating impact on such process measures is that if they move in the same direction as the end point, this provides evidence that the intervention is impacting the pathway as expected. These process measures were collected through a notes audit that was conducted at each contributing centre in order to document key aspects of the AKI treatment pathway from recognition to care bundle usage, including balancing measures such as urethral catheterisation.

Methodology - the use of the stepped wedge cluster randomised controlled trial design.

Each of the three projects set out to use a stepped wedge cluster randomised controlled trial (SWCRT) design for the quantitative evaluation[64]. In this design, the intervention is delivered in a staggered fashion from one site to the next in random order (see Figure 10). The SWCRT is an appropriate method to study the routine implementation of an intervention for which there is existing evidence since no sites are denied the therapy by the end of the trial and it therefore has ethical value.

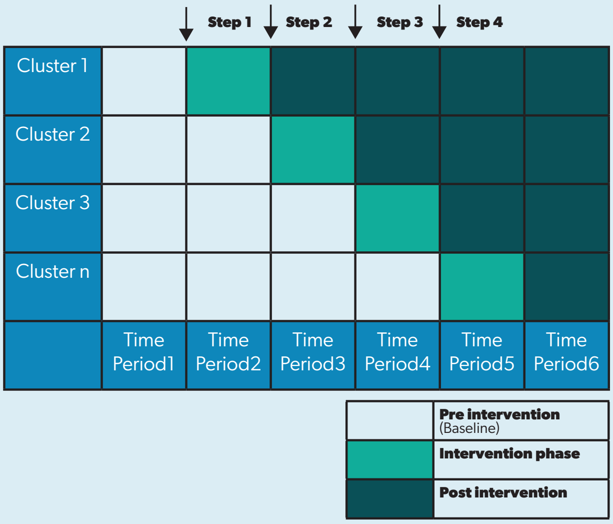
What is a STEPPED WEDGE Randomised cluster Trial - Why use it?

As a relatively novel design the SWRCT is increasingly popular particularly in the evaluation of complex interventions. After baseline data collection, the intervention is sequentially introduced to each cluster across fixed periods of time until all sites are exposed. This sequence is randomly determined. Data collection occurs at each step, including the post-intervention period.

PROS

- *Ethical approach as all sites and patients ultimatley get the interventions.*
- *Lends itself to a pragmatic study of real-world clinical approches.*
- *More robust than before/after studies*
- *Can be a very cost effective means of testing a complex intervention*

Generic stepped wedge design



CONS

- *Complex statistical approches required*
- *Size (power) of cluster is pre-determined and required to make results meaningful.*
- *Possibility of clusters being influenced by selection bias.*
- *Intervention to be delivered within a timeframe that is difficult to modify and can generate tension with QI approaches*

What to consider - if the rigid timeframe is suitable; ensure appropriate statisitical support; how long it takes to implement the intervention and for it to reach its maximal effect; that all sites should agree at the outset to commit to the intervention schedule

Figure 10 : What is a Stepped Wedge Randomised cluster Trial

As each cluster contributes to both the intervention and the control arm the effect of between cluster differences on outcomes is reduced. The methodology is particularly suited to evaluations that do not rely on individual patient recruitment. However, since more clusters are exposed to the intervention towards the end of the study than at its early stages, the effect of the intervention may be confounded if there is a tendency for the use of the intervention to change over time and this needs to be adjusted for in the analysis [64]. For example, SHAREHD documented a statistically significant increase in crude primary outcome measure data across the study that lost significance once an adjustment had been made for time.

For the SWCRT design to work, the intervention requires to be delivered discretely during predefined time intervals. This worked for both TAKI (notwithstanding the glitch due to the breakdown of the Leeds Laboratory) and SHAREHD, but ASSIST-CKD was confounded by the major reorganisation of the laboratory information management software, the need to redevelop the information technology platform from that which was established by the pilot and the IT complexities at each site. A key lesson therefore is the essential requirement that for an intervention to be able to be tested within the context of a stepped-wedge evaluation, it requires to be delivered within a predetermined time frame. Because the timing of moving through the steps of the study is difficult to modify, any lower than expected enrolment during a control period cannot be easily addressed by simply extending the timelines as would happen in a standard study. For TAKI and ASSIST-CKD, patient recruitment was not a concern since they were open cohorts i.e. the intervention was undertaken on any triggered patient who automatically became part of the cohort. In contrast, SHAREHD used a closed cohort of patients recruited during the baseline period across all sites. Fortunately, the required cohort of 600 patients was recruited on time and the study progressed using questionnaires completed at set intervals irrespective of where the team fitted to the stepped wedge intervention. Had the various measures not been collected at the appropriate times, the overall methodology would have been compromised. It should be noted that complications did arise where some instruments were not properly dated by participating units. This was very important because of the repeated measures over time that needed to relate to the sequences of the stepped wedge. For instruments that were not dated, it was necessary to manually look at the sequence of instruments from the sites to ensure that the sequence fitted with the appropriate window, otherwise the data could have become inadmissible. A key lesson is to ensure that all instruments have a date field included and that on receipt this is checked for completeness.

The editorial that accompanied the publication of the TAKI SWCRT observed that this was the first study of that design in nephrology[65]. Importantly, the trial was highly pragmatic: eligibility criteria were inclusive which is a feature of QI work; the settings were diverse; data used for the study endpoints was clinically acquired rather than trial-generated; the intervention was implemented by clinicians rather than researchers; and local adaption of the AKI care-bundle was built into the programme design. Advantages of the approach include: reduced cost over more conventional clinical trials; that interventions were tested under real-world conditions where they will ultimately be applied, thereby strengthening sustainability; and that clinical infrastructure is leveraged in the delivery of the work. A key challenge in real-world studies is that clinical pressures on the ground may have influenced the level of adherence to the intervention which is likely to have reduced the effect of the study, however there was good evidence of improvement in clinical processes of AKI care which was assessed through the notes audit.

A further issue that was the subject of much discussion during the planning for SHAREHD was how to introduce a complex intervention that involved site training in QI methodologies by means of learning events that formed part of a SWCRT[3]. This required the amalgamation of research and QI, with the particular challenges of delaying the start of the intervention for second wave teams and then getting them up to speed quickly during the appropriate time window within the collaborative. First wave teams took part in four learning events as a group, after which the second cohort commenced a single ‘catch up’ quality improvement learning event. All the participating teams attended the remainder of the learning events. It was clear from the study results that evaluation patients in the second step (cohort) had started to increase the number of dialysis related tasks they undertook before their teams had become involved in the learning events. This may have been simply a consequence of completing questionnaires that asked patients the number of dialysis related tasks that they were performing. Thus, although the structure of the stepped-wedge was evident, it was not possible to prevent centres randomised to the second phase of the study from engaging in the intervention before their allotted time and before they started attending learning events. SWCRTs with individual recruitment and without concealment of allocation are at risk of selection bias and this may have affected this programme [64] and is less likely to happen where the data collection is remote to the patients themselves, such as with the open designs utilised by TAKI and ASSIST-CKD.

In summary, if SWCRT designs are to be used, careful consideration needs to be given to the size and cohort type required, the timing of the steps and whether they can realistically be maintained, along with a reflection of the potential impact of time on the uptake of the intervention during the course of the study.

Table 12 highlights the characteristics of the stepped-wedge trial design as evidenced from the Scaling Up programmes.

Advantages	Disadvantages
All sites receive the intervention by the end of the study period	Once the study has started, the timing of the phases are committed to even if the delivery of the intervention is slower than planned
Lends itself to a pragmatic open study that tests real world clinical approaches	It may be difficult to prevent later phase sites from starting the intervention before their planned start time
Cluster randomisation means that a cluster (e.g. a hospital) is the unit of randomisation as opposed to the individual patient - it is a still a matter of the individual study/intervention to decide whether or not individual patient consent is required or not	The real life ‘unit’ of intervention (hospital department, laboratory etc.) may not exactly match the planned ‘unit’ analysis - additional complex analysis may be needed or the intervention effect may be watered down
Can provide a cost-effective means of testing a complex intervention	The real-world clinical setting may reduce the fidelity of the intervention

Table 12 : Characteristics of the Scaling Up SWCRT designs

8.4 Economic evaluation

Health economic evaluation focuses on the cost effectiveness of treatments and health service delivery, ensuring that NHS resources are used most effectively. Traditional approaches are either top-down (where whole service costs are used), or bottom-up (where each component of care is counted and costed). Commonly a hybrid approach is required that uses a range of tools – often giving indirect measures of costs.

A recognised unit of value is the quality adjusted life year (QALY) which requires for its assessment a standard approach to assessing quality of life for individuals. The conventional instrument that is used for this is the EQ-5D which is based on five domains: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. This formed part of the Your Health Survey that was developed by the TP-CKD team and was also used in the SHAREHD study. More detailed assessment necessary for health economic analysis in SHAREHD required staff observation (time-task analysis) which is a commonly adopted QI measure. However for this work, the ethics committee required consent to be obtained from individual patients who were being observed which complicated the work and was very likely to have altered the outcome. The health economic analysis in SHAREHD also relied on Hospital Episode Summary data in order to assess hospitalisation and episodes of bacteraemia. The permissions for this information were very time consuming. In retrospect, it may have been better to collect this information through the study.

The economic evaluation within ASSIST-CKD was planned by working in partnership with the Department of Health on the “Connecting for Change” scheme that was available at the time. Here, a junior health economist gained front line experience working with the ASSIST-CKD team and in return, the economic analysis will be undertaken when the data is provided in 2020. In addition, ASSIST-CKD worked with the East Midlands Network CCG to gain additional funding for a specific phase of work to spread the intervention in that geographical area. Experience from both these aspects allowed estimation of the ongoing cost of staffing and processing related to the intervention, alongside the savings that would be accrued from delaying renal replacement therapy. This information was used to build local cost-benefit business cases to support ongoing commissioning plans building sustainability. (See section 12.2.2).

Within the protocol for TAKI an economic evaluation was not explicitly identified, however the secondary endpoint analysis of length of hospital stay has a fundamental cost implication, both for the NHS and the individual concerned. It is still intended that a cost evaluation analysis will be conducted. It would have been clearly better if this analysis could have been conducted as part of the mixed methods approach with all elements of evaluation working and learning from each other to enhance their individual areas, but this was not included in the original proposal due to the funding constraints. This also highlights the limited national availability of health economists who are able to collaborate on this type of project.

The key message here is to identify members of the evaluation team as early as possible who will be responsible for the economic evaluation. Consider in detail and include what is expected to be undertaken in the protocol and Statistical Analysis Plan with the same rigour as the quantitative evaluation elements. This is essential if HRA ethics is to be sought so that it reduces any need for subsequent amendments, as that can delay the evaluation work.

8.5 Managing the evaluation component of a programme

The tension between research and quality improvement is seen at a number of levels. It has been observed by Mary Dixon-Woods that the evaluation component of QI work is commonly under resourced, insufficiently rigorous and not undertaken sufficiently objectively[2]. The three Scaling Up programmes here were able to allocate about 1/3 of their total funding towards the evaluation in part directed by the Health Foundation bid structure that included the requirement for an external team to undertake this role. When compared with the experience of TP-CKD where the evaluation was primarily undertaken within the programme team, the value of this requirement is clear.

Similarly to working with experienced evaluators, having an experienced management team to support the research evaluation is of great benefit as their understanding of processes that have to be followed will save the core programme team a lot of time. This was the case for all three programmes, with the UK Renal Registry operating that role for ASSIST-CKD and TAKI and the Sheffield Teaching Hospital Renal research team for SHAREHD. Despite this, difficulties were still encountered, including obtaining site research passports or the data linkage from NHS digital where specific experience was lacking. Formal trials units and support services from the NIHR that could perform this role but are expensive, were not used by any of the programmes. Central data collection is important and requires considerable forward planning, whether this is achieved through the Renal Registry or another team. Independence from the core programme team added robustness and consistency of control – in particular, in the timely management of data gaps being managed that were not then left to the end to be resolved.

TP-CKD considered external evaluation in their early planning. It was proposed to work with the York Health Economics Consortium and the University of Leicester but due to various constraints these were not pursued for the full extent of the programme. As a result of the project not having a formal evaluation partner, the TP-CKD core team took on much of this role itself. In effect, developmental evaluation methods were employed by patient site visits conducted by the patient centred care champion. The core team produced the final report, employing descriptive statistics to analyse the ‘Your Health Survey‘ data that was gathered[66]. Specific elements of learning for the PAM and CS-PAM were presented in the reports from the University of Leicester/NHS England[38].

The SHAREHD project adopted a mixed methods approach and included realist, quantitative and economic evaluation – all three elements of the evaluation were undertaken by the University of Sheffield School of Health and Related Research (ScHaRR) with separation from the intervention team who were based at Sheffield Teaching Hospitals. This separation was deliberate and was understood to be a requirement of the Health Foundation during the bidding process and it proved to be valuable objectivity to the evaluation team. The evaluation team drew on the experience and support of the wider University and regional CLAHRC that was also hosted at the University of Sheffield. Close links were maintained between the evaluation and intervention teams through work-stream reviews and with the evaluation lead also being a member of the programme board. A separate Evaluation Board was part of the formal organisation structure of the programme also. Feedback loops returned data to the participating 12 trust teams via specific learning event presentations including baseline data from the cohort study and initial realist evaluation themes, such as maintaining sustainability.

It is important to recognise that unpredictable events may occur during the course of the work that require adaptions to the planned approach. In order to keep progress under review and be in a position to plan mitigation if changes are required, it is essential to conduct regular programme board meetings and to maintain a risk log. Although it is not possible to anticipate all eventualities, regular review of the delivery of the programme against milestones allows emerging problems to be recognised early and responses designed.

8.6 Key learning and recommendations

	Key learning points related to study design and planning
Consider the appropriate study design	Several QI scale-up projects have found the stepped wedge cluster randomised trial design useful. It means that all participating sites benefit from an intervention for which there is already some evidence, over the course of a planned programme, with data comparison available between the early adopters and those yet to adopt the intervention. SWCRT is not appropriate for all interventions however.
Determine plausible and meaningful endpoints for the evaluation	For evaluation of the effect of the intervention it is necessary to set a primary outcome measure for the evaluation hypothesis, such as, reduction in 30-day mortality, with a rationale for how the intervention will impact on the measure. This needs to be achievable and able to be robustly measured throughout the study using a consistent methodology.
Plan how to understand user experience and context	Consider how and when patients/service users, carers and staff will participate in the evaluation, for example, plans to interview or carry out surveys. The approach adopted will be a key factor in what ethical approval for the evaluation study is required. Involve patient partners in the design and governance to be sure the evaluation is not misdirected or that the surveys are over burdensome.
Consider the place of ethics review	Carefully consider if ethics approval is going to benefit the resultant evaluation and dissemination of the findings, even if the project is deemed to be service improvement. It is necessary in order to assess the experience of users. Allow plenty of time for the process to gain the ethics approval, so that implementation is not delayed, or the evaluation team do not miss the opportunity to study the early stages of the programme.
Define the protocol early and publish it	Invest time early in the work to define the evaluation protocol, statistical analysis plan and data requirements by balancing the requirements of qualitative, quantitative and economic evaluation in as much detail as possible. Use framework guidelines to structure the protocol according to best practice. Publish it to formally document the programmes intentions as well as increasing the validity of subsequent publications.
Consider registration if appropriate	Register the study on the NIHR portfolio and a clinical trials register, before the first patient is recruited even if is deemed to be service improvement, as this will increase the provenance of the study results.
Decide what key documents are appropriate for your programme	Identify what key documents are needed or appropriate for your programme (see Figure 7 and Table 15) and the dissemination of results.
	Key learning points related to evaluation management
Link the evaluation to the programme real time	There is great value in the evaluation research team feeding back to the implementation teams via some form of developmental evaluation, to enable the emerging findings to inform the implementation during the programme period. Within realist evaluation this is a key part of the approach as it helps inform the learning of what works, in what circumstances and why.
Build in regular catch-ups between intervention and evaluation	Ensure the evaluation is distinct from the intervention but with close communication between the teams so that learning can be shared. Plan regular 'catch-up meetings' and hold them even if it is thought there is not much to update, as it is sometimes these informal conversations that have the greatest relevance.
Specialised resources and funding may be available	It may be appropriate to look wider than the immediate study funding for additional sources and skills to enhance the programme learning in specific areas.
Non-achievement of end points in scaling-up is not failure	If the primary outcome measure is not achieved that does not detract from the value of the work or reduce the important learning that can come from it.

9. Patient Involvement and Experience

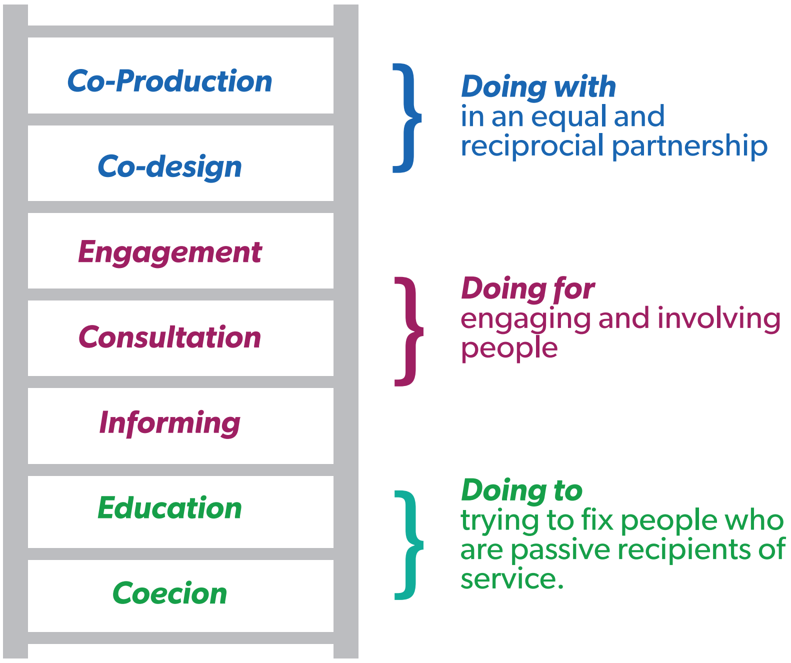
9.1 Introduction

There is increasing recognition of the importance of involving patients, service users, carers and members of the community in quality improvement work in healthcare. Service-user involvement is an emerging approach, which is rapidly evolving from somewhat tokenistic beginnings [67]. What is generally accepted is that for patient involvement to be meaningful, it is not easy to set up and manage throughout a project or programme and especially within health services[68].

Involvement takes many forms, with different levels of engagement, from consultation with service users and the wider community on service changes, to co-production of individual care, to direct involvement in the delivery and evaluation of improvement initiatives. Within this, patients, service users and carers play different roles, including as respondents (e.g. to surveys and questionnaires), as representatives (e.g. on advisory groups) and as patient leaders (e.g. for campaigns and development projects). It is important to understand what form of patient/user engagement a particular project is aiming for and the roles of patients /service users within that, as well as the expectations and motivations of the patient getting involved to ensure that these are matched with the aspirations of the project.

Kidney patients and their carers have been at the forefront of the developing patient involvement movement. This is not least due to the nature of the condition, which is long-term and requires regular clinical supervision and treatment reviews, meaning that patients know their clinical teams and the relationship continues over many years for a lot of people[69]. This only intensifies once a patient requires dialysis, with multiple clinic visits, on a more than weekly basis. Patient support groups, including the Kidney Patient Associations and Kidney Care UK, have been established over many years. Their original purpose was peer support on a local basis for patients and carers, together with a fundraising focus for research and equipment. While retaining these key activities, the groups have become more sophisticated in championing the patient voice at a policy level and in coordination with the renal professional associations and clinical research charities to highlight the needs of this patient group, such as the recent development of the more formal coordination between the different organisations and charities to establish the Kidney Patient Involvement Network KPIN **https://kpin.org.uk/.**

The quality improvement programmes reported here all included different components of patient involvement, from patient experience, to patient representation, to co-production of care that is in line with the types of co-production as depicted in the co-production ladder in Figure 11. The range of approaches were, to a large extent, driven by the different clinical contexts and implementation paths of the interventions: recognition of early stage kidney failure, patients with established long-term kidney disease, patients involved in dialysis and patients suffering the adverse clinical event of an acute kidney injury.



ref:http://www.thinklocalactpersonal.org.uk

Figure 11 : Co-production Ladder

9.2 How far were the programmes driven by patient experience?

Each of the programmes sought to improve the experience of patients during the specific part of the care journey which was the focus (see Figure 2). ASSIST-CKD is a technical intervention, implemented through laboratory IT systems, triggering an alert to the GP, thus the improvement intervention is somewhat removed from the patient. Early identification of failing kidney function is clearly an important patient benefit and has been endorsed by kidney patients, but this is not an intervention that has significant reliance on patient involvement and engagement for its success.

At the other end of the spectrum, SHAREHD is a patient centred, co-production initiative, which aims to enable people take control of their condition and is delivered directly with patients, providing support for joint management of in-centre dialysis, with the choice of involvement to be entirely decided by the individual patient. SHAREHD was based on principles of co-production in its design and implementation and these were carried over to the scaling up work. It was recognised that the role of the patient representatives would require adjustment to support the scaling up phase and this was continually developed in the light of experience, as the programme was implemented.

The TP-CKD programme focused on patient involvement as its major driver. However, it was notable that patients were not involved during the conceptualisation or the negotiation of the funding agreement, and therefore not involved in determining the deliverables at the outset, nor were the terms of patient involvement built into the project governance at the start. As one patient representative phrased it, “this flaw was overcome with lots of work and courage”. The project set out aspirations for the level of involvement that they were aiming to achieve, such as appointing co-chairs: a patient and a professional for the oversight board and on each work-stream, which was delivered. There was an aim for equal representation of unit staff and patients on local working groups and among the representatives from unit teams attending peer assist events, which was achieved to some extent. Programme delivery was supported by a board comprising a range of stakeholders including patients, carers, clinicians, NHS England representation, commissioners and academics.

TAKI was also a clinically driven project, aiming to increase healthcare professionals’ awareness of AKI and to reduce variation in its management. Since by its nature, AKI is an acute episode, rather than a long-term condition, there is no existing pool of interested and committed patients and carers in the same way that improvement programmes in chronic kidney disease can call upon. The intervention was focused on improving patient experience and outcomes for those who suffered AKI but did not require a high level of patient involvement in order to deliver the implementation. However, there were important examples including where a clinician with personal experience of AKI provided educational value at a nurse education day, bridging the gap between clinician and patient. Kidney patient representatives were included on project advisory groups at some of the sites and patient groups at each centre co-produced patient facing materials e.g. AKI information for patients. While chronic kidney patients could utilise their experience of prior involvement in service improvement, it did not feel that they had a personal stake in AKI, since it is very different from CKD. At times, patient involvement in the project felt a bit tokenistic as it did not naturally generate specific patients who were passionate about AKI. A learning point here is that engaging patients as partners in projects of this nature can be challenging, and to achieve this contributing health care professionals require experience in coproduction. This may require specific support from contributing partner organisations.

9.3 Approaches to involving patients in implementation and scale up

A common factor across the programmes was the inclusion of patients as service user representatives on the project board, advisory group, or steering committee (however named). While these structures had a somewhat different remit across the projects, they had in common an oversight role, with the group responsible for direct implementation reporting on progress to such a group. Each of the projects considered it important to ensure that there was representation of the patient voice on this group, to inform the development and direction of the work from a non-clinical perspective, to take a ‘rain check’ that the work of the project was concerned with outcomes and processes that were important to patients and to gain input on how the work would be presented to a patient/lay audience. For example, TAKI involved patient representatives in testing and advising on the development of patient-facing information on AKI. A key consideration for the patient role on an advisory group is to be very cautious about the extent to which patient members can ‘represent’ anyone other than themselves and their own experience. There needs to be clarity about whether they are on the group in an individual capacity, or as a nominated organisational representative, for example of the local Kidney Patient Association. If the latter, the group needs to consider issues such as how papers and other materials will be circulated, so that the representative has a chance to gain views from their organisation and present these at the meeting.

ASSIST-CKD initially recruited ten patients to be involved in the steering and advisory groups. There was some calculated ‘redundancy’ as it was recognised that due to health and other issues, it was unlikely that all ten would be able to stay with the project throughout the implementation life-cycle. In practice, there was a high attrition rate, not only due to illness/change in circumstances but also because of the nature of the project (technical, IT, at some distance from direct patient interaction). It was difficult to meaningfully involve patients and therefore to maintain motivation, which reduced the number of patients who maintained participation to three by the end of the project. The project experienced notable problems as it became clear that the software required re-writing which led to delays in implementation, another demotivating factor for the patients involved. With hindsight, there could have been more formal review of how the project should proceed, including the plans for patient involvement. As the timescales for the work extended over a much longer period, the original ideas on patient participation had to be reconsidered. At the same time, patient representatives were somewhat frustrated at the slow pace of working in the NHS for this type of programme, which involved painstaking negotiation between the programme team, NHS Trusts, laboratory services, IT departments and liaison with GPs, rather than a direct improvement intervention within renal services, which might be taken forward more quickly.

However, the project group did make use of the experience and skills of the patients involved, for example to develop patient stories to illustrate the importance of the work. Also, using the patients' professional expertise – in communications, business and finance – to develop the business case for investment in early identification which demonstrated the potential to reduce future care costs. The patients who remained involved had a wide skill set that was most relevant and pertinent to ASSIST-CKD. Their continued commitment was likely because they were enabled to meaningfully contribute. Other patients on the groups had no clear input and this may have been a factor in why they dropped out of the project.

SHAREHD was able to capitalise on patient involvement, both through the experience of the team in working in a co-production style and due to the nature of the intervention. From the start of SHAREHD there was the intent to have the patient at the heart of everything that was done within the intervention and throughout the organisation of the programme at every level. Overall, this has been reflected upon as a very positive experience for those involved. SHAREHD built upon the experience of the original intervention development and how the patient engagement evolved during that. Key learning from the original project was core to its development. There was true patient engagement in the discussion and planning for the scaling up phase. A patient representative was involved in the project design, the bid writing and submission, the interview at the Health Foundation and the project manager recruitment. Patient involvement continued to be built into in all the work-streams and boards as the programme went into the scaling up delivery phase.

SHAREHD had planned to start with a lead for patient involvement and then invite other patients to join a Patient Advisory Group (PAG), which was planned to have four members, with each member sitting on the group for the different work-streams and then coming together as the advisory group to discuss the project, before starting to engage patients from the other hospital sites. As the scaling up sites joined the programme, SHAREHD introduced local Patient Champions as a new concept over and above the existing PAG. The PAG membership did not come together as planned and the programme missed the benefit of having an active patient group at the overview level from the start, but the Patient Champions group worked well.

TP-CKD was successful in getting patients nominated and involved in all of the participating sites. However, as the project went on, some of the patient representatives were not able to continue, due to a range of factors, such as deterioration in health, a change in family or work circumstances and other commitments. Also, some local health 'systems' can easily get in the way rather than encourage patients involvement. This experience highlighted the factors which come into play with the involvement of service users, for example that people who have a long term condition may not continue to be well enough to maintain their commitment. The difference from professionals is that the project is not a formal work commitment and therefore has to take a different level of priority as circumstances change.

The TP-CKD project did achieve a high level of patient involvement such as appointment of patient co-chairs for the work-streams and setting the expectation that all renal unit teams involved would bring patient members to the events. Although this did not happen with all teams, most teams did include patients. The peer assist approach ensured that the events for the teams were fully integrated into the workflow, using a structured approach in which every event had a clear deliverable. It radically changed the way patients were involved as they co-produced the work in a truly collaborative way.

It was not possible to ensure that patient co-chairs had the same level of input as the healthcare professional co-chairs to issues such as setting meeting agendas and advance access to meeting papers and so forth. However, while there were occasional disagreements, the patient voice did come through and was reflected in the project outcomes and the work did make a real difference because patients were so involved. One frustration among the patients was that the programme was focused primarily on data collection, rather than moving on to determining what the data revealed and developing interventions to drive change, which had been a key motivator for the patients involved. Unfortunately, the project ran out of time and funding before it could move into the intervention stage.

9.4 Good practice for patient involvement

Aim for more than one patient representation

Projects should try to avoid having only one patient involved, as this can be seen as tokenistic and also puts a lot of pressure on the individual to try to represent the wider patient voice. There are advantages in aiming for a diverse group of patients (age, gender, ethnicity) balancing this against the advantages of enlisting those who volunteer, who may have a similar profile but have demonstrated an interest and commitment. While SHAREHD involved patients throughout the programme, at the development stage there was just one patient involved. This involvement was critical and persisted throughout the delivery of the programme – regularly holding the rest of the project to account, however on reflection it is recognised on both sides that it would have been preferable to have had wider representation. This would have provided a different dynamic and enabled more of the overall patient community voice to influence the programme.

Set expectations

All those running improvement work need to have a clear idea about what areas patients are expected to get involved in and what their role will be. Patient input should not be regarded as ‘free’ but rather ‘golden time’ that is in short supply. Project leads need to be careful not to over sell the benefits of the input of patients and therefore annoy or frustrate those who get involved if they become disappointed with the reality. SHAREHD for example worked with the Patient Champions to understand what their expectations were, and patient engagement descriptions were available which outlined the rationale for involving patients. The central programme team prepared adverts/posters and role descriptions to support participating sites in recruiting Patient Champions. Once recruited there was an induction programme that all Patient Champions were able to participate in. When expectations and commitments are outlined at the start it enables participants to know what to expect. If the level of agreed commitment is not being met, for example non-attendance at meetings, this should be addressed and expectations reset or alternatively recognise with the individual that this role does not suit them. Patient volunteers should be considered ‘replaceable’, just like a staff member, if they are not delivering for the project or want to move on for their own reasons. Patients do however also need to be held to account for the role and contribution they have committed to, since not tackling this may compromise the success of the work overall.

Describe the patient role clearly

In addition to a clear idea of the role and a written description of this, improvement projects need to consider how they will reimburse patient’s expenses and what expenses will be covered. It is standard to cover travel expenses, but people may also need to be reimbursed for childcare, other carer costs, or subsistence, if expected to be away from home for the day and so forth. Some projects and organisations pay a daily rate for patients’ involvement; this may be linked to the nature of the role they are undertaking. Where patients are directly involved in work of the improvement project, such as participating in or delivering training, running focus groups or interviewing staff/service users, a standard fee is one way to recognise the contribution. Not all patients will want to be paid but it needs to be considered and budgeted for. Appropriate fees are available from INVOLVE[70].

The reality of long-term conditions

Experience of the programmes has shown that it is realistic to plan patient involvement activities and roles with an expectation that some of the patients who start the engagement will not continue for the duration of the project. It is not always the people that seem most engaged initially who stay the distance and vice versa. Different projects will appeal to particular interests, and where an individual finds they have skills that are useful to the project, they are more likely to stay with it. The fact that not all stay involved and that people are not able to continue due to health and other non-project related reasons or priorities should not be seen as ‘failing’, rather that this is an expectation that is planned for.

Patient representation can be lonely

It can be ‘a lonely place’ to be the patient representative on an improvement project. It is important to provide links between patients involved at different sites where an intervention is being scaled up, or across different projects, so that there are other patients to turn to for support and advice. SHAREHD found it was extremely helpful to establish a programme-level Patient Forum which was established to build confidence among the patient representatives, with the recognition that a QI project team is a new environment for patient representatives. Specific patient group focus sessions were held at the programme learning events, to facilitate the links and support between the patient champions and to ensure that there was space in the programme to address their concerns and issues.

The SHAREHD patient lead reflected that he would have really liked to have met with patient leads from other projects before and during the scaling up implementation to share ideas and approaches. He did go to the Health Foundation learning event days as part of the team but on each occasion was the only patient from the seven different programmes in the Scaling up wave. The importance of patient representatives being able to network and get together to understand

and learn from each other across a range of improvement work cannot be over-stated. Involved patients need to have routes for communication between themselves and have access to meetings for patient representatives in a safe environment where they can say what they want.

Take care not to isolate the patient representative

Patient representatives have reported that they often feel ‘isolated’ in the project team and at advisory group meetings. Too often the patients are not included in the social chit-chat of the meetings, which takes place between the professionals, with patients only spoken to during the formal part of the proceedings. Patient representatives reported an experience of professionals not bothering to say ‘goodbye’ after the meeting which can put patients off if they feel they are doing something to contribute but feel ‘second class’.

Develop peer support

SHAREHD has kept the patient to patient relationship going informally between patient champions, through the efforts of a committed patient lead. This involves individual communication by email and phone and also a patient champions’ WhatsApp group. This relationship has continued and has grown into more of a coaching/mentoring role by the original patient lead, with patients more confidently advising each other of issues and possible solutions. This has now developed into a loose network and those involved are happy to continue to help where possible, such as linking with the Kidney Patient Involvement Network (KPIN).

KPIN was established in 2017 as a partnership of voluntary, charity and professional organisations bringing together experienced patient leaders from Kidney Care UK, SHAREHD, Devices for Dignity, PKD charity, Kidney Research UK, and the Greater Manchester Kidney Information Network (GMKIN). It provides a link for patients who are involved in projects to continue their wider involvement, as there may be a feeling of ‘let down’ as a project ends. As KPIN becomes more established it will provide a resource for projects to recruit patients with interest and experience in involvement activities as patient leads. The Network is becoming an established patient forum to share experience and learning via KPIN meetings. KPIN was selected as one of ten ‘test-bed’ organisations to evaluate the new INVOLVE standards, aimed at improving public involvement in research and has received financial support from Kidney Care UK.

Changing service culture

Healthcare professionals need to take an objective look at how they work with involved patients on advisory groups and as partners in the implementation of improvement and consider the extent to which ‘normalised’ working practices need to change, to enable the full partnership working with patients. A programme seeking to change the culture of services towards patient involvement and co-production needs to work in this way throughout, to promote and model the culture change before trying to get the other services to do the same.

For success, patient involvement has to work both ways, in that there needs to be a desire from the professionals to want the patient involvement as well as patients wanting to get involved and support the professionals. It is the responsibility of the professionals running the improvement work to consider how patients can be encouraged and supported to get involved and to ensure that the set-up and infrastructure of the work facilitates this voluntary engagement. Issues such as when and where meetings are held are key, ensuring this does not just fit clinicians’ timetables. Patients have other jobs and commitments and may not be able to join a meeting even by teleconference, if it is their work-time, meaning that they are effectively excluded from participation. Consideration needs to be given to the administration and planning of meetings to ensure that patient representatives have the opportunity to be as involved as they wish to be in issues such as setting the meeting agenda, contributing to papers and so forth, rather than omitting involve them, or making an assumption that ‘patients wouldn’t want to be bothered’ with these aspects.

Involve patients early

One of the key areas where patient involvement is often lacking is in the initial conception of service improvement interventions. It is necessary to engage patients before there is a formal project to be involved in, to help shape the thinking, focus and design. Too often the first stage of patient consultation is on developed proposals. For example, having patients involved in scoping and contract negotiations for TP-CKD may have made it a richer programme, with patients taking on a high level of responsibility because they were involved from the outset. Despite this, TP-CKD was successful in integrating and partnering with patients and the deliverables would not have been as rich if the patients had not been involved.

Patient involvement is essential to ensure that improvement is focused on the issues that matter to patients and that it will have a positive impact on their experience of the service and that the improvement reflects the reality of their care experience. Issues of concern to patients may not be those areas the clinical members think are crucial. This may cause tension in exploratory and planning phases but understanding what really matters to patients and focusing improvement effort in response is more likely to result in impact and sustainability.

What happens to the patient representatives when the project stops?

Project leads also need to consider whether there will be an ongoing mechanism for the patients to stay involved with their local service once the ‘project period’ is completed. In many cases, strong relationships are formed over the course of the project and people can feel let down and excluded when this does not continue. Again, it is a key difference between patients on a project team and the professionals, who will continue to be involved in running the service and probably other improvement and service development initiatives, while the patient members can feel left ‘high and dry’. One way would be for the project manager to build into the plan a supported and structured landing after the programme ends. It is important to nurture people’s passion for improving services and the desire to be involved in QI efforts. This is a key part of ensuring the sustainability of interventions after a specifically funded project, or implementation period, concludes. Signposting initiatives such as KPIN will enable people to continue their commitment and provide a route for involvement in other initiatives[34, 71].

For further reading see the TP-CKD and SHAREHD reports on coproduction[72, 73].

9.5 Key learnings and recommendations

	Key learning points related to patient involvement
Aim to involve more than one patient representative	Try to avoid a situation of having lone patient representation: where there is a planning or steering group of six to 12 people, aim for two or three patient/ service user or carer participants. For some interventions and approaches, it may be appropriate to aim for a 50:50 ratio of patients to healthcare professionals.
Involve patients early	Try to involve patients before there is a project, get input and ideas for what to improve and involve the patient voice throughout the scoping, development, funding/ contracting stages.
Describe the patient role clearly	Prepare a written brief for patient roles on committees, planning groups or in carrying out aspects of the intervention/ research. Give a personal briefing on the remit and expectations for those involved when they initially start.
Aim to be genuinely representative	Recognise the demographic of the intervention and try to match at least some of the patient involvement to that demographic.
Develop review mechanisms	Build in review mechanisms with patient partners to check experiences from both sides. This will facilitate the discussion of any issues that need to be addressed.
Match involvement to motivation	Understand the motivations for patients to get involved and try to give them activities that are relevant. All patients do not have to be involved in everything from start to finish - specific actions or timeframes may work better for some so be prepared to be flexible.
Be clear about expenses and remuneration	Consider what expenses remuneration will be provided and budget for this accordingly. Ensure this is transparent to all involved. This NHS England policy paper gives generic role descriptions and the level of expenses and remuneration linked to these, which is a useful guide. [78]
Consider accessibility of meetings	Consider the timing and venue for all activities involving patients, including teleconference options, to ensure maximum accessibility.
Develop peer support	Establish peer support between patients involved in the improvement work. For a scale up programme it is helpful to have a cross-programme patient support and communication mechanism.
Foster patient co-production more broadly	Consider how to support healthcare professionals to become more mindful of patient involvement and their care experience throughout all their interactions with patients and carers. Foster ongoing co-production, not just when in ‘improvement project’ mode.
Consider the longer term patient role	Maintain a level of communication and links with involved patients beyond a specific project and signpost organisations such as Kidney Patient Involvement Network https://kpin.org.uk/ and NIHR INVOLVE https://www.invo.org.uk/

Findings 4 : Patient Involvement and Experience

10. Management Methods and Mechanics

During discussions in the preparation of this report, project managers and team members universally commented that their projects were exceptionally rewarding. They were harder work than they had anticipated and only possible to achieve with the relevant leadership and energy. No one said they would not have undertaken the programmes had they known this, however key experiences and lessons can be identified from the featured programmes in terms of structures, planning, engaging stakeholders, management and delivery. These lessons are drawn together here to help future planning of improvement interventions, particularly the spread of an intervention beyond the initial development and implementation site. It is anticipated that early consideration of these points will prepare project teams to negotiate the inevitable challenges that arise.

It is recognised that there are inherent tensions between pure principles of project management – delivering to the agreed timescale and to budget – and the more flexible approach of quality improvement initiatives which aim to identify the right solution through a process of testing and refining the intervention, then working with staff to embed and sustain it in practice. Within quality improvement theory, some will argue that even the concept of a time bounded project is unhelpful and contrary to the spirit of continuous improvement, with teams constantly refining their interventions over time. The problems of 'project-ness' have been explored as a barrier to sustained improvement[74]. Meanwhile, Stephen Spear, highlights the need to 'discover your way to a solution' which poses another challenge to the classic project model[75]. Each of these scaling up programmes found their own way of navigating these tensions that was necessary to deliver the larger ambitions of scaling up their intervention.

10.1 Programme structures and approaches

10.1.1 Planning and bid teams

The initial planning stages (often prior to the funding award) were seen across all the programmes as vitally important in terms of scoping and cost apportionment in order to provide a solid basis for a successful project. It was essential to get expert advice to ensure that consideration was given to all key aspects of the programme in a manner that was meaningful and understandable to stakeholders, from senior managers to patients.

The programme 'bid teams' usually included evaluation, QI expertise, project management and clinical input. As already mentioned it is important to consider patient representation at this stage, to be sure that the work is relevant and focussed on issues that are important to quality of care and patient experience. For SHAREHD and ASSIST-CKD, their lead patients were involved in the bid phase whereas the patient chair of TP-CKD only became involved after the bid process which may have made their patient representation ambition harder. All the scaling up programmes had core team members that had been working together already for many years but also brought in appropriate support including 'critical friends' to strengthen and validate the proposal. Examples included the Microsystem Coaching Academy to provide QI expertise, external management consultants or professional body representatives for validating proposed structures, as well as the UK Renal Registry to validate data.

It was important to recruit early and budget appropriately for project management, patient involvement and evaluation. These are key programme components that ensure the project runs to plan, that it is meaningful for patients and that there is objective appraisal of the results.

10.1.2 Programme structures and governance

These large-scale QI programmes required sophisticated structures to underpin implementation and evaluation as well as providing overview and governance of these functions. The programmes had quite different structures, depending on:

- *where they were situated – a joint approach between several organisations, or led by one NHS trust*
- *how centrally controlled the implementation was, as opposed to delegated to adopter sites*
- *whether evaluation was integrated or separately commissioned.*

Figure 12 shows the organograms of the three Scaling Up programmes, as well as for TP-CKD for comparison purposes, and Table 13 shows the comparative structures.

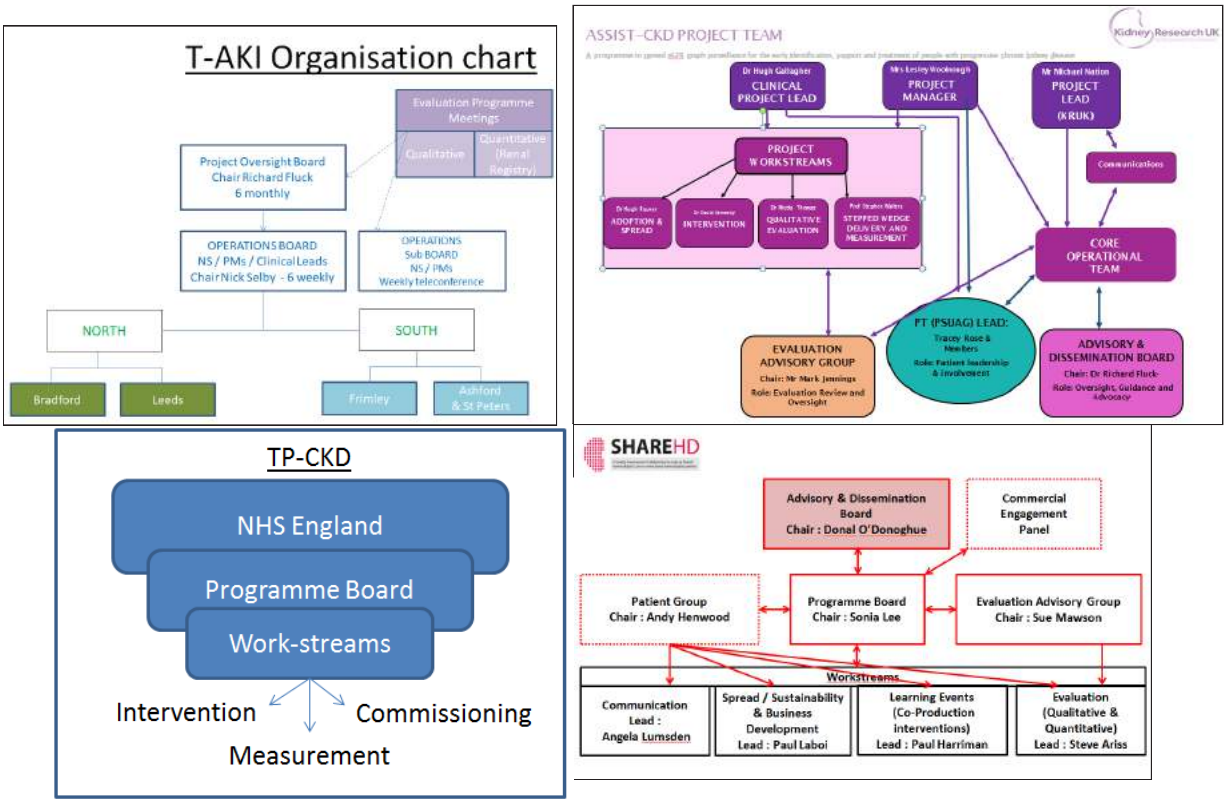


Figure 12 : Programme organisation charts

Organisational structures	**ASSIST-CKD**	**Tackling AKI**	**SHAREHD**	**TP-CKD**
Core implementation team	Initially a distributed approach moving to the core central team to manage software redesign	Core team but geographically spread	Central team – loosely co-located	Central team
Evaluation team	Externally engaged but integrated with core team	Externally engaged and autonomous from the project	Externally engaged and autonomous from the project but regular joint meetings every 3 weeks	Internal to core team
Governance Meetings & Frequency				
Steering group / programme board	Face to face or telecom every 6 months with a 'core operation' group meeting more regularly TOR and minutes produced	Every 3 months, included advisory aspects in steering committee	Face to face & teleconference 6 weekly TOR and minutes produced	Every 12 weeks
Advisory groups	Advisory & dissemination – every 6 months TOR and minutes produced Board agenda and papers issued 2 weeks before the meeting	No	Advisory & dissemination – every 4 months External chair with programme acting as secretariat Formal TOR and minutes Agenda and papers issued 2 weeks in advance Commercial forum, every 4 months, arranged and chaired by external agency (Devices for Dignity), TOR and minutes	No
Patient advisory group	Every 6 months, led by formally recruited lead who had job description TOR in place	Local engagement as required	Every 3 months then moved to WhatsApp group alongside patient champions TOR and job descriptions for participants and lead by patient lead	50/50 representation and patient co-chairs for all boards and work streams so no separate PAG required
Evaluation advisory Group	Yes	Yes	Yes	No
Work-stream meetings	Teleconference or face to face with a regular cadence depending on stream	Weekly core team teleconference Local meetings locally	Teleconference or face to face with a regular cadence depending on stream	Quarterly face to face plus monthly calls

Table 13 : Programme structures comparison

Regular planned and structured meetings were important across all projects. This maintained momentum, built trust and team cohesion which was invaluable when issues arose that required resolution. All programmes confirmed that consideration of the appointees to implementation work streams, boards and advisory groups was a critical part of the planning and preparatory work. Implementation teams needed to be cohesive, with a mix of all the necessary professional, clinical and research knowledge and expertise to run the programme. All those involved in key roles had to believe in the programme's aims, which translate into the commitment required to overcome barriers when they invariably arise. The recruitment usually was based around networks and contacts that the team already had. It is an important message, however, to reflect the diversity of services users in the boards as much as possible.

The first step was to identify chairs and the terms of reference that the group needed to fulfil. The chair was then able help to select the group members ensuring an appropriate balance. All four programmes were extremely successful in engaging a wide variety of people to work with, ranging from very experienced and eminent members of the kidney community such as Richard Fluck, Fergus Caskey and Donal O'Donoghue, to consultants and interested parties from outside the kidney community such as Mark Jennings (Oxygen Consulting), Liz Hill Smith (SPACE Consulting), Berni Stribling (DeSMOND) and Sue Mawson (Director of NIHR CLAHRC Yorkshire & Humber).

Members of advisory groups were required to have the interest and commitment to constructively support the programme, yet provide challenge where that was required. Donal O'Donoghue advised SHAREHD that the group should be no larger than 12 and that the meeting should be structured around 2 or 3 key questions, as well as an update of programme progress. As time went on the focus was more on these key questions and less on discussing progress, which had been summarised in a progress report supplied in advance of the meeting. This worked where the advisory and dissemination groups were separate to the programme board but would not have been appropriate for a combined steering committee, hence reiterating the importance of ensuring the scope of the board is clear from the start of the programme.

As the programmes developed, some of the structures did not fulfil their roles as planned which is not unusual and can be as a result of changing circumstances. Another example across the three scaling up programmes was that they struggled to maintain attendance at evaluation advisory groups. When this happened within SHAREHD, individual telephone conversations were made with each member to gain individual feedback. Terms of reference 'Verification points' were also built into some programme board agendas to ensure that it continued to be fit for purpose (for example every 12 months). This allowed for changes to take place to the length and frequency of the meetings for example, rather than slavishly sticking to what was originally agreed.

10.1.3 Programme governance

The programmes needed to determine the appropriate governance structures to support their key scaling up change work. As seen in Figure 11 above, each programme had some combination of steering group, advisory board/committee, and evaluation advisory group.

When setting up multiple groups, it was crucial to have a written purpose and terms of reference for each group, with clarity on whether its function was primarily managerial, advisory or governance oversight, as these are quite distinct functions and any blurring of remit or overlap of responsibilities could have been confusing and detrimental to the programme. In addition, a structure chart, showing how each group related to the central project management / implementation team and to each other was helpful, to ensure that members had clarity on the groups' role and to help avoid 'mission creep'.

While governance structures are necessary, it is important that they serve the improvement work, rather than constrain it. The role of a governance group was to have an overview of progress, ensuring that budget spend was appropriate with oversight of emerging evaluation findings, but not to manage the programme. The governance group, as a whole, needed the requisite expertise to offer guidance on areas that are not progressing well. If steering/advisory groups met too often, reporting requirements diverted energy and resources from the implementation effort. If members were not clear on their remit, they may have seemed more adversarial than supportive. One project manager reported that it took three days to prepare for the project board and that the core team received a real 'grilling', more akin to a contractual review rather than a quality improvement project.

10.1.4 Programme teams

The approach to project management influenced the setup and delivery of the programmes. Project management was needed at both a programme level and within the individual local teams that were adopting and implementing the interventions. Programme level project management focused on end-to-end planning for the funded period, setting up organisational structures, clarifying the skills needed and funding available, together with allocation of time, skills and budget to the varying components of each programme.

As each of the programmes were subject to a formal bid, this forced a clarity of budget, plan and scope to be determined at this stage, in effect 'projectising' the quality improvement work. The following explains how for each programme the management was initially considered and how it evolved.

SHAREHD

The experience from the pilot ‘Closing the Gap’ work, together with advice from the funder and quality improvement consultants, placed emphasis on the importance of a full-time project manager for the scaling up programme. This post was included in the budget for the funding bid. The team worked closely with the Microsystems Coaching Academy (MCA) and the University of Sheffield during the project definition stage to plan the level of QI leadership, evaluation and project management that was to be included. This enabled the programme to start on a sound basis with an achievable project plan for the delivery of the programme objectives.

Once the funding was secured, MCA provided a temporary project manager via their fellowship programme, this post supported the recruitment to the permanent post for the duration of the programme. Initial start-up activities followed PRINCE2 type methodology to establish critical deliverables, such as learning events – ensuring that these dates were fixed and communicated from the outset, together with communication to the chief executives of the participating trusts, to set out high-level expectations for the programme. Getting these foundations in place before the programme activities were up and running and before the full time project manager was recruited facilitated the smooth running for the remainder of the programme.

This experience shows that it is not essential to have the same individuals involved from design to implementation, especially if standard project management methodologies are used. Each stage requires a sufficient level of technical expertise and an understanding of the overall objectives to develop and execute an achievable project plan.

Tackling AKI

The funding bid to the Health Foundation included appropriate project management support, though the majority of this was devolved to the local implementation teams, to support their setup and delivery of the programme activities on the ground. The core team had minimal funding for project management with the Principal Investigator (PI) for the research project primarily covering the core programme management functions. Across the five sites, three part time project managers were engaged who between them covered quality and service improvement, project management and nursing experience. Because of the geographical spread, weekly conference calls were held between this core group to discuss progress and arrange next stages in the plan. Towards the end of the programme, the Health Foundation provided additional funds for a programme manager from the UK Renal Registry to work alongside the PI.

ASSIST-CKD

The original programme proposal included a part-time programme manager to provide co-ordination between the software providers, the adopting sites and the evaluation teams (quantitative and qualitative) and support the administration of the steering and advisory group meetings. The level of project management input was planned on the assumption that the software was ready to roll out to laboratories. The subsequent decision that the software was not fit for purpose and the need to commission a new software programme necessitated a greater level of project management.

An external project manager was employed to manage these developments and continue to provide the overall coordination and administrative support for the programme. The first programme board they attended was 3.5 hours long which the project manager realised would be unmanageable going forward to have any chance of delivering at the pace that was needed. As a result it was agreed to constitute a smaller and more dynamic ‘core team’ for the next stage of the programme where dynamic decision making was required. This shows that team members should not be afraid to challenge what does not seem to be working and also that an external view – which can come from patient partners – can highlight where simple changes can make a big impact.

TP-CKD

A programme manager was in place at the start of the programme, as part of the infrastructure provided through the Think Kidneys Renal Registry (RR) however the person-centred care coordinator (PCCC) took on a lot of the project management activity supported by an administrative/ programme support role.

Table 14 presents the size and shape of the teams as well as the funding allocations for the projects.

	SHAREHD	**TAKI**	**ASSIST-CKD**	**TP-CKD**
% Budget on Programme/ Project management	25%	30%	20% (estimate)	
Programme Management	Full Time	Part Time	Part Time	Full Time (PCCC)
Other Core implementation Team members	Part Time Clinical Lead/PI Nurse educator QI expert Lead evaluator Patient Lead Sustainability Lead Communication Lead Governance Lead	Part Time Clinical Lead/ PI Lead evaluator PM (towards end of programme) 4 x 0.5 full time equivalent salaries supporting local implementation teams	Part Time Governance Lead	Full Time PCCC Part Time Admin support
Local Teams	Local Team lead by PIs Funded locally for each of the 19 trusts	Local teams lead by PIs funded with support from the project budget for each of the 5 trusts	Funded locally except for initial support of the graph reading as per a local Memorandum of Understanding	Funded locally
% Patient involvement Budget	7%	1%	7% (estimate)	
% Budget on Evaluation Team	30%	12%	13%	Undertaken by core team
Evaluation teams	Lead Evaluator, Health economist & Support, Clinical Statistician, Principal Statistician, Realist Evaluator,Team Support	Lead Clinical Evaluator, Principal Statistician, Lead Realist Evaluator and Support Evaluator	Lead Clinical Evaluator, Principal Statistician, Lead Statistician, Development Evaluator	Programme team and renal registry support team

Table 14 : Programme team composition and funding (PCCC = patient care co-ordinator).

Each of the implementation teams had a principal investigator/ clinical lead and various team members as can be seen in Table 14 above. The constitution of the team depended on the balance of the intervention and methods that it had been determined to deploy. It was critically important to have clear expectations of what was required from team members both in terms of time and input so that expectations could be aligned. As was reported in section 10, Andy Henwood, patient lead for SHAREHD reported that being a patient lead can be a lonely place. This experience was also reported by programme managers who are often the only full time member of the team, hence team cohesion and ownership of outcomes is important to generate.

10.2 Engagement

10.2.1 The role of engaging front-line staff in local ownership

Engagement of front-line staff is essential for the successful implementation of quality improvement. It is particularly important to consider how staff are introduced to an intervention that has been developed elsewhere and which they are now expected to adopt, with more or less scope for local adaptation. Understanding the experience of front-line staff and services users is essential if the intervention is to be delivered successfully – and this formed a central part of the evaluation of the Scaling Up programmes.

Local leadership is essential if an organisation is to successfully implement a particular intervention. Replicating a successful intervention from elsewhere without local adaption is unlikely to be successful since it is dependent on contextual characteristics and priorities of each individual organisation. It is important that there is local “ownership”, rather than relying on ‘top down’ dissemination and this is dependent on the characteristics of the specific intervention. It is therefore essential to recognise the importance of front-line staff engagement and to facilitate local ownership in a consistent way that fits with the intervention and team ethic.

For example, TAKI engaged local ownership by enabling local units to employ their own project management. TP-CKD and SHAREHD adopted the opposite approach, not providing any funds to local teams (other than expenses to attend learning events by SHAREHD) and using project funds to employ centralised project management and experts who could then provide training and ongoing central support for implementation. Where this centralisation occurred, the local teams implemented the intervention using their own resources. ASSIST-CKD funded the eGFR graph interpretation for one year, but it was then expected that this would be funded locally going forward. However it was done, it was necessary to both enable local engagement, while providing central direction of the project and therefore a combination of approaches was required that recognised both of these components.

There were pros and cons with either approach. The important aspect was that it was ensured that whichever structure was planned, it was resourced and managed accordingly and expectations were set.

10.2.2 Organisational readiness to engage with the programme

All the programmes had to engage with the teams across adopter sites, in order to facilitate the spread of the intervention. They all set out a broad ‘call’ for renal services to get involved and selected participant teams from those who responded. TAKI identified the number of teams they planned to work with, and stuck to those teams originally engaged, to enable the planned stepped wedge evaluation. ASSIST-CKD, TP-CKD and SHAREHD all tried to accommodate additional teams who wanted to get involved, as the programmes progressed.

While it was positive that so many renal services wanted to get involved, it was important that the selection process considered a number of characteristics including team readiness, geography and suitability of the local context in order to ensure the best chance of successful implementation.

Within the programmes there was some site drop off. In ASSIST-CKD some sites expressed initial interest but then did not proceed through to the intervention stage citing issues such as lack of administrative support to send out letters to the GPS and the need for additional encryption processes that could not be accommodated locally. Within TP-CKD, the final report identified that factors such as a depleted work force, lack of staff time and a reduced senior leader ‘buy-in’ alongside competing priorities contributed to those sites that were less successful. For SHAREHD, two sites stopped attending the learning events mainly due the distance being too far from their base locations, in addition to local priorities not being aligned. It was therefore key to set expectations with the local teams and build on the desire to be involved with local ownership and frontline engagement.

Development of selection criteria can help to shape the programme and site selection. SHAREHD was able to do this with their Wave 3 recruitment, since based on the reputation of the previous waves there was a degree of competition with more applications being made than the 6 places available. One key aspect of the teams having been ‘selected’ was that they then felt prouder to be involved, resulting in better attendance at the events and a desire to succeed. For this to happen, the programme has to be seen to have “value” to teams that are considering applying. This is, to an extent, dependent on the success and reputation of the programme and therefore may not be there at the outset.

The programmes devised information and education for the adopter sites, to support local implementation. It was crucial to gain an understanding of where teams were starting from, so that the resources and training were relevant to the goals for local implementation. Local setup meetings were found to be very beneficial to achieve this and to facilitate teams to get together that were planning to work together – such as with TAKI for Peer Assist, or SHAREHD on initial site visits. It was reported by all the programmes that local teams did not get the opportunity to get together as a team as often as they would like, which can hamper progress. This challenge was responded to by planning in these opportunities by way of kick off events, local site visits or teams attending learning events and creating ‘team time’ to work on the implementation.

In addition, the style and level of ongoing support for the adopter sites needed to be considered and made clear to participating teams. The programmes adopted different approaches to support the teams, ranging from local project management and QI support (TAKI), face to face ongoing contact (TP-CKD), action period calls and telephone support (SHAREHD, TP-CKD and ASSIST-CKD). Each approach had its particular attributes and it was necessary to reassess how they were working as the programme progressed so that adjustments could be made as required.

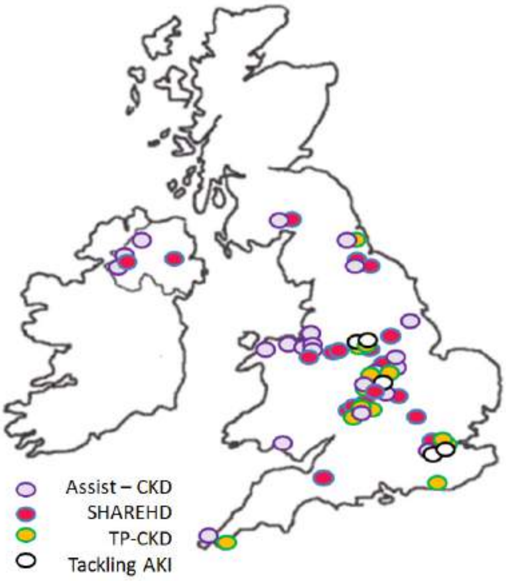


Figure 13 : Participant trusts across the four programmes

Figure 13 shows the spread of participating teams for the contributing programmes across the country, presented in detail in Appendix 12.3. This indicates that though there are core teams that gained considerable experience with quality improvement initiatives, there are parts of the UK that new initiatives could take advantage of. It also shows that there are areas where there has been less exposure, and therefore new scaling up initiatives should consider working with less experienced sites in order to support the KQuIP objective of developing QI expertise across renal services.

10.2.3 Engaging team members

Project management for improvement interventions within the NHS is not a recognised career path. Often those who take on a project management role will have 'evolved' into this from nursing, clinical or operational backgrounds. If the necessary funding is available, it is advantageous to engage a project manager specifically for the project and do so early so that they are in post from the start with the appropriate hours, banding and tenure for the project manager built into the funding model. This appointment will help to ensure that the project is their focus for delivery, without distraction of day to day operational issues, or having to fit in project management of improvement work alongside the 'day job'. Professional project management training is common outside healthcare but of the four programmes reported here, only SHAREHD had a formally trained 'career' project manager. It is likely, therefore, that the selected project manager will lack some aspect of experience, be that quality improvement, service delivery in the required field, NHS / clinical experience or knowledge of planning, coordination and progress tracking of a complex intervention. Once in post, the project manager needs to be given enough autonomy to operate effectively and training opportunities provided to fill gaps in experience. For TAKI, it was fortunate that between the three local PMs the required experience was covered and so they could share and support each other. The team comprised an experienced QI lead with nursing background, a more junior QI lead working alongside but without clinical background, and an NHS nurse with senior roles but relatively new to project management.

The renal QI programmes all had key team members who were totally committed, engaged and believed in the work they were doing because the projects had clear patient benefits. Ownership from the project manager and clinical lead facilitates the commitment and drive that is needed to follow the project through, which is essential for success.

10.3 Tools and techniques

10.3.1 Tools and documentation

Project management tools are an essential element in maintaining control and oversight of an improvement spread programme. The experience from the programmes was that time invested in the setting up appropriate project management documentation and identifying the necessary tools from the outset was very worthwhile. Project management capacity for the set-up needs to be built in at the planning stage. No individual approach will guarantee smooth progress but judicious use of the array of project management tools will enable an overview and provide focus on key elements, such as risk management, or time slippage. The choice of methods and approach to using these tools depends on the stage of the project, expertise of the project manager and the focus of the steering group. For example, the ASSIST-CKD Programme Board reviewed the risk register in detail at every meeting, whereas for SHAREHD, only the top three risks were highlighted for discussion.

Table 15 highlights key documents the programmes identified as fundamental to the project. Below are some specifics on key aspects of documentation that are not elaborated on elsewhere in this report.

Project Documentation	**TAKI**		**ASSIST-CKD**		**SHAREHD**		**TP-CKD**	
Project Initiation Document (PID)	No	The Health Foundation bid and protocol was really the PID	Yes	In addition to bid proposal	No	The Health Foundation bid and protocol was really the PID	Yes	Was aspirational in content
Communication Plan	Yes	Central & local plans	Yes	Central plan	Yes	Central plan	Yes	
Risk & Issue Log	Yes	Regularly maintained and reviewed at steering committee meetings	Yes	Regularly maintained and reviewed at board	Yes	Regularly maintained	Yes	
Meeting Minutes	Yes	Actions mainly	Yes	Actions mainly	Yes	Completed after each board – detail and actions	Yes	
Finance Outlook	Yes	Done centrally	Yes		Yes		Yes	
Learning Needs Analysis	Yes	Used for local tailoring of education	No		Yes	Not undertaken formally	Yes	Not used
Progress Reports	Yes	As required for Funder and boards Also included the monitoring of data collection, data returns to UKRR and receipt of data by the UKRR	Yes	As required for Funder and boards	Yes	As required for Funder and boards	Yes	As required for Funder and boards
Lessons Learnt	Yes		Yes		Yes	Updates made and requested at each Board meeting	Yes	
Programme Plan / Gantt	Yes	Stepped wedge plan at core level and local plans	Yes	Trello system for managing software development	Yes	Project manager maintained detailed Gantt chart	Yes	High level plan

Table 15 : Key documentation and their use within programmes

Project Initiation Document (PID): For two of the programmes no formal PID was produced as the document put together for the Health Foundation application defined the project. What all teams identified however was that it become clear once the project had started that the initial PID (as in the case of TP-CKD) was over ambitious. It was necessary, therefore, to revisit and redefine realistically what could be achieved, setting expectations to ensure that scope creep did not lead to disappointment from implementation teams and programme boards.

Risks and issue registers: The appropriate use of a risk log can help project delivery. It should be a live document that is constantly reviewed and updated as there is little point in listing potential problems and then not using the information or mitigating to ensure the problem does not arise. The very act of noting and highlighting a risk and considering what mitigation may be required often helps to prevent the problem from occurring. The nature and timing of the response depends on the urgency and significance of the problem. It is important that there are clear mechanisms in place for key risks to be reviewed promptly by project teams so that responses can be planned.

Meeting minutes: All the programmes confirmed that writing 'traditional minutes' were time consuming and did not add significant value, as they were often not read in full (or even at all). Their main use was as a record to support report writing, however, other less arduous ways of keeping progress notes supported this function equally well. All the programmes gravitated towards use of summary notes, with a focus on the actions agreed, to be brought forward to check progress at the next meeting. A good tip was to include the 'actions' in the covering email sent out with notes, as this was more likely to be read.

Finance documentation: Understanding the "spend made" and "expected spend to complete" is standard practice for project managers but depending on the organisation and level of authority provided this may be undertaken by a finance department or other responsible member of the team. The responsibility and process for approving invoices / expenses etc. needed to be defined at the start of the programme so that there was a clear view at all times. As mentioned previously, TAKI devolved much of the funding to local teams with the local PMs filing reports to the central PI whereas TP-CKD kept the funding very centralised. Whatever approach was adopted, it was important that there was regular review of spend against expectations and that the systems were clear to all team members. Mechanisms for claiming travel expenses and time worked were required to be clear so that patient partners could access these easily and without embarrassment.

Progress reports: These were a mainstay of identifying how the programme was evolving against plan and was a prerequisite for reporting to boards and funder organisations. For these reports the Health Foundation required a defined structure. A clear value of the progress reports was that the discipline of documenting progress was necessary to maintain momentum, and provide transparent account of the programme. It was important to be clear early on who was responsible for providing input to these reports. In the event, the programme managers were primarily responsible for these but they needed to be supported with sufficient input from the team to report correctly and on time.

10.3.2 Internal and external communication

Each programme had a communication strategy which was essential to ensure dissemination of information to the wide groups of stakeholders concerned: the adopter sites and specifically the involved improvement teams, patient participants, programme funders, patient associations, professional networks and NHS networks (including commissioners).

The communications strategies were kept at an overview level, rather than a detailed plan, so the appropriate channels and media could be brought into play, such as when there was key information to be communicated, or a dissemination opportunity arose. In some circumstances, notably for TAKI and SHAREHD, local teams were encouraged to produce their own local communications plans and work with local trust communications teams to use their skills and standards. Programmes used the plan pragmatically and chose appropriate approaches at different points. For example, TAKI deployed screen savers as a communication reminder that the national AKI notification trigger was coming up. It was important to start small, since it would have been very easy to spend a significant amount of money early that would have been very difficult to live up to for the remainder of the programme. TP-CKD for example reflected that their 'kick-off' event had perhaps not added the value it could have done, as while it set out objectives and the possible direction for several years forward, there was not a specific focus on the immediate project aims which, for some, led to the setting of unrealistic expectations.

Programmes did invest in the development of a 'branded identity' or logo for the work, so that this could be used from the outset on information materials (e.g. pens, lanyards), at programme events, in training packs and programme manuals. Having a clear identity was found by the programmes to be helpful in terms of engendering the feeling that adopter sites were joining something 'solid' with established credentials. Building the brand was found to be a good investment to help with the sustainability of the work beyond the end of the funded programme period, ensuring that it had its own identity with which the adopter teams could identify and be proud to be part of. All four programmes created their own brands or built on ones previously created in the pre-work phases.

Social media was embraced to varying degrees of success. SHAREHD for example used Twitter for general culture change / movement messages (administered by the clinical lead and programme manager) alongside a closed Facebook group for lead nurses and a WhatsApp group for the patient advisory group and project teams to share ideas, progress and ask questions. TAKI found social media to be less useful and saw unconvincing uptake that petered out over time.

Newsletters were produced by all the programmes. TAKI found them to be very well received as they provided updates of how other centres were doing, but for ASSIST-CKD, SHAREHD and TP-CKD they were disappointing in terms of how widely they were read, and this did not equate to the effort required to produce them. ASSIST-CKD tackled this by creating ‘NEWSBITES’ that were shorter, sharper and therefore easier to produce and read. The production of newsletters was a helpful way to enable information to be pulled together for a progress report for stakeholders, together with a summary of forward plans. A well-produced, professional looking newsletter (whether in hard copy, or online) has longevity in a way social media does not. Newsletters capture and convey programme information with immediacy, in advance of formal articles and publications being available, and provide a useful ‘history’ of the work, in addition to their contemporary value as a programme is progressing.

The programmes adopted pragmatic and sustained approaches to their communications plan to make it meaningful and cost effective. The lesson is to try things and if they are not working to stop and consider whether the effort is worthwhile or if an alternative approach would be more useful.

10.4 Overcoming challenges

10.4.1 Delivering QI within the wider context

As with all improvement work in healthcare, these four programmes were not working in isolation. While each had specific objectives and a timeline to achieve, they were also subject to the wider culture of shifting priorities and system change. TAKI had to accommodate the implementation of a national patient safety alert for AKI detection, which required specific actions to align project timescales with the national deadlines. The structured approach of the stepped wedge cluster randomised control trial was planned within this timescale and supported the rollout by providing a rigorous basis for evaluation.

The learning from the programmes is to acknowledge this at the start. If setting aspirational aims, be clear about expectation management to match the scope that funding and timescale allows, avoiding mission creep. ASSIST-CKD dealt with this by not talking to teams in terms of a project that had an ‘end’, rather referring to the new process as a way of working that once in place would remain the norm with establishing local funding being part of the implementation process.

Both TAKI and SHAREHD have noted disadvantages in linking too closely to CQUINs both in terms of their potential promotion of a ‘tick box’ culture as well as the funding that is associated with their achievement not being long term. When the timeframe of the CQUIN expired, the resources were often redirected on the assumption that the purpose had been achieved and funding no longer necessary. If heart and minds of all staff have not been changed and there is no longer any target, then the intervention often drops off.

The programmes all benefitted from seeing their work as part of a bigger picture, in terms of the ‘movement’ to which the programme linked, such as patient involvement or a policy focus on prevention or delaying progression of disease. The sustainability work stream in SHAREHD documented a shared care ‘strategy’ that defined specific elements that the programme would focus on delivering, such as the inclusion in Renal Association haemodialysis guidelines. The TAKI programme linked their intervention with similar SEPSIS interventions via Patient Safety Link Nurses and SHAREHD was able to link with TP-CKD as they built on work undertaken in that programme, in particular using the Your Health Survey and PAM® instruments.

Sustaining this work for the future can be supported by KQuIP, enabling projects to link into national policy initiatives and to work together for greater effect by putting projects working on similar issues in touch with each other. Mary Dixon Woods in her Oration states that “it may be necessary to plan in terms of long-term programmes of work that are coordinated through some central hub, that doctors in training and others work on for particular period of time as part of contribution to a bigger effort”[2]. There is an opportunity perhaps for KQuIP to formalise an overarching quality improvement register for the renal sector, which could facilitate timely linkages being formed between projects. At present these links happen due to informal networks, when healthcare professionals read about initiatives, or see work presented at academic conferences. A coordinating role would be beneficial in helping renal services move forward as a healthcare community, rather than individual services working in isolation. There is also much that can be done within NHS Trusts to better coordinate QI teams, rather than the potentially wasteful approach of allowing ‘a thousand flowers to bloom’.

10.4.2 IT expectations

Information technology is increasingly important for the successful delivery of quality improvement, but all the programmes to some extent experienced negative impact from unexpected IT issues. IT enables great advances in how improvement interventions are delivered but it can appear deceptively simple to those with little expertise in the development or implementation of IT systems. It is important to work closely with NHS IT departments from the outset to consider how project IT will interface with existing systems, and any improvement project with a bespoke IT component will need to ensure expert input to the project.

The projects reviewed in this report experienced a variety of issues – some were in respect of the technology itself and others in terms of the choices in design or assumptions in the IT’s supportability. In ASSIST-CKD, the software at the heart of the intervention which compiled the eGFR graphs used to highlight declining kidney function needed to be re-written to support a wider rollout. The requirement to commission new software caused a delay of over eight months to programme implementation. TP-CKD experienced significant complications and delays in enabling Your Health Survey returns to be scanned into the Registry database. SHAREHD experienced severe delays in acquiring data from NHS Digital that impacted the delivery of its final evaluation report. TAKI created the care bundle in one NHS Trust where it was based in a restricted IT system which only allowed access to doctors, thereby reducing the range of care staff who could action the bundle. Restrictions of the hosting IT system also meant that it proved impossible to extract measurement information from this system. These were not issues with the technology as such, rather expectations that were not supported by appropriate design.

Be aware that an IT-based system may not always be the best way to measure and track improvement efforts. While NHS IT is improving, it is still hampered by aspects such inoperability of systems and lack of easy access for all staff. The IT component of any programme needs to be thought through and validated to confirm it works and actually can provide an adequate and sustainable service for either the lifetime of the project, or as an ongoing support for the intervention. Manual data collection may be impractical (such as for TAKI in collecting measurement for improvement data) so without an IT solution the data collection could not proceed. However, often alternative options to IT may be available, for example where SHAREHD decided early in the programme planning to collect the research data on paper forms and create a local research database that the questionnaires were manually entered into, rather than relying on central collation and reporting through the Renal Registry. This worked and gave the project flexibility to respond as data collection issues emerged, but was only feasible as temporary support to a time-limited programme and was not intended to be a permanent solution. Alternatively for TAKI, each trust produced a comprehensive report (from their IT systems) that matched a data specification; this was sent directly to the UKRR that assimilated and cleaned the data, and then performed the analysis. The planning, management and monitoring processes put in place to ensure data transfer from each hospital to the UKRR validated the data robustness and hence ability to assess outcomes, published in the resultant paper[17].

In summary, when considering any IT solution within an improvement project the team needs to systematically think through the consequences, with expert input and appropriate funding early in the scoping stage. Specifications for the system/software need to be very detailed with consideration of what might not work and what the unintended consequences could be. Importantly, the timeliness of data flows need to be considered, since if data is required for improvement work it generally needs to be available in real-time. The timeframe and estimated costs for development, stages of testing, refinement and implementation need to be realistic, with expert input from individuals who know the business. Contracting for the work also needs to be carried out to industry / trust IT organisation standards.

The key lesson is not to assume that these things will just happen. It is necessary to plan, address issues that arise openly, with consideration and in as timely a manner as possible.

10.4.3 Dealing with a showstopper

The fundamental purpose of project management is to plan, be aware of what is going on against the plan, and put in mitigations as early as possible to ensure risks and issues do not derail the project. However all projects have things that do not go according to plan, the trick is how these are dealt with when they arise. Each of the projects in this report had watershed moments that potentially could have had significant impact but were dealt with to ensure this was not the case. Within ASSIST-CKD, the IT rewrite and changing the evaluation methodology was critical, whereas SHAREHD had assumed that the Renal Registry would be able to easily gather the data items for task measurement and link this to the wider data helped by the registry. It became clear very early in the project that this was not going to be simple, hence a decision was made to use paper questionnaires and manually add these into a local secure database linking to HES data at the end of the programme only. Within TAKI, the Leeds lab failure meant that the AKI alert was not being triggered i.e. the central plank of the intervention was missing and so mitigation was required to maintain the integrity of the stepped wedge whilst keeping to the overall programme timescales.

In each of these circumstances the benefit of the governance structures established at the start of the programme came into their own to carefully consider the implications of the issue on the project and what the alternative route needed to be in order to minimise 'damage' to the original objectives.

10.5 Key learnings and recommendations

	Key learning points related to engagement and management
Develop formal structures and a clear identity	Managing a scaling up programme for an intervention is more complex than managing a local project. Appropriate formal governance structures, project documentation and effective communications need to be in place and professionally managed to ensure programme resilience A clear identity was found by the programmes to be helpful in terms of building confidence that adopter sites were joining something 'solid' with some established credentials.
Engage project management	Consider the significant time and effort needed to manage a scale up programme and the project management input that will be needed. A dedicated project manager will facilitate day-to-day continuity, which clinical leads are unlikely to be able to provide. Consider the level of authority and autonomy that the project manager needs to carry out the role (it's not just superior admin input).
Identify suitable project management to get the project started	If possible, engage the project manager from the start-up period, or bring in experienced advice to ensure initial activities are appropriate and are creating a sound base.
Consider specific QI expertise	Be aware that project and quality improvement management are different fields and the expertise is not interchangeable. The expertise that is required may change at different stages of implementation. Consider having a QI 'director' if the PM does not have the necessary experience to give the relevant direction and support.
Plan sustainability from the beginning of the programme	Be mindful of what happens to the intervention when the project finishes and the programme team is no longer in place. CQUINs are beneficial in the short term but can promote a temporary tick-box culture rather than changing practice sustainably.
Ensure a balanced financial profile	Consider the financial plan for the programme and whether the balance between different elements such as evaluation, programme management, patient involvement and so forth are appropriate.
Plan required data collection in detail	Plan in detail what data items are needed, where they will come from and what the quality, data completeness etc. is likely to be. Be prepared regarding implications for analysis if the data is not available on time, or to the quality required so that early mitigations can be put in place.
Plan and hold regular programme board meetings	Regular planned and structured meetings, including face to face, will maintain programme momentum and build team cohesion.

Develop lean and responsive meeting structures	Facilitate an environment for active and effective steering committees as this allows for quick and decisive actions when problems arise. Ensure terms of reference and expectations are in place but not onerous.
Review progress against the plan	Have a robust structured plan which includes any formal research protocol or bid. Regularly report progress against the plan and hold team members to account.
Actively manage risks	Review and put in mitigations for all risks - Be prepared specifically regarding implications for analysis if the data is not available on time, or to the quality required so that early mitigations can be put in place.
Link with existing networks	Harness the power of networks, linking with related projects and interested individuals but be mindful how robust their structures are and what will happen if they dissolve during your project.

Findings 5 : Management Methods and Mechanics


'THINK KIDNEYS'
Sarah Jenkins
General, Sheffield

11. Discussion

Introduction

SHAREHD, Tackling AKI and ASSIST-CKD are complex intervention programmes that benefit patient care. The best way to initiate such programme, provide robust evidence of their impact and achieve sustainable, repeatable implementation beyond the original team and the location where they were designed is still not fully established. There are excellent publications describing how to undertake quality improvement initiatives and how to deploy them at scale [39],[43] [44]. This report is intended to compliment these, by adding to the body of knowledge of testing and executing such complex interventions in a "real world" kidney care setting.

Delivering an initiative at scale presents challenges that are in many ways distinct to those of creating and implementing an intervention in a local health care environment. In this discussion we draw together key transferable lessons from the three Health Foundation funded Renal Quality Improvement programmes focussing on factors that contributed to their successes and challenges as they took tested pilot interventions and deployed them over multiple sites. Although the programmes were impactful, they had to respond to – and overcome – key challenges. It is the manner in which the teams responded to those difficulties that provides, we believe, the best learning for teams that plan to follow in their footsteps.

To be successful in scaling up a QI initiative requires a professional and coordinated approach with clear objectives based on robust plans resulting in key deliverables that is not dissimilar to launching a new product into the marketplace. The learning in this report presented below is organised according to those topics that distinguish between scaled up programmes and single site QI projects.

Robust governance

The accountability for delivering the goals and timescales for local projects lies with the immediate line and work managers with delays or non-achievement being understood in that context. As an intervention spreads to additional teams, organisations and bodies that invest their time, resources and energy, those teams will expect the delivery team to follow through on commitments that have been set out, therefore the mechanisms of delivery need to be dependable, and the outcomes robust. This is actioned by creating external governance mechanisms such as programme boards and advisory groups responsible for evaluation, patient participation and dissemination aspects. To be effective, the boards should be run formally and populated with members who both support and challenge the intervention and are prepared to hold the project to account.

Each of the programmes experienced difficulties along the way – some were significant. With robust management structures in place, difficulties were quickly escalated and mitigations planned. The process was enhanced by a spirit of openness where teams were encouraged to report difficulties early and not be afraid of failure. For example, within ASSIST-CKD there was a quick response when it was realised that the original version of the eGFR graph software was not sufficiently robust to support spread; TAKI faced the unprecedented failure of the Leeds biochemistry laboratory; and SHAREHD had protracted delays with the mechanism of obtaining Hospital Episode Summary data from NHS digital. Each of these required robust programme management processes to understand the significance of the problem and determine a suitable response.

Appropriate funding, patient involvement and skills

The three programmes in this report obtained vital significant funding from the Health Foundation. Sufficient funding is an absolute requirement to roll out an intervention programme since no matter how important the initiative appears to be, it will not be possible to do so without the necessary resources to support it. Local initiatives may not require significant additional resources, since they use local resources with time generally donated by local staff within existing job roles. Yet, to roll out more widely and adhere to the necessary governance, members of the originator team and adopter sites need to secure the necessary time away from the day job to focus on the programme.

Appropriately skilled resources, such as evaluators and project managers need to be brought into the team to deliver the obligations. Events and meetings will need to be planned, with funding allocated for travel and accommodation. Time away from the day job for attendees, both medical and patients, is likely to be significant and may need to be compensated. All this needs to be included in a formal cost model.

Without patient involvement QI programmes, whether local or national, are likely to be misdirected and of limited relevance. The value of co-production to contribute to refining the intervention is a key component of these programmes. For SHAREHD, the concept itself was developed by patient partners in the piloting phases and indeed changed its focus from "self" to "shared" care. In TP-CKD, patients co-chaired each work stream and enabled a key output which was the annual report of kidney patient experience measures.

Engaging patients in local projects can present challenges and frustrations for both patients and staff often due to lack of confidence, expectations and experience of working together. Indeed, those frustrations can be amplified at a national level if the practicalities of patient involvement are not considered formally during the planning stage. The Kidney Patient Involvement Network (KPIN) initiative recognises this and aims to bridge this gap. Key to both local and scaling up programmes is to ensure that patients feel part of the team not an 'afterthought', requiring clarity of role description and expectation management, in exactly the same way as for any other team member from the outset.

The value of collaborative working extends to peer assist methods, where those with experience share their learning with teams that are new to the programme. This was used to great effect in TAKI where it had real value because it provided a structure for teams to test their own understanding. This provided a lived experience of execution that was able to 'jump start' inexperienced teams by providing the enthusiasm and encouragement that they could make real change. Sharing experiences with others reminds those delivering the experience of what they have achieved, which sustains momentum.

Such methods are unusual in local initiatives since they tend to be smaller in size and based on individual ideas tested iteratively to resolve a specific problem alongside other work activities. To extract the greatest value from events that involve patients and peers, they must be carefully designed with teams given preparation work and the programme gathering feedback which is acted on. This is only realistic if the time, space and right skills are formally built into the programme and tasked to deliver those actions.

Plan the programme and build the team

Focussing on the detail of setting up a local project or national programme is essential to ensure everything is in place and all team members know their roles. As a local project is usually setup and run alongside other work-related activities, specialised resources are rarely brought in to do this.

Each programme found that employing a programme manager as close to the beginning as possible made a significant difference to facilitating planning, as it allowed all team members to focus on their roles in the knowledge that the bigger picture was being taken care of.

The success of these complex programmes is reliant on resilient teams who have a strong sense of networking across the renal community. It is of great value if the team is in place early in the development of programme and has a track record of working together; this comes naturally from working together on the pilot work. It is important to cultivate an environment in which it is possible to share honestly and to disagree frankly, while working through to practical agreements that enable the prompt decision making that these programmes require. This closeness would be a trait that local projects would have naturally but for national projects needs to be cultivated specifically.

During the planning it is necessary to involve experienced "critical friends" in order ensure that key risks are identified so that they can be mitigated, building confidence that the delivery plan is fundamentally achievable. Grant funding processes should be embraced, since the process focusses the mind, builds the team, refines the intervention and subjects it to peer review. It focuses decisions about how much funding is required and how it will be deployed. For example, SHAREHD was rejected on the first round by the funders. Their formal feedback strengthened the subsequent re-application. As part of the financial planning, adequate funds need to be allocated for programme management, patient involvement and comprehensive evaluation.

Justifying the evaluation

For a local project to scale, it is necessary to provide proof that it will be replicable in order to persuade both grant funders and other trusts to commit. To achieve this, formal evaluation is necessary. Local evidence can be gathered via service improvement and quality improvement measurement tools but as the project grows and scales, so too does the need to have externally validated evidence. If a goal is to achieve inclusion in clinical practice guidelines then robust evidence is a pre-requisite.

Time must be taken to fully understand how the intervention may or may not work and in what circumstances for both patients and staff. This information will feed into the key considerations around the design of the evaluation of the intervention, relevant outcome measures and ethical requirements. It is important that mechanisms are built in to understand the experience of those who receive as well as those who deliver the intervention.

The three scaling up programmes used the Stepped Wedge Cluster Randomised Controlled Trial (SWCRT) design which was innovative for nephrology and pragmatic. This approach requires sufficient patient numbers to generate sufficient power which would be unusual to achieve in a local initiative. An advantage of the SWCRT design is that all teams access the intervention by the end of the programme. Against that, disadvantages include the immutable timeline that has to be followed once set which, for example, resulted in ASSIST-CKD changing their design approach part way through.

The "theory of change" as a concept was not well understood by front line teams and as such would be unusual to be built into local initiatives unless it was supported by experienced QI staff. However a scaling up programme has the size to validate the theory across multiple sites. SHAREHD engaged evaluation partners who were able to develop practical involvement models for staff and patients that will inform the future implementation of similar interventions.

Developing your "why"

Meaningful delivery of an intervention at scale requires more than overcoming a local challenge that everyone recognises. For spread to be successful it is critical to convince the hearts and minds of potential adopters within multiple contexts. The message has to be clear, concise, well-rehearsed and easily shared. In the preparation for the Health Foundation interview for SHAREHD, the team were tested regularly by the Sheffield MCA academy to describe the intervention.

Even if the intervention becomes adopted and incorporated into practice, it is important that the underlying rationale is bought into by participants, otherwise the exercise can become procedural and meaningless. All three programmes recognised this at various stages and adapted their activities accordingly. For example, TAKI recognised that it was the more permanent nursing staff who needed to recognise the value of undertaking the care bundle to build sustainability rather than the transient registrars. ASSIST-CKD engaged laboratory staff to review the eGFR graphs giving them a direct opportunity to influence individual care. SHAREHD found that a multifaceted sustainability plan helped to pull the necessary threads together ranging from the #whyidosharedcare personal placards to the inclusion of shared haemodialysis care in Renal Association Haemodialysis guidelines[76].

Spreading via communication

Even when running a local project, it is very hard to ensure that all the relevant frontline staff, across all shifts, are aware of the work, inevitably the challenge is even greater when scaling up to wider teams and national bodies, therefore a more formalised communication plan is required. Such plans take time, specialised skills and a distinct work-stream to ensure that the messages are consistent and to reach all stakeholders and interested parties. The communication plan should include a range of approaches from the simple to the complex and take into consideration that embedding a large initiative is not a single activity, but is a rolling and iterative process. The communication plan needs to be selective, focussing initially on a clear brand and simple messages before building on this with infographics, embracing social media and websites, as well as writing articles and giving presentations. Each communication initiative should have defined deliverables and an expected impact that is reviewed to ensure the aims were actually achieved. If they have not, it is necessary to understand what has been achieved, and why, and be prepared to stop or change the approach as required.

Managing project tensions

It is not surprising that unforeseen problems arise during the course of programmes some of which are highlighted in the tension table in section 5. Taking an intervention from the local to the national will amplify such tensions as more stakeholders and dynamics are in play. Having a strong, yet open and honest project core team with pragmatic leadership allows these tensions to be openly debated and appropriate decisions and directions taken.

Team leaders need the determination to see the work through while at the same time being sufficiently collaborative to ensure that contributing voices are represented valued and heard. That leadership has to be ready to take decisions when necessary, yet understand when it is appropriate to step back and let matters take their own course. They need to balance enjoying stepping up to the podium to articulate the message and celebrate the progress that has been made, while also allowing airtime to others who will take the programme forward. Central to the sustainability of any programme are second leaders, whether patients or health care professionals. These individuals will create the movement needed to succeed. Above all, the team leader requires resilience to overcome pushbacks when they arise, the insight to recognise when they are wrong and be ready to learn from their mistakes and to review decisions or positions taken. These characteristics are required for both local initiatives and scaling up programmes to be successful and team leaders need mechanisms of support to enable them to meet the challenges with confidence.

For any intervention to be successful, whether local or national, it is necessary to engage senior management and wider interested parties. When scaling up an initiative, this is multiplied by each of the trusts involved, as well as extending to the support and endorsement required from professional societies and charities. Engaging this level of support takes time and is required to be planned and managed within the communication plan so that messages are consistent and continually reinforced.

Dealing with a wide degree of contextual variation

As identified in the fidelity section of this report, it is important to be clear about which components of the intervention are core and which can be flexed locally adjusting for context to aid adoption. Forcing teams to apply a generic model - even if it fits perfectly - will be met with resistance as this approach does not encourage local ownership. All three projects found that the local variation from the original pilots and between sites was much greater than anticipated, even though a baseline assessment had been made. What was found was that by having a clear view of a core that will work in different settings variation could be embraced and shared rather than feared.

Giving local teams components that they can work on and adapt using quality improvement methodologies facilitates engagement and local ownership. Through this process second leaders can develop, succeed and be celebrated. TAKI exemplified this process with parts of the intervention that were fixed such as the AKI electronic alert and core components of the care bundle, whereas other aspects of the care bundle and the educational programme were locally adapted and delivered. This approach gave teams flexibility to make local adjustments that they can take ownership of while remaining true to the principles of the work.

Be honest about the intervention - is it really ready to scale?

Not all interventions developed and working locally will automatically scale. Testing the “what” and “how” it works in different environments and evaluating the results in a structured way - with objective honesty - is critical to understand whether it can scale, how to make that happen or if the intervention is just not appropriate or ready to scale.

For ASSIST-CKD the intervention was evidently scalable, but the spread programme was based on IT infrastructure that turned out not to be able to support spread to other sites to enable its adoption. To the credit of the programme and supported by the Health Foundation, the barriers were overcome and objectives achieved.

Summary

Nephrology is not unique in its interest in quality improvement, but quality improvement has formed an important part of the speciality from early on leading to the early development of UK Renal Registry and clinical guidelines from the Renal Association. A commitment to multidisciplinary working and co-production has placed it in a strong position to continue to plan strategic initiatives to improve the quality of care, taking advantage of opportunities as they arise such as the more recent development of KQuIP and rollout of the Getting It Right First Time initiative. The understanding that comes from these programmes has relevance not just to renal medicine, but also to broader health care settings and wider industries. Embedding an understanding of the impact of the context of renal medicine on QI mechanisms enables a structured approach to progressively develop healthcare processes.

Each scaling up programme presented in this report tackled a problem that was widely considered to be a priority for kidney care and contained within it an intervention that had been tested considerably in a local setting. Through the pilot work, investigators had developed a good idea of what outcome measures should be used and a clear concept of how the intervention should be delivered.

Setting up and executing a large-scale national programme requires different approaches to those necessary for running local initiatives and not all locally successful projects can or will scale. The lessons identified here and summarised in Figures 14 are relevant for both implementation and evaluation teams and will give programmes the greatest chance of sustainable success, raising the bar of care in their chosen area.

Figure 14 : Key differences between implementing locally and scaling nationally

12.Appendices

12.1 'Other' project themes

Below is the initially identified table of the themes and sub themes determined from the analysis of the project reports. The main body of this report has covered the five key themes that were identified, however some other important learnings or project outputs can be found below that were felt to be relevant and beneficial to readers.

Theme/ Domain	Theme Objective	Detail / Sub Themes	
Pre-launch preparation	To identify a framework of what to consider in preparing for scaling up a locally implemented project to provide the best chance of success.	• *Defining the intervention (scope definition)* • *What makes the intervention ready for scale and spread -* • *Is the intervention truly understood, the core components and the adaptable components?* • *Renal policy support / awareness / Credibility for the intervention* • *Making the case (programme & Intervention)* • *Application stakeholders & support needs*	
Engagement & Management	To highlight how effective projects are set up recognising this may take more planning and resources than expected if inexperienced in this area.	• *Methods of engaging participating units*	
		• *Project management at project and programme levels* • *Organisational and local team structures and skills available (including QI)* • *Communication methods*	Section 10
		• *Patient involvement and engagement within the project* • *Patient voice, experience of and benefit from the intervention*	Section 9
		• *To what extent was culture change needed to implement and sustain - how was that enabled?*	Case Study 12.2.8 : #whyidosharedcare campaign
Intervention Fidelity	Change can happen which can be appropriate or disastrous depending on the intervention being scaled. This section looks to understand this in more detail to given lessons to enable change to be controlled appropriately per project.	• *Level of change to intervention during the Scaling Up period* • *Common barriers & how they were resolved* • *Measurement of intervention (not success of programme but how teams could measure change)* • *Contextual variation in implementation of intervention*	Section 6

Evaluation Methods & Mechanics	To identify what is the value of undertaking formal evaluation and identify key lessons to consider when determining a project's evaluation approaches.	- *Use of protocols* - *Comparison of projects methods chosen* - *Ability of project to stick with chosen methods / if not, why not* - *Gaining approvals to ethics, research registration, analysis of data learning points* - *Evaluation learning feedback loops* - *Exploration of 'mixed methods' and the value of qualitative evaluation*	Section 8 Case Study 12.2.9 Programme theory
Spread & Sustainability after the programme concludes	Without sustainability and ability to spread, an intervention is undermined. This section looks to highlight how to build this in from the outset.	- *Sustainability of the intervention & methods of maintaining awareness* - *Consideration of ease of commissioning or issues with* - *Approaches for new starters to use the intervention without the programme support*	Case study 12.2.1 : Programme tools Case study 12.2.2 Local Business Case Case study 12.2.4 : website & software availability package Case Study 12.2.3 : SHAREHD sustainability mind-map and multi-faceted approach.

Table 16 : Theme table

12.2 Useful project outputs / case studies

12.2.1 Programme tools made available for others to share

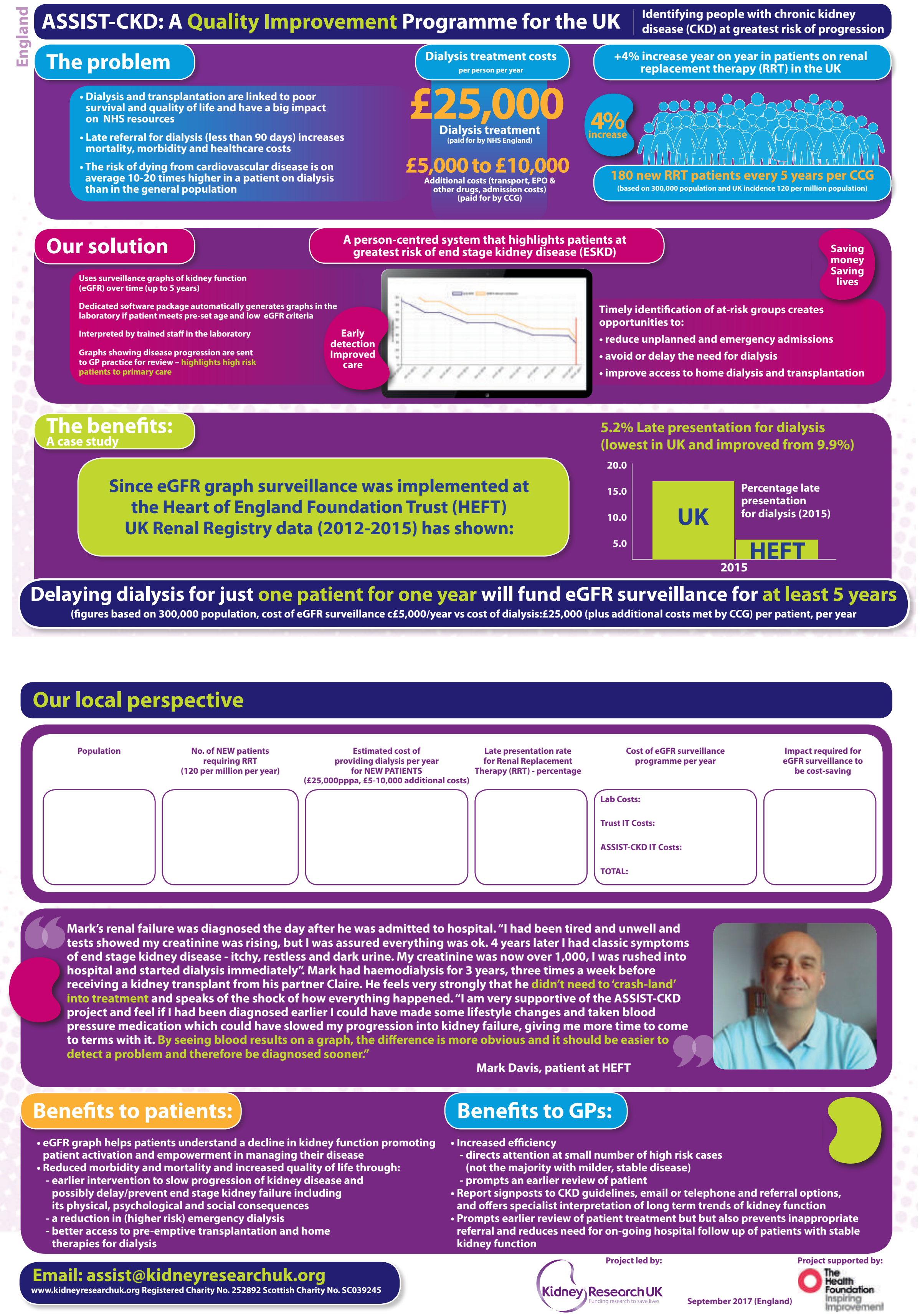
The TAKI programme webpage was created within the wider KQuIP website and served as a repository of project and study generated materials that was a repository of project and study generated materials. The webpages include study documents and published results, but in the main are the materials that were generated by the project teams at each of the five participating centres. It also includes reflections on 'lessons learnt' on key aspects of implementing the intervention on a hospital wide basis. By sharing these in a simple yet structured manner the project hoped to benefit other teams undertaking similar work.

The website was kept simple and included Care bundles, Communication materials, Nurse Study days, Patient involvement, QI methodology, Team building, value of the MDT, Protocol and publication sections. In some sections short videos have been created that provide multimedia guides and top tips that are easily transferable to other projects.

Whilst writing this report, it was determined to build on this and, via the KQuIP Hub National Project page, provide key documents and website links for SHAREHD and ASSIST-CKD https://www.thinkkidneys.nhs.uk/kquip/hub-cat/national-qi-projects/. As the TP-CKD project was part of the 'Think Kidney' programme, documentation for that project is also available from within the same suite of pages.

12.2.2 Locally customisable business case infographic

A one page simple and generic business case was put together that had an easily understandable message "delaying dialysis for just one patient for one year will fund eGFR surveillance for at least 5 years". This was produced as an infographic, but locally, context could also be added. This meant that the benefits of having a business case was ready made for trusts allowing them to focus on how and who within their organisation would act on the case.



England

ASSIST-CKD: A Quality Improvement Programme for the UK

Identifying people with chronic kidney disease (CKD) at greatest risk of progression

The problem

- Dialysis and transplantation are linked to poor survival and quality of life and have a big impact on NHS resources
- Late referral for dialysis (less than 90 days) increases mortality, morbidity and healthcare costs
- The risk of dying from cardiovascular disease is on average 10-20 times higher in a patient on dialysis than in the general population

Dialysis treatment costs
per person per year

£25,000
Dialysis treatment
(paid for by NHS England)

£5,000 to £10,000
Additional costs (transport, EPO & other drugs, admission costs)
(paid for by CCG)

+4% increase year on year in patients on renal replacement therapy (RRT) in the UK

4% increase

180 new RRT patients every 5 years per CCG
(based on 300,000 population and UK incidence 120 per million population)

Our solution

A person-centred system that highlights patients at greatest risk of end stage kidney disease (ESKD)

Uses surveillance graphs of kidney function (eGFR) over time (up to 5 years)

Dedicated software package automatically generates graphs in the laboratory if patient meets pre-set age and low eGFR criteria

Interpreted by trained staff in the laboratory

Graphs showing disease progression are sent to GP practice for review – highlights high risk patients to primary care

Early detection
Improved care

Saving money
Saving lives

Timely identification of at-risk groups creates opportunities to:
- reduce unplanned and emergency admissions
- avoid or delay the need for dialysis
- improve access to home dialysis and transplantation

The benefits:
A case study

Since eGFR graph surveillance was implemented at the Heart of England Foundation Trust (HEFT) UK Renal Registry data (2012-2015) has shown:

5.2% Late presentation for dialysis (lowest in UK and improved from 9.9%)

Delaying dialysis for just one patient for one year will fund eGFR surveillance for at least 5 years
(figures based on 300,000 population, cost of eGFR surveillance c£5,000/year vs cost of dialysis:£25,000 (plus additional costs met by CCG) per patient, per year

Our local perspective

Population	No. of NEW patients requiring RRT (120 per million per year)	Estimated cost of providing dialysis per year for NEW PATIENTS (£25,000pppa, £5-10,000 additional costs)	Late presentation rate for Renal Replacement Therapy (RRT) - percentage	Cost of eGFR surveillance programme per year	Impact required for eGFR surveillance to be cost-saving
				Lab Costs: Trust IT Costs: ASSIST-CKD IT Costs: TOTAL:	

> Mark's renal failure was diagnosed the day after he was admitted to hospital. "I had been tired and unwell and tests showed my creatinine was rising, but I was assured everything was ok. 4 years later I had classic symptoms of end stage kidney disease - itchy, restless and dark urine. My creatinine was now over 1,000, I was rushed into hospital and started dialysis immediately". Mark had haemodialysis for 3 years, three times a week before receiving a kidney transplant from his partner Claire. He feels very strongly that he didn't need to 'crash-land' into treatment and speaks of the shock of how everything happened. "I am very supportive of the ASSIST-CKD project and feel if I had been diagnosed earlier I could have made some lifestyle changes and taken blood pressure medication which could have slowed my progression into kidney failure, giving me more time to come to terms with it. By seeing blood results on a graph, the difference is more obvious and it should be easier to detect a problem and therefore be diagnosed sooner."
>
> Mark Davis, patient at HEFT

Benefits to patients:

- eGFR graph helps patients understand a decline in kidney function promoting patient activation and empowerment in managing their disease
- Reduced morbidity and mortality and increased quality of life through:
  - earlier intervention to slow progression of kidney disease and possibly delay/prevent end stage kidney failure including its physical, psychological and social consequences
  - a reduction in (higher risk) emergency dialysis
  - better access to pre-emptive transplantation and home therapies for dialysis

Benefits to GPs:

- Increased efficiency
  - directs attention at small number of high risk cases (not the majority with milder, stable disease)
  - prompts an earlier review of patient
- Report signposts to CKD guidelines, email or telephone and referral options, and offers specialist interpretation of long term trends of kidney function
- Prompts earlier review of patient treatment but but also prevents inappropriate referral and reduces need for on-going hospital follow up of patients with stable kidney function

Email: assist@kidneyresearchuk.org
www.kidneyresearchuk.org Registered Charity No. 252892 Scottish Charity No. SC039245

Project led by:
Kidney Research UK
Funding research to save lives

September 2017 (England)

Project supported by:
The Health Foundation
Inspiring Improvement

Figure 17 : Sample business case

12.2.3 Multi-faceted sustainability approach - mindmap

Within the SHAREHD project its organisational structure and particular inclusion of sustainability as a section to be reported against in the Health Foundation progress reports perhaps influenced the project to focus heavily on sustainability. The issue was that it meant many things and so was in some ways a meaningless term when used generally.

In order to overcome this confusion a mind-map (see Figure 18) was created that covered all the aspects that were mentioned. The form was simple to discuss both with the wider teams and the advisory and dissemination group but was also easy to add to and rework if necessary. It was not intended to be a hard and fast depiction of sustainability rather what it meant to this project.

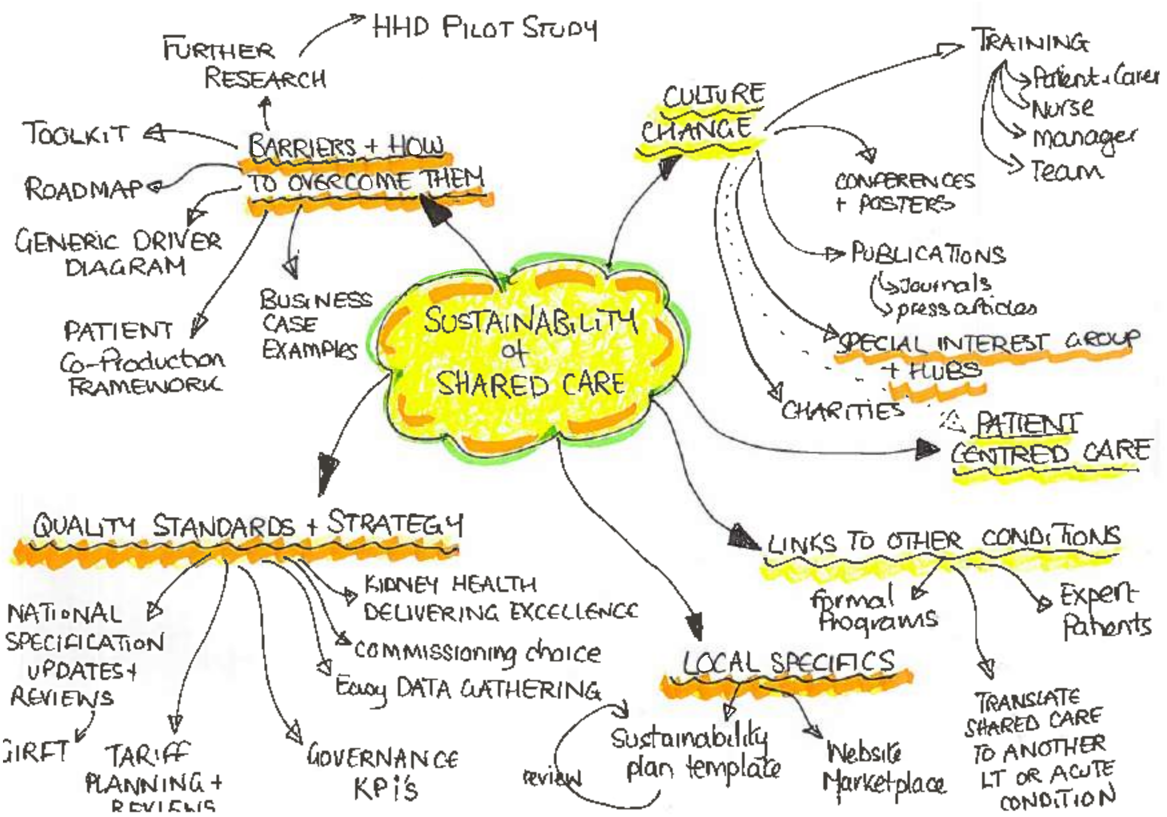


Figure 18 : Sustainability mindmap

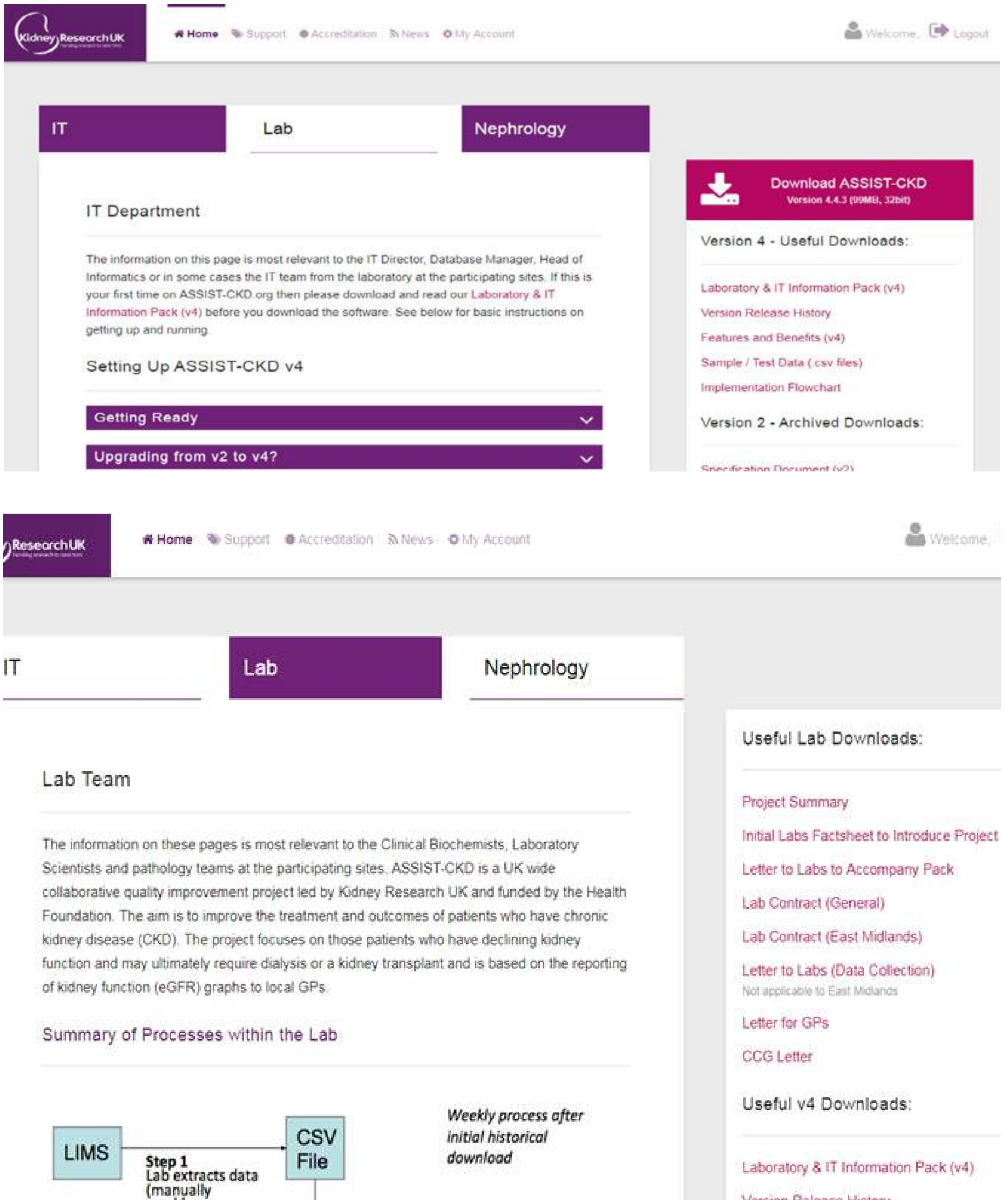
This led to the recognition that there were multiple levels of sustainability at both national and local levels. Influencing NICE or Renal Association guidelines was going to require a different strategy for example to that of embedding co-production and a shared care culture in local standard practices. Both elements were critical to sustainability but neither were sustainability in their own right. A supporting document was created to explain what, in the context of the project, each component meant.

As the project had a specific timeframe, having the sustainability document and mind-map made it easier to recognise that not everything could be achieved no matter how many resources were provided and so prioritisation was required. This prioritisation was included in the opening section of the document so that was clear which tasks the project planned to do and why.

In many ways focusing on what sustainability meant and what the project could achieve to take that forward, released the project from worrying about things that were in effect beyond its control. It also ensured that it could show that sustainability had been achieved (in the case of SHAREHD for example getting a section included in the Renal Association Guidelines and included as part of the 'Get it right first time' review).

12.2.4 Website and software packages

ASSIST-CKD did not refer to the project as having a completion date as a way of indicating that the capability and capacity to continue CKD monitoring was ongoing. This is both for the benefit of the trusts that have deployed the project to date but also to allow other trusts to take advantage of the created functionality and implement it if they want. To that end, a website that includes (1) the software, (2) documentation of how to deploy and use (3) competency tests for the labs to prove fidelity is available so trusts do not have to 'reinvent the wheel'. In addition, as the website https://assist-ckd.org/welcome/ is hosted by KRUK, teams wanting to get started have some initial contacts and potential support via that route.



IT Department

The information on this page is most relevant to the IT Director, Database Manager, Head of Informatics or in some cases the IT team from the laboratory at the participating sites. If this is your first time on ASSIST-CKD.org then please download and read our Laboratory & IT Information Pack (v4) before you download the software. See below for basic instructions on getting up and running.

Setting Up ASSIST-CKD v4

Version 4 - Useful Downloads:

Laboratory & IT Information Pack (v4)
Version Release History
Features and Benefits (v4)
Sample / Test Data (.csv files)
Implementation Flowchart

Version 2 - Archived Downloads:

Specification Document (v2)

Lab Team

The information on these pages is most relevant to the Clinical Biochemists, Laboratory Scientists and pathology teams at the participating sites. ASSIST-CKD is a UK wide collaborative quality improvement project led by Kidney Research UK and funded by the Health Foundation. The aim is to improve the treatment and outcomes of patients who have chronic kidney disease (CKD). The project focuses on those patients who have declining kidney function and may ultimately require dialysis or a kidney transplant and is based on the reporting of kidney function (eGFR) graphs to local GPs.

Summary of Processes within the Lab

Weekly process after initial historical download

Useful Lab Downloads:

Project Summary
Initial Labs Factsheet to Introduce Project
Letter to Labs to Accompany Pack
Lab Contract (General)
Lab Contract (East Midlands)
Letter to Labs (Data Collection)
Not applicable to East Midlands
Letter for GPs
CCG Letter

Useful v4 Downloads:

Laboratory & IT Information Pack (v4)

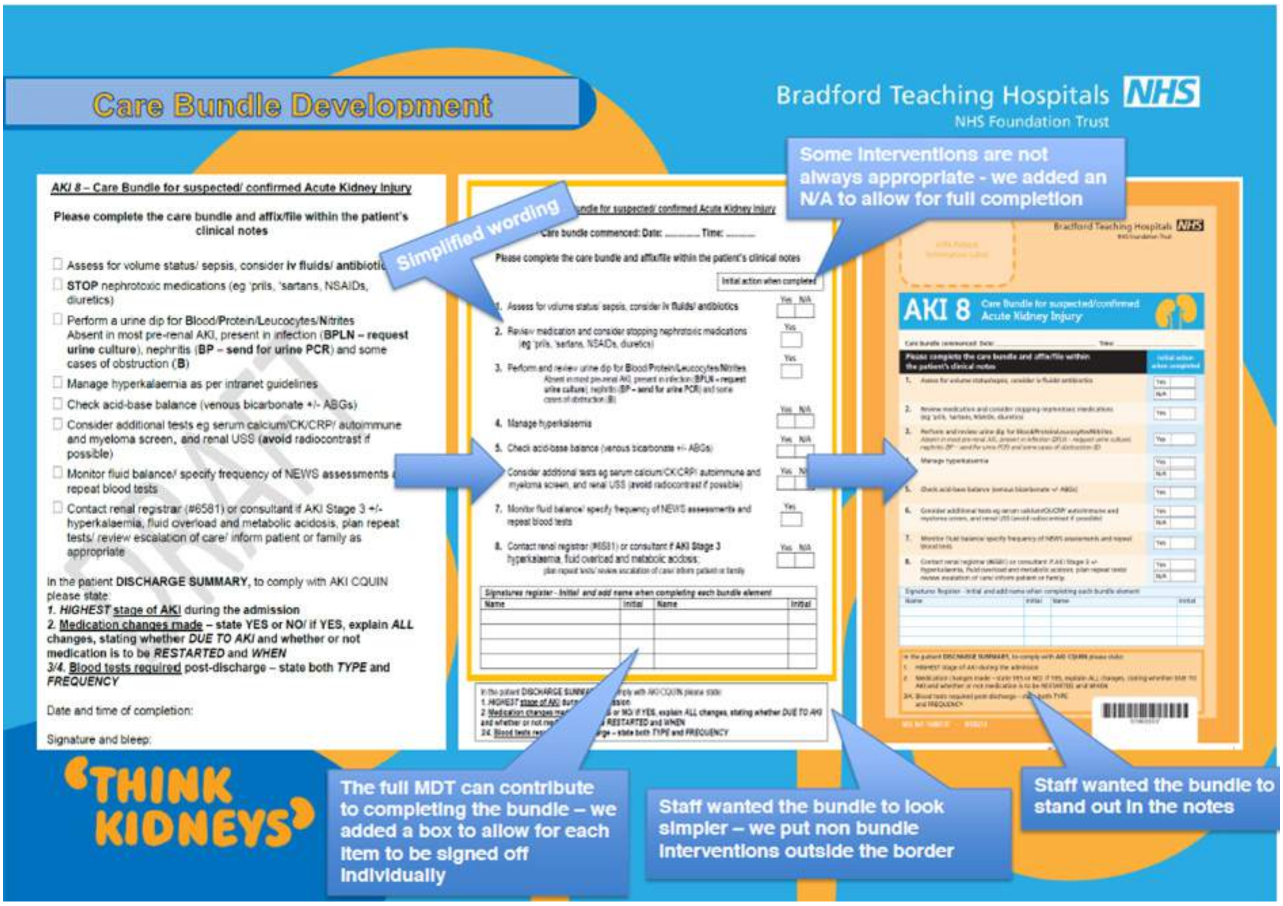
Figure 19 : ASSIST-CKD software website

12.2.5 Iterative development - Tackling AKI care bundle development

The effectiveness of implementation of an AKI care bundle had been proven in Derby where 3717 AKI episodes had demonstrated a mortality reduction from 24.4% to 20.4% [16]. As part of that work, the care bundle was developed to include the diagnosis of AKI, urinalysis, assessment of volume status, medication review, informing the patient of the diagnosis and seeking further advice as needed.

The AKI care bundles were developed and adapted locally and showed some variation between hospitals in terms of design (one electronic, the others paper), presentation and content. The processes of design and checking on completeness of the care bundles gave an opportunity for engagement with local teams and the development of publicity and messages around engagement. In some locations the design included bright colours or memory aids, as well as stickers to raise prominence. There was considerable variation in the number of actionable items, ranging from 8 at Bradford to 39 at Frimley - representing key differences in the time staff would require to complete the forms. Interestingly, Frimley made their care bundle more detailed and didactic (not necessarily in line with the view of the project team) - possibly because there was no nephrologist on site.

The figure below is taken from TAKI and demonstrates the stepwise approach to developing the care bundle at Bradford.



Care Bundle Development

Bradford Teaching Hospitals NHS
NHS Foundation Trust

AKI 8 – Care Bundle for suspected/ confirmed Acute Kidney Injury

Please complete the care bundle and affix/file within the patient's clinical notes

☐ Assess for volume status/ sepsis, consider **iv fluids/ antibiotic**
☐ **STOP** nephrotoxic medications (eg 'prils, 'sartans, NSAIDs, diuretics)
☐ Perform a urine dip for **B**lood/**P**rotein/**L**eucocytes/**N**itrites
Absent in most pre-renal AKI, present in infection (**BPLN – request urine culture**), nephritis (**BP – send for urine PCR**) and some cases of obstruction (**B**)
☐ Manage hyperkalaemia as per intranet guidelines
☐ Check acid-base balance (venous bicarbonate +/- ABGs)
☐ Consider additional tests eg serum calcium/CK/CRP/ autoimmune and myeloma screen, and renal USS (**avoid** radiocontrast if possible)
☐ Monitor fluid balance/ specify frequency of NEWS assessments & repeat blood tests
☐ Contact renal registrar (#6581) or consultant if AKI Stage 3 +/- hyperkalaemia, fluid overload and metabolic acidosis, plan repeat tests/ review escalation of care/ inform patient or family as appropriate

In the patient **DISCHARGE SUMMARY,** to comply with AKI CQUIN please state:
***1. HIGHEST** stage of AKI* **during the admission**
2. Medication changes made – state YES or NO/ if YES, explain *ALL* changes, stating whether *DUE TO AKI* and whether or not medication is to be *RESTARTED* and *WHEN*
3/4. Blood tests required post-discharge – state both *TYPE* and *FREQUENCY*

Date and time of completion:

Signature and bleep:

DRAFT

Simplified wording

…ndle for suspected/ confirmed Acute Kidney Injury

Care bundle commenced: Date: ……… Time: ………

Please complete the care bundle and affix/file within the patient's clinical notes

Initial action when completed

1. Assess for volume status/ sepsis, consider **iv fluids/ antibiotics** Yes N/A ☐ ☐
2. Review medication and consider stopping nephrotoxic medications (eg 'prils, 'sartans, NSAIDs, diuretics) Yes ☐
3. Perform and review urine dip for **B**lood/**P**rotein/**L**eucocytes/**N**itrites Yes ☐
Absent in most pre-renal AKI, present in infection (**BPLN – request urine culture**), nephritis (**BP – send for urine PCR**) and some cases of obstruction (**B**)
4. Manage hyperkalaemia Yes N/A ☐ ☐
5. Check acid-base balance (venous bicarbonate +/- ABGs) Yes N/A ☐ ☐
Consider additional tests eg serum calcium/CK/CRP/ autoimmune and myeloma screen, and renal USS (**avoid** radiocontrast if possible) Yes N/A ☐ ☐
7. Monitor fluid balance/ specify frequency of NEWS assessments and repeat blood tests Yes ☐
8. Contact renal registrar (#6581) or consultant **if AKI Stage 3** hyperkalaemia, fluid overload and metabolic acidosis; plan repeat tests/ review escalation of care/ inform patient or family Yes N/A ☐ ☐

Signatures register - *Initial and add name when completing each bundle element*			
Name	Initial	Name	Initial

Some interventions are not always appropriate - we added an N/A to allow for full completion

AKI 8 Care Bundle for suspected/confirmed Acute Kidney Injury

'THINK KIDNEYS'

The full MDT can contribute to completing the bundle – we added a box to allow for each item to be signed off individually

Staff wanted the bundle to look simpler – we put non bundle interventions outside the border

Staff wanted the bundle to stand out in the notes

Figure 20 : Bradford Tackling AKI care bundle

12.2.6 Learning event PDSA examples

Within SHAREHD, teams utilised PDSA cycles to find ways of engaging patients in activities related to their own dialysis. An example is presented below from wave 1 teams and demonstrates the various PDSAs that were selected. When this was done well teams had immediate evidence of engagement that they could share and learn from. It did provide a means for teams to select activities that they could focus on and bring back to the next event.

It is important that the training around measurement for improvement is accessible and meaningful to frontline staff and presented in a way that they can engage in. Clearly they require to be supported as they progress, and to that end the periodic teleconferences (action period calls) had value.

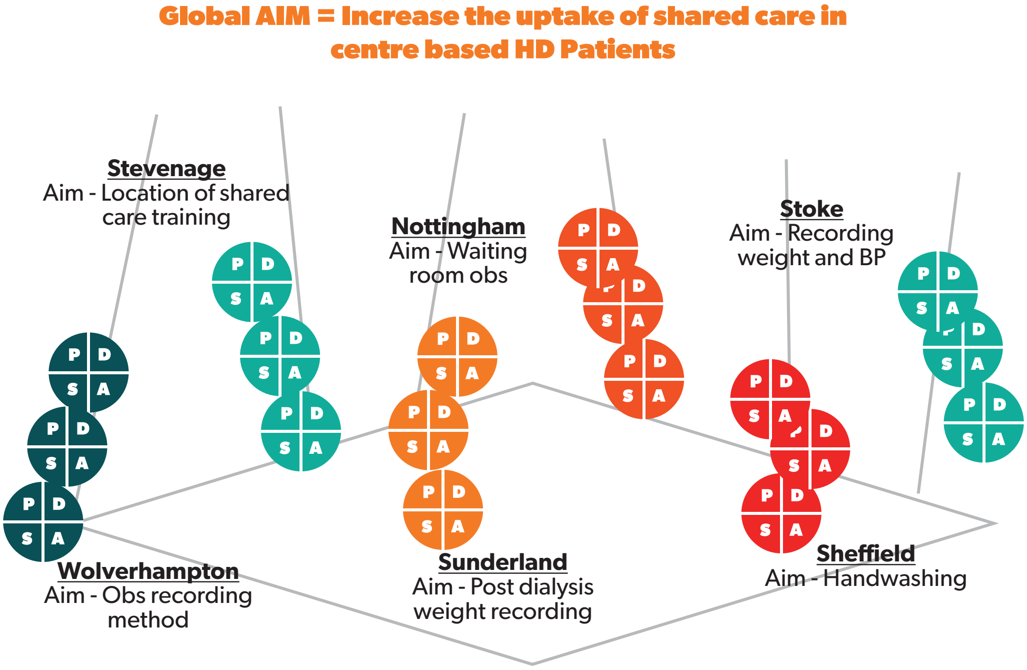


Figure 21 : SHAREHD PDSA cycles in wave 1

12.2.7 CPD credited learning events

The KRUK charity had existing links with the Royal College of Physicians (for the clinicians involved) through their Annual Fellows Day programme which meant it was possible to build on this to provide CPD credits for the three learning events within the ASSIST-CKD project.

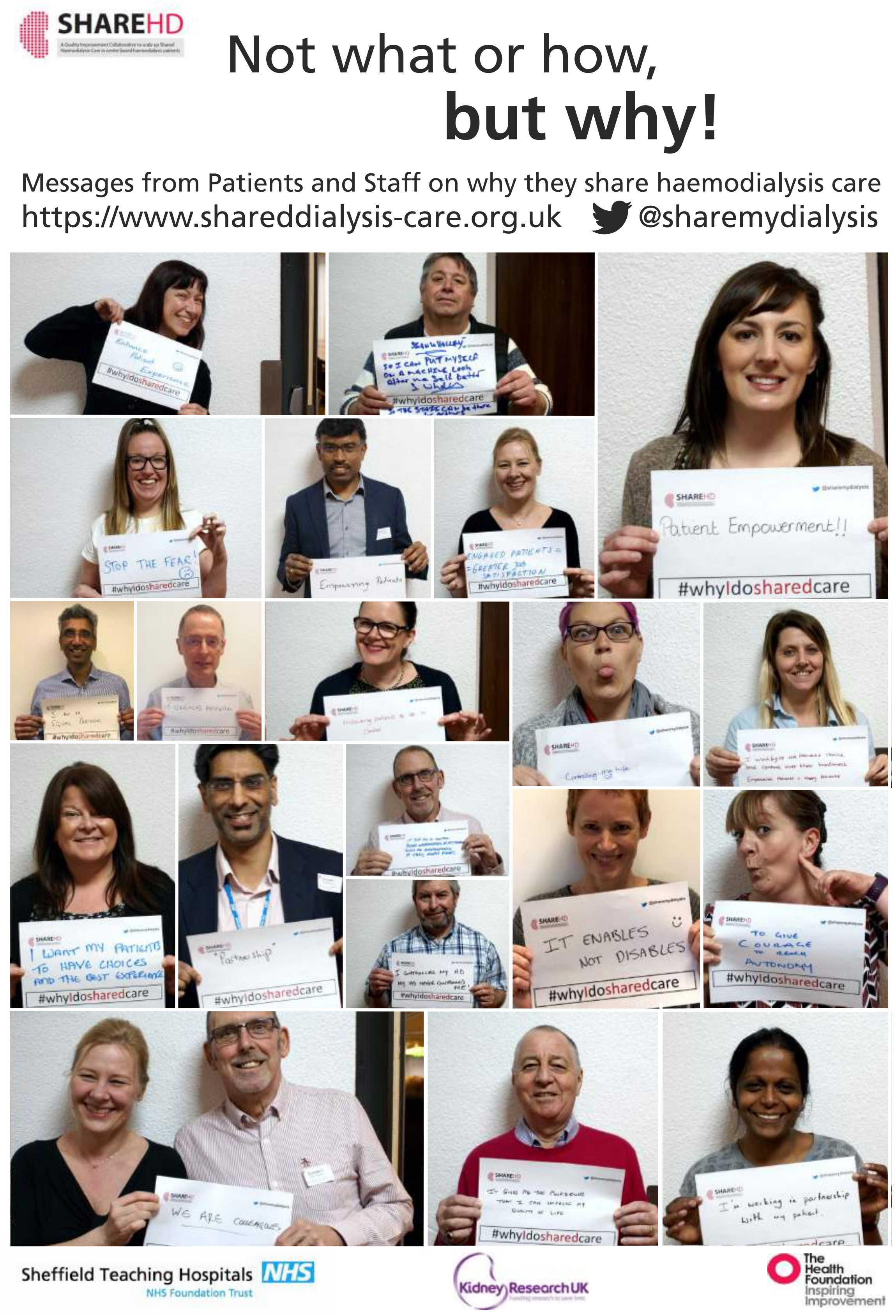
The project also considered the other MDT disciplines who would be attending the learning events and applied for CPD credits for the lab scientists through the Institute of Biomedical Scientists. CPD credits were not sought for nursing staff as they were not the key audience of the learning events or pharmacists, as the process for them changed mid-project. However, guidance was provided on how elements of the project could be used as CPD evidence, revalidation and reflective practice examples.

To obtain CPD accreditation, the process is usually a case of registering as an educational provider with the RCP (or IBMS) and completing the online application which includes the programme, learning objectives, structure of the programme (so that it isn't just presentations etc). If approved, a number of CPD points are allocated for each attendee and certificates of attendance must be issued.

The learning events held by SHAREHD did not provide CPD credits however signed attendance certificates were supplied to all attendees so they could be used for evidence. It had been considered that obtaining CPD credits for 'one off' type events would have been onerous but on reflection, if starting the process early in the project, this could have been achieved. It should be noted however that no issues were raised that CPD points were not available or the lack of accreditation used as a reason for any non-attendance.

12.2.8 #whyidosharedcare campaign and Shared Care movement

The #whyidosharedcare campaign started as a simple way of appealing to every learning event attendee to consider why shared care is important to them so that a simple montage could be put together.



SHAREHD

Not what or how,

but why!

Messages from Patients and Staff on why they share haemodialysis care

https://www.shareddialysis-care.org.uk @sharemydialysis

Sheffield Teaching Hospitals NHS Foundation Trust

Kidney Research UK

The Health Foundation Inspiring Improvement

Figure 22 : #whyidosharedcare campaign

The approach grew and was easily replicable in many situations such as the conferences and at the end of shared care courses. It also was taken on-board as a communication method within units, where patients could share their ‘why’ and the picture posted up on notice boards to share with other patients and potentially influence and encourage others to give shared care a go. One team had the idea to create a video of patients explaining their #why which the programme built on to create a video of patients, staff and carers from several units. https://youtu.be/1dBMYrLP5E8

This approach is exceptionally easy, quick and cheap to reproduce and would be especially powerful if the project is fundamentally about culture change.

12.2.9 Programme theory (theory of change)

Programme theory was utilised as a means to understand practical aspects of implementation with a focus on changes to improve delivery in both TAKI and SHAREHD. Different approaches to this were adopted by these programmes.

For TAKI, each site was encouraged to develop a theory of change and driver diagram and to update that at the end of the programme. It formed the basis of one of the four evaluation questions - What is the 'theory of change' in each hospital? - which was informed by the frame work analysis using information from peer assist and peer review, change methodology documentation and key informant interviews. Ten themes were identified that contributed to delivery of the intervention and to its beneficial effect on patient outcome. It was planned that each hospital would develop two logic models to provide details of alterations that occurred in their theory of change over time. However, staff at the hospitals did not perceive the models to be as useful for their implementation process as first hoped and they were not maintained as live documents. Completion was heavily facilitated by the qualitative evaluation team in certain instances.

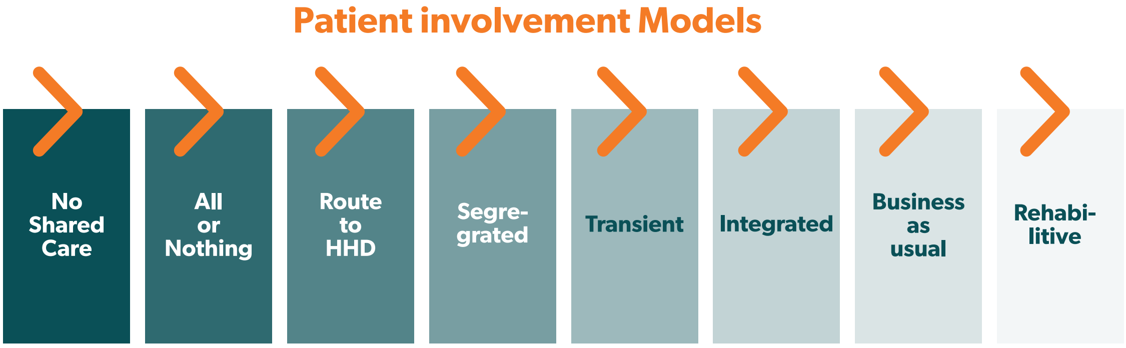
Pragmatic changes to the delivery of the intervention resulted from this work including changes in resources (eg addition of senior Trust level support, of a nurse specialist, a quality team and the loss of AKI project team members); changes in actions (performing a root cause analysis of every AKI, developing additional materials, or removing the requirement to create run charts); changes in outputs, from the removal of improved communications between primary and secondary care (Bradford) to the removal of training for HCAs, capturing website hits and producing weekly feedback charts for wards (Ashford). In addition, Ashford reported new assumptions that had not been borne out, for example, the ability to recruit an AKI nurse and good clinician uptake, as well as a new external factor, lack of allocated time for auditing.

The TAKI team concluded the theory of change in each hospital was more complex than the implementation teams were able to describe using a logic model. Their findings were broadly consistent with Carroll et al. [77] who noted that implementation fidelity can be moderated by factors such as intervention complexity (i.e. simple interventions are easier to implement with a high level of fidelity) and participant responsiveness (e.g. participant resistance can result in poor uptake and spread). More training is required for clinical staff in 'theory of change' models and how to use these to tailor the non-core elements of the intervention for optimal local adoption.

The SHAREHD team adopted a different approach developing a single logic model for the whole programme that was built and iterated over time from the results of the qualitative evaluation. The theory-led element of the evaluation was focused on uncovering relevant Contexts, Mechanisms and Outcome Conjectures (CMOCs). This began with informal discussions with the implementation team to develop initial programme theories. This was supplemented with questions posed to the wider team and a network of shared care trained nurses through social media. Each wave of the intervention saw a modified set of interview schedules for patients and staff to further refine and test existing theories and explore emerging theories. There were two main periods of qualitative data analysis. The first was thematic and was used to establish content related to contexts, mechanisms and outcomes. The second set of analysis explored the data in terms of relationships to specific mechanisms related to established theories of change and led to the development of service delivery models. Throughout the process, a CMOC table was continually updated to catalogue contexts, mechanisms and outcomes to be explored and to develop hypotheses about the relationships between these theoretical elements. The complex findings were ultimately used to construct simplified organisational and individual models with which to frame service improvement activities and engagement of patients. These models of staff and patient involvement were further developed as strategic tools to help locate dialysis units within a landscape of shared care and help define the aims and ambitions of service improvement initiatives. Patient involvement models developed through several stages, where the most progressive describes a rehabilitation model where services seek to enable involvement of patients who wish to take part in their care despite any problems that they might be experiencing.

Involvement models

The qualitative information allowed the development of a series of models of shared care both for staff and patient involvement. The granular explanation behind these models supports an understanding of how mechanisms of change might operate differently in these different contexts. Thereby, demonstrating what works for whom, in what circumstances and why. More expansive explanations on these are due to be published by the SHAREHD evaluation team during 2020.



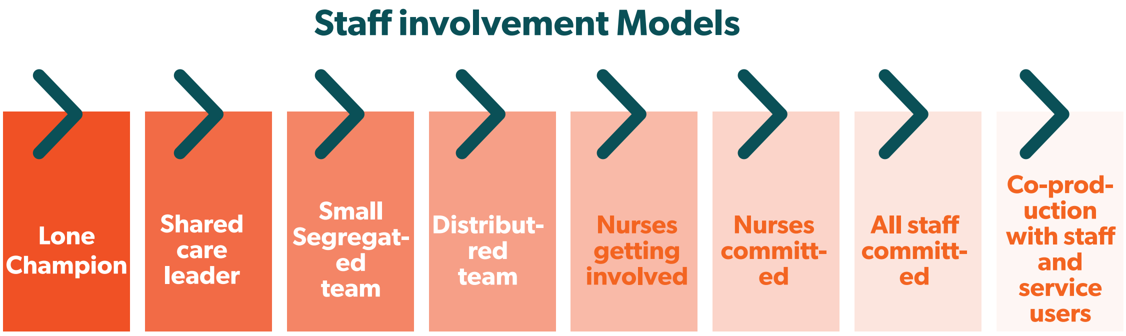


Figure 23 : Patient involvement models

Figure 24 : Staff involvement models

12.3 Table of trusts

Trust	Specific hospital	TAKI	ASSIST-CKD	SHAREHD	TP-CKD
Bradford Teaching Hospital NHS Foundation Trust	St Luke's Hospital / Bradford Royal Infirmary	2		Pilot	Cohort 1
University Hospitals Coventry & Warwickshire NHS Trust	Coventry				Cohort 1
Derby teaching Hospitals Foundation Trust	Derby	Pilot	Wave 4		Cohort 1
Imperial College Hospital NHS Trust	Hammersmith Hospital				Cohort 1
Kings College Hospital NHS Trust	Kings London				Cohort 1
Newcastle Upon Tyne Hospitals NHS Foundation Trust	Freeman Hospital		Wave 2		Cohort 1
Nottingham University Hospitals NHS Trust	City Hospital			Wave 1	Cohort 1
Plymouth Hospitals NHS Trust	Derriford Hospital				Cohort 1
Sheffield Teaching Hospitals NHS Foundation Trust	Northern General Hospital			Pilot &	Cohort 1
Wave 1	Cohort 1				Cohort 2
Brighton & Sussex University Hospital Trust	Brighton & Sussex County Hospital				Cohort 2

Royal Wolverhampton NHS Trust	New Cross Hospital			Wave 1	Cohort 2
Heart of England NHS Foundation Trust	Birmingham Heartlands		Pilot	Wave 2	Cohort 1
University Hospitals of North Midlands NHS Trust	Royal Stoke University Hospital			Wave 1	Cohort 2
The Leeds teaching Hospital NHS Trust	Leeds General Infirmary	4		Pilot & Wave 2	
	Leeds St James	4			
Royal Cornwall Hospitals NHS Trust			Wave 1		
Doncaster and Bassetlaw Teaching Hospitals NHS Foundation trust	Doncaster Hospital		Wave 1	Pilot	
NHS Lanarkshire			Wave 1		
Wirral University Teaching Hospital NHS Foundation Trust			Wave 1		
Chester Lab			Wave 1		
St Helens & Knowsley Hospitals NHS Trust **Southport and Ormskirk Hospital NHS Trust**			Wave 2		
Epsom & St Helier University Hospitals NHS Trust			Wave 3		
South Tyneside and Sunderland NHS Foundation Trust			Wave 4	Wave 1	
Swansea NHS Trust			Wave 4		
Kettering General NHS Foundation Trust			East Midlands		
University Hospitals of Leicester NHS Trust			East Midlands		
Ashford & St Peters Hospital		3			
Frimley Park Hospital		1			
Manchester University NHS Foundation Trust				Wave 2	
East & North Heartfordshire NHS Trust				Wave 1	
Guys & St Thomas NHS Foundation Trust				Wave 2	
North Bristol NHS Trust				Wave 2	
York Teaching Hospital NHS Foundation Trust				Wave 2	
Liverpool and Broadgreen University Hospitals NHS Trust				Wave 3	
NHS Ayrshire & Arran				Wave 3	

Western Health & Social Care Trust	Omagh		X	Wave 3	
	Derry			Wave 3	
	Newry		Wave 2		
	Antrim		Wave 3		
Belfast Health & Social Care Trust				Wave 3	
Salford Royal NHS Foundation trust				Wave 3	
South Tees NHS Trust				Wave 3	
University Hospitals Birmingham NHS foundation trust				Wave 3	
Betsi Calwaladr University Health Board	Wrexham		Wave 3		
	Glan Clwyd		Wave 4		
North West Wales NHS Trust	Bangor		Wave 3		
Hywel Dda University Health Board			Wave 4		
Northampton General Hospital NHS Trust			East Midlands		
Sherwood Forrest Hospital NHS Trust			East Midlands		
Hull University Teaching Hospitals NHS Trust			Wave 3		

Table 17 : Table of trusts

12.4 Glossary

Kidney Patient Involvement Network (KPIN)	KPIN is a network of kidney (renal) organisations, charities and individuals committed to quality patient and public involvement and engagement (PPI/E) who are willing to work collaboratively on initiatives to improve standards and develop patient leaders of the future.
Kidney Quality Improvement Partnership (KQuIP)	KQuIP is a dynamic network of kidney health professionals, patients and carers who are committed to developing, supporting and sharing quality improvement in kidney services in order to enhance outcomes and quality of life for patients with kidney disease.
Renal Replacement Therapy (RRT)	Life supporting treatments for kidney failure, encompassing all forms of dialysis and also kidney transplantation.
National Institute for health and Care Excellence (NICE)	This is a national body that provides national guidance and advice to improve health and social care.
School of Health and Related Research (ScHaRR)	ScHaRR is a leading UK centre for Health Services and Public Health Research. The School brings together a wide range of health research related skills including health economics, medical statistics, health technology assessment, sociology, epidemiology, and information science, as well as clinical skills in medicine and allied health professions.

Multi Disciplinary Team (MDT)	A multidisciplinary team is a group of health care workers who are members of different disciplines (professions e.g. Psychiatrists, Social Workers, etc.), each providing specific services to the patient.
Stepped Wedge Cluster Randomised Trial (SWCRT)	A stepped-wedge trial (or SWT) is a type of randomised controlled trial (or RCT), a scientific experiment which is structured to reduce bias when testing new medical treatments, social interventions, or other testable hypotheses.
Microsystem Coaching Academy (MCA)	Based in Sheffield the MCA aims to; Build improvement capability into the workforce; To maximise quality and value to patients; Help multi-disciplinary front line teams rethink and redesign services. Coaches are trained in the art of team coaching and the science of quality improvement to work with front line teams to help them re-design the services they deliver.
Academic Health Science Networks (AHSN)	Established by NHS England in 2013 to spread innovation at pace and scale - improving health and generating economic growth. Each AHSN works across a distinct geography serving a different population in each region
End Stage Kidney Disease (ESKD)	The stage in kidney disease when a person's kidneys fail and dialysis treatment or a transplant is required to sustain life.
Chronic Kidney Disease (CKD)	Loss of kidney function (measured using the estimated glomerular filtration rate) or damage to the kidney (usually albuminuria, but there can be other signs such as an abnormal appearance of the kidneys on scanning) that is sustained over time. In a minority of people it is progressive and leads to end-stage kidney disease.
Acute Kidney Injury (AKI)	Acute kidney injury is a sudden and recent reduction in a person's kidney function. It is not caused as a result of a physical blow to the body
Think Kidneys	Think Kidneys was the NHS's campaign programme for tackling acute kidney injury. The aims continue to be to reduce avoidable harm and death for people with acute kidney injury, and to improve care for patients whether in hospital or at home.
Estimated glomerular filtration rate (eGFR)	GFR is Glomerular Filtration Rate and it is a key indicator of renal function. eGFR is estimated GFR and is a mathematically derived entity based on a patient's serum creatinine level, age, sex and race. This is usually calculated by the laboratory analysing the blood sample and is reported along with the serum creatinine result.
Get it Right First Time (GIRFT)	An NHS England programme helping to improve the quality of care within the NHS by bringing efficiencies and improvements.
Commissioning for Quality and Innovation	The Commissioning for Quality and Innovation (CQUIN) framework supports improvements in the quality of services and the creation of new, improved patterns of care.
ISRCTN	The ISRCTN registry is a primary clinical trial registry recognised by WHO and ICMJE that accepts all clinical research studies (whether proposed, ongoing or completed), providing content validation and curation and the unique identification number necessary for publication. All study records in the database are freely accessible and searchable.
NHS Kidney Care	Part of NHS Diabetes and Kidney Care from 2008- 2012 NHS Kidney Care aimed to enabe a consistent implementation of the Renal National Services Framework.
NHS Right Care	Part of NHS England/NHS Improvement the NHS Right Care programme supports local systems to make improvements to both spend and patient outcomes by using a diagnosis of data and evidence from that local population to identify opportunities and threats.

12.5 Quality improvement literature reading list

The history of quality improvement in renal care

- *Thomas N et al (2013) Supplement: Quality improvement. Journal of Renal Care. Volume 39, Issue S2*

Understanding the role of context in quality improvement

- *Mannion R, Davies H (2018) Understanding organisational culture for healthcare quality improvement. BMJ 2018;363: k4907*
- *Braithwaite J et al (2017) Association between organisational and workplace cultures, and patient outcomes: systematic review. BMJ Open2017;7: e017708*
- *Dixon-Woods M et al (2014) Culture and behaviour in the English National Health Service: overview of lessons from a large multimethod study. BMJ Qual Saf 2014; 23:106-15*
- *Bate P et al (2014) Perspectives on context. A selection of essays considering the role of context in successful quality improvement. The Health Foundation.*
- *Harvey G et al (2014) Analysing organisational context: case studies on the contribution of absorptive capacity theory to understanding inter-organisational variation in performance improvement BMJ Qual Saf 2015;24:48-55.*
- *Liberati E et al (2019) How to be a very safe maternity unit: An ethnographic study. Social Science & Medicine Volume 223*

The characteristics of effective improvement collaboratives, communities and networks

- *Wells N et al (2018) Are quality improvement collaboratives effective? A systematic review BMJ Qual Saf 2018; 27:226-240.*
- *Bradley E et al (2018) How guiding coalitions promote positive culture change in hospitals: a longitudinal mixed methods interventional study: BMJ Quality & Safety 2018; 27:218-225.*
- *Carter P et al (2014) How collaborative are quality improvement collaboratives: a qualitative study in stroke care. Implementation Science volume 9, Article number: 32*
- *Aveling E et al (2014) Quality improvement through clinical communities: Eight lessons from practice. Journal of Health Organization and Management, Vol. 26 No. 2*
- *Gould L et al (2015) Clinical Communities at Johns Hopkins Medicine: An Emerging Approach to Quality Improvement. The Joint Commission Journal on Quality and Patient Safety Volume 41, Issue 9*
- *Drew J et al (2014) Effective networks for improvement: Developing and managing effective networks to support quality improvement in healthcare. The Health Foundation*

Spreading and scaling improvements in healthcare

- *Greenhalgh T, Papoutsis C (2019) Spreading and scaling up innovation and improvement. BMJ 2019;365: l2068*
- *Horton T et al (2018) The spread challenge: How to support the successful uptake of innovations and improvements in health care. The Health Foundation*
- *Albury D et al (2018) Against the odds: Successfully scaling innovation in the NHS. London: Innovation Unit*
- *Greenhalgh T et al (2004) Diffusion of innovations in service organizations: systematic review and recommendations. Milbank Q 2004;82:581-629*
- *Gabbay J, Le May A (2004) Evidence based guidelines or collectively constructed “mindlines?” Ethnographic study of knowledge management in primary care. BMJ 2004;329:1013*

Individual, team and organisational behaviours and skills that facilitate effective quality improvement

- *Lucas B, Nacer H (2015) The habits of an improver: Thinking about learning for improvement in healthcare. The Health Foundation*
- *Gabbay J et al (2014) Skilled for Improvement: Learning communities and the skills needed to improve care: an evaluative service development. The Health Foundation*
- *Spear S (2017) Fast discovery: The imperative for high velocity learning by everyone, about everything, all of the time. The Health Foundation*
- *Nancarrow S et al (2013) Ten principles of good interdisciplinary team work. Human Resources for Health Volume 11, Article number: 19 (2013)*
- *Baker D et al (2006) Teamwork as an Essential Component of High-Reliability Organizations. Health Serv Res. 2006 Aug; 41(4 Pt 2)*
- *Fitzgerald E et al (2013) Distributed leadership patterns and service improvement: Evidence and argument from English healthcare. The Leadership Quarterly. Volume 24, Issue 1, February 2013*
- *Carroll J, Edmondson A (2002) Leading organisational learning in health care. BMJ Qual Saf 2002; 11:51-56.*
- *Leape L et al (2012) Creating a culture of respect. Academic Medicine, Vol. 87, No. 7 / July 2012*

Patient and public involvement in quality improvement

- *Batalden P (2018) Getting more health from healthcare: quality improvement must acknowledge patient coproduction. BMJ 2018; 362: k3617*
- *Batalden M et al (2016) Coproduction of healthcare service. BMJ Qual Saf 2016; 25:509-17.*
- *Ocloo J, Matthews R (2016) From tokenism to empowerment: progressing patient and public involvement in healthcare improvement. BMJ Qual Saf 2016; 25: 626-632.*
- *Loud F et al (2013) How to develop a patient and carer advisory group in a quality improvement study. Journal of Renal Care. Volume 39, Issue S2*

Quality improvement methods and approaches - Practical guides, primers and resource collections

- *Boaden R et al (2008) Quality Improvement: Theory and Practice in Healthcare. NHS Institute*
- *Leis J, Shojania K (2017) A primer on PDSA: executing plan-do-study-act cycles in practice, not just in name BMJ Qual Saf 2017; 26:572-577.*
- *Shah A (2019) Using data for improvement BMJ 2019;364:l189*
- *Clarke G et al (2019) Evaluating the impact of healthcare interventions using routine data BMJ 2019;365:l2239.*
- *NHS Improvement Quality, service improvement and redesign (QSIR) tools*
- *Institute for Healthcare Improvement (IHI) Quality Improvement Essentials Toolkit*

Analyses of the implementation of quality improvement methods, tools and approaches

- *Dixon Woods M, Martin G (2016) Does quality improvement improve quality? Future Hospital Journal 2016 Vol 3, No 3: 191-4*
- *Reed J, Card A (2016) The problem with Plan-Do-Study-Act cycles. BMJ Qual Saf 2016; 25:147-152*
- *Chopra V, Shojania K (2012) Recipes for checklists and bundles: one part active ingredient, two parts measurement. BMJ Qual Saf 2013; 22: 93-96.*
- *Dixon-Woods M et al (2012) Ten challenges in improving quality in healthcare: lessons from the Health Foundation's programme evaluations and relevant literature. BMJ Qual Saf 2012; 21*

Medical Research Council Intervention Guidance

- *Developing and evaluating complex interventions (2006). Note that following considerable development in the field since 2006, MRC and NIHR have jointly commissioned an update of this guidance to be published in 2019. This is as yet not released but is expected to be a valuable source of information for the scaling up, as well as the evaluation of complex interventions.*

Top 10 tips for innovators and adaptors taken from the Webinar "Spreading Innovation & Improvement in the NHS" - Presented by Tim Horton, Dr Amanda Begley and Anna Burhouse.

Horton T et al (2018) The spread challenge: How to support the successful uptake of innovations and improvements in health care. The Health Foundation :

- *Consider the right strategy for describing you intervention*
- *Capture learning form the early stages of spread and use it to refine the intervention*
- *Build networks that allow adopter to share their experiences and insights*
- *Involve patients at all stages of innovation and spread, to give direction and resilience*
- *Acknowledge the complexity of adoption - be prepared for lots of trialing and adaptation*
- *Build long-term partnerships with multiple champions*
- *Make a compelling case for adoption, aiming for hearts as well as minds*
- *Focus on the adopter's unique systems and contexts*
- *Celebrate the creativity of adopters as well as innovators*
- *Don't underestimate that successful adoption can take time.*

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