TACKLING ACUTE KIDNEY INJURY - A MULTI-CENTRE QUALITY IMPROVEMENT PROJECT

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Table of contents

Project summary

Title	Tackling acute kidney injury - a multi-centre quality improvement project
Protocol version and date	V5.1 October 2016
Objectives	To upscale an effective package of interventions for Acute Kidney Injury (AKI) and to measure the impact of its introduction across several partner organisations (across two regional networks) representing the range of UK hospitals.
Methodology	Quality improvement project with stepped wedge design for introduction of interventions. The package of interventions will be introduced sequentially across each network, one centre per three month period.
Project duration	30 months (including 6 month set up period)
Number of patients	Not defined – all patients sustaining AKI during the project lifespan will be included
Inclusion criteria	All hospitalised patients sustaining AKI in any of the partner organisations during the evaluation period of the project
Statistical methodology and analysis	We propose to evaluate the project on several different levels: *Patient outcomes:* Primary and secondary patient outcomes over each three month time period will be analysed, including effects for centre, time period and treatment variation between centres. A time series comparison between pre and post intervention periods will be made. Primary outcomes: 30 day mortality in patients with AKI Secondary outcomes: Incidence of hospital acquired AKI (h-AKI) Incidence of AKI progression Incidence of separate AKI stages Hospital length of stay (LoS) in patients with AKI Number of critical care bed days for patients with AKI Proportion of AKI patients with renal recovery by hospital discharge *Standards of care* Baseline and serial post-intervention audits (at each of the stepped wedges) of defined metrics of basic standards of care for patients who have sustained AKI. *Qualitative evaluation of the intervention package* Qualitative data about the utility and practicality of interventions will be collected, and will incorporate lessons learnt during the implementation process.

1 Introduction

This is a service improvement project, which includes an extensive measurement component to allow assessment of the efficacy of the interventions. We have aligned the proposal to the NHS England AKI programme to promote ongoing sustainability beyond the life of this proposal, but also to provide a project template that is transferrable and can be used in other AKI quality improvement projects. Data collection and analysis will be established via data streams to the UK Renal Registry and University of Bristol within existing approvals from the Health Research Authority (previously National Information Governance Board).

1.1 Background

Acute Kidney Injury (AKI) is a sudden reduction in kidney function. It is common, harmful and often preventable, thus representing a major patient safety challenge for the NHS [1]. AKI occurs in as many as 10-15% of hospital admissions [2], usually in conjunction with other acute illnesses. Elderly patients and those with chronic conditions such as heart failure, diabetes and chronic kidney disease (CKD) are most vulnerable [3]. The presence of AKI dramatically increases severity of patients' illness. Mortality rates of hospitalised patients with AKI are as high as 20-33% [4], whilst these patients are subject to longer, more complex hospital stays [5]. It is increasingly recognised that AKI also contributes to long term effects, in particular the development or progression of CKD [6].

As well as the adverse effects of AKI itself, there are many reports (in particular the 2009 National Confidential Enquiry into Patient Outcome and Death (NCEPOD) Report) demonstrating that a significant component of the harm associated with AKI arises from poor standards of care [7]. It is also clear that only a minority of patients are cared for by nephrologists and AKI occurs regularly across all acute specialties. A major problem identified in the NCEPOD report were delays in diagnosis or even failure to recognise the presence of AKI, which often has a silent clinical course. Concurrently, it was demonstrated that early intervention focussed on basic elements of care can significantly improve the outcome of AKI [8]. It is therefore imperative that robust and scalable interventions are deployed to target these deficiencies.

2 Objectives

We propose to upscale an effective package of interventions for Acute Kidney Injury (AKI) and to measure the impact of their introduction across several partner organisations representing the range of UK hospitals. The aim is to improve the delivery of healthcare to patients with AKI that in turn will translate into better outcomes. We will assess the efficacy and the process of implementing the intervention on several levels:

1. *Impact on patient outcomes*
   A series of patient outcomes will be compared before and after introduction of the interventional package within a stepped wedge study design.
2. *Impact on quality of care delivered*
   Clinical audit of a series of defined metrics of basic care for patients who have sustained AKI
3. *Qualitative assessment of change process*
   Qualitative data from health care professionals (including members of the project team) will be used to evaluate practicality, acceptability and utility of interventions, whilst shared learning will allow ongoing tailoring of both the interventions and change methodology employed during implementation.

3 Project design

3.1 General design

This is a multi-centre quality improvement project using a stepped wedge design to sequentially introduce a package of interventions that has been trialled and shown to be successful at improving basic care and outcomes in patients who have sustained AKI in a single centre [9]. The interventions will comprise:

- An electronic AKI detection system based on biochemistry results and situated within pathology laboratory software, aimed at improving early recognition of AKI on a hospital-wide basis (section 5.1)
- An education programme to raise awareness and knowledge levels in all major medical and surgical specialities and across the range of health care workers (section 5.2)
- An AKI care bundle aimed at systematic improvements in the delivery of basic components of AKI care (section 5.3)

All patients sustaining AKI in the partner centres will be included; data collection will encompass a baseline measurement period before any change is instituted that will be compared with measurements after introduction of the package of interventions. Data collection will occur at each three month period of the stepped-wedge design in each partner organisation to provide additional methodological rigour over simple time-series comparisons. Baseline variation in current practice and differences in hospital characteristics (context) will be carefully recorded at project outset to allow subsequent assessment as to whether these differences impact on efficacy of interventions. Data collection and analysis will occur via links to the UK Renal Registry and University of Bristol, who will also provide expertise in change methodology and statistical support. NHS England will also provide partnership, and by aligning the proposal to the NHS England AKI programme board, we can demonstrate a realistic model to sustain change beyond the life of the proposal as well as a mechanism for wider scale adoption.

3.1.1 Change methodology

In addition to employing tried and tested interventions, their introduction will be supported by a structured approach to change management. This will be developed across each network of partner organisations (Yorkshire and Surrey) with arrangements for joint learning put in place. The detail of this will be tailored to each participating partner organisation but will consist of the following:

1. Planning stage, during which the following will be determined: profile of change characteristics, organisational attributes/characteristics profile, change management strategy, structure of local project teams, high level Trust engagement. There will also be a single learning event with representation from all partner organisations to refine the existing package of interventions. Pre-existing work from lead and partner organisations will be shared and discussed. From this, ideas will be shared and local versions of the most successful approaches to the interventions will be developed.
2. During the planning stage, the governance structure for the project will be settled, along with clear roles and responsibilities for key project team members.
3. Implementing change, of which there will be two main aspects:
    a. A peer-assist and peer-review programme. Centres at the start of implementation period will host a meeting during which their plans for implementating the interventions will be presented to team members from centres with experience (either the lead centre or centres ahead in the stepped wedge). With a challenge and confirm process, the following will be reviewed to maximise learning from prior experience (both explicit and tacit): where are you going to start; what formal/informal meeting structures exist to support the programme; measures intended; resources available and how they will be deployed; change methodology and expertise to support it; education plans; technology plans to support the project; how staff will be engaged; scope; timelines; risks how monitored
    At the end of implementation, a peer-review event will be held to include members from all centres, but in particular the next centre to implement in the stepped wedge. This will capture learning: What were our plans; What actually happened; What worked; What did we

have to change; What would we have done differently; What are they key learning points to share with the next organisation.

b. Measurement for improvement. Use of run charts or statistical process control charts (SPC) to monitor frequently progress with delivery/uptake of interventions, particularly around introduction of the care bundle. This measurement is separate from the other aspects of evaluation.

4. In addition, other key components will be: communication plan, senior engagement and buy-in.
5. Reinforcement to sustain change e.g. post-intervention audit to look at uptake, corrective action plans, individual and group recognition approaches, success celebrations, end of project review

Rather than adopting a reactive response to resistance to AKI improvement measures, the aim is to engage and empower clinicians caring for patients with AKI. We aim to demonstrate the clinical need, instil a desire to participate and support the changes as well as making the necessary knowledge available. Ease of use of interventions will be an over-riding principle and the change management process will be integrated from the beginning of the project, being a major focus of the six month set up period.

3.2 Primary endpoints

Patient outcome measures are taken as the primary end points for this project. Comparisons will be within-cluster (pre- versus post-intervention) and between-cluster to estimate the treatment effect. This approach is necessary to avoid confounding the treatment effect with changes over time comparing baseline and post-intervention time periods. The primary outcome measures are defined as:

1. 30 day mortality rate in patients with AKI

3.3 Secondary endpoints

Secondary outcome measures are separated into three groups. Comparisons will be within-cluster (pre- versus post-intervention) and between-cluster to estimate the treatment effect for patient outcome and clinical audit measures.

Patient outcome measures:

1. Incidence of hospital acquired AKI (h-AKI)
2. Incidence of AKI progression (defined as AKI that increases by at least one stage from AKI stage at time of first detection)
3. Incidence of individual AKI stages (stage 1, stage 2 and stage 3)
4. Length of hospital stay of patients with AKI
5. Number of critical care bed days used by patients with AKI
6. Proportion of patients with AKI who achieve complete renal recovery by hospital discharge. Renal recovery will be defined as serum creatinine returning to a value less than 27µmol/l above baseline creatinine value.

Measures of basic care:

Clinical audit will be completed in each centre to assess the proportion of patients with AKI who receive a series of metrics of basic care.

Qualitative data:

Qualitative data about the utility and practicality of interventions will be collected from health care workers involved in the provision of care to patients with AKI and from project team members. Specific record of facilitators and barriers to implementation would be made, alongside successful solutions to aid subsequent dissemination. These data will be collected at each partner organisation in the following ways: Face to Face interviews or Focus groups, and SurveyMonkey style questionnaires. Depending on local resources, we will explore the possibility of using TurningPoint software to collect data before and after teaching sessions. Results will be complied and compared between partner organisations.

4 Methods

4.1 Subjects

All patients aged ≥18 years who sustain AKI at the participating centres during the project lifespan will be included. The incidence of AKI will be expressed per number of hospital admissions during each time period. For the purposes of this project, patients will defined as having AKI if they have an inpatient blood test that triggers an AKI Warning Stage test result, using the NHS England AKI detection algorithm (http://www.england.nhs.uk/wp-content/uploads/2014/06/psa-aki-alg.pdf). Hospital acquired AKI (h-AKI) will be defined as AKI that occurs >24hrs after hospital admission. Patients on long term dialysis will be excluded.

4.2 Data collection

All data used to assess the effectiveness of this project will be collected as part of routine clinical care. These data will be collected from electronic or paper hospital records without any additional patient interactions outside of that of routine clinical care.

Patient outcome data:
The following data points will be collected by setting up an IT report linking hospital outcome stay to electronic AKI detection results. It will also be acceptable to send separate files to the UKRR (for biochemical data and for hospital stay data) providing they both contain unique identifiers to allow subsequent linkage and removal of duplicates by the UKRR. A data specification will be issued to allow standardisation of data fields).
Data collection will need to occur when the results are suppressed (not visible to end-users during baseline periods) and when live in clinical practice (implementation periods). A report will be generated to cover each three month data collection period (as per figure below, section 4.3). Data collection will continue until each centre has completed two 3-month periods after the implementation phase. The report will include every patient aged 18 or over who has a hospital admission lasting ≥24hrs and with one or more AKI warning stage results generated from an inpatient serum creatinine concentration measurement. Depending on technical capabilities, ESRF patients will either be excluded based on dialysis clinical codes/unique monthly dialysis blood sets/location of blood samples (dialysis/renal unit).
Data set will include:

- Patient demographics: age at time of hospital admission, sex (male=1, female =0), ethnic group name/code
- NHS number (numerical field)/local identifier (text field)
- Date of admission (date field)
- Primary speciality (text field)
- Charlson co-morbidity score (numeric score) and constituent chronic disease binary scoring (1=present, 0=absent)*
- AKI data: initial AKI warning stage (numerical field limited to 1,2 or 3), highest AKI warning stage (numerical field limited to 1,2 or 3), time between admission and first AKI Warning stage result (numerical field, in hours), final inpatient creatinine result to assess recovery (numerical field, micromol/l)
- Hospital length of stay (numerical field, in days)
- ICU admission (1=admitted to ICU during hospital stay, 0=no ICU admission) and ICU admission length of stay (numerical field in days)
- In hospital mortality (numerical field, 1=died in hospital 0=survived to discharge)
- 30 day mortality (numerical field, 1=died within 30days of first AKI warning stage result 0=survived to >30days)
- Date of death (date field)

- In addition, for each three month period, the total number of hospital admissions will need to be returned (= elective and non-elective admissions, excluding day case contacts and patient discharged directly from ED).

[*] *Acute myocardial infarction, cerebrovascular accident, congestive heart failure, Connective tissue disorder, Dementia, Diabetes, Liver disease, Peptic ulcer disease, Peripheral vascular disease, Pulmonary disease, Cancer, Diabetes complications, Paraplegia, Renal disease, Metastatic disease, Severe liver disease, HIV*

UKRR data submission:
AKI warning stage data and serum creatinine concentration data will be submitted to the UKRR in line with the national guidance as per the following:

Audit of basic standards of care:
Sequential patients with AKI will be selected from designated audit periods, to include an equal number of patients with AKI stage 1, 2 and 3; AKI stage will be defined as maximum AKI stage during stay. Audit periods will consist of the final calendar month of each three month study period (1st baseline audit period May 2015). A list of all patients with AKI during these periods will be produced and used locally to select 30 patients at each centre (10 sequential cases for each AKI stage). Patients will be preferentially selected from the clinical areas in which the interventions are planned to or have been deployed with follow up audits in a similar hospital location.
Patients on a palliative care pathway will be exluded as will patients with End Stage Renal Failure on dialysis (NB patients with end stage renal failure with a renal transplant WILL be included). Audits will be carried out at baseline and then at each block of the stepped wedge period (total seven cycles per organisation, see figure below, section 4.3).

The following data points will be collected:

- Centre code
- Audit period (number field)
- Patient age (years), sex (male=1, female =0) plus other demographics as follows: ethnicity (as per NHS defn), NHS number, date of birth
- Date of admission (date field)
- Route of hospital admission (text field, limited list)
- First AKI stage during admission (number field limited to 1,2 or 3)
- Date of first AKI result (date field)
- Highest AKI stage during admission (number field limited to 1,2 or 3)
- Date of highest AKI result (date field)
- Ward descriptor of patient at time of AKI (text field, limited list)
- Duration of AKI
    a. Definition: number of days until serum creatinine returns to within 27micromol of baseline level for that individual
    b. Response options: 1 (=1-2days), 2 (=2-4days), 3 (= >4days), 99 (=not possible to define duration, e,g, creatinine not repeated, patient discharged prior to AKI resolution)
- Was AKI recognised?
    a. Definition: AKI recorded in hospital notes at any point during admission including discharge summary, use of AKI care bundle, investigation requested specifically for AKI
    b. Response options: 0 (=no), 1 (=yes within <6hrs), 2 (=yes between 6-12hrs), 3 (=yes between 12-24hrs), 4 (yes between 24-48hrs), 5 (=yes >48hrs), 6 (=yes but timing not known)
- Was cause of AKI documented?
    a. Definition: cause of AKI recorded in hospital notes at any point during admission including discharge summary
    b. Response options: 1 (=yes), 0 (=no)

- If cause of AKI documented, enter all contributing factors as documented in hospital notes (text field)
- Was AKI care bundle used?
    a. Definition: AKI care bundle incorporated into patient record
    b. Response options: 0 (=no), 1 (=yes started within <6hrs), 2 (=yes started between 6-12hrs), 3 (=yes started between 12-24hrs), 4 (yes started between 24-48hrs), 5 (=yes started >48hrs), 6 (=yes but timing not known)
- Was AKI care bundle completed?
    a. DefinItion: All fields of AKI care bundle completed/signed for – this is an 'all or none' assessment
    b. Response options: 1 (=yes, 100% complete), 0 (=no, partially completed), 99(=care bundle not utilised)
- Did the patient receive a fluid balance assessment?
    a. Definition: any one of: patient examination incorporating assessment of volume status (including euvolaemia), clinical impression that includes reference to volume status, treatment plan includes correction of over- or under- hydration
    b. Response options: 0 (=no), 1 (=yes within <6hrs), 2 (=yes between 6-12hrs), 3 (=yes between 12-24hrs), 4 (yes between 24-48hrs), 5 (=yes >48hrs), 6 (=yes but timing not known)
- Did the patient receive urinalysis at time of or following AKI?
    a. Definition: urinalysis results recorded in medical or nursing record
    b. Response options: 0 (=no), 1 (=yes within <6hrs), 2 (=yes between 6-12hrs), 3 (=yes between 12-24hrs), 4 (yes between 24-48hrs), 5 (=yes >48hrs), 6 (=yes but timing not known), 99(=not possible due to anuria).
    Urinary ACR/PCR is not equivalent and should not be counted as an acceptable alternative
- Proportion of patients with AKI who were taking relevant medications at time of AKI*
    a. Response options: 1 (=yes), 0 (=no) for each of the following:
    b. *Relevent medications: ACE inhibitor, ARB, MRA (e.g. spironolactone), NSAIDs ,diuretics in setting of dehydration, aminoglycosides, trimethoprim
- Proportion of patients with AKI who have had medication review
    a. Definition: treatment plan includes cessation of relevant medication*, treatment plan includes avoidance of relevant medication, relevant medications stopped within 24hrs of first AKI warning stage result, documented pharmacy review
    b. Response options: 0 (=no), 1 (=yes within <6hrs), 2 (=yes between 6-12hrs), 3 (=yes between 12-24hrs), 4 (yes between 24-48hrs), 5 (=yes >48hrs), 6 (=yes but timing not known)
- Proportion of patients with AKI stage 2 or 3 who receive renal imaging
    a. Definition: renal ultrasound/CT/MRI imaging following onset of AKI
    b. Response options: 0 (=no), 1 (=yes within <6hrs), 2 (=yes between 6-12hrs), 3 (=yes between 12-24hrs), 4 (yes between 24-48hrs), 5 (=yes >48hrs), 6 (=yes but timing not known) 99(=not appropriate – AKI stage 1 or senior clinician decision)
    c. If recording 99, state reason for coding as such (text field)
- Proportion of patients with AKI stage 3 who are discussed, referred to or seen by nephrology/ICU
    a. Definition: medical record contains documentation of telephone discussion with nephrology/ICU SpR or more senior, nephrology/ICU review or transfer to nephrology ward/ICU
    b. Response options: 1(=yes, discussion with nephrology), 2(=yes, referral to nephrology), 3(yes, discussion with ICU/outreach), 4(referral to ICU/outreach), 5(transfer to more specialist area; includes renal ward, high dependency or ICU), 0(=no), 99(=not appropriate – AKI stage 1 or senior clinician decision)
- In hospital mortality
    a. Definition: death during index hospital admission
    b. Response options: 1(=died during admission), 0(=survived to hospital discharge)

The audit will also include a process measure of care bundle usage and compliance. As well as a measure of implementation, this will also be used as a tool to promote ongoing usage of the care bundle. This will happen as part of the three monthly audit cycle of basic care, and will be the responsibility of the clinicians in each centre.

Other process measures:

- Number and type of educational interactions delivered at each site during each three month data collection period.
- Number of hits on local AKI guideline webpage in each three month data collection period. This will be used as a surrogate measure of AKI awareness in the organisation.

Qualitative data collection:

This will comprise of the following:

- Baseline questionnaire to be completed by each partner organisation prior to and during the design event to document context of their organisation and prior AKI work
- Recording implementation and validation of the AKI detection algorithm using the NHS England test script; this will evidence that each site is able to detect AKI and measure it in the same way. This will occur once at point of installation, supervised by lead biochemist in each organisation.
- Questionnaire/interview to be carried out with key personnel during implementation stepped wedge (therefore five in total)
- Depending on ethics approvals, we will explore widening this process to include frontline clinicians outside of the project team
- Review of transcripts/minutes of monthly project team teleconferences/meetings
- Collation of structured feedback from teaching sessions and on other educational materials (e.g. website, guidelines etc) and their interpretation within local context
- End of project interviews with project team members to record lessons for wider dissemination
- Results will be reviewed by participants to confirm and challenge (e.g. 'is this your experience…')

The focus of the analysis will be to identify patterns, themes, insights and understanding that will be organised into categories to aid presentation.

4.3 Flow diagram

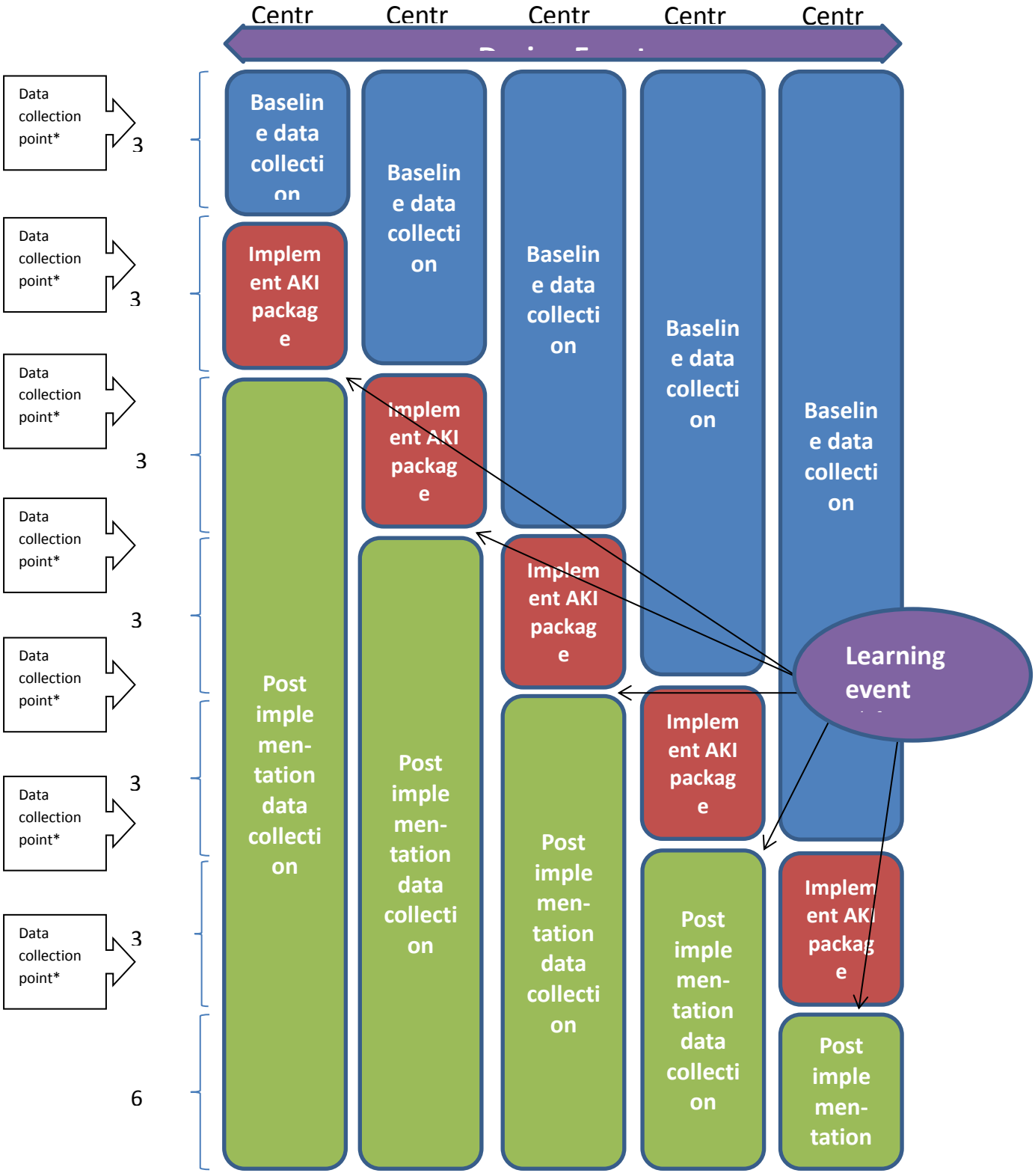

*Figure 1. Flow diagram showing step wedge design for implementation. *Data collection at each organisation will occur on a three monthly recurrenct cycle including baseline (1-5 times depending on position in stepped wedge), implementation (1 time per centre) and post-implementation (1-5 times). At each timepoint, data will be collected on: three monthly AKI incidence and outcomes (pt outcome data), process (audit of care bundle usage and basic standards of care, and number/type of education sessions delivered)*

5 Project procedures

The intervention package will be based on that implemented successfully at the lead centre. During the project planning stage, all centres will meet to share current experiences, review existing materials and refine these to maximise success in each partner organisation. Within this, there will be an ambition to standardise as much as possible. Variation in each of the interventions will be carefully documented throughout the life of the proposal.

5.1 Electronic AKI detection

Fully automated electronic AKI detection will be installed in the pathology Laboratory Information Management System (LIMS) at each participating centre. This algorithm will conform to the NHS England algorithm for the Early Detection of AKI (http://www.england.nhs.uk/wp-content/uploads/2014/06/psa-aki-alg.pdf) and ensure compliance with the category 3 (directive) patient safety alert issued by NHS England in July 2014 (http://www.england.nhs.uk/wp-content/uploads/2014/06/psa-aki.pdf). This algorithm will generate a pathology test result (called AKI Warning Stage) for each creatinine result that is consistent with a diagnosis of AKI. This test result will be sent to each hospital's results reporting system or patient management system as for any other biochemical test result, and in this way be communicated to the clinicians caring for that patient. The warning score will be accompanied by a text string giving advice to the clinician.
Local variation in enhancements to alerting process will be explored depending on capability (e.g. linkage to electronic prescribing or other more interactive alerting processes.). Each centre will decide locally as to whether AKI results will be telephoned to clinical areas, and at which stage of AKI this will occur.

5.2 AKI guidelines

Intranet guidelines for the diagnosis, management and referral of AKI will support the introduction of electronic detection at each centre. The number of hits on the webpage will be recorded (if possible) as one measure of AKI awareness. A sample guideline (that can be locally adapted) is included as an appendix.

5.3 Education package

Specific education programmes will be deployed as part of the intervention. This will have several components, including face to face teaching (both small and large groups) and e-learning. The programme will encompass the major acute medical and surgical specialities, all grades of clinician and other members of the health care team that provide care to patients with AKI. The number, type and audience of teaching sessions delivered will be recorded across each partner centre. Education materials already available in participating units will be reviewed and shared during the project set up period (e.g. e-learning package that be viewed at http://www.uhl-library.nhs.uk/aki/). Sample education materials are included as appendices.

5.4 Care bundle

An AKI care bundle will be introduced at each centre alongside the detection and education elements of the intervention. The care bundle in use in the lead centre will be shared and then adapted for use in each partner organisation. The care bundles will be configured locally but will be based upon the following principles:

- Structured way of improving the care of patients
- Set of small, straightforward, evidence-based practices – generally three to five in total
- Occur at the same timepoint and in the same location
- Have to occur in totality (i.e. completing four out of five actions is non-compliant): compliance will be scored as all or nothing
- Clear accountability to 'who owns it' and 'who delivers it'
- Use of 'measurement for improvement' approach to support introduction and ongoing usage

6 Statistical plan

6.1 Sample size estimation

Sample size calculations were performed by UK Renal Registry. Annual number of admissions for each institution were taken from HSCIC (total admissions across all partner organisations 434,000pa). A conservative assumption of AKI incidence of 2.5% of admissions and a mortality rate of 27.5% were made; in this setting a stepped wedge design with three month adoption periods would give >80% power to detect a relative reduction of 20% in 30d mortality. This is both clinically relevant (equating to 597 fewer deaths each year) and plausible.

6.2 Statistical methods

A full statistical analysis plan will be developed as a separate document.

7 Data handling and Record Keeping

7.1 Confidentiality

Information about patients will be kept confidential and managed according to the requirements of the Data Protection Act, NHS Calldicott Guardian, individual Trusts' IM&T Policy and the Health Research Authority. All audit data and hospital level patient outcome data will be stored on Trust password-protected computer/servers. Data transfer to the UKRR will occur within the UKRR's comprehensive governance framework that is already in place, and will contain only those specific data items that have given approvals by the HRA. Patients will not be identifiable from any reports or publications that arise from this project.

7.2 Source documents

Source documents will include:

- Electronic hospital admission data
- Hospital notes
- Laboratory reports and electronic reports that are generated using AKI warning score
- Paper copies of audit forms
- Run charts/SPC charts as appropriate

8 Ethical considerations

This project uses interventions consistent with minimum standards of care as per the NHS England AKI programme workstreams; Derbyshire Research Ethics Committee has designated this proposal as quality improvement and waived the requirement for formal ethical approval and individual patient consent. Transfer and collation of patient data by the UK Renal Registry (UKRR) is approved by the Health Research Authority under section 251 of the NHS Act 2006. Ethical approval for the qualitative evaluation of staff will be sought from the University of Bradford ethical committee.

9 Financial considerations

Funding will be provided by the Health Foundation (Scaling Up Improvement call).

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