

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (http://bmjopen.bmj.com).

If you have any questions on BMJ Open's open peer review process please email info.bmjopen@bmj.com

BMJ Open

Acute kidney injury electronic alerts: mixed methods Normalization Process Theory evaluation of their implementation into secondary care

Journal:	BMJ Open
Manuscript ID	bmjopen-2019-032925
Article Type:	Research
Date Submitted by the Author:	12-Jul-2019
Complete List of Authors:	Scott, Jason; Northumbria University Finch, Tracy; Northumbria University, Nursing, Midwifery and Health Bevan, Mark; Northumbria University Maniatopoulos, Gregory; Newcastle University, Institute of Health and Society Gibbins, Chris; Newcastle Upon Tyne Hospitals NHS Foundation Trust Yates, Bryan; Northumbria Healthcare NHS Foundation Trust Kilimangalam, Narayanan; Gateshead Health NHS Foundation Trust Sheerin, Neil; Newcastle University Kanagasundaram, Suren; Newcastle University, Institute of Cellular Medicine; Newcastle Upon Tyne Hospitals NHS Foundation Trust
Keywords:	Acute renal failure < NEPHROLOGY, Health informatics < BIOTECHNOLOGY & BIOINFORMATICS, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Nephrology < INTERNAL MEDICINE, QUALITATIVE RESEARCH

SCHOLARONE™ Manuscripts

Acute kidney injury electronic alerts: mixed methods Normalization Process Theory evaluation of their implementation into secondary care

Title Page

- Jason Scott,1* Tracy Finch,1 Mark Bevan,1 Gregory Maniatopoulos,2 Chris
- 8 Gibbins,³ Bryan Yates,⁴ Narayanan Kilimangalam,⁵ Neil S Sheerin,^{3,6} Nigel Suren
- 9 Kanagasundaram,^{3,6*}

- 11 ¹ Northumbria University, Newcastle upon Tyne, England
- 12 Institute of Health and Society, Newcastle University, Newcastle upon Tyne, England
- 13 Renal Services, Newcastle upon Tyne Hospitals NHS Foundation Trust, Newcastle upon Tyne,
- 14 England
- 15 ⁴ Northumbria Healthcare NHS Foundation Trust, Newcastle upon Tyne, England
- 16 ⁵ Gateshead Health NHS Foundation Trust, Gateshead, England
 - ⁶ Institute of Cellular Medicine, Newcastle University, Newcastle upon Tyne, England

- 19 *Corresponding author
- 20 Dr Jason Scott
- 21 Faculty of Health & Life Sciences
- 22 Northumbria University
- 23 Coach Lane Campus West
- 24 Newcastle upon Tyne
- 25 England
- 26 NE7 7XA
- 27 jason.scott@northumbria.ac.uk

Word count: 3,920

ABSTRACT

Objective

Around one in five emergency hospital admissions are affected by acute kidney injury (AKI). To address poor quality of care in relation to AKI, electronic alerts (e-alerts) are mandated across primary and secondary care in England and Wales. Evidence of the benefit of AKI e-alerts remains conflicting, with at least some uncertainty explained by poor or unclear implementation. The objective of this study was to identify factors relating to implementation, using Normalization Process Theory (NPT), which promote or inhibit use of AKI e-alerts in secondary care.

Design

Mixed methods combining qualitative (observations, semi-structured interviews) and quantitative (survey) methods.

Setting and participants

Three secondary care hospitals in North East England, representing two distinct AKI e-alerting systems. Observations (>44 hours) were conducted in Emergency Assessment Units (EAUs). Semi-structured interviews were conducted with clinicians (n=29) from EAUs, Vascular or General Surgery, or Care of the Elderly. Qualitative data were supplemented by NoMAD surveys (n=101).

Analysis

Qualitative data were analysed using the NPT framework, with quantitative data analysed descriptively and using Chi Square and Wilcoxon Signed Ranks Test for differences in current and future normalization.

Results

Participants reported familiarity with the AKI e-alerts but that the e-alerts would become more normalized in the future (p<0.001). No single NPT mechanism led to current (un)successful implementation of the e-alerts, but analysis of the underlying sub-constructs identified several mechanisms indicative of successful normalization (*internalization*, *legitimation*) or unsuccessful normalization (*initiation*, *differentiation*, *skill set workability*, *systematization*).

Conclusions

Clinicians recognised the value and importance of AKI e-alerts in their practice, though this was not sufficient for the e-alerts to be routinely engaged with by clinicians. To further normalize the use of AKI e-alerts, there is a need for tailored training on use of the e-alerts and routine feedback to clinicians on the impact that e-alerts have on patient outcomes.

Key words

Acute kidney injury, Normalization Process Theory, Implementation, Mixed methods, Human factors, Patient safety

ARTICLE SUMMARY

Strengths and limitations

- This is the first known mixed methods study to use Normalization Process Theory to investigate the implementation of AKI e-alerts, providing a unique lens on their implementation
- The study was conducted in clinical areas where AKI incidence is high; it is unknown whether the e-alert would be more useful (and whether it would be more or less poorly implemented) in clinical areas where AKI incidence is lower.
- The study was also conducted in one region, and so implementation of the AKI e-alert may have been influenced by local networks.
- It is unknown whether the e-alerts had a quantifiable impact on AKI outcomes or staff actions, and so it is not possible to draw conclusions about the effectiveness of the AKI e-alerts studied as a result of implementation.

INTRODUCTION

Acute kidney injury (AKI) affects around one in five emergency hospital admissions.¹ AKI is both dangerous, with around 15,000 excess deaths in National Health Service (NHS) England inpatients per year,² and costly, imposing an estimated additional financial burden on this system of £1.02 billion per annum.² Increasing age and co-morbidity in the hospital population has increased the number of patients at risk from the condition, which is only likely to rise further with an ageing population. AKI care itself is often poor, with systematic failings in its recognition and management, and frequent omissions of even the basics of care.³

AKI alerting systems are mandated for all NHS England primary and secondary care providers, using a biochemical detection algorithm.^{4,5} The algorithm, which appears to perform with a high degree of sensitivity (>90%),⁶ has resolved ambiguities in modern diagnostic criteria⁷ around how to interpret baseline serum creatinine (SCr), a historical impediment to the standardisation of automated AKI detection. The exact nature of the AKI alerts is not, however, dictated, and may take a number of forms.

The efficacy of AKI electronic alerts (e-alerts) is limited and has not shown consistent benefit⁸ in terms of reduced mortality or use of renal support, or positive impacts on processes of care,⁹ which may be the result of alert fatigue^{6,10} or disrupted workflow.¹⁰ Inadequate implementation can explain the poor outcomes, particularly as there are some examples of improved care processes¹¹ and treatment outcomes through successful implementation.¹²⁻¹⁴ Mandatory incorporation of AKI alerts into all secondary care organisations in England lacked a clear implementation strategy, and recently published systematic reviews recognised large variation in implementation,¹² with an association between poor implementation and poor outcome.⁹ One review specifically identified a paucity of research on the implementation of AKI alerts internationally.⁹ To address this paucity of research, the present study aimed to identify factors relating to implementation which promoted or inhibited use of AKI e-alerting systems in secondary care.

METHODS

This study incorporated mixed methods to investigate the implementation of AKI alerts from multiple perspectives, including observations, surveys and semi-structured interviews. Normalization Process

Theory (NPT)^{15,16} was chosen as the theoretical basis for the study as it is an internationally recognised theory of implementation that has been used to explain successful and suboptimal implementation in over 100 healthcare initiatives.¹⁷ NPT therefore provides the explanatory power for understanding how complex interventions, such as AKI alerts, become integrated into existing practice through individual and collective implementation. This integration is proposed to occur via four mechanisms: 'Coherence': how people make sense of what needs to be done, 'Cognitive participation': how relationships with others influence outcomes, 'Collective action': how people work together to make practices work, and 'Reflexive monitoring': how people assess the impact of the new intervention. The four constructs are operationalised under 16 sub-constructs, which are described in table 1.

Table 1: Description of NPT mechanisms and sub-constructs

Coherence

Differentiation: How participants understand a set of practices and their objects to be different (or not) from each other.

Communal specification: Extent to which participants have a shared understanding of the aims, objectives, and expected benefits of a set of practices.

Individual specification: How participants understand their own specific tasks and responsibilities around a set of practices.

Internalization: How participants perceive the value, benefits and importance of a set of practices.

Cognitive Participation

Initiation: Whether or not key participants are working to drive a new set of practices forward.

Enrolment: The extent to which participants organize or reorganize themselves and others in order to collectively contribute to the work involved in new practices.

Legitimation: The work of ensuring that other participants believe it is right for them to be involved in the new set of practices, and that they can make a valid contribution to it.

Activation: The work that participants do collectively to define the actions and procedures needed to sustain a new practice and to stay involved.

Collective Action

Interactional Workability: The interactional work that people do with each other, with tools/systems, and with other elements of a set of practices, when implementing a new practice.

Relational Integration: The work that is needed to build accountability and maintain confidence in a set of practices and in each other as they use them.

Skill set Workability: The allocation of work amongst participants with different roles and skills in relation to the new set of practices.

Contextual Integration: The work of managing a set of practices through the allocation of different kinds of resources and the execution of protocols, policies and procedures to support the practices.

Reflexive Monitoring

Systematization: The work undertaken by participants to determine how effective and useful the new set of practices is for them and for others, and the information collected to enable this.

Communal appraisal: The work undertaken by participants collectively (sometimes in formal collaboratives, sometimes in informal groups) to evaluate the worth of a set of practices.

Individual appraisal: Individual participants' own appraisals, based on their experiences, of the effects of a new set of practices on them and the contexts in which they are set.

Reconfiguration: The extent to which appraisal work by individuals or groups may lead to respecification or modification of the set of practices.

Sampling and recruitment

Three NHS Trusts in North East England were invited to take part in the study based on being within a single NHS Trust's renal department catchment area, and the catchment area for referral for complex AKI (see table 2 for a description of Trusts and their AKI e-alerting systems). Three clinical areas were purposively chosen for study at each NHS Trust based on anticipated high levels of AKI incidence; (1) Emergency Admissions, (2) Internal Medicine/Care of the Elderly, and (3) General/Vascular Surgery.

Table 2: Characteristics of participating NHS Trusts and their AKI electronic alert. See Additional files 1 and 2 for images of the alerting systems.

NHS Trust	Trust Characteristics	AKI electronic alert
Trust 1	University-affiliated, 1800 bed, multiple site tertiary referral hospital; contains regional renal unit, transplantation, cardiothoracic and hepato-biliary surgery as well as other major specialisms; The Renal Unit is based at one Trust site and although providing consultative input to	Passive electronic alert consisting of a line of black text appearing underneath serum creatinine results in the patient's electronic medical record (<i>Powerchart, Cerner Millennium, Cerner Corporation,</i> Kansas, MO, USA) which stated the stage of AKI where present.
	the rest of the Trust, has no routine, on- site presence at these venues which include the emergency admissions suite and significant sections of general surgical, internal medical and elderly care services.	Additional pop-up electronic alert that appeared when accessing the patient's electronical medical record, and required dismissal to remove from the screen. A 'more info' link on the pop-up window, if clicked, took the end-user to a second window that contained further links to the Trust AKI protocol and specific guidance on aspects of management including essential assessments, key bedside observations & key investigations. The latter linked to quick order test panels including essential blood tests and urgent renal ultrasound requesting.
Trust 2	Multi-site university-affiliated district general with approximately 900 beds. All acute services on one site with internal medicine, elderly services, general and orthopaedic surgery along with obstetrics and paediatrics. Renal replacement provision from critical care. Renal input,	Passive electronic alert consisting of a line of black text appearing underneath serum creatinine results in the patient's electronic medical record (TelePath Information Management System, Mill Systems Limited, Belper, UK) which stated the stage of AKI where present.
	provided from Trust 1 by remote consultation, no renal consultant presence within the trust.	Alert does not link with any other hospital information system, but instructs users to access local AKI guidelines.
Trust 3	District general hospital with 300 beds in medicine. Renal input is from Trust 1 through a combination of remote consultation and weekly availability at the time of an out-patient clinic on site.	Passive electronic alert consisting of a line of black text appearing underneath serum creatinine results in the patient's electronic medical record (Medical Information Technology (MEDITECH) Inc., Westwood, MA, USA) which stated the stage of AKI where present.
		Alert does not link with any other hospital information system, but instructs users to access local AKI guidelines.

Participants for semi-structured interviews were purposively sampled based on specialty and clinical experience (determined by grade). Participants were invited through direct contact by JS, or by leaving contact details after completing a survey. Recruitment to survey was conducted through direct contact by JS, or electronically via an internal email by (or on behalf of) the lead consultant for the clinical specialty. Teaching sessions at Trust 3 were also used to invite staff to participate in the survey. Access to observe practice on emergency admission units was facilitated by the lead consultant(s) for the unit.

Data collection

Semi-structured interviews were conducted by a male research associate, JS (PhD), with participants in their place of work or via telephone between May 2017 to September 2017, and lasted an average of 26 minutes (range 17 to 41). A topic guide (see supplementary materials) was constructed by the research team based on the four mechanisms of NPT (coherence, cognitive participation, collective action, reflexive monitoring; see table 1) and from previous qualitative work on implementation of AKI alerts. ¹⁰ In addition to questions based on the four NPT mechanisms, the topic guide also included questions about the participants' clinical experience (job role, length of time in role, experience in other roles) and their experience with AKI alerts. Ethnographic data were obtained by observing practice in emergency admission units, guided tours, shadowing of staff, and informal conversations and handover meeting attendance. Observational data were documented in fieldnotes.

The Emergency Admission Units function to provide early assessment of adult patients referred via their general practitioner or the emergency department. One of the units (Trust 3) was a hybrid Emergency Admission Unit and Acute Medicine ward. A total of 44.25 hours of observations were conducted at various times of day (morning, afternoon and evening) during the working week (Monday to Friday).

The NoMAD survey,¹⁸⁻²⁰ a validated instrument for measuring implementation,²¹ was adapted for use with AKI alerts (see supplementary materials). Questions were added to identify characteristics of respondents, including:

- Profession
- Grade
- Years since obtaining primary medical qualification
- Years working in the Trust
- Years working in the department
- Formal or informal AKI training received in previous 24 months
- AKI initiatives to improve awareness of AKI other than alerts

In addition, five questions from the Hospital Survey on Patient Safety Culture™ (SOPS™; version 1.0)²² were included. SOPS™ contains a construct containing four questions titled 'Overall perceptions of patient safety'. All four questions from this construct were included, along with an overall patient safety grade. Paper and electronic versions of the study survey were made available to potential participants. All data collection was conducted after the AKI alerts had been implemented into practice for at least one year.

Data analysis

Framework analysis was used for qualitative data, ²³ with the four NPT mechanisms and their subconstructs forming the framework (see table 1). For interview data, one interview transcript was jointly charted by JS and TF, with interpretations of the data discussed until agreement was reached. This discussion familiarised JS with the differential meanings underpinning the 16 sub-constructs for subsequent analysis of qualitative data, as TF is an expert in NPT as a co-developer of the theory. ^{22,23} JS then charted the remaining interview data into the framework. For observational data, in-depth observer notes were summarised by the observer (JS), then all observation data were charted into the framework jointly with TF.^{15,16} NVivo software (*QSR International Pty Ltd, version 10*) was used to facilitate coding of qualitative data. Once initial analysis was complete, all authors reviewed and

discussed the coding in a team meeting before coming to agreement on the final interpretations, which is an established process of qualitative data analysis.²⁴ Participants were not invited to comment on findings.

IBM SPSS Statistics for Windows (*IBM Corp, version 24.0*) was used for quantitative analysis. Inferential statistics (chi square) were used to compare patient safety culture between NHS Trusts and specialties to identify whether safety culture could influence the subsequent analysis. Wilcoxon Signed Ranks Test was used to analyse differences in current and future normalization of the alerts. Survey items relating to the four NPT mechanisms were then analysed by examining descriptive statistics for each of the four mechanisms. Mechanism scores for each participant were created by taking their average score in each mechanism and dividing by the number of valid responses, which stopped data from being skewed where respondents stated a question was not applicable. Higher scores represent better perceived implementation in relation to each mechanism. Data were then triangulated by exploring (dis)agreements and silences across the qualitative and survey data sets through discussion amongst the research team.

Patient and public involvement

There was no patient and public involvement in this study.

RESULTS

Semi-structured interviews were conducted with 29 staff members. 28 interviews were with doctors, and one interview was with a pharmacist involved in implementing AKI alerts at Trust 1. The survey was distributed to 157 staff, and 102 (65%) responded. 94 (92.2%) completed the paper version, and eight (7.8%), the online version. See table 3 for a summary of interview participants and survey respondent characteristics. Table 3 also acts as a key to participants' grades, which is used to infer level of experience (grades are competency based) and is also used in the reporting of qualitative data. One survey was excluded as the participant reported on an alerting system at an NHS Trust not included in the study, leaving a final sample of 101.

Table 3: Participant characteristics of interviews and survey

Characteristic	Interview participants	Survey respondents
Job grade	N (%)	N (%)
Foundation doctor year 1 (F1)	9 (31.0)	16 (15.8)
Foundation doctor year 2 (F2)	4 (13.8)	25 (24.8)
Specialty registrar doctor year 1/2 (ST1/2)	4 (13.8)	23 (22.8)
Specialty registrar doctor year 3/4/5 (ST3/4/5)	3 10.3)	10 (9.9)
Specialty registrar doctor year 6/7 (ST6/7)	2 (6.9)	4 (4.0)
Staff grade doctor	0 (0)	5 (5.0)
Consultant	6 (20.7)	15 (14.9)
Nurse (band 6)	0 (0)	1 (1.0)
Other	1 (3.4)*	2 (1.0)†
NHS Trust	N (%)	N (%)
Trust 1	11 (37.9)	30 (29.4)
Trust 2	8 (27.6)	60 (58.8)
Trust 3	10 (34.5)	11 (10.8)

Department	N (%)	N (%)
Internal Medicine/Care of the Elderly	10 (34.5)	46 (45.5)
Emergency Admission	8 (27.6)	26 (25.7)
General / Vascular surgery	10 (34.5)	20 (19.8)
Other	1 (3.4)‡	9 (8.9)§

- * Pharmacist
- † Medical student=1, Locum Senior House Doctor=1
- 224 ‡ Pharmacy

§ Palliative care=4, Acute medicine=2, Cardiology=1, ITU=1, Nephrology=1.

Patient safety

Overall patient safety culture, graded on a Likert scale from 1 (very poor) to 5 (excellent), had a mean score of 3.75. A chi-square analysis comparing the three NHS Trusts identified no significant difference in patient safety culture (χ 2=1.784, df=2, p=0.410). Using the same method, there was also no significant difference between the specialties surveyed (χ 2=1.453, df=3, p=0.693). These results indicated that different sites or specialties did not confound the analysis.

Familiarity and perceived normalization

Participants reported that they were mostly familiar with the e-alerts (mean=7.27, sd=2.562) and that the alert was part of their normal work (mean=7.28, sd=2.649). However, it was reported that the alerts would become a more normal part of their work (mean=8.32, sd=2.059), with a Wilcoxon Signed Ranks Test confirming the difference was statistically significant (Z=-5.049, p<0.001), suggesting that the alerts were not yet fully embedded.

NPT mechanisms and sub-constructs

Descriptive analysis of the mean scores of the four NPT mechanisms – coherence (\bar{x} =72.3%), cognitive participation (\bar{x} =66.4%), collective action (\bar{x} =66.5%) and reflexive monitoring (\bar{x} =68.8%) – suggested there was no key mechanism that led to (un)successful implementation of the alerts. Further analysis of the 16 sub-constructs (table 1) identified several sub-constructs indicative of (un)successful implementation; mean ratings for the 16 sub-constructs are presented in figure. More specifically, following triangulation with qualitative data, the NPT sub-constructs that were identified to contribute to successful normalization of the AKI alerts were *internalization* and *legitimation*, and those that contributed to unsuccessful normalization were *initiation*, *differentiation*, *skill set workability*, and *systematization*. As with the survey data, there were no identified differences in qualitative findings between the two alerting systems. Supporting qualitative data (quotes and field notes) for all sixteen sub-constructs are provided in table 4. The remainder of the results will focus on where there were identified (dis)agreements and silences within the dataset as a result of the triangulation.

[Insert Figure 1 around here]

Differentiation

How clinicians differentiated the AKI alert from what was deemed to be normal practice prior to the implementation of the AKI alert, was often based upon the length of time that the clinician had been qualified. Clinicians who were newly qualified, particularly foundation-year doctors, consistently

reported that they had no experience of working without an alerting system, and so using the AKI alert by default was deemed to be normal practice.

"I suppose I haven't ever realised it's actually a new thing. Obviously, I've only worked here 11 months, I just assumed it was always there" [F1 interview, General/Vascular Surgery, Trust 3]

Contrary to this, observations identified instances where clinicians were unaware of an alert for AKI, or were unaware of how the alert should work. In the following extract from observation notes, the clinician initially conceived of an alert as always being a pop-up, rather than text embedded into the system.

'I chat with [a doctor] and we talk about the AKI alerts. When I explain what it is I'm observing for, he looks a bit confused, says he doesn't know about the alerts. He opens up a patient record and explains he thinks this patient has AKI, so wants to see if there is an alert there. After I describe what the alert should look like, he says he thought I meant "a pop-up rather than a bit of text"; I think he doesn't see the text as an alert by itself.' [Trust 3 observation of Emergency Admissions, approx. 17:00]

Clinicians also identified that the lack of differentiation was related to the clinical area in which they were working. For instance, it was deemed to be routine to check renal function of all patients entering emergency admission suites. In this setting, clinicians often mentally risk-assessed patients for AKI. For these patients, the clinicians would more regularly check to see if blood test results had been returned.

"At the moment, probably not an awful lot else than I would normally do. Normally if I go through people's bloods specifically for renal function I usually click on each of the numbers and compare it to what it has been previously. I think I interpret renal function quite a lot in the context of what the patient's renal function IS? Or [sic] usually like. I click on each of the five elements that we get reported here and then have a look at how that varies from the previous. To be honest I would do that irrespective of whether the alert is there or not." [ST1 interview, Emergency Admissions, Trust 3]

Internalization

Clinicians often reported that, despite not always utilising the AKI alert, they valued the potential of it, which was reflected in the survey score of 4.16. This demonstrated that they had a fundamental understanding of the importance of recognising AKI early, and many clinicians recognised that it was possible to make mistakes and to miss AKI.

"in something like renal function, where there's so much variety, [the AKI alert] just helps jolt you to it and especially how severe AKIs can be, it's even more necessary because hopefully things like that wouldn't be missed, but there's always the potential that it could be. And having it say in black and white, this is an AKI, you

know, they shouldn't be missed at all." [F1 interview, Emergency Admissions, Trust 2]

"The times I think it's probably useful is when it's one of those slightly sneakier ones, more subtle ones. The creatinine might have only peaked at 120 but, actually, if their creatinine is normally 45, that's still a big deal but it doesn't jump out at you as a creatinine of 600 would." [Consultant interview, Internal Medicine/Care of the Elderly, Trust 2]

Initiation

Initiation received a mean score of 2.8. This remained consistent across all three Trusts, and was supported by interview participants who consistently reported that either the alerts "just appeared at some point" [F1 interview, General/Vascular Surgery, Trust 3], or that the alerts were already implemented when they began working for the Trust, as identified in the differentiation theme. However, there was a key difference; even where alerts were already implemented and thus deemed to be 'normal', where a lack of training was provided to clinicians on how to use the alerts. This finding was consistent (and is partly duplicated) with the skill set workability sub-construct of NPT.

"I think [the AKI alerts] just started popping up. So, we didn't get any training or anything like that on them, or why they were there, or who put them there, or what the purpose was." [ST2 interview, Internal Medicine/Care of the Elderly, Trust 1]

In one Trust, the person who contributed to the implementation of the AKI alerts acknowledged this sub-optimal initiation or training for doctors; "When we first went live we switched the rules on but we didn't really do a lot of education, and I think [the alerts] were relatively unpopular" [Pharmacist interview, Trust 1]. Education consisted of an email with information about the AKI alerts to clinical directors asking them to cascade it to their staff.

Legitimation

Despite the lack of initiation, perceived or otherwise, clinicians still largely understood that responding to the AKI alerts was their responsibility, though this was moderated by the clinician's seniority. For instance, all clinicians regardless of seniority recognised that the AKI alert was important to the work of junior doctors. In particular, some senior staff (consultants and registrars) felt that junior staff did not place sufficient priority on renal function; "For [junior staff] it might make a difference because they might not look at all the figures. If it says an AKI alert, then they might make the effort to actually do that" [ST6 interview, General/Vascular Surgery, Trust 3]. However, particularly on surgical wards where foundation-year doctors were mostly responsible for ward-care of patients, the alerts were not seen to be part of the senior doctor's role, even though the AKI alerts were still valued.

"I think you'll find that as people progress, their focus of how they manage the patient shifts. They're more interested in dealing with the active problems and these outcomes of quite secondary issues that solve around the problem. The attitude is a bit like mine: someone more junior will deal with it and you totally lose interest in the other things." [ST3 interview, General/Vascular Surgery, Trust 3]

Skill set workability

The lack of training provided on how to use the alerts, as previously reported in the initiation theme, also contributes to the skill set workability theme. Participants reported that they generally had responsibility for AKI and thus the alerts, demonstrating to an extent that that there was appropriate skill set workability amongst those receiving the alerts. However, there were also occasions where participants demonstrated or recognised their own lack of knowledge related to the AKI alerts such as incorrectly describing how they thought the alerts worked. More specifically, participants regularly did not know how the alerts should be incorporated into their own practice.

"A teaching session would be really good of explaining, like, how to use the alert, like, the situations when the alert isn't effective and, then, just, kind of, what to do if you do get an alert." [Consultant interview, Internal Medicine/Care of the Elderly, Trust 2]

Systematization

Across all three of the NHS Trusts, no participants (regardless of seniority) collected information on the effectiveness of the AKI alert. While the data collected did not indicate whether anyone in the Trusts collected information regarding the effectiveness of the AKI alerts, it was consistently reported by all interview participants that feedback was not given to those using the AKI alerts. Furthermore, participants were unaware of whether the AKI alert, or more specifically responding to the AKI alert, had any effect.

"I think maybe a bit of feedback or a bit of education [would help staff to engage with the AKI alert]. So, feedback as to how things had changed since the alert was introduced. [...] Some sort of outcome measure would be quite interesting. That might, just to show people that it's actually having a benefit." [Consultant interview, Internal Medicine/Care of the Elderly, Trust 1]

Table 4: Summary of the qualitative framework analysis for the 16 NPT sub-constructs with supportive evidence

NPT mechanisms and sub-constructs	Coding summary	Supporting evidence
Differentiation Mean survey score: 3.18	Clinicians often did not differentiate between normal practice and use of the AKI alert; checking the patient's renal function was deemed to be routine in the clinical areas studied.	'A doctor says that it's a routine part of their job to check renal function and would check it anyway – this is the case even in the emergency department if a patient came in with a broken arm to check for a potential underlying condition' [Trust 1 observation of Emergency Admissions, approx. 19:30]
Communal specification Mean survey score: 3.29	Working with the AKI alert was perceived to be an individual rather than team action. The alert was rarely discussed or used to initiate discussion, with staff often not	"I don't think we've had much discussion about the AKI alerts, it's certainly not something that I'm aware of, that other people have commented on." [F1 interview, General/Vascular Surgery, Trust 2]
	knowing what others thought about the alert.	"I haven't spoken to anyone else [about the AKI alert]. I know just from being in the doctor's office, with the other doctors that sometimes, you know, you see people glance at the screen, and go 'click'

		whilet they are still talking to you " [ST3 interniers
		whilst they are still talking to you." [ST2 interview, Internal Medicine/Care of the Elderly, Trust 2]
Individual specification Mean survey score: 3.8	AKI alerts often made staff consider the patient's AKI and to double check renal function.	"I guess it's to draw attention to it quickly rather than bloods getting lost in the system for the day, because especially on a busy ward [] there'll be I don't know 20 bloods sent in the morning and then if you're busy with sick people it could go well into the afternoon before you get to check on bloods." [F1 interview, Emergency Admissions, Trust 2]
Internalization Mean survey score: 4.16	Many staff saw the potential value of the AKI alert and understood the need for the alerts.	"I think it's probably the most useful out of the alerts. It generally comes on when the patients genuinely do have an AKI, although, that's often sometimes not the case. Like we said before, often it does require action, so, yes, they're pretty useful." [F1 interview, Emergency Admissions, Trust 1]
Initiation Mean survey score: 2.8	Participants frequently cited a lack of initiation in relation to the AKI alerts. This occurred for one of two reasons; 1) the alerts just appeared without any training on how to use them, or 2) clinicians were newly qualified (or new to the Trust) and the alerts were already implemented, but again no was training provided.	"Yes they just sort of bob up. We never had really any induction about them" [F1 interview, General/Vascular Surgery, Trust 3]
Legitimation Mean survey score: 4.16	For the more junior doctors, the alerts are perceived to be a legitimate part of their role. However for more senior doctors, particularly in surgical units, the alerts were a useful intervention but only for junior doctors. Some clinicians felt that there should be a specialist AKI nurse.	"we have specialist nurses who provide input for absolutely everything. So, the idea that there isn't one for an AKI, is a bit silly, in my opinion. Because, somebody coming their purpose in my opinion would be to come around, read what they are in for, review their pathology, review the patient, and review reversible factors. Then make a recommendation to the junior and the consultant about reversible factors that hadn't been looked at yet." [ST1 interview, Internal Medicine/Care of the Elderly, Trust 2]
Enrolment Mean survey score: 4.24	As working with the AKI alert was an individual action, it often had no influence on working relationships. For the few clinicians who saw the relational value, it was beneficial by providing the AKI stage that could be easily reported.	"if one of the F1's came to me and said, 'this woman's creatinine has gone up', then yes, absolutely we would have a chat about meds, and fluid, and have they had an ultrasound scan, and what do you think we should do? But, I don't think the alert has ever prompted me to do that" [ST2 interview, Internal Medicine/Care of the Elderly, Trust 1]
		"It's good if you're doing a handover on the phone or something or talking to seniors in critical care or other hospitals. You can say this is Stage 2 AKI and that is sort of a standard term that people do understand even if we don't use it in general day-to- day discussion in the notes as much as we should do." [F1 interview, General/Vascular Surgery, Trust 3]
Activation Mean survey score: 4.06	Prolonged exposure to the AKI alerts impacted upon clinician's support for them; the alerts had more impact when new, but they became part of	"Yes, I do actually. I think it's a big component of patient safety and I think it is the direction of travel of where we're going. As time goes on, looking forward, I think we're going to expect more and

	the milieu and lost amongst other alerts or working practices.	more of these alerts related to algorithms and severity." [Consultant interview, Emergency Admissions, Trust 1]
Interactional workability Mean survey score: 3.98	It was generally deemed easy to integrate the AKI alerts into normal working practices; they are there as a 'check' or 'backup' as most clinicians were routinely checking renal function. The alerts were perceived to speed up the process of calculating the stage of	"I think if it's not someone I already know, then yes, the alerts at least make me glance at the U&Es, which I would do anyway, but you know, just an extra reminder to check back what their previous U&Es were." [ST7 interview, Emergency Admissions, Trust 1]
	AKI. Alerts are seen to be useful where Creatinine was within normal range, but with an increase of >1.5 from baseline.	"I think in some ways, it probably does speed things up, because you have got that alert there, and I think, when you open up a page of bloods, and it's quite obvious, and the first thing you see is they have an AKI." [ST3 interview, Emergency Admissions, Trust 3]
Relational integration Mean survey score: 3.67	The AKI alert did not appear to affect working relationships. Staff mostly do not refer to the alert when discussing AKI, and AKI care is often an isolated task. An exception is stage 3 alerts, which sometimes trigger discussions with renal services.	"I don't know about the other staff and how they engage because actually I've not had a lot of feedback from them. I haven't actually been hearing the juniors saying, 'Oh there was an AKI alert' on anyone so I suspect most of them are just clicking and moving on, dismissing and moving on because they probably already know what the creatinine's doing." [Consultant interview, General/Vascular Surgery, Trust 1]
Skill set workability Mean survey score: 3.27	There was a lack of training on how to best use the AKI alerts (also reported in <i>initiation</i>), and some clinicians demonstrated a lack of understanding about AKI, particularly the meaning of the different stages.	"when you come to the Trust you get- I don't know how long the sessions are and I don't know what they cover, and I don't know whether they cover alerts and things like that. If they do have [AKI alert training], I suspect it comes at the end of a very long day of induction where they've been told about every single problem under the sun and they've probably switched off." [ST7 interview, Emergency Admissions, Trust 1]
		"And there's [AKI stages] 1, 2 and 3, I can't really remember the difference between the three of them but if it flags up something I go, 'oh, okay, there's something different here.'" [F1 interview, General/Vascular Surgery, Trust 3]
Contextual integration Mean survey score: 3.32	Clinicians did not report any specific resource requirements for the AKI alert other than training and time. Management support (where considered in the capacity of those responsible for alerts; the laboratory) was not identified by participants.	"I've no idea [who has responsibility for the AKI alerts], no. I assume somebody will do but I don't know, it's not been communicated." [F1 interview, General/Vascular Surgery, Trust 3]
Systematisation Mean survey score: 2.5	Feedback was never provided to staff on the effect of the AKI alert.	"I haven't had any feedback since the new version [of the AKI alert] went in actually [] I don't know whether there is a formal mechanism for that getting to anyone." [Pharmacist interview, Trust 1]
Communal appraisal Mean survey score: 3.39	The alert was rarely (if ever) discussed amongst clinicians, but participants often stated they felt that others would find it worthwhile.	"Most people I'm sure would know it's a good idea having them. That's what I'd say to someone about these alerts." [Consultant interview, Emergency Admissions, Trust 1]

Individual appraisal	Whilst a small minority of clinicians felt the AKI alert had no effect on their	'Speaking to a doctor, they felt that the AKI alerts are very useful. He says that if he sees an alert then he'll
Mean survey score: 3.52	work, many did but placed the effect within constraints relating to edgecase scenarios where AKI was most likely to be missed. These included marginal AKI thresholds within 'normal Cr range', busy workloads, and AKI presenting in CKD patients. The pop-up alert was sometimes perceived to be intrusive, whilst the passive alert was often described as being too easy to dismiss.	check the patient's renal function. He also explains that things at handover will often get missed so doesn't always know that the patient will have an AKI' [Trust 1 observation of Emergency Admissions, approx. 19:45]
Reconfiguration Mean survey score: 3.89	Clinicians often did not know who was responsible for the AKI alert. They would never consider providing feedback about the alert, and there	"I'm not sure if there is a feedback mechanism. If there is, I'm not aware of it." [F1 interview, Emergency Admissions, Trust 1]
	was no formal mechanism for doing so.	"[To provide feedback] I would ring IT and they would probably be very unhelpful and I would give up at that point." [ST2 interview, Internal Medicine/Care of the Elderly, Trust 1]

DISCUSSION

This is the first known mixed methods study to use Normalization Process Theory to investigate the implementation of AKI e-alerts,¹⁷ an area identified as being an international research priority.⁹ The findings of this study suggest that AKI e-alerts are somewhat embedded into routine practice in the English NHS Trusts studied, with several aspects of implementation indicative of successful or unsuccessful normalization. Using the AKI e-alert was a legitimate part of clinician's role, with recognised potential benefits. This demonstrates an understanding of the importance of early AKI detection and treatment.²⁵ Despite this understanding, there were several areas where implementation could be improved.

Initiation to the e-alerts, such as via Trust-specific training, was lacking or of insufficient quality, demonstrated by a lack of knowledge about what differentiates the stages of AKI, and how the e-alerts were expected to be used. The definition of AKI has been refined considerably over the past decade, partly in an attempt to reduce variation in practice, 7,26 but our findings reflect previous studies which have identified gaps in AKI knowledge amongst medical staff.27 Although education is important in improving AKI care, 28 there is a gap between the objective volume of delivery of AKI teaching and endusers' perception of its paucity.27 This dissonance might also be consistent with an alternative interpretation to our findings, which is that the existing definition of AKI lacks intuition and/or clinical credibility. Clinicians in our study reported using the terms minor, moderate, or severe, even when they knew the different stages as per the 2012 KDIGO guidelines⁷ as they felt it easier to communicate to others. This corresponds closely with our finding, that some clinicians had difficulty in recognising and prioritising AKI e-alerts. Little research has focussed on how staff are educated about AKI e-alerts, but some tentative links have been made between effective education and successful implementation.29

Another area of implementation identified as needing improvement was the systematization of the AKI e-alerts through implementing feedback to end-users of the e-alerts. There was no system for

providing feedback to clinicians, despite a wide range of safety literature identifying the importance of providing this to people involved in the process.³⁰⁻³² NPT proposes that an intervention is normalized through agents' continuous actions which are enacted over a sustained period of time and space.³³ As approval ratings for AKI e-alerts have been reported to reduce over time, giving feedback to those involved in the safety behaviour could slow, pause or even reverse the decline,^{34,35} and can be a transformative process that can lead to improved performance.³⁶

Alert fatigue or disruptions to workflow have been identified as barriers to implementation,^{6,10} and there were examples of these identified in this study. Both e-alert systems produced opposing perspectives on how or whether the e-alerts influenced workflow. It was however common for those receiving the pop-up e-alert to dismiss it instantly and comment on its intrusiveness, whilst those who received the passive e-alert commented on it not being intrusive enough and being too easy to ignore. This suggests that there is no one-size-fits-all e-alert presentation, and instead they may require tailoring to either the individual or clinical unit. However, the causes of these differing perspectives were unclear and require further research.

It was also notable that collaborative working in response to the AKI e-alert were dismissed or downplayed by participants. Implementation of a complex intervention, or of a simple intervention into a complex environment, requires social activity that results in joint action; agents' continuous actions are enacted over a sustained period of time and space.³³ Using and incorporating the e-alert into practice was often perceived to be an individual action that did not result in or alter discussions amongst clinicians. Future research should investigate whether the individual nature of an intervention, such as AKI e-alerting, contributes to poorer implementation, and whether such interventions require more collaborative working to be built-in to improve optimality.

CONCLUSIONS

Clinicians recognised the value and importance of AKI e-alerts in their clinical practice, though not sufficiently for AKI e-alerts to be routinely engaged with. To further normalize and promote clinician engagement with AKI e-alerting systems, there is a need for tailored training on AKI and how to use e-alerts; feedback should, also, be routinely given to staff about their impact on outcomes. The findings of this study provide a potential explanation for conflicting data on the reported effectiveness of AKI e-alerting systems. The findings have the potential to inform future national improvements to the way in which AKI e-alerts are implemented in the NHS and could be transferred into other countries' healthcare systems where AKI e-alerts have either not yet been implemented or where this has been suboptimal.

Declarations

Ethical approval and consent to participate

All participants provided informed consent to participate. Interview participants provided written consent. Consent for observations was provided verbally by the lead consultant of each unit and individuals being observed. Survey respondents provided consent by returning the survey. The project was reviewed and Approved by the National Health Service's Health Research Authority (https://www.hra.nhs.uk/) [reference 16/HRA/2106]. HRA Approval brings together the HRA's assessment of governance and legal compliance with the independent ethical opinion by a Research Ethics Committee. HRA Approval is for all project based research involving the NHS and Health and Social Care that is being led from England.

Consent for publication

Not applicable

Availability of data and materials

The quantitative datasets used and/or analysed during the current study are available from the corresponding author on reasonable request. Participants were not asked to provide consent to share their transcripts beyond the research team. The study team would be happy to interrogate the data on behalf of others upon reasonable request to the corresponding author.

Competing interests

NS received travel funding from Alexion Pharmaceuticals to attend ERA-EDTA 2018 congress. NS is also a grant holder for a project 'Imaging in Chronic Kidney Disease', funded by GlaxoSmithKline. No other authors have competing interests to declare.

Funding and Acknowledgements

This work was supported by funds from Northern Counties Kidney Research Fund (www.nckrf.org.uk). The funder had no role in the design and conduct of the study, including the collection, management, analysis, interpretation of the data, preparation, review or approval of the manuscript, and decision to submit the manuscript for publication.

Author contributions

TF, MB, GM, CB, BY, NK, NS, NSK conceived and designed the study. JS collected the data. JS, TF, GM and NSK analysed the data. JS and NSK drafted the manuscript, with all authors providing critical revisions and approval for the final version. JS and NSK agree to be accountable for all aspects of the work.

Acknowledgements

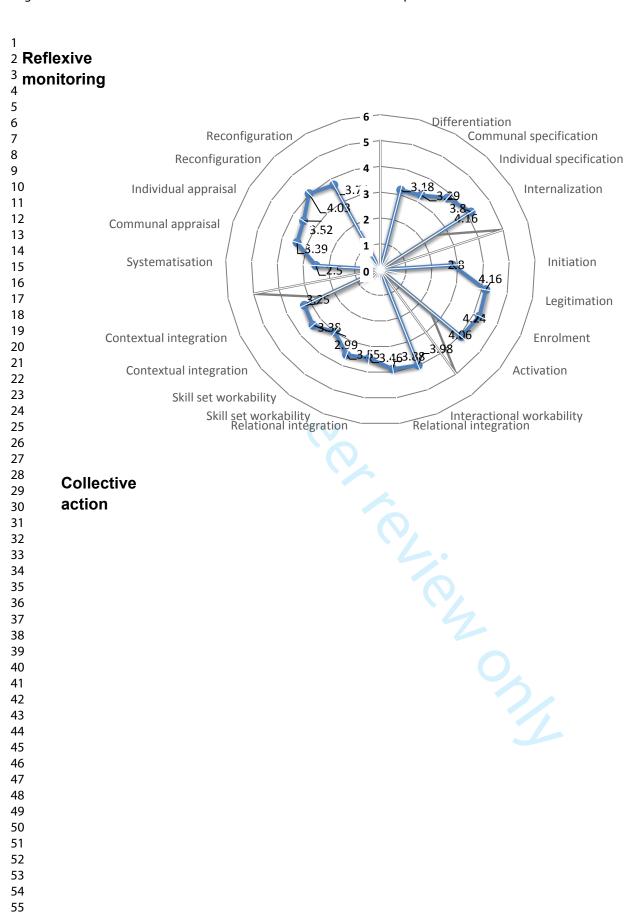
We would like to thank the NHS Trusts and departments for allowing us access, and the participants for giving their time.

References

 National Institute for Health and Care Excellence. Acute kidney injury: Prevention, detection and management of acute kidney injury up to the point of renal replacement therapy.
 National Institute for Health and Care Excellence; 2013.

- 490 2. Kerr M, Bedford M, Matthews B, O'Donoghue D. The economic impact of acute kidney injury 491 in England. *Nephrology Dialysis Transplantation*. 2014;29(7):1362-1368.
- 492 3. Stewart J, Findlay G, Smith N, Kelly K, Mason M. *Adding insult to injury: a review of the care*493 of patients who died in hospital with a primary diagnosis of acute kidney injury (acute renal
 494 failure). London: National Confidential Enquiry into Patient Outcome and Death; 2009.
- 495 4. Meyer J. Qualitative research in health care: Using qualitative methods in health related action research. *BMJ*. 2000;320(7228):178-181.
- 5. Selby NM, Hill R, Fluck RJ. Standardizing the Early Identification of Acute Kidney Injury: The NHS England National Patient Safety Alert. *Nephron.* 2015;131(2):113-117.
- Sawhney S, Fluck N, Marks A, et al. Acute kidney injury—how does automated detection perform? *Nephrology Dialysis Transplantation*. 2015;30(11):1853-1861.
- 7. KDIGO. KDIGO Clinical Practice Guideline for Acute Kidney Injury. *Kidney International Supplements*. 2012;2(1).
- 503 8. Kashani KB. Automated acute kidney injury alerts. *Kidney International*. 2018;94(3):484-490.
- 504 9. Lachance P, Villeneuve P-M, Rewa OG, et al. Association between e-alert implementation for detection of acute kidney injury and outcomes: a systematic review. *Nephrology Dialysis*506 *Transplantation.* 2017;32(2):265-272.
- 507 10. Kanagasundaram NS, Bevan MT, Sims AJ, Heed A, Price DA, Sheerin NS. Computerized clinical decision support for the early recognition and management of acute kidney injury: a qualitative evaluation of end-user experience. *Clinical Kidney Journal*. 2015;9(1):57-62.
- 510 11. Park S, Baek SH, Ahn S, et al. Impact of Electronic Acute Kidney Injury (AKI) Alerts With 511 Automated Nephrologist Consultation on Detection and Severity of AKI: A Quality 512 Improvement Study. *American Journal of Kidney Diseases*. 2018;71(1):9-19.
- 513 12. Haase M, Kribben A, Zidek W, et al. Electronic Alerts for Acute Kidney Injury: A Systematic S14 Review. *Deutsches Ärzteblatt International*. 2017;114(1-2):1-8.
- 515 13. Selby NM, Crowley L, Fluck RJ, et al. Use of Electronic Results Reporting to Diagnose and
 516 Monitor AKI in Hospitalized Patients. *Clinical Journal of the American Society of Nephrology*.
 517 2012;7(4):533-540.
- 518 14. Colpaert K, Hoste EA, Steurbaut K, et al. Impact of real-time electronic alerting of acute 519 kidney injury on therapeutic intervention and progression of RIFLE class*. *Critical Care Medicine*. 2012;40(4):1164-1170.
- 521 15. May C, Finch T. Implementing, Embedding, and Integrating Practices: An Outline of Normalization Process Theory. *Sociology*. 2009;43(3):535-554.
- 523 16. May CR, Mair F, Finch T, et al. Development of a theory of implementation and integration: 524 Normalization Process Theory. *Implementation Science*. 2009;4(1):29.
- 525 17. May CR, Cummings A, Girling M, et al. Using Normalization Process Theory in feasibility 526 studies and process evaluations of complex healthcare interventions: a systematic review. *Implementation Science*. 2018;13(1):80.
- 528 18. Finch TL, Rapley T, Girling M, et al. Improving the normalization of complex interventions: 529 measure development based on normalization process theory (NoMAD): study protocol. *Implementation Science*. 2013;8(1):43.
- Finch TL, Girling M, May CR, et al. NoMAD: Implementation measure based on Normalization
 Process Theory [Measurement instrument]. 2015; http://www.normalizationprocess.org.
 Accessed 12th April 2018.

- 20. Rapley T, Girling M, Mair FS, et al. Improving the normalization of complex interventions: part 1 - development of the NoMAD instrument for assessing implementation work based on normalization process theory (NPT). *BMC Medical Research Methodology*. 2018;18(1):133.
- 538 21. Finch TL, Girling M, May CR, et al. Improving the normalization of complex interventions: 539 part 2 - validation of the NoMAD instrument for assessing implementation work based on 540 normalization process theory (NPT). *BMC Medical Research Methodology*. 2018;18(1):135.
- 541 22. Agency for Healthcare Research and Quality (AHRQ). Hospital Survey on Patient Safety
 542 Culture. 2004; https://www.ahrq.gov/sops/quality-patient-safety/patientsafetyculture/hospital/index.html. Accessed 12 January 2017.
- 544 23. Gale N, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the 545 analysis of qualitative data in multi-disciplinary health research. *BMC Medical Research Methodology.* 2013;13(1):117.
- 547 24. Barbour RS. Checklists for improving rigour in qualitative research: a case of the tail wagging the dog? *BMJ*. 2001;322(7294):1115-1117.
- 549 25. Kolhe NV, Staples D, Reilly T, et al. Impact of Compliance with a Care Bundle on Acute Kidney 550 Injury Outcomes: A Prospective Observational Study. *PLoS ONE*. 2015;10(7):e0132279.
- Thomas ME, Blaine C, Dawnay A, et al. The definition of acute kidney injury and its use in practice. *Kidney International*. 2015;87(1):62-73.
- 553 27. Muniraju TM, Lillicrap MH, Horrocks JL, Fisher JM, Clark RMW, Kanagasundaram NS.
 554 Diagnosis and management of acute kidney injury: deficiencies in the knowledge base of
 555 non-specialist, trainee medical staff. *Clinical Medicine*. 2012;12(3):216-221.
- 556 28. Selby NM. Electronic alerts for acute kidney injury. *Current Opinion in Nephrology and Hypertension*. 2013;22(6):637-642.
- 558 29. Sykes L, Nipah R, Kalra P, Green D. A narrative review of the impact of interventions in acute kidney injury. *Journal of Nephrology.* 2017.
- 560 30. Benn J, Arnold G, Wei I, Riley C, Aleva F. Using quality indicators in anaesthesia: feeding back data to improve care. *British Journal of Anaesthesia*. 2012;109(1):80-91.
- 562 31. Macrae C. The problem with incident reporting. *BMJ Quality & amp; Safety.* 2016;25(2):71-563 75.
- Brún AD, Heavey E, Waring J, Dawson P, Scott J. PReSaFe: A model of barriers and facilitators
 to patients providing feedback on experiences of safety. *Health Expectations*.
 2017;20(4):771-778.
- 33. May C. Towards a general theory of implementation. *Implementation Science*. 2013;8(1):18.
- Wilson FP, Shashaty M, Testani J, et al. Automated, electronic alerts for acute kidney injury:
 a single-blind, parallel-group, randomised controlled trial. *The Lancet*. 2015;385(9981):1966 1974.
- 571 35. Oh J, Bia JR, Ubaid-Ullah M, Testani JM, Wilson FP. Provider acceptance of an automated electronic alert for acute kidney injury. *Clinical Kidney Journal*. 2016.
- Karsh B-T, Holden RJ, Alper SJ, Or CKL. A human factors engineering paradigm for patient
 safety: designing to support the performance of the healthcare professional. *Quality and* Safety in Health Care. 2006;15(suppl 1):i59-i65.



Internalization

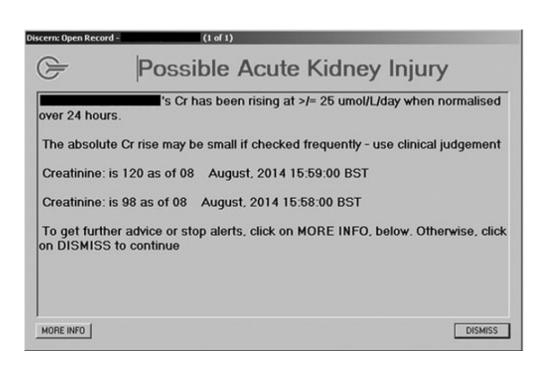
Initiation

Legitimation

Enrolment

Cognitive participation

Sodium		137	mmol/L	133 - 146
Potassium		4.4	mmol/L	3.5 - 5.3
Chloride		108	mmol/L	95 - 108
Bicarbonate	*	21	mmol/L	22 - 29
Urea	*	8.6	mmol/L	2.5 - 7.8
Enzymatic Creatinine	*	203	umol/L	49 - 90



Acute Kidney Injury Alert Study

Interview Questions

Themes:

- Coherence: Meaning-making sense of the technology and the work, differentiation, embedding
- Cognitive participation: Commitment-what is done to work with others
- Collective action: Effort-what is done whilst using this tool
- **Reflexive monitoring:** Comprehension- How the new technology affects them, others and patient care

Introduction

- Introduce myself and my role in the research
- Ensure information has been read and consent (x2) is signed and they retain a copy
- Ask the participant to briefly explain:
 - Who they are
 - O What they do (role) e.g. Dr (registrar etc.) nurse.
 - How long they have been on the ward
 - What other experience do they have, eg previous roles

Opening question

- Q Please describe your first/last encounter with the AKI alerts: this should provide a basis for further questions as it will point to aspects of his or her experience
 - O What sort of experience do you have of using AKI alerts?
- Q How do you currently use electronic alerts (not necessarily AKI) within the electronic record? Are some alerts more important than others? (if yes, what makes them so?)
- Q Use screen prints of each page to ask questions about user experience: ease of use, visual appearance, nuisance factors etc.
 - If appropriate make memos of facial expressions, hand gestures, non-verbals
 - Make memos in relation to comments for further questioning/investigation at the interview and/or subsequent participants.

List of potential (Not in order of importance) Normalization Process Theory-based questions as a reminder used on the basis of answers to the opening questions

Many descriptive and explanatory questions are used to elicit detail of actions, processes, outcomes and correlations. Some questions may overlap one or more theme.

Questions will develop given the kind of answer and may include questions not cited below.

Coherence Type Questions

- Q What do you understand as the purpose of the alerting tool? Is it important to the patient's safety? Why do you think the alerts have been implemented?
- Q Ideally, where do you think this tool should fit in to your daily work?

- Q How do others in your unit / clinical setting use the tool? From your own experience, is this specific to your clinical setting?
- Q From your perspective, how do AKI alerts compare to other alerts / computer tools
- Q How do you think you are expected to use the alert?
- Q What benefits/value do you think the alert provides?

Cognitive Participation type questions

- Q Who leads the use of this on your ward/unit? What does this role / task consist of for them? Does it include responsibility for AKI outcomes?
- Q How do the different professionals on the ward interact / use / respond to the alert? Do people have different roles / interactions with the alert depending on their profession / role?
- Q From your perspective, what would help staff to engage better with the alerting system?
- Q Have you shown others how to use it? If so, describe what you did and why. If not, why not?

Collective Action type questions

- Q Please describe what you do when you encounter the alert?
- Q Please explain how the tool helps/hinders working with others
- Q How does the alert affect how you work? Eg use of time and resources

Reflexive monitoring

- Q How does it make you feel when you see the alert?
- Q Would you say the alert is useful or not? Explain
- Q What do you think of the alert? (elicit a personal opinion)
- Q What do others say about it?
- Q To what extent do you and/or others have the ability to provide feedback / influence improvements to the system? What helps or hinders this ability?
- Q Has it altered the way you work/think about acute kidney injury?
- Q Does the alert effect change in medical management of the patient? Does this lead to a change in the patient's outcome?
- Q Is the alert worthwhile? Explain the answer
- Q Are there any improvements you would like to make to the system? Eg alert, interaction with alerts, validation, visual etc.

Remember to thank them for their time and effort

Survey Instructions

This survey is designed to help get a better understanding of how to apply and integrate new technologies and complex interventions in health care.

This survey asks questions about the implementation of acute kidney injury (AKI) electronic alerts into patients' medical records. We understand that people involved with AKI alerts have different roles, and that people may have more than one role. For this survey, please answer all the statements from the perspective of being an end-user of AKI alerts.

The survey is in 3 parts, Parts A-C:

- Part A asks some brief questions about yourself and your role.
- Part B asks general questions about patient safety and AKI alerts.
- Part C contains four sets of statements about AKI alerts. For each statement in Part C, there is the option to agree or disagree with what is being asked. However, if you feel that the statement is not relevant to you, you can answer 'not relevant'.

The survey is on both sides of paper. Answers to all questions are required, except where it is stated as being optional. The only optional questions are Q15b, Q16b, Q17b, and Q18b.

Please take the time to decide which answer best suits your experience for each statement and tick the appropriate circle.

If you would like to complete this version electronically (on mobile, tablet or desktop) please use the address below.

[address removed for publication]

Electronic alerts for acute kidney injury - end user survey

Part A: About yourself

Part A: About yourself	Survey number (admin only)
Q1. How would you describe your professional job category?	(ddiffiir offiy)
□ Medical doctor (go to Q2a)	
Surgical doctor (go to Q2a)	
Nurse (go to Q2b)	
Other (go to Q2c)	
Q2a. How would you describe your professional job level?	
□ Foundation-years doctor 1 (F1)	
□ Foundation-years doctor 2 (F2)	
□ Specialist trainee doctor (ST1 or ST2)	
□ Specialist trainee doctor (ST3, ST4 or ST5)□ Specialist trainee doctor (ST6 or ST7)	
□ Staff grade doctor	
□ Consultant	
□ Other (go to Q2d)	
Please go to question 3 on the next page	
Q2b. How would you describe your professional job level?	
□ Band 4	
Band 5	
□ Band 6	
□ Band 7 □ Band 8a	
□ Band 8b	
□ Band 8c	
□ Other (go to Q2d)	
Please go to question 3 on the next page	
Q2c. How would you describe your professional job category? For example	
healthcare assistant, nurse, doctor.	
Please go to question 2d below	
Q2d. How would you describe your professional job level? For example, your o	urrent
grade / band	

Please go to question 3 on the next page

Part A: About yourself (continued)

Q3	. How many full years have you held your primary professional qualification?
Q4	. Which NHS Trust do you currently work at?
	Gateshead Health NHS Foundation Trust
	Newcastle upon Tyne Hospitals NHS Foundation Trust
	Northumbria Healthcare NHS Foundation Trust
	Other (please specify in box below)
05	. How many full years have you worked in your current role at this NHS Trust?
	our Trust has merged with another or changed its name, please include in your answer all
-	time you have worked with this Trust and its predecessors
uic	time you have worked with this Trust and its predecessors
Q6	. Which best describes the department / unit that you work in?
	Internal Medicine / Care of the Elderly
	Emergency Admissions
	General / Vascular Surgery
	Other (please specify)
	. How many full years have you worked in your current role in this department /
uni	it?

Part A: About yourself (continued)

Q8. Have you received any formal or informal training in relation to acute kinds and the poor 24 months?	idney
injury in the past 24 months? □ No	
☐ Yes (please specify)	
Q9. Does your team, unit or NHS Trust have any initiatives other than acute injury electronic alerts to improve acute kidney injury awareness? No	kidney
□ Yes (please specify)	

This is the end of Part A. Please turn over for Part B.

Part B: General questions about patient safety

Q10. Perceptions of patient safety in your work area / unit

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
It is just by chance that more serious mistakes do not happen around here					
Patient safety is never sacrificed to get more work done					
We have patient safety problems in this unit					
Our procedures and systems are good at preventing errors from happening					

Q11. Please give your work area / unit in this hospital an overall grade on patient safety

	Failing	Poor	Acceptable	Very good	Excellent
Patient safety grade					

Part B: General questions about acute kidney injury alerts

Q12. When you see an acute kidney injury alert within the patient's record, how familiar does it feel?

	Still feels very new									Feels completely familiar
	1	2	3	4	5	6	7	8	9	10
Familiarity of AKI alert										

Q13. Do you feel the acute kidney injury alert is currently a normal part of your work?

	Not at all									Completely
	1	2	3	4	5	6	7	8	9	10
Responding to the AKI alert is currently normal (present)					2					

Q14. Do you feel the acute kidney injury alert will become a normal part of your work?

	Not at all									Completely
	1	2	3	4	5	6	7	8	9	10
Responding to the AKI alert will become normal (future)										

This is the end of Part B. Please turn over for Part C1.

Part C1: Detailed questions about acute kidney injury alerts

Q15a. For each statement, please select one answer that best suits your experience.

	Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Not relevant
I can see how the AKI alert differs from usual ways of working						
Staff in this organisation have a shared understanding of the purpose of the AKI alert						
I understand how the AKI alert affects the nature of my own work						
I can see the potential value of the AKI alert for my work						

Q15b. Please elaborate on your answers provided in this part (optional)							

This is the end of Part C1. Please turn over for Part C2.

Part C2: Detailed questions about acute kidney injury alerts (continued)

Q16a. For each statement, please select one answer that best suits your experience.

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Not relevant
There are key people who drive the AKI alert forward and get others involved						
I believe that responding to the AKI alert is a legitimate part of my role						
I'm open to working with colleagues in new ways when responding to the AKI alert						
I will continue to support the AKI alert			1			

Q16b. Please elaborate on yo	Q16b. Please elaborate on your answers provided in this part (optional)									

This is the end of Part C2. Please turn over for Part C3.

Part C3: Detailed questions about acute kidney injury alerts (continued)

Q17a. For each statement, please select one answer that best suits your experience.

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Not relevant
I can easily integrate the AKI alert into my existing work						
The AKI alert disrupts working relationships						
I have confidence in other people's ability to respond to the AKI alert						
Work is assigned to those with skills appropriate to responding to the AKI alert						
Sufficient training is provided to enable staff to implement the AKI alert						
Sufficient resources are available for the AKI alert				G,		
Management adequately supports the AKI alert				.7		

Q17b. Plea	Q17b. Please elaborate on your answers provided in this part (optional)									

This is the end of Part C3. Please turn over for Part C4.

Part C4: Detailed questions about acute kidney injury alerts

Q18a. For each statement, please select one answer that best suits your experience.

	Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Not relevant
I am aware of reports about the effects of the AKI alert						
The staff agree that the AKI alert is worthwhile	0-					
I value the effects that the AKI alert has had on my work						
Feedback about the AKI alert can be used to improve it in the future						
I can modify how I work with the AKI alert			-7			
Ω18h Please elaborate					.	

Q18b. Please elaborate on your answers provided in this part (optional)					

Please turn over

This is the end of the survey

Thank you for completing the survey; your participation is greatly appreciated. We understand that the nature of a survey may not allow you to fully express your thoughts and opinions about the acute kidney injury alerts. If you feel this is the case and would be interested in participating in an interview (if you have not already), please leave your name and email address below and we will be in touch shortly with more information. These will not be linked back to your survey responses. If you are not interested in hearing more about an interview, please leave the box blank.

Name	
Email address	

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on
Domesia 4. Bassansk taans			Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	
Occupation	3	What was their occupation at the time of the study?	
Gender	4	Was the researcher male or female?	
Experience and training	5	What experience or training did the researcher have?	
Relationship with			
participants			
Relationship established	6	Was a relationship established prior to study commencement?	
Participant knowledge of	7	What did the participants know about the researcher? e.g. personal	
the interviewer		goals, reasons for doing the research	
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator?	
		e.g. Bias, assumptions, reasons and interests in the research topic	
Domain 2: Study design	•		
Theoretical framework			
Methodological orientation	9	What methodological orientation was stated to underpin the study? e.g.	
and Theory		grounded theory, discourse analysis, ethnography, phenomenology,	
		content analysis	
Participant selection			•
Sampling	10	How were participants selected? e.g. purposive, convenience,	
		consecutive, snowball	
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail,	
		email	
Sample size	12	How many participants were in the study?	
Non-participation	13	How many people refused to participate or dropped out? Reasons?	
Setting	l		1
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	
Presence of non-	15	Was anyone else present besides the participants and researchers?	
participants			
Description of sample	16	What are the important characteristics of the sample? e.g. demographic	
		data, date	
Data collection	l		1
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot	
		tested?	
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	
Field notes	20	Were field notes made during and/or after the inter view or focus group?	
Duration	21	What was the duration of the inter views or focus group?	
Data saturation	22	Was data saturation discussed?	
Transcripts returned	23	Were transcripts returned to participants for comment and/or	
		w only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	1

Торіс	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and			•
findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	
Description of the coding	25	Did authors provide a description of the coding tree?	
tree			
Derivation of themes	26	Were themes identified in advance or derived from the data?	
Software	27	What software, if applicable, was used to manage the data?	
Participant checking	28	Did participants provide feedback on the findings?	
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings?	
		Was each quotation identified? e.g. participant number	
Data and findings consistent	30	Was there consistency between the data presented and the findings?	
Clarity of major themes	31	Were major themes clearly presented in the findings?	
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.

BMJ Open

Acute kidney injury electronic alerts: mixed methods Normalization Process Theory evaluation of their implementation into secondary care in England

Journal:	BMJ Open
Manuscript ID	bmjopen-2019-032925.R1
Article Type:	Original research
Date Submitted by the Author:	27-Sep-2019
Complete List of Authors:	Scott, Jason; Northumbria University Finch, Tracy; Northumbria University, Nursing, Midwifery and Health Bevan, Mark; Northumbria University Maniatopoulos, Gregory; Newcastle University, Institute of Health and Society Gibbins, Chris; Newcastle Upon Tyne Hospitals NHS Foundation Trust Yates, Bryan; Northumbria Healthcare NHS Foundation Trust Kilimangalam, Narayanan; Gateshead Health NHS Foundation Trust Sheerin, Neil; Newcastle University Kanagasundaram, Suren; Newcastle University, Institute of Cellular Medicine; Newcastle Upon Tyne Hospitals NHS Foundation Trust
Primary Subject Heading :	Renal medicine
Secondary Subject Heading:	Health services research, Health informatics
Keywords:	Acute renal failure < NEPHROLOGY, Health informatics < BIOTECHNOLOGY & BIOINFORMATICS, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Nephrology < INTERNAL MEDICINE, QUALITATIVE RESEARCH

SCHOLARONE™ Manuscripts Acute kidney injury electronic alerts: mixed methods Normalization Process Theory evaluation of their implementation into secondary care in England

Title Page

Jason Scott,1* Tracy Finch,1 Mark Bevan,1 Gregory Maniatopoulos,2 Chris

- Gibbins,³ Bryan Yates,⁴ Narayanan Kilimangalam,⁵ Neil S Sheerin,^{3,6} Nigel Suren
- 9 Kanagasundaram,^{3,6*}

- ¹ Faculty of Health and Life Sciences, Northumbria University, Newcastle upon Tyne, England
- 12 Institute of Health and Society, Newcastle University, Newcastle upon Tyne, England
- 13 Renal Services, Newcastle upon Tyne Hospitals NHS Foundation Trust, Newcastle upon Tyne,
- 14 England
- 15 ⁴ Northumbria Healthcare NHS Foundation Trust, Newcastle upon Tyne, England
- 16 ⁵ Gateshead Health NHS Foundation Trust, Gateshead, England
 - ⁶ Institute of Cellular Medicine, Newcastle University, Newcastle upon Tyne, England

- *Corresponding author
- 20 Dr Jason Scott
- 21 Faculty of Health & Life Sciences
- 22 Northumbria University
- 23 Coach Lane Campus West
- 24 Newcastle upon Tyne
- 25 England
- 26 NE7 7XA
- 27 jason.scott@northumbria.ac.uk

Word count: 3,920

ABSTRACT

Objective

Around one in five emergency hospital admissions are affected by acute kidney injury (AKI). To address poor quality of care in relation to AKI, electronic alerts (e-alerts) are mandated across primary and secondary care in England and Wales. Evidence of the benefit of AKI e-alerts remains conflicting, with at least some uncertainty explained by poor or unclear implementation. The objective of this study was to identify factors relating to implementation, using Normalization Process Theory (NPT), which promote or inhibit use of AKI e-alerts in secondary care.

Design

Mixed methods combining qualitative (observations, semi-structured interviews) and quantitative (survey) methods.

Setting and participants

Three secondary care hospitals in North East England, representing two distinct AKI e-alerting systems. Observations (>44 hours) were conducted in Emergency Assessment Units (EAUs). Semi-structured interviews were conducted with clinicians (n=29) from EAUs, Vascular or General Surgery, or Care of the Elderly. Qualitative data were supplemented by NoMAD surveys (n=101).

Analysis

Qualitative data were analysed using the NPT framework, with quantitative data analysed descriptively and using Chi Square and Wilcoxon Signed Ranks Test for differences in current and future normalization.

Results

Participants reported familiarity with the AKI e-alerts but that the e-alerts would become more normalized in the future (p<0.001). No single NPT mechanism led to current (un)successful implementation of the e-alerts, but analysis of the underlying sub-constructs identified several mechanisms indicative of successful normalization (*internalization*, *legitimation*) or unsuccessful normalization (*initiation*, *differentiation*, *skill set workability*, *systematization*).

Conclusions

Clinicians recognised the value and importance of AKI e-alerts in their practice, though this was not sufficient for the e-alerts to be routinely engaged with by clinicians. To further normalize the use of AKI e-alerts, there is a need for tailored training on use of the e-alerts and routine feedback to clinicians on the impact that e-alerts have on patient outcomes.

Key words

Acute kidney injury, Normalization Process Theory, Implementation, Mixed methods, Human factors, Patient safety

ARTICLE SUMMARY

Strengths and limitations

- This is the first known mixed methods study to use Normalization Process Theory to investigate the implementation of AKI e-alerts, providing a unique lens on their implementation
- The study was conducted in clinical areas where AKI incidence is high; it is unknown whether the e-alert would be more useful (and whether it would be more or less poorly implemented) in clinical areas where AKI incidence is lower.
- The study was also conducted in one region, and so implementation of the AKI e-alert may have been influenced by local networks.
- It is unknown whether the e-alerts had a quantifiable impact on AKI outcomes or staff actions, and so it is not possible to draw conclusions about the effectiveness of the AKI e-alerts studied as a result of implementation.

INTRODUCTION

Acute kidney injury (AKI) affects around one in five emergency hospital admissions.¹ AKI is both dangerous, with around 15,000 excess deaths in National Health Service (NHS) England inpatients per year,² and costly, imposing an estimated additional financial burden on this system of £1.02 billion per annum.² Increasing age and co-morbidity in the hospital population has increased the number of patients at risk from the condition, which is only likely to rise further with an ageing population. AKI care itself is often poor, with systematic failings in its recognition and management, and frequent omissions of even the basics of care.³

AKI alerting systems are mandated for all NHS England primary and secondary care providers, using a biochemical detection algorithm⁴ and usually implemented electronically. The algorithm, which appears to perform with a high degree of sensitivity (>90%),⁵ has resolved ambiguities in modern diagnostic criteria⁶ around how to interpret baseline serum creatinine (SCr), a historical impediment to the standardisation of automated AKI detection, and as well as outputs for the three stages of disease severity, it also flags out-of-range SCrs in the absence of an historical baseline. AKI electronic alerts (e-alerts) are thought to improve patient outcomes by improving early detection of AKI and triggering earlier intervention by clinicians.⁷ The exact nature of the AKI alerts is not, however, dictated, and may take a number of forms.

The efficacy of AKI e-alerts is limited and has not shown consistent benefit⁸ in terms of reduced mortality or use of renal support, or positive impacts on processes of care,⁹ which may be the result of alert fatigue^{5,10} or disrupted workflow.¹⁰ Inadequate implementation can explain the poor outcomes, particularly as there are some examples of improved care processes¹¹ and treatment outcomes through successful implementation.¹²⁻¹⁴ Mandatory incorporation of AKI alerts into all secondary care organisations in England lacked a clear implementation strategy, and recently published systematic reviews recognised large variation in implementation,¹² with an association between poor implementation and poor outcome.⁹ One review specifically identified a paucity of research on the implementation of AKI e-alerts internationally.⁹ To address this paucity of research, the present study aimed to identify factors relating to implementation which promoted or inhibited use of AKI e-alerting systems in secondary care.

METHODS

This study incorporated mixed methods (qualitative interviews and observations combined with quantitative surveys) to investigate the implementation of AKI e-alerts from multiple perspectives, including observations, surveys and semi-structured interviews. Normalization Process Theory (NPT)^{15,16} was chosen as the theoretical basis for the study as it is an internationally recognised theory of implementation that has been used to explain successful and suboptimal implementation in over 100 healthcare initiatives, ¹⁷ including through the use of mixed methods. ¹⁸⁻²⁰ NPT therefore provides the explanatory power for understanding how complex interventions, such as AKI e-alerts, become integrated into existing practice through individual and collective implementation. This integration is proposed to occur via four mechanisms: 'Coherence': how people make sense of what needs to be done, 'Cognitive participation': how relationships with others influence outcomes, 'Collective action': how people work together to make practices work, and 'Reflexive monitoring': how people assess the impact of the new intervention. The four constructs are operationalised under 16 sub-constructs, which are described in table 1.

Table 1: Description of NPT mechanisms and sub-constructs

Coherence

Differentiation: How participants understand a set of practices and their objects to be different (or not) from each other.

Communal specification: Extent to which participants have a shared understanding of the aims, objectives, and expected benefits of a set of practices.

Individual specification: How participants understand their own specific tasks and responsibilities around a set of practices.

Internalization: How participants perceive the value, benefits and importance of a set of practices.

Cognitive Participation

Initiation: Whether or not key participants are working to drive a new set of practices forward. **Enrolment:** The extent to which participants

organize or reorganize themselves and others in order to collectively contribute to the work involved in new practices.

Legitimation: The work of ensuring that other participants believe it is right for them to be involved in the new set of practices, and that they can make a valid contribution to it.

Activation: The work that participants do collectively to define the actions and procedures needed to sustain a new practice and to stay involved.

Collective Action

Interactional Workability: The interactional work that people do with each other, with tools/systems, and with other elements of a set of practices, when implementing a new practice.

Relational Integration: The work that is needed to build accountability and maintain confidence in a set of practices and in each other as they use them.

Skill set Workability: The allocation of work amongst participants with different roles and skills in relation to the new set of practices.

Contextual Integration: The work of managing a set of practices through the allocation of different kinds of resources and the execution of protocols, policies and procedures to support the practices.

Reflexive Monitoring

Systematization: The work undertaken by participants to determine how effective and useful the new set of practices is for them and for others, and the information collected to enable this. **Communal appraisal:** The work undertaken by

Communal appraisal: The work undertaken by participants collectively (sometimes in formal collaboratives, sometimes in informal groups) to evaluate the worth of a set of practices.

Individual appraisal: Individual participants' own appraisals, based on their experiences, of the effects of a new set of practices on them and the contexts in which they are set.

Reconfiguration: The extent to which appraisal work by individuals or groups may lead to respecification or modification of the set of practices.

Sampling and recruitment

Three NHS Trusts in North East England were invited to take part in the study based on being within a single NHS Trust's renal department catchment area, and the catchment area for referral for complex AKI (see table 2 for a description of Trusts and their AKI e-alerting systems). Three clinical areas were purposively chosen for study at each NHS Trust based on anticipated high levels of AKI incidence; (1) Emergency Admissions, (2) Internal Medicine/Care of the Elderly, and (3) General/Vascular Surgery.

Table 2: Characteristics of participating NHS Trusts and their AKI electronic e-alert. See Additional files 1 and 2 for images of the e-alerting systems.

NHS	Trust Characteristics	AKI electronic alert
Trust 1	University-affiliated, 1800 bed, multiple site tertiary referral hospital; contains regional renal unit, transplantation, cardiothoracic and hepato-biliary surgery as well as other major specialisms; The Renal Unit is based at one Trust site and although providing consultative input to the rest of the Trust, has no routine, onsite presence at these venues which include the emergency admissions suite and significant sections of general surgical, internal medical and elderly care services.	Passive electronic alert consisting of a line of black text appearing underneath serum creatinine results in the patient's electronic medical record (<i>Powerchart, Cerner Millennium, Cerner Corporation</i> , Kansas, MO, USA) which stated the stage of AKI where present. Additional pop-up electronic alert that appeared when accessing the patient's electronical medical record, and required dismissal to remove from the screen. A 'more info' link on the pop-up window, if clicked, took the end-user to a second window that contained further links to the Trust AKI protocol and specific guidance on aspects of management including essential assessments, key bedside observations & key investigations. The latter linked to quick order test panels including essential blood tests and urgent renal ultrasound requesting.
Trust 2	Multi-site university-affiliated district general with approximately 900 beds. All acute services on one site with internal medicine, elderly services, general and orthopaedic surgery along with obstetrics and paediatrics. Renal replacement provision from critical care. Renal input, provided from Trust 1 by remote consultation, no renal consultant presence within the trust.	Passive electronic alert consisting of a line of black text appearing underneath serum creatinine results in the patient's electronic medical record (TelePath Information Management System, Mill Systems Limited, Belper, UK) which stated the stage of AKI where present. Alert does not link with any other hospital information system, but instructs users to access local AKI guidelines.
Trust 3	District general hospital with 300 beds in medicine. Renal input is from Trust 1 through a combination of remote consultation and weekly availability at the time of an out-patient clinic on site.	Passive electronic alert consisting of a line of black text appearing underneath serum creatinine results in the patient's electronic medical record (Medical Information Technology (MEDITECH) Inc., Westwood, MA, USA) which stated the stage of AKI where present. Alert does not link with any other hospital information system, but instructs users to access

Participants for semi-structured interviews were purposively sampled based on specialty and clinical experience (determined by grade). Participants were invited through direct contact by JS, or by leaving contact details after completing a survey. Recruitment to survey was conducted through direct contact

by JS, or electronically via an internal email by (or on behalf of) the lead consultant for the clinical specialty. Teaching sessions at Trust 3 were also used to invite staff to participate in the survey. Access to observe practice on emergency admission units was facilitated by the lead consultant(s) for the unit. Participants were able to take part in the research activities (interviews, observations and/or survey) in any order, based upon what was most convenient. Where possible, the order of activities was balanced to reduce confounding variables.

Data collection

Semi-structured interviews were conducted by a male research associate, JS (PhD), with participants in their place of work or via telephone between May 2017 to September 2017, and lasted an average of 26 minutes (range 17 to 41). Interviews were recorded using a digital voice recorder and transcribed verbatim by a professional transcription company. A topic guide (see Additional file 3) was constructed by the research team based on the four mechanisms of NPT (coherence, cognitive participation, collective action, reflexive monitoring; see table 1) and from previous qualitative work on implementation of AKI e-alerts. In addition to questions based on the four NPT mechanisms, the topic guide also included questions about the participants' clinical experience (job role, length of time in role, experience in other roles) and their experience with AKI e-alerts. Ethnographic data were obtained by observing practice in emergency admission units, guided tours, shadowing of staff, and informal conversations and handover meeting attendance. Observational data were documented in fieldnotes.

The Emergency Admission Units function to provide early assessment of adult patients referred via their general practitioner or the emergency department. One of the units (Trust 3) was a hybrid Emergency Admission Unit and Acute Medicine ward. A total of 44.25 hours of observations were conducted at various times of day (morning, afternoon and evening) during the working week (Monday to Friday).

The NoMAD survey,²¹⁻²³ a validated instrument for measuring implementation,²⁴ was adapted for use with AKI e-alerts (see Additional file 4). Questions were added to identify characteristics of respondents, including:

- Profession
- Grade
- Years since obtaining primary medical qualification
- Years working in the Trust
- Years working in the department
- Formal or informal AKI training received in previous 24 months
- AKI initiatives to improve awareness of AKI other than e-alerts

In addition, five questions from the Hospital Survey on Patient Safety Culture™ (SOPS™; version 1.0)²⁵ were included. SOPS™ contains a construct containing four questions titled 'Overall perceptions of patient safety'. All four questions from this construct were included, along with an overall patient safety grade. Paper and electronic versions of the study survey were made available to potential participants. All data collection was conducted after the AKI e-alerts had been implemented into practice for at least one year.

Data analysis

Framework analysis was used for qualitative data, ²⁶ with the four NPT mechanisms and their subconstructs forming the framework (see table 1). For interview data, one interview transcript was jointly charted by JS and TF, with interpretations of the data discussed until agreement was reached. This discussion familiarised JS with the differential meanings underpinning the 16 sub-constructs for subsequent analysis of qualitative data, as TF is an expert in NPT as a co-developer of the theory. ^{22,23} JS then charted the remaining interview data into the framework. For observational data, in-depth observer notes were summarised by the observer (JS), then all observation data were charted into the framework jointly with TF.^{15,16} NVivo software (*QSR International Pty Ltd, version 10*) was used to facilitate coding of qualitative data. Once initial analysis was complete, all authors reviewed and discussed the coding in a team meeting before coming to agreement on the final interpretations, which is an established process of qualitative data analysis.²⁷ Participants were not invited to comment on findings.

IBM SPSS Statistics for Windows (*IBM Corp, version 24.0*) was used for quantitative analysis. Inferential statistics (chi square) were used to compare patient safety culture between NHS Trusts and specialties to identify whether safety culture could influence the subsequent analysis. Wilcoxon Signed Ranks Test was used to analyse differences in current and future normalization of the e-alerts. Survey items relating to the four NPT mechanisms were then analysed by examining descriptive statistics for each of the four mechanisms. Mechanism scores for each participant were created by taking their average score in each mechanism and dividing by the number of valid responses, which stopped data from being skewed where respondents stated a question was not applicable. Higher scores represent better perceived implementation in relation to each mechanism. Data were then triangulated by exploring (dis)agreements and silences across the qualitative and survey data sets. This was conducted by a single researcher (JS) identifying and listing sub-constructs that demonstrated particularly high or low normalization, comparing these against qualitative themes and then discussed amongst the research team.

Patient and public involvement

There was no patient and public involvement in the design or planning of the study.

RESULTS

Semi-structured interviews were conducted with 29 staff members. 28 interviews were with doctors, and one interview was with a pharmacist involved in implementing AKI e-alerts at Trust 1. The survey was distributed to 157 staff, and 102 (65%) responded. 94 (92.2%) completed the paper version, and eight (7.8%), the online version. See table 3 for a summary of interview participants and survey respondent characteristics. Table 3 also acts as a key to participants' grades, which is used to infer level of experience (grades are competency based) and is also used in the reporting of qualitative data. One survey was excluded as the participant reported on an e-alerting system at an NHS Trust not included in the study, leaving a final sample of 101.

Table 3: Participant characteristics of interviews and survey

Characteristic	Interview participants	Survey respondents
Job grade	N (%)	N (%)
Foundation doctor year 1 (F1)	9 (31.0)	16 (15.8)
Foundation doctor year 2 (F2)	4 (13.8)	25 (24.8)
Specialty registrar doctor year 1/2 (ST1/2)	4 (13.8)	23 (22.8)
Specialty registrar doctor year 3/4/5 (ST3/4/5)	3 10.3)	10 (9.9)
Specialty registrar doctor year 6/7 (ST6/7)	2 (6.9)	4 (4.0)
Staff grade doctor	0 (0)	5 (5.0)
Consultant	6 (20.7)	15 (14.9)
Nurse (band 6)	0 (0)	1 (1.0)
Other	1 (3.4)*	2 (1.0)†
NHS Trust	N (%)	N (%)
Trust 1	11 (37.9)	30 (29.4)
Trust 2	8 (27.6)	60 (58.8)
Trust 3	10 (34.5)	11 (10.8)
Department	N (%)	N (%)
Internal Medicine/Care of the Elderly	10 (34.5)	46 (45.5)
Emergency Admission	8 (27.6)	26 (25.7)
General / Vascular surgery	10 (34.5)	20 (19.8)
Other	1 (3.4)‡	9 (8.9)§

- * Pharmacist
- † Medical student=1, Locum Senior House Doctor=1
- 239 ‡ Pharmacy
 - § Palliative care=4, Acute medicine=2, Cardiology=1, ITU=1, Nephrology=1.

Patient safety

Overall patient safety culture, graded on a Likert scale from 1 (very poor) to 5 (excellent), had a mean score of 3.75. A chi-square analysis comparing the three NHS Trusts identified no significant difference in patient safety culture (χ 2=1.784, df=2, p=0.410). Using the same method, there was also no significant difference between the specialties surveyed (χ 2=1.453, df=3, p=0.693). These results indicated that different sites or specialties did not confound the analysis.

Familiarity and perceived normalization

Participants reported that they were mostly familiar with the e-alerts (mean=7.27, sd=2.562) and that the e-alert was part of their normal work (mean=7.28, sd=2.649). However, it was reported that the e-alerts would become a more normal part of their work (mean=8.32, sd=2.059), with a Wilcoxon Signed Ranks Test confirming the difference was statistically significant (Z=-5.049, p<0.001), suggesting that the e-alerts were not yet fully embedded.

NPT mechanisms and sub-constructs

Descriptive analysis of the mean scores of the four NPT mechanisms – coherence (\bar{x} =72.3%), cognitive participation (\bar{x} =76.4%), collective action (\bar{x} =66.5%) and reflexive monitoring (\bar{x} =68.8%) – suggested there was no key mechanism that led to (un)successful implementation of the e-alerts. Further

analysis of the 16 sub-constructs (table 1) identified several sub-constructs indicative of (un)successful implementation; mean ratings for the 16 sub-constructs are presented in Figure 1. More specifically, following triangulation with qualitative data, the NPT sub-constructs that were identified to contribute to successful normalization of the AKI e-alerts were *internalization* and *legitimation*, and those that contributed to unsuccessful normalization were *initiation*, *differentiation*, *skill set workability*, and *systematization*. As with the survey data, there were no identified differences in qualitative findings between the two e-alerting systems. Supporting qualitative data (quotes and field notes) for all sixteen sub-constructs are provided in table 4. The remainder of the results will focus on NPT sub-constructs that demonstrate where normalization was most positive or negative, based upon the triangulation of all data sources, representing sub-constructs that most promote or inhibit use of AKI e-alerts in secondary care.

[Insert Figure 1 around here]

Sub-constructs demonstrating positive normalization

Internalization

Clinicians often reported that, despite not always utilising the AKI e-alert, they valued the potential of it, which was reflected in the survey score of 4.16. This demonstrated that they had a fundamental understanding of the importance of recognising AKI early, and many clinicians recognised that it was possible to make mistakes and to miss AKI.

"in something like renal function, where there's so much variety, [the AKI e-alert] just helps jolt you to it and especially how severe AKIs can be, it's even more necessary because hopefully things like that wouldn't be missed, but there's always the potential that it could be. And having it say in black and white, this is an AKI, you know, they shouldn't be missed at all." [F1 interview, Emergency Admissions, Trust 2]

"The times I think it's probably useful is when it's one of those slightly sneakier ones, more subtle ones. The creatinine might have only peaked at 120 but, actually, if their creatinine is normally 45, that's still a big deal but it doesn't jump out at you as a creatinine of 600 would." [Consultant interview, Internal Medicine/Care of the Elderly, Trust 2]

Legitimation

Despite the lack of initiation (as identified in the Initiation theme), perceived or otherwise, clinicians still largely understood that responding to the AKI e-alerts was their responsibility, though this perspective was sometimes dependent on the clinician's seniority. For instance, all clinicians regardless of seniority recognised that the AKI e-alert was important to the work of junior doctors. In particular, some senior staff (consultants and registrars) felt that junior staff did not place sufficient priority on renal function; "For [junior staff] it might make a difference because they might not look at all the figures. If it says an AKI e-alert, then they might make the effort to actually do that" [ST6 interview, General/Vascular Surgery, Trust 3]. However, particularly on surgical wards where

foundation-year doctors were mostly responsible for ward-care of patients, the e-alerts were not seen to be part of the senior doctor's role, even though the AKI e-alerts were still valued.

"I think you'll find that as people progress, their focus of how they manage the patient shifts. They're more interested in dealing with the active problems and these outcomes of quite secondary issues that solve around the problem. The attitude is a bit like mine: someone more junior will deal with it and you totally lose interest in the other things." [ST3 interview, General/Vascular Surgery, Trust 3]

Sub-constructs demonstrating negative normalization

Differentiation

How clinicians differentiated the AKI e-alert from what was deemed to be normal practice prior to the implementation of the AKI e-alert, was often based upon the length of time that the clinician had been qualified. Clinicians who were newly qualified, particularly foundation-year doctors, consistently reported that they had no experience of working without an e-alerting system, and so using the AKI e-alert by default was deemed to be normal practice.

"I suppose I haven't ever realised it's actually a new thing. Obviously, I've only worked here 11 months, I just assumed it was always there" [F1 interview, General/Vascular Surgery, Trust 3]

Contrary to this, observations identified instances where clinicians were unaware of an e-alert for AKI, or were unaware of how the e-alert should work. In the following extract from observation notes, the clinician initially conceived of an e-alert as always being a pop-up, rather than text embedded into the system.

'I chat with [a doctor] and we talk about the AKI alerts. When I explain what it is I'm observing for, he looks a bit confused, says he doesn't know about the alerts. He opens up a patient record and explains he thinks this patient has AKI, so wants to see if there is an alert there. After I describe what the alert should look like, he says he thought I meant "a pop-up rather than a bit of text"; I think he doesn't see the text as an alert by itself.' [Trust 3 observation of Emergency Admissions, approx. 17:00]

Clinicians also identified that the lack of differentiation was related to the clinical area in which they were working. For instance, it was deemed to be routine to check renal function of all patients entering emergency admission suites. In this setting, clinicians often mentally risk-assessed patients for AKI. For these patients, the clinicians would more regularly check to see if blood test results had been returned.

"At the moment, probably not an awful lot else than I would normally do. Normally if I go through people's bloods specifically for renal function I usually click on each of the numbers and compare it to what it has been previously. I think I interpret renal function quite a lot in the context of what the patient's renal function IS? Or [sic] usually like. I click on each of the five elements that we get reported here and then

have a look at how that varies from the previous. To be honest I would do that irrespective of whether the alert is there or not." [ST1 interview, Emergency Admissions, Trust 3]

Initiation

Initiation received a mean score of 2.8. This remained consistent across all three Trusts, and was supported by interview participants who consistently reported that either the e-alerts "just appeared at some point" [F1 interview, General/Vascular Surgery, Trust 3], or that the e-alerts were already implemented when they began working for the Trust, as identified in the differentiation theme. However, there was a key difference; even where alerts were already implemented and thus deemed to be 'normal', there was a lack of training provided to clinicians on how to use the e-alerts. This finding was consistent (and is partly duplicated) with the *skill set workability* sub-construct of NPT.

"I think [the AKI e-alerts] just started popping up. So, we didn't get any training or anything like that on them, or why they were there, or who put them there, or what the purpose was." [ST2 interview, Internal Medicine/Care of the Elderly, Trust 1]

In one Trust, the person who contributed to the implementation of the AKI e-alerts acknowledged this sub-optimal initiation or training for doctors; "When we first went live we switched the rules on but we didn't really do a lot of education, and I think [the alerts] were relatively unpopular" [Pharmacist interview, Trust 1]. Education consisted of an email with information about the AKI alerts to clinical directors asking them to cascade it to their staff.

Skill set workability

The lack of training provided on how to use the e-alerts, as previously reported in the initiation theme, also contributes to the skill set workability theme. Participants reported that they generally had responsibility for AKI and thus the e-alerts, demonstrating to an extent that that there was appropriate skill set workability amongst those receiving the e-alerts. However, there were also occasions where participants demonstrated or recognised their own lack of knowledge related to the AKI e-alerts such as incorrectly describing how they thought the e-alerts worked. More specifically, participants regularly did not know how the e-alerts should be incorporated into their own practice.

"A teaching session would be really good of explaining, like, how to use the alert, like, the situations when the alert isn't effective and, then, just, kind of, what to do if you do get an alert." [Consultant interview, Internal Medicine/Care of the Elderly, Trust 2]

Systematization

Across all three of the NHS Trusts, no participants (regardless of seniority) collected information on the effectiveness of the AKI e-alert. While the data collected did not indicate whether anyone in the Trusts collected information regarding the effectiveness of the AKI e-alerts, it was consistently reported by all interview participants that feedback was not given to those using the AKI e-alerts. Furthermore, participants were unaware of whether the AKI e-alert, or more specifically responding to the AKI e-alert, had any effect.

"I think maybe a bit of feedback or a bit of education [would help staff to engage with the AKI alert. So, feedback as to how things had changed since the alert was introduced. [...] Some sort of outcome measure would be quite interesting. That might, just to show people that it's actually having a benefit." [Consultant interview, Internal Medicine/Care of the Elderly, Trust 1]

Table 4: Summary of the qualitative framework analysis for the 16 NPT sub-constructs with supportive evidence

NPT mechanisms and sub- constructs	Coding summary	Supporting evidence
Coherence		
Differentiation Mean survey score: 3.18	Clinicians often did not differentiate between normal practice and use of the AKI e-alert; checking the patient's renal function was deemed to be routine in the clinical areas studied.	'A doctor says that it's a routine part of their job to check renal function and would check it anyway – this is the case even in the emergency department if a patient came in with a broken arm to check for a potential underlying condition' [Trust 1 observation of Emergency Admissions, approx. 19:30]
Communal specification Mean survey score: 3.29	Working with the AKI e-alert was perceived to be an individual rather than team action. The e-alert was rarely discussed or used to initiate discussion, with staff often not knowing what others thought about the e-alert.	"I don't think we've had much discussion about the AKI alerts, it's certainly not something that I'm aware of, that other people have commented on." [F1 interview, General/Vascular Surgery, Trust 2] "I haven't spoken to anyone else [about the AKI ealert]. I know just from being in the doctor's office, with the other doctors that sometimes, you know, you see people glance at the screen, and go 'click' whilst they are still talking to you." [ST2 interview, Internal Medicine/Care of the Elderly, Trust 2]
Individual specification Mean survey score: 3.8	AKI e-alerts often made staff consider the patient's AKI and to double check renal function.	"I guess it's to draw attention to it quickly rather than bloods getting lost in the system for the day, because especially on a busy ward [] there'll be I don't know 20 bloods sent in the morning and then if you're busy with sick people it could go well into the afternoon before you get to check on bloods." [F1 interview, Emergency Admissions, Trust 2]
Internalization Mean survey score: 4.16	Many staff saw the potential value of the AKI e-alert and understood the need for the e-alerts.	"I think it's probably the most useful out of the alerts. It generally comes on when the patients genuinely do have an AKI, although, that's often sometimes not the case. Like we said before, often it does require action, so, yes, they're pretty useful." [F1 interview, Emergency Admissions, Trust 1]
Cognitive participa	ntion	
Initiation Mean survey score: 2.8	Participants frequently cited a lack of initiation in relation to the AKI e-alerts. This occurred for one of two reasons; 1) the e-alerts just appeared without any training on how to use them, or 2) clinicians were newly qualified (or new to the Trust) and the e-alerts were already implemented, but again no was training provided.	"Yes they just sort of bob up. We never had really any induction about them" [F1 interview, General/Vascular Surgery, Trust 3]
Legitimation	For the more junior doctors, the e- alerts are perceived to be a legitimate	"we have specialist nurses who provide input for absolutely everything. So, the idea that there isn't

Mean survey score: 4.16	part of their role. However for more senior doctors, particularly in surgical units, the e-alerts were a useful intervention but only for junior doctors. Some clinicians felt that there should be a specialist AKI nurse.	one for an AKI, is a bit silly, in my opinion. Because, somebody coming their purpose in my opinion would be to come around, read what they are in for, review their pathology, review the patient, and review reversible factors. Then make a recommendation to the junior and the consultant about reversible factors that hadn't been looked at yet." [ST1 interview, Internal Medicine/Care of the Elderly, Trust 2]
Enrolment Mean survey score: 4.24	As working with the AKI e-alert was an individual action, it often had no influence on working relationships. For the few clinicians who saw the relational value, it was beneficial by providing the AKI stage that could be easily reported.	"if one of the F1's came to me and said, 'this woman's creatinine has gone up', then yes, absolutely we would have a chat about meds, and fluid, and have they had an ultrasound scan, and what do you think we should do? But, I don't think the alert has ever prompted me to do that" [ST2 interview, Internal Medicine/Care of the Elderly, Trust 1]
		"It's good if you're doing a handover on the phone or something or talking to seniors in critical care or other hospitals. You can say this is Stage 2 AKI and that is sort of a standard term that people do understand even if we don't use it in general day-to- day discussion in the notes as much as we should do." [F1 interview, General/Vascular Surgery, Trust 3]
Activation Mean survey score: 4.06	Prolonged exposure to the AKI e-alerts impacted upon clinician's support for them; the e-alerts had more impact when new, but they became part of the milieu and lost amongst other e-alerts or working practices.	"Yes, I do actually. I think it's a big component of patient safety and I think it is the direction of travel of where we're going. As time goes on, looking forward, I think we're going to expect more and more of these alerts related to algorithms and severity." [Consultant interview, Emergency Admissions, Trust 1]
Collective action		4
Interactional workability Mean survey score: 3.98	It was generally deemed easy to integrate the AKI e-alerts into normal working practices; they are there as a 'check' or 'backup' as most clinicians were routinely checking renal function. The e-alerts were perceived to speed up the process of calculating the stage of AKI. E-alerts were seen to be useful where Creatinine was within normal range, but with an increase of >1.5 from baseline.	"I think if it's not someone I already know, then yes, the alerts at least make me glance at the U&Es, which I would do anyway, but you know, just an extra reminder to check back what their previous U&Es were." [ST7 interview, Emergency Admissions, Trust 1] "I think in some ways, it probably does speed things up, because you have got that alert there, and I think, when you open up a page of bloods, and it's quite obvious, and the first thing you see is they have an AKI." [ST3 interview, Emergency Admissions, Trust 3]
Relational integration Mean survey score: 3.67	The AKI e-alert did not appear to affect working relationships. Staff mostly do not refer to the e-alert when discussing AKI, and AKI care is often an isolated task. An exception is stage 3 e-alerts, which sometimes trigger discussions with renal services.	"I don't know about the other staff and how they engage because actually I've not had a lot of feedback from them. I haven't actually been hearing the juniors saying, 'Oh there was an AKI alert' on anyone so I suspect most of them are just clicking and moving on, dismissing and moving on because they probably already know what the creatinine's doing." [Consultant interview, General/Vascular Surgery, Trust 1]

Skill set workability Mean survey score: 3.27	There was a lack of training on how to best use the AKI e-alerts (also reported in <i>initiation</i>), and some clinicians demonstrated a lack of understanding about AKI, particularly the meaning of the different stages.	"when you come to the Trust you get- I don't know how long the sessions are and I don't know what they cover, and I don't know whether they cover alerts and things like that. If they do have [AKI e-alert training], I suspect it comes at the end of a very long day of induction where they've been told about every single problem under the sun and they've probably switched off." [ST7 interview, Emergency Admissions, Trust 1]
		"And there's [AKI stages] 1, 2 and 3, I can't really remember the difference between the three of them but if it flags up something I go, 'oh, okay, there's something different here.'" [F1 interview, General/Vascular Surgery, Trust 3]
Contextual integration Mean survey score: 3.32	Clinicians did not report any specific resource requirements for the AKI ealert other than training and time. Management support (where considered in the capacity of those responsible for e-alerts; the laboratory) was not identified by participants.	"I've no idea [who has responsibility for the AKI e-alerts], no. I assume somebody will do but I don't know, it's not been communicated." [F1 interview, General/Vascular Surgery, Trust 3]
Reflexive monitor	ing	
Systematisation Mean survey score: 2.5	Feedback was never provided to staff on the effect of the AKI e-alert.	"I haven't had any feedback since the new version [of the AKI e-alert] went in actually [] I don't know whether there is a formal mechanism for that getting to anyone." [Pharmacist interview, Trust 1]
Communal appraisal <i>Mean survey</i>	The e-alert was rarely (if ever) discussed amongst clinicians, but participants often stated they felt that	"Most people I'm sure would know it's a good idea having them. That's what I'd say to someone about these alerts." [Consultant interview, Emergency
score: 3.39 Individual appraisal	others would find it worthwhile. Whilst a small minority of clinicians felt the AKI e-alert had no effect on their	Admissions, Trust 1] 'Speaking to a doctor, they felt that the AKI alerts are very useful. He says that if he sees an alert then he'll
Mean survey score: 3.52	work, many did but placed the effect within constraints relating to edgecase scenarios where AKI was most likely to be missed. These included marginal AKI thresholds within 'normal Cr range', busy workloads, and AKI	check the patient's renal function. He also explains that things at handover will often get missed so doesn't always know that the patient will have an AKI' [Trust 1 observation of Emergency Admissions, approx. 19:45]
	presenting in CKD patients. The pop-up e-alert was sometimes perceived to be intrusive, whilst the passive e-alert was often described as being too easy to dismiss.	
Reconfiguration Mean survey score: 3.89	Clinicians often did not know who was responsible for the AKI e-alert. They would never consider providing feedback about the e-alert, and there	"I'm not sure if there is a feedback mechanism. If there is, I'm not aware of it." [F1 interview, Emergency Admissions, Trust 1]
	was no formal mechanism for doing so.	"[To provide feedback] I would ring IT and they would probably be very unhelpful and I would give up at that point." [ST2 interview, Internal Medicine/Care of the Elderly, Trust 1]

DISCUSSION

This is the first known mixed methods study to use Normalization Process Theory to investigate the implementation of AKI e-alerts,¹⁷ an area identified as being an international research priority.⁹ The findings of this study suggest that AKI e-alerts are somewhat embedded into routine practice in the English NHS Trusts studied, with several aspects of implementation indicative of positive or negative normalization. Given AKI e-alerts are now mandated across primary and secondary care in England and Wales,⁴ these findings suggest that more consideration was needed for how the AKI e-alert could be integrated into existing healthcare processes to influence both individual and collective behaviours. Furthermore, the findings highlight how other healthcare systems, where AKI e-alerts are not mandated, could implement AKI e-alerts in the future to improve their use.

The two aspects that particularly promoted normalization of the AKI e-alert were that the e-alert was seen to be a legitimate part of a clinician's role, and clinicians within the study mostly recognised the potential benefits of using the AKI e-alert. This demonstrates insight amongst clinicians that AKI is a significant risk to patient safety,² and consequently clinicians understand the importance of early AKI detection and treatment,²⁸ which have been historically poor.³ This finding also suggests that, when operated raising awareness of AKI and AKI e-alerting is insufficient, when operated as a single strategy, in addressing the problem of poor AKI care. Instead, attention should focus on other aspects of implementation that could be improved.

One such aspect that required improving was initiation to the e-alerts, such as via Trust-specific training, which was lacking or of insufficient quality. This was demonstrated by a lack of knowledge amongst clinicians about what differentiates the stages of AKI, and how the e-alerts were expected to be used. The definition of AKI has been refined considerably over the past decade, partly in an attempt to reduce variation in practice, 6,29 but our findings reflect previous studies which have identified gaps in AKI knowledge amongst medical staff. Although education is important in improving AKI care, there is a gap between the objective volume of delivery of AKI teaching and end-users' perception of its paucity. This dissonance might also be consistent with an alternative interpretation to our findings, which is that the existing definition of AKI lacks intuition and/or clinical credibility. Clinicians in our study reported using the terms minor, moderate, or severe, even when they knew the different stages as per the 2012 KDIGO guidelines as they felt it easier to communicate to others. This corresponds closely with our finding, that some clinicians had difficulty in recognising and prioritising AKI e-alerts. Little research has focussed on how staff are educated about AKI e-alerts, but some tentative links have been made between effective education and successful implementation.

Another area of implementation identified as needing improvement was the systematization of the AKI e-alerts through implementing feedback to end-users of the e-alerts. There was no system for providing feedback to clinicians, despite a wide range of safety literature identifying the importance of providing this to people involved in the process.³²⁻³⁴ NPT proposes that an intervention is normalized through agents' continuous actions which are enacted over a sustained period of time and space.³⁵ As approval ratings for AKI e-alerts have been reported to reduce over time, giving feedback to those involved in the safety behaviour could slow, pause or even reverse the decline,^{36,37} and can be a transformative process that can lead to improved performance.³⁸

Alert fatigue or disruptions to workflow have been identified as barriers to implementation,^{5,10} and there were examples of these identified in this study. Both e-alert systems produced opposing perspectives on how or whether the e-alerts influenced workflow. It was however common for those receiving the pop-up e-alert to dismiss it instantly and comment on its intrusiveness, whilst those who received the passive e-alert commented on it not being intrusive enough and being too easy to ignore. This suggests that there is no one-size-fits-all e-alert presentation, and instead they may require tailoring to either the individual or clinical unit. However, the causes of these differing perspectives were unclear and require further research.

It was also notable that collaborative working in response to the AKI e-alert were dismissed or downplayed by participants. Implementation of a complex intervention, or of a simple intervention into a complex environment, requires social activity that results in joint action; agents' continuous actions are enacted over a sustained period of time and space.³⁵ Using and incorporating the e-alert into practice was often perceived to be an individual action that did not result in or alter discussions amongst clinicians. Future research should investigate whether the individual nature of an intervention, such as AKI e-alerting, contributes to poorer implementation, and whether such interventions require more collaborative working to be built-in to improve optimality.

Limitations

Firstly, the study was conducted in clinical areas where AKI incidence is high, which may limit the generalisability of the findings; it is unknown whether the e-alert would be more useful (and whether it would be more or less poorly implemented) in clinical areas where AKI incidence is lower and thus clinicians have lower contact time with the AKI e-alert. Secondly, the study was conducted in one region, and so implementation of the AKI e-alert may have been influenced by local networks. Finally, it is unknown whether the e-alerts had a quantifiable impact on AKI outcomes or staff actions, and so it is not possible to draw conclusions about the effectiveness of the AKI e-alerts studied as a result of implementation. However, the identification of perceived differences between the NPT mechanisms, including sub-constructs that were successfully implemented, suggests that a more focused approach, aligned with Safety-II principles, could help to identify successful implementation. Investigating where AKI e-alerts have been successfully implemented on a larger scale would provide valuable lessons for future implementation of both AKI e-alerts and other e-alerts.

CONCLUSIONS

Clinicians recognised the value and importance of AKI e-alerts in their clinical practice, though not sufficiently for AKI e-alerts to be routinely engaged with. To further normalize and promote clinician engagement with AKI e-alerting systems, there is a need for tailored training on AKI and how to use e-alerts; feedback should, also, be routinely given to staff about their impact on outcomes. The findings of this study provide a potential explanation for conflicting data on the reported effectiveness of AKI e-alerting systems. The findings have the potential to inform future national improvements to the way in which AKI e-alerts are implemented in the NHS and could be transferred into other countries' healthcare systems where AKI e-alerts have either not yet been implemented or where this has been suboptimal.

Declarations

Ethical approval and consent to participate

All participants provided informed consent to participate. Interview participants provided written consent. Consent for observations was provided verbally by the lead consultant of each unit and individuals being observed. Survey respondents provided consent by returning the survey. The project was reviewed and Approved by the National Health Service's Health Research Authority (https://www.hra.nhs.uk/) [reference 16/HRA/2106]. HRA Approval brings together the HRA's assessment of governance and legal compliance with the independent ethical opinion by a Research Ethics Committee. HRA Approval is for all project based research involving the NHS and Health and Social Care that is being led from England.

Consent for publication

Not applicable

Availability of data and materials

The quantitative datasets used and/or analysed during the current study are available from the corresponding author on reasonable request. Participants were not asked to provide consent to share their transcripts beyond the research team. The study team would be happy to interrogate the data on behalf of others upon reasonable request to the corresponding author.

Competing interests

NSS received travel funding from Alexion Pharmaceuticals to attend ERA-EDTA 2018 congress. NSS is also a grant holder for a project 'Imaging in Chronic Kidney Disease', funded by GlaxoSmithKline. No other authors have competing interests to declare.

Funding and Acknowledgements

This work was supported by funds from Northern Counties Kidney Research Fund (www.nckrf.org.uk). The funder had no role in the design and conduct of the study, including the collection, management, analysis, interpretation of the data, preparation, review or approval of the manuscript, and decision to submit the manuscript for publication.

Author contributions

TF, MB, GM, CB, BY, NK, NSS, NSK conceived and designed the study. JS collected the data. JS, TF, GM and NSK analysed the data. JS and NSK drafted the manuscript, with all authors providing critical revisions and approval for the final version. JS and NSK agree to be accountable for all aspects of the work.

Acknowledgements

We would like to thank the NHS Trusts and departments for allowing us access, and the participants for giving their time.

References

1. National Institute for Health and Care Excellence. *Acute kidney injury: Prevention, detection and management of acute kidney injury up to the point of renal replacement therapy.*National Institute for Health and Care Excellence; 2013.

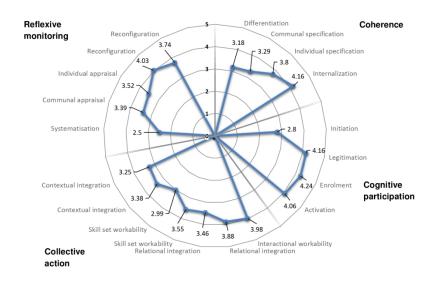
- 536 2. Kerr M, Bedford M, Matthews B, O'Donoghue D. The economic impact of acute kidney injury in England. *Nephrology Dialysis Transplantation*. 2014;29(7):1362-1368.
- 538 3. Stewart J, Findlay G, Smith N, Kelly K, Mason M. *Adding insult to injury: a review of the care*539 of patients who died in hospital with a primary diagnosis of acute kidney injury (acute renal failure). London: National Confidential Enquiry into Patient Outcome and Death; 2009.
- 541 4. Selby NM, Hill R, Fluck RJ. Standardizing the Early Identification of Acute Kidney Injury: The NHS England National Patient Safety Alert. *Nephron.* 2015;131(2):113-117.
- 543 5. Sawhney S, Fluck N, Marks A, et al. Acute kidney injury—how does automated detection perform? *Nephrology Dialysis Transplantation*. 2015;30(11):1853-1861.
- 545 6. KDIGO. KDIGO Clinical Practice Guideline for Acute Kidney Injury. *Kidney International Supplements*. 2012;2(1).
- 547 7. Selby NM. Electronic alerts for acute kidney injury. *Current Opinion in Nephrology and Hypertension.* 2013;22(6):637-642.
- 549 8. Kashani KB. Automated acute kidney injury alerts. *Kidney International*. 2018;94(3):484-490.
- 550 9. Lachance P, Villeneuve P-M, Rewa OG, et al. Association between e-alert implementation for detection of acute kidney injury and outcomes: a systematic review. *Nephrology Dialysis*552 *Transplantation*. 2017;32(2):265-272.
- 553 10. Kanagasundaram NS, Bevan MT, Sims AJ, Heed A, Price DA, Sheerin NS. Computerized 554 clinical decision support for the early recognition and management of acute kidney injury: a 555 qualitative evaluation of end-user experience. *Clinical Kidney Journal*. 2015;9(1):57-62.
- 556 11. Park S, Baek SH, Ahn S, et al. Impact of Electronic Acute Kidney Injury (AKI) Alerts With 557 Automated Nephrologist Consultation on Detection and Severity of AKI: A Quality 558 Improvement Study. *American Journal of Kidney Diseases*. 2018;71(1):9-19.
- Haase M, Kribben A, Zidek W, et al. Electronic Alerts for Acute Kidney Injury: A Systematic Review. *Deutsches Ärzteblatt International*. 2017;114(1-2):1-8.
- Selby NM, Crowley L, Fluck RJ, et al. Use of Electronic Results Reporting to Diagnose and
 Monitor AKI in Hospitalized Patients. *Clinical Journal of the American Society of Nephrology*.
 2012;7(4):533-540.
- 564 14. Colpaert K, Hoste EA, Steurbaut K, et al. Impact of real-time electronic alerting of acute kidney injury on therapeutic intervention and progression of RIFLE class*. *Critical Care Medicine*. 2012;40(4):1164-1170.
- 567 15. May C, Finch T. Implementing, Embedding, and Integrating Practices: An Outline of Normalization Process Theory. *Sociology.* 2009;43(3):535-554.
- May CR, Mair F, Finch T, et al. Development of a theory of implementation and integration:
 Normalization Process Theory. *Implementation Science*. 2009;4(1):29.
- 571 17. May CR, Cummings A, Girling M, et al. Using Normalization Process Theory in feasibility 572 studies and process evaluations of complex healthcare interventions: a systematic review. *Implementation Science*. 2018;13(1):80.
- Henderson EJ, Rubin GP. The utility of an online diagnostic decision support system (Isabel) in general practice: a process evaluation. *JRSM Short Reports*. 2013;4(5):1-11.
 - Hooker L, Small R, Humphreys C, Hegarty K, Taft A. Applying normalization process theory to understand implementation of a family violence screening and care model in maternal and child health nursing practice: a mixed method process evaluation of a randomised controlled trial. *Implementation science*. 2015;10(1):39.
 - 20. Kennedy A, Rogers A, Chew-Graham C, et al. Implementation of a self-management support approach (WISE) across a health system: a process evaluation explaining what did and did not work for organisations, clinicians and patients. *Implementation Science*. 2014;9(1):129.
 - Finch TL, Rapley T, Girling M, et al. Improving the normalization of complex interventions: measure development based on normalization process theory (NoMAD): study protocol. Implementation Science. 2013;8(1):43.

- Finch TL, Girling M, May CR, et al. NoMAD: Implementation measure based on Normalization
 Process Theory [Measurement instrument]. http://www.normalizationprocess.org.
 Published 2015. Accessed 12th April 2018.
- Rapley T, Girling M, Mair FS, et al. Improving the normalization of complex interventions:
 part 1 development of the NoMAD instrument for assessing implementation work based
 on normalization process theory (NPT). *BMC Medical Research Methodology*.
 2018;18(1):133.
- 593 24. Finch TL, Girling M, May CR, et al. Improving the normalization of complex interventions: 594 part 2 - validation of the NoMAD instrument for assessing implementation work based on 595 normalization process theory (NPT). *BMC Medical Research Methodology*. 2018;18(1):135.
 - Agency for Healthcare Research and Quality (AHRQ). Hospital Survey on Patient Safety
 Culture. https://www.ahrq.gov/sops/quality-patient-safety/patientsafet
- Gale N, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the
 analysis of qualitative data in multi-disciplinary health research. *BMC Medical Research Methodology*. 2013;13(1):117.
- Barbour RS. Checklists for improving rigour in qualitative research: a case of the tail wagging the dog? *BMJ.* 2001;322(7294):1115-1117.
 - 28. Kolhe NV, Staples D, Reilly T, et al. Impact of Compliance with a Care Bundle on Acute Kidney Injury Outcomes: A Prospective Observational Study. *PLoS ONE*. 2015;10(7):e0132279.
 - 29. Thomas ME, Blaine C, Dawnay A, et al. The definition of acute kidney injury and its use in practice. *Kidney International*. 2015;87(1):62-73.
- Muniraju TM, Lillicrap MH, Horrocks JL, Fisher JM, Clark RMW, Kanagasundaram NS.

 Diagnosis and management of acute kidney injury: deficiencies in the knowledge base of non-specialist, trainee medical staff. *Clinical Medicine*. 2012;12(3):216-221.
- Sykes L, Nipah R, Kalra P, Green D. A narrative review of the impact of interventions in acute kidney injury. *Journal of Nephrology.* 2017.
 - Benn J, Arnold G, Wei I, Riley C, Aleva F. Using quality indicators in anaesthesia: feeding back data to improve care. *British Journal of Anaesthesia*. 2012;109(1):80-91.
 - 615 33. Macrae C. The problem with incident reporting. *BMJ Quality & amp; Safety.* 2016;25(2):71-616 75.
- 81. Brún AD, Heavey E, Waring J, Dawson P, Scott J. PReSaFe: A model of barriers and facilitators to patients providing feedback on experiences of safety. *Health Expectations*.
 2017;20(4):771-778.
- 620 35. May C. Towards a general theory of implementation. *Implementation Science*. 2013;8(1):18.
- 36. Wilson FP, Shashaty M, Testani J, et al. Automated, electronic alerts for acute kidney injury:
 a single-blind, parallel-group, randomised controlled trial. *The Lancet*. 2015;385(9981):1966 1974.
- 624 37. Oh J, Bia JR, Ubaid-Ullah M, Testani JM, Wilson FP. Provider acceptance of an automated electronic alert for acute kidney injury. *Clinical Kidney Journal*. 2016.
 - 38. Karsh B-T, Holden RJ, Alper SJ, Or CKL. A human factors engineering paradigm for patient safety: designing to support the performance of the healthcare professional. *Quality and Safety in Health Care.* 2006;15(suppl 1):i59-i65.

Figure title & legend

- 631 Figure 1 title: Petal chart showing mean scores for the sixteen NPT sub-constructs
- Figure 1 legend: Likert scale of 1 (strongly disagree) to 5 (strongly agree).

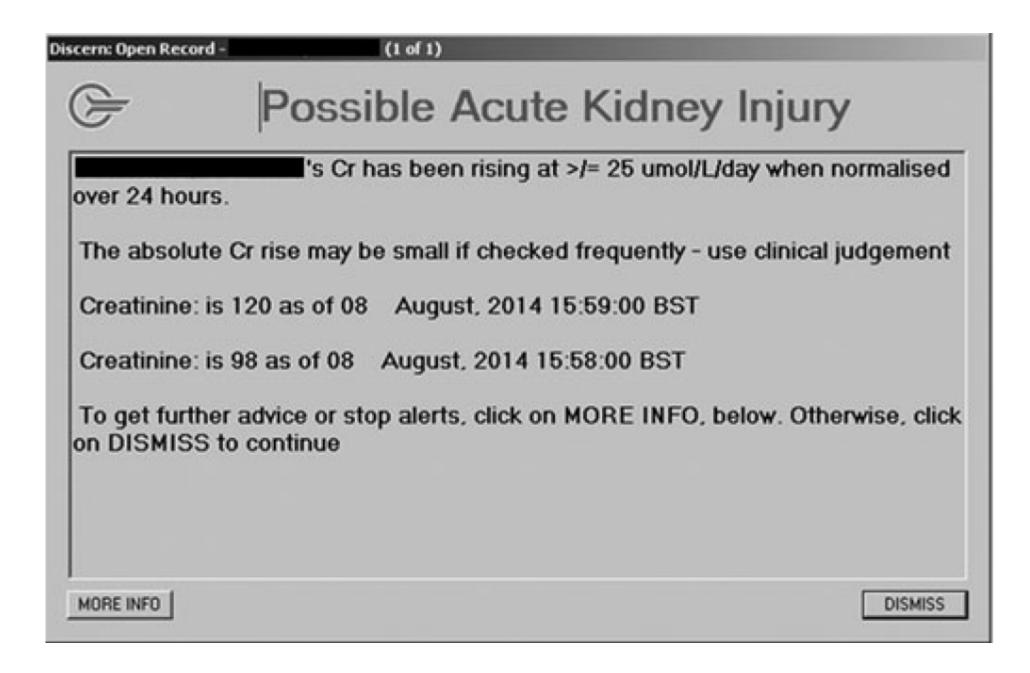


Petal chart showing mean scores for the sixteen NPT sub-constructs. Likert scale of 1 (strongly disagree) to 5 (strongly agree).

210x297mm (200 x 200 DPI)

1	
2	
3 4 5	
4	
2	
6 7	
/	
8	
9 10	
10	
11	
12	
13	
14	
14 15 16	
16	
16 17	
18	
19	
20	
21	
22	
23	
24	
25	
26	
26 27	
28	
29 30 31	
31	
32	
33	
34	
34 35	
36	
37	
38	
39	
40	
41	
42	
43	
43	
44	

06	
mmol/L	133 - 146
mmol/L	3.5 - 5.3
mmol/L	95 - 108
mmol/L	22 - 29
mmol/L	2.5 - 7.8
umol/L	49 - 90



Acute Kidney Injury Alert Study

Interview Questions

Themes:

- Coherence: Meaning-making sense of the technology and the work, differentiation, embedding
- Cognitive participation: Commitment-what is done to work with others
- Collective action: Effort-what is done whilst using this tool
- **Reflexive monitoring:** Comprehension- How the new technology affects them, others and patient care

Introduction

- Introduce myself and my role in the research
- Ensure information has been read and consent (x2) is signed and they retain a copy
- Ask the participant to briefly explain:
 - Who they are
 - O What they do (role) e.g. Dr (registrar etc.) nurse.
 - How long they have been on the ward
 - What other experience do they have, eg previous roles

Opening question

- Q Please describe your first/last encounter with the AKI alerts: this should provide a basis for further questions as it will point to aspects of his or her experience
 - O What sort of experience do you have of using AKI alerts?
- **Q** How do you currently use electronic alerts (not necessarily AKI) within the electronic record? Are some alerts more important than others? (if yes, what makes them so?)
- Q Use screen prints of each page to ask questions about user experience: ease of use, visual appearance, nuisance factors etc.
 - If appropriate make memos of facial expressions, hand gestures, non-verbals
 - Make memos in relation to comments for further questioning/investigation at the interview and/or subsequent participants.

List of potential (Not in order of importance) Normalization Process Theory-based questions as a reminder used on the basis of answers to the opening questions

Many descriptive and explanatory questions are used to elicit detail of actions, processes, outcomes and correlations. Some questions may overlap one or more theme.

Questions will develop given the kind of answer and may include questions not cited below.

Coherence Type Questions

- **Q** What do you understand as the purpose of the alerting tool? Is it important to the patient's safety? Why do you think the alerts have been implemented?
- **Q** Ideally, where do you think this tool should fit in to your daily work?

- **Q** How do others in your unit / clinical setting use the tool? From your own experience, is this specific to your clinical setting?
- **Q** From your perspective, how do AKI alerts compare to other alerts / computer tools
- **Q** How do you think you are expected to use the alert?
- **Q** What benefits/value do you think the alert provides?

Cognitive Participation type questions

- **Q** Who leads the use of this on your ward/unit? What does this role / task consist of for them? Does it include responsibility for AKI outcomes?
- **Q** How do the different professionals on the ward interact / use / respond to the alert? Do people have different roles / interactions with the alert depending on their profession / role?
- **Q** From your perspective, what would help staff to engage better with the alerting system?
- **Q** Have you shown others how to use it? If so, describe what you did and why. If not, why not?

Collective Action type questions

- **Q** Please describe what you do when you encounter the alert?
- Q Please explain how the tool helps/hinders working with others
- **Q** How does the alert affect how you work? Eg use of time and resources

Reflexive monitoring

- **Q** How does it make you feel when you see the alert?
- **Q** Would you say the alert is useful or not? Explain
- **Q** What do you think of the alert? (elicit a personal opinion)
- **Q** What do others say about it?
- **Q** To what extent do you and/or others have the ability to provide feedback / influence improvements to the system? What helps or hinders this ability?
- **Q** Has it altered the way you work/think about acute kidney injury?
- Q Does the alert effect change in medical management of the patient? Does this lead to a change in the patient's outcome?
- **Q** Is the alert worthwhile? Explain the answer
- **Q** Are there any improvements you would like to make to the system? Eg alert, interaction with alerts, validation, visual etc.

Remember to thank them for their time and effort

Survey Instructions

This survey is designed to help get a better understanding of how to apply and integrate new technologies and complex interventions in health care.

This survey asks questions about the implementation of acute kidney injury (AKI) electronic alerts into patients' medical records. We understand that people involved with AKI alerts have different roles, and that people may have more than one role. For this survey, please answer all the statements from the perspective of being an end-user of AKI alerts.

The survey is in 3 parts, Parts A-C:

- Part A asks some brief questions about yourself and your role.
- Part B asks general questions about patient safety and AKI alerts.
- Part C contains four sets of statements about AKI alerts. For each statement in Part C, there is the option to agree or disagree with what is being asked. However, if you feel that the statement is not relevant to you, you can answer 'not relevant'.

The survey is on both sides of paper. Answers to all questions are required, except where it is stated as being optional. The only optional questions are Q15b, Q16b, Q17b, and Q18b.

Please take the time to decide which answer best suits your experience for each statement and tick the appropriate circle.

If you would like to complete this version electronically (on mobile, tablet or desktop) please use the address below.

[address removed for publication]

Electronic alerts for acute kidney injury - end user survey

Part A. About vourself

Part A: About yourself	Survey number (admin only)
 Q1. How would you describe your professional job category? Medical doctor (go to Q2a) Surgical doctor (go to Q2a) Nurse (go to Q2b) Other (go to Q2c) 	
 Q2a. How would you describe your professional job level? Foundation-years doctor 1 (F1) Foundation-years doctor 2 (F2) Specialist trainee doctor (ST1 or ST2) Specialist trainee doctor (ST3, ST4 or ST5) Specialist trainee doctor (ST6 or ST7) Staff grade doctor Consultant Other (go to Q2d) 	
Please go to question 3 on the next page	
Q2b. How would you describe your professional job level? Dand 4 Band 5 Band 6 Band 7 Band 8a Band 8b Dand 8c Other (go to Q2d)	
Please go to question 3 on the next page	
Q2c. How would you describe your professional job category? For example healthcare assistant, nurse, doctor.	
Please go to question 2d below Q2d. How would you describe your professional job level? For example, your c grade / band	urrent

Please go to question 3 on the next page

Part A: About yourself (continued)

Q3. How many full years have you held your primary professional qualificat	ion?
Q4. Which NHS Trust do you currently work at?	
O Gateshead Health NHS Foundation Trust	
O Newcastle upon Tyne Hospitals NHS Foundation Trust	
O Northumbria Healthcare NHS Foundation Trust	
Other (please specify in box below)	
10	
Q5. How many full years have you worked in your current role at this NHS 1	
If your Trust has merged with another or changed its name, please include in you	ır answer all
the time you have worked with this Trust and its predecessors	
Q6. Which best describes the department / unit that you work in?	
O Internal Medicine / Care of the Elderly	
O Emergency Admissions	
O General / Vascular Surgery	
Other (please specify)	
O7 How many full years have you worked in your coment role in this denom	4man4 /
Q7. How many full years have you worked in your current role in this depar unit?	tment /
unit :	

Part A: About yourself (continued)

Q8. Have you received any formal or informal training in relation to acute kidney injury in the past 24 months?	
O No	
O Yes (please specify)	
Q9. Does your team, unit or NHS Trust have any initiatives other than acute kidney injury electronic alerts to improve acute kidney injury awareness? No	
O Yes (please specify)	

This is the end of Part A. Please turn over for Part B.

Part B: General questions about patient safety

Q10. Perceptions of patient safety in your work area / unit

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
It is just by chance that more serious mistakes do not happen around here	0	0	•	•	0
Patient safety is never sacrificed to get more work done	0	0	0	0	0
We have patient safety problems in this unit	0	0	•	•	•
Our procedures and systems are good at preventing errors from happening	0	•	•	•	0

Q11. Please give your work area / unit in this hospital an overall grade on patient safety

	Failing	Poor	Acceptable	Very good	Excellent
Patient safety grade	•	•	0	0	0

Part B: General questions about acute kidney injury alerts

Q12. When you see an acute kidney injury alert within the patient's record, how familiar does it feel?

	Still feels very new									Feels completely familiar
	1	2	3	4	5	6	7	8	9	10
Familiarity of AKI alert	0	0	0	0	0	0	0	•	0	0

Q13. Do you feel the acute kidney injury alert is currently a normal part of your work?

	Not at all									Completely
	1	2	3	4	5	6	7	8	9	10
Responding to the AKI alert is currently normal (present)	0	0	0	0	0	0	•	0	0	•

Q14. Do you feel the acute kidney injury alert will become a normal part of your work?

	Not at all									Completely
	1	2	3	4	5	6	7	8	9	10
Responding to the AKI alert will become normal (future)	•	0	0	0	0	0	0	0	0	•

This is the end of Part B. Please turn over for Part C1.

Part C1: Detailed questions about acute kidney injury alerts

Q15a. For each statement, please select one answer that best suits your experience.

	Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Not relevant
I can see how the AKI alert differs from usual ways of working	•	•	•	O	•	•
Staff in this organisation have a shared understanding of the purpose of the AKI alert		•	0	O	0	O
I understand how the AKI alert affects the nature of my own work	0	0	0	0	0	0
I can see the potential value of the AKI alert for my work	•	•		•	O	•

15b. Please elaborate on your answers provided in this part (optional)								

This is the end of Part C1. Please turn over for Part C2.

Part C2: Detailed questions about acute kidney injury alerts (continued)

Q16a. For each statement, please select one answer that best suits your experience.

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Not relevant
There are key people who drive the AKI alert forward and get others involved	0	0	•	O	•	•
I believe that responding to the AKI alert is a legitimate part of my role	90	0	0	0	O	O
I'm open to working with colleagues in new ways when responding to the AKI alert	0	0	0	O	0	O
I will continue to support the AKI alert	0	0	0/2	0	O	0

Q16b. Please elaborate on	16b. Please elaborate on your answers provided in this part (optional)								

This is the end of Part C2. Please turn over for Part C3.

Part C3: Detailed questions about acute kidney injury alerts (continued)

Q17a. For each statement, please select one answer that best suits your experience.

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Not relevant
I can easily integrate the AKI alert into my existing work	0	O	0	O	0	O
The AKI alert disrupts working relationships	0	•	•	•	•	0
I have confidence in other people's ability to respond to the AKI alert	0	•	•	•	•	•
Work is assigned to those with skills appropriate to responding to the AKI alert	•	0	0	•	•	0
Sufficient training is provided to enable staff to implement the AKI alert	0	0	0	0	0	O
Sufficient resources are available for the AKI alert	0	0	0	G	0	0
Management adequately supports the AKI alert	•	•	•	0	•	0

Q17b.	Q17b. Please elaborate on your answers provided in this part (optional)								

This is the end of Part C3. Please turn over for Part C4.

Part C4: Detailed questions about acute kidney injury alerts

Q18a. For each statement, please select one answer that best suits your experience.

	Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Not relevant
I am aware of reports about the effects of the AKI alert	0	0	0	0	0	0
The staff agree that the AKI alert is worthwhile	0	O	0	•	0	O
I value the effects that the AKI alert has had on my work	0	0	•	•	0	•
Feedback about the AKI alert can be used to improve it in the future	0	0	0	O	•	•
I can modify how I work with the AKI alert	O	•	0	0	0	•

Q18b. Please elaborate on your answers provided in this part (optional)			

Please turn over

This is the end of the survey

Thank you for completing the survey; your participation is greatly appreciated. We understand that the nature of a survey may not allow you to fully express your thoughts and opinions about the acute kidney injury alerts. If you feel this is the case and would be interested in participating in an interview (if you have not already), please leave your name and email address below and we will be in touch shortly with more information. These will not be linked back to your survey responses. If you are not interested in hearing more about an interview, please leave the box blank.

Name	
Email address	

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on
Domain 1: Research team			Page No.
and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	
Occupation	3	What was their occupation at the time of the study?	
Gender	4	Was the researcher male or female?	
Experience and training	5	What experience or training did the researcher have?	
Relationship with			
participants			
Relationship established	6	Was a relationship established prior to study commencement?	
Participant knowledge of	7	What did the participants know about the researcher? e.g. personal	
the interviewer		goals, reasons for doing the research	
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator?	
		e.g. Bias, assumptions, reasons and interests in the research topic	
Domain 2: Study design			
Theoretical framework			
Methodological orientation	9	What methodological orientation was stated to underpin the study? e.g.	
and Theory		grounded theory, discourse analysis, ethnography, phenomenology,	
		content analysis	
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience,	
		consecutive, snowball	
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail,	
		email	
Sample size	12	How many participants were in the study?	
Non-participation	13	How many people refused to participate or dropped out? Reasons?	
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	
Presence of non-	15	Was anyone else present besides the participants and researchers?	
participants			
Description of sample	16	What are the important characteristics of the sample? e.g. demographic	
		data, date	
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot	
		tested?	
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	
Field notes	20	Were field notes made during and/or after the inter view or focus group?	
Duration	21	What was the duration of the inter views or focus group?	
Data saturation	22	Was data saturation discussed?	
Transcripts returned	23	Were transcripts returned to participants for comment and/or w only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

Topic	Item No. Guide Questions/Description		Reported on
			Page No.
		correction?	
Domain 3: analysis and			
findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	
Description of the coding	25	Did authors provide a description of the coding tree?	
tree			
Derivation of themes	26	Were themes identified in advance or derived from the data?	
Software	27	What software, if applicable, was used to manage the data?	
Participant checking	28	Did participants provide feedback on the findings?	
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings?	
		Was each quotation identified? e.g. participant number	
Data and findings consistent	30	Was there consistency between the data presented and the findings?	
Clarity of major themes	31	Were major themes clearly presented in the findings?	
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.

BMJ Open

Acute kidney injury electronic alerts: mixed methods Normalization Process Theory evaluation of their implementation into secondary care in England

Journal:	BMJ Open
Manuscript ID	bmjopen-2019-032925.R2
Article Type:	Original research
Date Submitted by the Author:	06-Nov-2019
Complete List of Authors:	Scott, Jason; Northumbria University Finch, Tracy; Northumbria University, Nursing, Midwifery and Health Bevan, Mark; Northumbria University Maniatopoulos, Gregory; Newcastle University, Institute of Health and Society Gibbins, Chris; Newcastle Upon Tyne Hospitals NHS Foundation Trust Yates, Bryan; Northumbria Healthcare NHS Foundation Trust Kilimangalam, Narayanan; Gateshead Health NHS Foundation Trust Sheerin, Neil; Newcastle University Kanagasundaram, Suren; Newcastle University, Institute of Cellular Medicine; Newcastle Upon Tyne Hospitals NHS Foundation Trust
Primary Subject Heading :	Renal medicine
Secondary Subject Heading:	Health services research, Health informatics
Keywords:	Acute renal failure < NEPHROLOGY, Health informatics < BIOTECHNOLOGY & BIOINFORMATICS, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Nephrology < INTERNAL MEDICINE, QUALITATIVE RESEARCH

SCHOLARONE™ Manuscripts Acute kidney injury electronic alerts: mixed methods Normalization Process Theory evaluation of their implementation into secondary care in England

Title Page

Jason Scott,1* Tracy Finch,1 Mark Bevan,1 Gregory Maniatopoulos,2 Chris

- Gibbins,³ Bryan Yates,⁴ Narayanan Kilimangalam,⁵ Neil S Sheerin,^{3,6} Nigel Suren
- 9 Kanagasundaram,^{3,6*}

- ¹ Faculty of Health and Life Sciences, Northumbria University, Newcastle upon Tyne, England
- 12 Institute of Health and Society, Newcastle University, Newcastle upon Tyne, England
- 13 Renal Services, Newcastle upon Tyne Hospitals NHS Foundation Trust, Newcastle upon Tyne,
- 14 England
- 15 ⁴ Northumbria Healthcare NHS Foundation Trust, Newcastle upon Tyne, England
- 16 ⁵ Gateshead Health NHS Foundation Trust, Gateshead, England
 - ⁶ Institute of Cellular Medicine, Newcastle University, Newcastle upon Tyne, England

- *Corresponding author
- 20 Dr Jason Scott
- 21 Faculty of Health & Life Sciences
- 22 Northumbria University
- 23 Coach Lane Campus West
- 24 Newcastle upon Tyne
- 25 England
- 26 NE7 7XA
- 27 jason.scott@northumbria.ac.uk

Word count: 3,920

ABSTRACT

Objective

Around one in five emergency hospital admissions are affected by acute kidney injury (AKI). To address poor quality of care in relation to AKI, electronic alerts (e-alerts) are mandated across primary and secondary care in England and Wales. Evidence of the benefit of AKI e-alerts remains conflicting, with at least some uncertainty explained by poor or unclear implementation. The objective of this study was to identify factors relating to implementation, using Normalization Process Theory (NPT), which promote or inhibit use of AKI e-alerts in secondary care.

Design

Mixed methods combining qualitative (observations, semi-structured interviews) and quantitative (survey) methods.

Setting and participants

Three secondary care hospitals in North East England, representing two distinct AKI e-alerting systems. Observations (>44 hours) were conducted in Emergency Assessment Units (EAUs). Semi-structured interviews were conducted with clinicians (n=29) from EAUs, Vascular or General Surgery, or Care of the Elderly. Qualitative data were supplemented by NoMAD surveys (n=101).

Analysis

Qualitative data were analysed using the NPT framework, with quantitative data analysed descriptively and using Chi Square and Wilcoxon Signed Ranks Test for differences in current and future normalization.

Results

Participants reported familiarity with the AKI e-alerts but that the e-alerts would become more normalized in the future (p<0.001). No single NPT mechanism led to current (un)successful implementation of the e-alerts, but analysis of the underlying sub-constructs identified several mechanisms indicative of successful normalization (*internalization*, *legitimation*) or unsuccessful normalization (*initiation*, *differentiation*, *skill set workability*, *systematization*).

Conclusions

Clinicians recognised the value and importance of AKI e-alerts in their practice, though this was not sufficient for the e-alerts to be routinely engaged with by clinicians. To further normalize the use of AKI e-alerts, there is a need for tailored training on use of the e-alerts and routine feedback to clinicians on the impact that e-alerts have on patient outcomes.

Key words

Acute kidney injury, Normalization Process Theory, Implementation, Mixed methods, Human factors, Patient safety

ARTICLE SUMMARY

Strengths and limitations

- This is the first known mixed methods study to use Normalization Process Theory to investigate the implementation of AKI e-alerts, providing a unique lens on their implementation
- The study was conducted in clinical areas where AKI incidence is high; it is unknown whether the e-alert would be more useful (and whether it would be more or less poorly implemented) in clinical areas where AKI incidence is lower.
- The study was also conducted in one region, and so implementation of the AKI e-alert may have been influenced by local networks.
- It is unknown whether the e-alerts had a quantifiable impact on AKI outcomes or staff actions, and so it is not possible to draw conclusions about the effectiveness of the AKI e-alerts studied as a result of implementation.

INTRODUCTION

Acute kidney injury (AKI) affects around one in five emergency hospital admissions.¹ AKI is both dangerous, with around 15,000 excess deaths in National Health Service (NHS) England inpatients per year,² and costly, imposing an estimated additional financial burden on this system of £1.02 billion per annum.² Increasing age and co-morbidity in the hospital population has increased the number of patients at risk from the condition, which is only likely to rise further with an ageing population. AKI care itself is often poor, with systematic failings in its recognition and management, and frequent omissions of even the basics of care.³

AKI alerting systems are mandated for all NHS England primary and secondary care providers, using a biochemical detection algorithm⁴ and usually implemented electronically. The algorithm, which appears to perform with a high degree of sensitivity (>90%),⁵ has resolved ambiguities in modern diagnostic criteria⁶ around how to interpret baseline serum creatinine (SCr), a historical impediment to the standardisation of automated AKI detection, and as well as outputs for the three stages of disease severity, it also flags out-of-range SCrs in the absence of an historical baseline. AKI electronic alerts (e-alerts) are thought to improve patient outcomes by improving early detection of AKI and triggering earlier intervention by clinicians.⁷ The exact nature of the AKI alerts is not, however, dictated, and may take a number of forms.

The efficacy of AKI e-alerts is limited and has not shown consistent benefit⁸ in terms of reduced mortality or use of renal support, or positive impacts on processes of care,⁹ which may be the result of alert fatigue^{5,10} or disrupted workflow.¹⁰ Inadequate implementation can explain the poor outcomes, particularly as there are some examples of improved care processes¹¹ and treatment outcomes through successful implementation.¹²⁻¹⁴ Mandatory incorporation of AKI alerts into all secondary care organisations in England lacked a clear implementation strategy, and recently published systematic reviews recognised large variation in implementation,¹² with an association between poor implementation and poor outcome.⁹ One review specifically identified a paucity of research on the implementation of AKI e-alerts internationally.⁹ To address this paucity of research, the present study aimed to identify factors relating to implementation which promoted or inhibited use of AKI e-alerting systems in secondary care.

METHODS

This study incorporated mixed methods (qualitative interviews and observations combined with quantitative surveys) to investigate the implementation of AKI e-alerts from multiple perspectives, including observations, surveys and semi-structured interviews. Normalization Process Theory (NPT)^{15,16} was chosen as the theoretical basis for the study as it is an internationally recognised theory of implementation that has been used to explain successful and suboptimal implementation in over 100 healthcare initiatives, ¹⁷ including through the use of mixed methods. ¹⁸⁻²⁰ NPT therefore provides the explanatory power for understanding how complex interventions, such as AKI e-alerts, become integrated into existing practice through individual and collective implementation. This integration is proposed to occur via four mechanisms: 'Coherence': how people make sense of what needs to be done, 'Cognitive participation': how relationships with others influence outcomes, 'Collective action': how people work together to make practices work, and 'Reflexive monitoring': how people assess the impact of the new intervention. The four constructs are operationalised under 16 sub-constructs, which are described in table 1.

Table 1: Description of NPT mechanisms and sub-constructs

Coherence

Differentiation: How participants understand a set of practices and their objects to be different (or not) from each other.

Communal specification: Extent to which participants have a shared understanding of the aims, objectives, and expected benefits of a set of practices.

Individual specification: How participants understand their own specific tasks and responsibilities around a set of practices.

Internalization: How participants perceive the value, benefits and importance of a set of practices.

Cognitive Participation

Initiation: Whether or not key participants are working to drive a new set of practices forward. **Enrolment:** The extent to which participants

organize or reorganize themselves and others in order to collectively contribute to the work involved in new practices.

Legitimation: The work of ensuring that other participants believe it is right for them to be involved in the new set of practices, and that they can make a valid contribution to it.

Activation: The work that participants do collectively to define the actions and procedures needed to sustain a new practice and to stay involved.

Collective Action

Interactional Workability: The interactional work that people do with each other, with tools/systems, and with other elements of a set of practices, when implementing a new practice.

Relational Integration: The work that is needed to build accountability and maintain confidence in a set of practices and in each other as they use them.

Skill set Workability: The allocation of work amongst participants with different roles and skills in relation to the new set of practices.

Contextual Integration: The work of managing a set of practices through the allocation of different kinds of resources and the execution of protocols, policies and procedures to support the practices.

Reflexive Monitoring

Systematization: The work undertaken by participants to determine how effective and useful the new set of practices is for them and for others, and the information collected to enable this. **Communal appraisal:** The work undertaken by

Communal appraisal: The work undertaken by participants collectively (sometimes in formal collaboratives, sometimes in informal groups) to evaluate the worth of a set of practices.

Individual appraisal: Individual participants' own appraisals, based on their experiences, of the effects of a new set of practices on them and the contexts in which they are set.

Reconfiguration: The extent to which appraisal work by individuals or groups may lead to respecification or modification of the set of practices.

Sampling and recruitment

Three NHS Trusts in North East England were invited to take part in the study based on being within a single NHS Trust's renal department catchment area, and the catchment area for referral for complex AKI (see table 2 for a description of Trusts and their AKI e-alerting systems). Three clinical areas were purposively chosen for study at each NHS Trust based on anticipated high levels of AKI incidence; (1) Emergency Admissions, (2) Internal Medicine/Care of the Elderly, and (3) General/Vascular Surgery.

Table 2: Characteristics of participating NHS Trusts and their AKI electronic e-alert. See Additional files 1 and 2 for images of the e-alerting systems.

NHS	Trust Characteristics	AKI electronic alert
Trust 1	University-affiliated, 1800 bed, multiple site tertiary referral hospital; contains regional renal unit, transplantation, cardiothoracic and hepato-biliary surgery as well as other major specialisms; The Renal Unit is based at one Trust site and although providing consultative input to the rest of the Trust, has no routine, onsite presence at these venues which include the emergency admissions suite and significant sections of general surgical, internal medical and elderly care services.	Passive electronic alert consisting of a line of black text appearing underneath serum creatinine results in the patient's electronic medical record (<i>Powerchart, Cerner Millennium, Cerner Corporation</i> , Kansas, MO, USA) which stated the stage of AKI where present. Additional pop-up electronic alert that appeared when accessing the patient's electronical medical record, and required dismissal to remove from the screen. A 'more info' link on the pop-up window, if clicked, took the end-user to a second window that contained further links to the Trust AKI protocol and specific guidance on aspects of management including essential assessments, key bedside observations & key investigations. The latter linked to quick order test panels including essential blood tests and urgent renal ultrasound requesting.
Trust 2	Multi-site university-affiliated district general with approximately 900 beds. All acute services on one site with internal medicine, elderly services, general and orthopaedic surgery along with obstetrics and paediatrics. Renal replacement provision from critical care. Renal input, provided from Trust 1 by remote consultation, no renal consultant presence within the trust.	Passive electronic alert consisting of a line of black text appearing underneath serum creatinine results in the patient's electronic medical record (TelePath Information Management System, Mill Systems Limited, Belper, UK) which stated the stage of AKI where present. Alert does not link with any other hospital information system, but instructs users to access local AKI guidelines.
Trust 3	District general hospital with 300 beds in medicine. Renal input is from Trust 1 through a combination of remote consultation and weekly availability at the time of an out-patient clinic on site.	Passive electronic alert consisting of a line of black text appearing underneath serum creatinine results in the patient's electronic medical record (Medical Information Technology (MEDITECH) Inc., Westwood, MA, USA) which stated the stage of AKI where present. Alert does not link with any other hospital information system, but instructs users to access

Participants for semi-structured interviews were purposively sampled based on specialty and clinical experience (determined by grade). Participants were invited through direct contact by JS, or by leaving contact details after completing a survey. Recruitment to survey was conducted through direct contact

by JS, or electronically via an internal email by (or on behalf of) the lead consultant for the clinical specialty. Teaching sessions at Trust 3 were also used to invite staff to participate in the survey. Access to observe practice on emergency admission units was facilitated by the lead consultant(s) for the unit. Participants were able to take part in the research activities (interviews, observations and/or survey) in any order, based upon what was most convenient. Where possible, the order of activities was balanced to reduce confounding variables.

Data collection

Semi-structured interviews were conducted by a male research associate, JS (PhD), with participants in their place of work or via telephone between May 2017 to September 2017, and lasted an average of 26 minutes (range 17 to 41). Interviews were recorded using a digital voice recorder and transcribed verbatim by a professional transcription company. A topic guide (see Additional file 3) was constructed by the research team based on the four mechanisms of NPT (coherence, cognitive participation, collective action, reflexive monitoring; see table 1) and from previous qualitative work on implementation of AKI e-alerts. In addition to questions based on the four NPT mechanisms, the topic guide also included questions about the participants' clinical experience (job role, length of time in role, experience in other roles) and their experience with AKI e-alerts. Ethnographic data were obtained by JS by observing practice in emergency admission units, guided tours, shadowing of staff, and informal conversations and handover meeting attendance. Observational data were documented in fieldnotes.

The Emergency Admission Units function to provide early assessment of adult patients referred via their general practitioner or the emergency department. One of the units (Trust 3) was a hybrid Emergency Admission Unit and Acute Medicine ward. A total of 44.25 hours of observations were conducted at various times of day (morning, afternoon and evening) during the working week (Monday to Friday).

The NoMAD survey,²¹⁻²³ a validated instrument for measuring implementation,²⁴ was adapted for use with AKI e-alerts (see Additional file 4). Questions were added to identify characteristics of respondents, including:

- Profession
- Grade
- Years since obtaining primary medical qualification
- Years working in the Trust
- Years working in the department
- Formal or informal AKI training received in previous 24 months
- AKI initiatives to improve awareness of AKI other than e-alerts

In addition, five questions from the Hospital Survey on Patient Safety Culture™ (SOPS™; version 1.0)²⁵ were included. SOPS™ contains a construct containing four questions titled 'Overall perceptions of patient safety'. All four questions from this construct were included, along with an overall patient safety grade. Paper and electronic versions of the study survey were made available to potential participants. All data collection was conducted after the AKI e-alerts had been implemented into practice for at least one year.

Data analysis

Framework analysis was used for qualitative data, ²⁶ with the four NPT mechanisms and their subconstructs forming the framework (see table 1). For interview data, one interview transcript was jointly charted by JS and TF, with interpretations of the data discussed until agreement was reached. This discussion familiarised JS with the differential meanings underpinning the 16 sub-constructs for subsequent analysis of qualitative data, as TF is an expert in NPT as a co-developer of the theory. ^{22,23} JS then charted the remaining interview data into the framework. For observational data, in-depth observer notes were summarised by the observer (JS), then all observation data were charted into the framework jointly with TF.^{15,16} NVivo software (*QSR International Pty Ltd, version 10*) was used to facilitate coding of qualitative data. Once initial analysis was complete, all authors reviewed and discussed the coding in a team meeting before coming to agreement on the final interpretations, which is an established process of qualitative data analysis.²⁷ Participants were not invited to comment on findings.

IBM SPSS Statistics for Windows (*IBM Corp, version 24.0*) was used for quantitative analysis. Inferential statistics (chi square) were used to compare patient safety culture between NHS Trusts and specialties to identify whether safety culture could influence the subsequent analysis. Wilcoxon Signed Ranks Test was used to analyse differences in current and future normalization of the e-alerts. Survey items relating to the four NPT mechanisms were then analysed by examining descriptive statistics for each of the four mechanisms. Mechanism scores for each participant were created by taking their average score in each mechanism and dividing by the number of valid responses, which stopped data from being skewed where respondents stated a question was not applicable. Higher scores represent better perceived implementation in relation to each mechanism. Data were then triangulated by exploring (dis)agreements and silences across the qualitative and survey data sets. This was conducted by a single researcher (JS) identifying and listing sub-constructs that demonstrated particularly high or low normalization, comparing these against qualitative themes and then discussed amongst the research team.

Patient and public involvement

There was no patient and public involvement in the design or planning of the study.

RESULTS

Semi-structured interviews were conducted with 29 staff members. 28 interviews were with doctors, and one interview was with a pharmacist involved in implementing AKI e-alerts at Trust 1. The survey was distributed to 157 staff, and 102 (65%) responded. 94 (92.2%) completed the paper version, and eight (7.8%), the online version. See table 3 for a summary of interview participants and survey respondent characteristics. Table 3 also acts as a key to participants' grades, which is used to infer level of experience (grades are competency based) and is also used in the reporting of qualitative data. One survey was excluded as the participant reported on an e-alerting system at an NHS Trust not included in the study, leaving a final sample of 101.

Table 3: Participant characteristics of interviews and survey

Characteristic	Interview participants	Survey respondents
Job grade	N (%)	N (%)
Foundation doctor year 1 (F1)	9 (31.0)	16 (15.8)
Foundation doctor year 2 (F2)	4 (13.8)	25 (24.8)
Specialty registrar doctor year 1/2 (ST1/2)	4 (13.8)	23 (22.8)
Specialty registrar doctor year 3/4/5 (ST3/4/5)	3 10.3)	10 (9.9)
Specialty registrar doctor year 6/7 (ST6/7)	2 (6.9)	4 (4.0)
Staff grade doctor	0 (0)	5 (5.0)
Consultant	6 (20.7)	15 (14.9)
Nurse (band 6)	0 (0)	1 (1.0)
Other	1 (3.4)*	2 (1.0)†
NHS Trust	N (%)	N (%)
Trust 1	11 (37.9)	30 (29.4)
Trust 2	8 (27.6)	60 (58.8)
Trust 3	10 (34.5)	11 (10.8)
Department	N (%)	N (%)
Internal Medicine/Care of the Elderly	10 (34.5)	46 (45.5)
Emergency Admission	8 (27.6)	26 (25.7)
General / Vascular surgery	10 (34.5)	20 (19.8)
Other	1 (3.4)‡	9 (8.9)§

- * Pharmacist
- † Medical student=1, Locum Senior House Doctor=1
- 239 ‡ Pharmacy
 - § Palliative care=4, Acute medicine=2, Cardiology=1, ITU=1, Nephrology=1.

Patient safety

Overall patient safety culture, graded on a Likert scale from 1 (very poor) to 5 (excellent), had a mean score of 3.75. A chi-square analysis comparing the three NHS Trusts identified no significant difference in patient safety culture (χ 2=1.784, df=2, p=0.410). Using the same method, there was also no significant difference between the specialties surveyed (χ 2=1.453, df=3, p=0.693). These results indicated that different sites or specialties did not confound the analysis.

Familiarity and perceived normalization

Participants reported that they were mostly familiar with the e-alerts (mean=7.27, sd=2.562) and that the e-alert was part of their normal work (mean=7.28, sd=2.649). However, it was reported that the e-alerts would become a more normal part of their work (mean=8.32, sd=2.059), with a Wilcoxon Signed Ranks Test confirming the difference was statistically significant (Z=-5.049, p<0.001), suggesting that the e-alerts were not yet fully embedded.

NPT mechanisms and sub-constructs

Descriptive analysis of the mean scores of the four NPT mechanisms – coherence (\bar{x} =72.3%), cognitive participation (\bar{x} =76.4%), collective action (\bar{x} =66.5%) and reflexive monitoring (\bar{x} =68.8%) – suggested there was no key mechanism that led to (un)successful implementation of the e-alerts. Further

analysis of the 16 sub-constructs (table 1) identified several sub-constructs indicative of (un)successful implementation; mean ratings for the 16 sub-constructs are presented in Figure 1. More specifically, following triangulation with qualitative data, the NPT sub-constructs that were identified to contribute to successful normalization of the AKI e-alerts were *internalization* and *legitimation*, and those that contributed to unsuccessful normalization were *initiation*, *differentiation*, *skill set workability*, and *systematization*. As with the survey data, there were no identified differences in qualitative findings between the two e-alerting systems. Supporting qualitative data (quotes and field notes) for all sixteen sub-constructs are provided in table 4. The remainder of the results will focus on NPT sub-constructs that demonstrate where normalization was most positive or negative, based upon the triangulation of all data sources, representing sub-constructs that most promote or inhibit use of AKI e-alerts in secondary care.

[Insert Figure 1 around here]

Sub-constructs demonstrating positive normalization

Internalization

Clinicians often reported that, despite not always utilising the AKI e-alert, they valued the potential of it, which was reflected in the survey score of 4.16. This demonstrated that they had a fundamental understanding of the importance of recognising AKI early, and many clinicians recognised that it was possible to make mistakes and to miss AKI.

"in something like renal function, where there's so much variety, [the AKI e-alert] just helps jolt you to it and especially how severe AKIs can be, it's even more necessary because hopefully things like that wouldn't be missed, but there's always the potential that it could be. And having it say in black and white, this is an AKI, you know, they shouldn't be missed at all." [F1 interview, Emergency Admissions, Trust 2]

"The times I think it's probably useful is when it's one of those slightly sneakier ones, more subtle ones. The creatinine might have only peaked at 120 but, actually, if their creatinine is normally 45, that's still a big deal but it doesn't jump out at you as a creatinine of 600 would." [Consultant interview, Internal Medicine/Care of the Elderly, Trust 2]

Legitimation

Despite the lack of initiation (as identified in the Initiation theme), perceived or otherwise, clinicians still largely understood that responding to the AKI e-alerts was their responsibility, though this perspective was sometimes dependent on the clinician's seniority. For instance, all clinicians regardless of seniority recognised that the AKI e-alert was important to the work of junior doctors. In particular, some senior staff (consultants and registrars) felt that junior staff did not place sufficient priority on renal function; "For [junior staff] it might make a difference because they might not look at all the figures. If it says an AKI e-alert, then they might make the effort to actually do that" [ST6 interview, General/Vascular Surgery, Trust 3]. However, particularly on surgical wards where

foundation-year doctors were mostly responsible for ward-care of patients, the e-alerts were not seen to be part of the senior doctor's role, even though the AKI e-alerts were still valued.

"I think you'll find that as people progress, their focus of how they manage the patient shifts. They're more interested in dealing with the active problems and these outcomes of quite secondary issues that solve around the problem. The attitude is a bit like mine: someone more junior will deal with it and you totally lose interest in the other things." [ST3 interview, General/Vascular Surgery, Trust 3]

Sub-constructs demonstrating negative normalization

Differentiation

How clinicians differentiated the AKI e-alert from what was deemed to be normal practice prior to the implementation of the AKI e-alert, was often based upon the length of time that the clinician had been qualified. Clinicians who were newly qualified, particularly foundation-year doctors, consistently reported that they had no experience of working without an e-alerting system, and so using the AKI e-alert by default was deemed to be normal practice.

"I suppose I haven't ever realised it's actually a new thing. Obviously, I've only worked here 11 months, I just assumed it was always there" [F1 interview, General/Vascular Surgery, Trust 3]

Contrary to this, observations identified instances where clinicians were unaware of an e-alert for AKI, or were unaware of how the e-alert should work. In the following extract from observation notes, the clinician initially conceived of an e-alert as always being a pop-up, rather than text embedded into the system.

'I chat with [a doctor] and we talk about the AKI alerts. When I explain what it is I'm observing for, he looks a bit confused, says he doesn't know about the alerts. He opens up a patient record and explains he thinks this patient has AKI, so wants to see if there is an alert there. After I describe what the alert should look like, he says he thought I meant "a pop-up rather than a bit of text"; I think he doesn't see the text as an alert by itself.' [Trust 3 observation of Emergency Admissions, approx. 17:00]

Clinicians also identified that the lack of differentiation was related to the clinical area in which they were working. For instance, it was deemed to be routine to check renal function of all patients entering emergency admission suites. In this setting, clinicians often mentally risk-assessed patients for AKI. For these patients, the clinicians would more regularly check to see if blood test results had been returned.

"At the moment, probably not an awful lot else than I would normally do. Normally if I go through people's bloods specifically for renal function I usually click on each of the numbers and compare it to what it has been previously. I think I interpret renal function quite a lot in the context of what the patient's renal function IS? Or [sic] usually like. I click on each of the five elements that we get reported here and then

have a look at how that varies from the previous. To be honest I would do that irrespective of whether the alert is there or not." [ST1 interview, Emergency Admissions, Trust 3]

Initiation

Initiation received a mean score of 2.8. This remained consistent across all three Trusts, and was supported by interview participants who consistently reported that either the e-alerts "just appeared at some point" [F1 interview, General/Vascular Surgery, Trust 3], or that the e-alerts were already implemented when they began working for the Trust, as identified in the differentiation theme. However, there was a key difference; even where alerts were already implemented and thus deemed to be 'normal', there was a lack of training provided to clinicians on how to use the e-alerts. This finding was consistent (and is partly duplicated) with the *skill set workability* sub-construct of NPT.

"I think [the AKI e-alerts] just started popping up. So, we didn't get any training or anything like that on them, or why they were there, or who put them there, or what the purpose was." [ST2 interview, Internal Medicine/Care of the Elderly, Trust 1]

In one Trust, the person who contributed to the implementation of the AKI e-alerts acknowledged this sub-optimal initiation or training for doctors; "When we first went live we switched the rules on but we didn't really do a lot of education, and I think [the alerts] were relatively unpopular" [Pharmacist interview, Trust 1]. Education consisted of an email with information about the AKI alerts to clinical directors asking them to cascade it to their staff.

Skill set workability

The lack of training provided on how to use the e-alerts, as previously reported in the initiation theme, also contributes to the skill set workability theme. Participants reported that they generally had responsibility for AKI and thus the e-alerts, demonstrating to an extent that that there was appropriate skill set workability amongst those receiving the e-alerts. However, there were also occasions where participants demonstrated or recognised their own lack of knowledge related to the AKI e-alerts such as incorrectly describing how they thought the e-alerts worked. More specifically, participants regularly did not know how the e-alerts should be incorporated into their own practice.

"A teaching session would be really good of explaining, like, how to use the alert, like, the situations when the alert isn't effective and, then, just, kind of, what to do if you do get an alert." [Consultant interview, Internal Medicine/Care of the Elderly, Trust 2]

Systematization

Across all three of the NHS Trusts, no participants (regardless of seniority) collected information on the effectiveness of the AKI e-alert. While the data collected did not indicate whether anyone in the Trusts collected information regarding the effectiveness of the AKI e-alerts, it was consistently reported by all interview participants that feedback was not given to those using the AKI e-alerts. Furthermore, participants were unaware of whether the AKI e-alert, or more specifically responding to the AKI e-alert, had any effect.

"I think maybe a bit of feedback or a bit of education [would help staff to engage with the AKI alert. So, feedback as to how things had changed since the alert was introduced. [...] Some sort of outcome measure would be quite interesting. That might, just to show people that it's actually having a benefit." [Consultant interview, Internal Medicine/Care of the Elderly, Trust 1]

Table 4: Summary of the qualitative framework analysis for the 16 NPT sub-constructs with supportive evidence

NPT mechanisms and sub- constructs	Coding summary	Supporting evidence
Coherence		
Differentiation Mean survey score: 3.18	Clinicians often did not differentiate between normal practice and use of the AKI e-alert; checking the patient's renal function was deemed to be routine in the clinical areas studied.	'A doctor says that it's a routine part of their job to check renal function and would check it anyway – this is the case even in the emergency department if a patient came in with a broken arm to check for a potential underlying condition' [Trust 1 observation of Emergency Admissions, approx. 19:30]
Communal specification Mean survey score: 3.29	Working with the AKI e-alert was perceived to be an individual rather than team action. The e-alert was rarely discussed or used to initiate discussion, with staff often not knowing what others thought about the e-alert.	"I don't think we've had much discussion about the AKI alerts, it's certainly not something that I'm aware of, that other people have commented on." [F1 interview, General/Vascular Surgery, Trust 2] "I haven't spoken to anyone else [about the AKI ealert]. I know just from being in the doctor's office, with the other doctors that sometimes, you know, you see people glance at the screen, and go 'click' whilst they are still talking to you." [ST2 interview, Internal Medicine/Care of the Elderly, Trust 2]
Individual specification Mean survey score: 3.8	AKI e-alerts often made staff consider the patient's AKI and to double check renal function.	"I guess it's to draw attention to it quickly rather than bloods getting lost in the system for the day, because especially on a busy ward [] there'll be I don't know 20 bloods sent in the morning and then if you're busy with sick people it could go well into the afternoon before you get to check on bloods." [F1 interview, Emergency Admissions, Trust 2]
Internalization Mean survey score: 4.16	Many staff saw the potential value of the AKI e-alert and understood the need for the e-alerts.	"I think it's probably the most useful out of the alerts. It generally comes on when the patients genuinely do have an AKI, although, that's often sometimes not the case. Like we said before, often it does require action, so, yes, they're pretty useful." [F1 interview, Emergency Admissions, Trust 1]
Cognitive participa	ntion	
Initiation Mean survey score: 2.8	Participants frequently cited a lack of initiation in relation to the AKI e-alerts. This occurred for one of two reasons; 1) the e-alerts just appeared without any training on how to use them, or 2) clinicians were newly qualified (or new to the Trust) and the e-alerts were already implemented, but again no was training provided.	"Yes they just sort of bob up. We never had really any induction about them" [F1 interview, General/Vascular Surgery, Trust 3]
Legitimation	For the more junior doctors, the e- alerts are perceived to be a legitimate	"we have specialist nurses who provide input for absolutely everything. So, the idea that there isn't

Mean survey score: 4.16	part of their role. However for more senior doctors, particularly in surgical units, the e-alerts were a useful intervention but only for junior doctors. Some clinicians felt that there should be a specialist AKI nurse.	one for an AKI, is a bit silly, in my opinion. Because, somebody coming their purpose in my opinion would be to come around, read what they are in for, review their pathology, review the patient, and review reversible factors. Then make a recommendation to the junior and the consultant about reversible factors that hadn't been looked at yet." [ST1 interview, Internal Medicine/Care of the Elderly, Trust 2]
Enrolment Mean survey score: 4.24	As working with the AKI e-alert was an individual action, it often had no influence on working relationships. For the few clinicians who saw the relational value, it was beneficial by providing the AKI stage that could be easily reported.	"if one of the F1's came to me and said, 'this woman's creatinine has gone up', then yes, absolutely we would have a chat about meds, and fluid, and have they had an ultrasound scan, and what do you think we should do? But, I don't think the alert has ever prompted me to do that" [ST2 interview, Internal Medicine/Care of the Elderly, Trust 1]
		"It's good if you're doing a handover on the phone or something or talking to seniors in critical care or other hospitals. You can say this is Stage 2 AKI and that is sort of a standard term that people do understand even if we don't use it in general day-to- day discussion in the notes as much as we should do." [F1 interview, General/Vascular Surgery, Trust 3]
Activation Mean survey score: 4.06	Prolonged exposure to the AKI e-alerts impacted upon clinician's support for them; the e-alerts had more impact when new, but they became part of the milieu and lost amongst other e-alerts or working practices.	"Yes, I do actually. I think it's a big component of patient safety and I think it is the direction of travel of where we're going. As time goes on, looking forward, I think we're going to expect more and more of these alerts related to algorithms and severity." [Consultant interview, Emergency Admissions, Trust 1]
Collective action		4
Interactional workability Mean survey score: 3.98	It was generally deemed easy to integrate the AKI e-alerts into normal working practices; they are there as a 'check' or 'backup' as most clinicians were routinely checking renal function. The e-alerts were perceived to speed up the process of calculating the stage of AKI. E-alerts were seen to be useful where Creatinine was within normal range, but with an increase of >1.5 from baseline.	"I think if it's not someone I already know, then yes, the alerts at least make me glance at the U&Es, which I would do anyway, but you know, just an extra reminder to check back what their previous U&Es were." [ST7 interview, Emergency Admissions, Trust 1] "I think in some ways, it probably does speed things up, because you have got that alert there, and I think, when you open up a page of bloods, and it's quite obvious, and the first thing you see is they have an AKI." [ST3 interview, Emergency Admissions, Trust 3]
Relational integration Mean survey score: 3.67	The AKI e-alert did not appear to affect working relationships. Staff mostly do not refer to the e-alert when discussing AKI, and AKI care is often an isolated task. An exception is stage 3 e-alerts, which sometimes trigger discussions with renal services.	"I don't know about the other staff and how they engage because actually I've not had a lot of feedback from them. I haven't actually been hearing the juniors saying, 'Oh there was an AKI alert' on anyone so I suspect most of them are just clicking and moving on, dismissing and moving on because they probably already know what the creatinine's doing." [Consultant interview, General/Vascular Surgery, Trust 1]

Skill set workability Mean survey score: 3.27	There was a lack of training on how to best use the AKI e-alerts (also reported in <i>initiation</i>), and some clinicians demonstrated a lack of understanding about AKI, particularly the meaning of the different stages.	"when you come to the Trust you get- I don't know how long the sessions are and I don't know what they cover, and I don't know whether they cover alerts and things like that. If they do have [AKI e-alert training], I suspect it comes at the end of a very long day of induction where they've been told about every single problem under the sun and they've probably switched off." [ST7 interview, Emergency Admissions, Trust 1]
		"And there's [AKI stages] 1, 2 and 3, I can't really remember the difference between the three of them but if it flags up something I go, 'oh, okay, there's something different here.'" [F1 interview, General/Vascular Surgery, Trust 3]
Contextual integration Mean survey score: 3.32	Clinicians did not report any specific resource requirements for the AKI ealert other than training and time. Management support (where considered in the capacity of those responsible for e-alerts; the laboratory) was not identified by participants.	"I've no idea [who has responsibility for the AKI e-alerts], no. I assume somebody will do but I don't know, it's not been communicated." [F1 interview, General/Vascular Surgery, Trust 3]
Reflexive monitor	ing	
Systematisation Mean survey score: 2.5	Feedback was never provided to staff on the effect of the AKI e-alert.	"I haven't had any feedback since the new version [of the AKI e-alert] went in actually [] I don't know whether there is a formal mechanism for that getting to anyone." [Pharmacist interview, Trust 1]
Communal appraisal <i>Mean survey</i>	The e-alert was rarely (if ever) discussed amongst clinicians, but participants often stated they felt that	"Most people I'm sure would know it's a good idea having them. That's what I'd say to someone about these alerts." [Consultant interview, Emergency
score: 3.39 Individual appraisal	others would find it worthwhile. Whilst a small minority of clinicians felt the AKI e-alert had no effect on their	Admissions, Trust 1] 'Speaking to a doctor, they felt that the AKI alerts are very useful. He says that if he sees an alert then he'll
Mean survey score: 3.52	work, many did but placed the effect within constraints relating to edgecase scenarios where AKI was most likely to be missed. These included marginal AKI thresholds within 'normal Cr range', busy workloads, and AKI	check the patient's renal function. He also explains that things at handover will often get missed so doesn't always know that the patient will have an AKI' [Trust 1 observation of Emergency Admissions, approx. 19:45]
	presenting in CKD patients. The pop-up e-alert was sometimes perceived to be intrusive, whilst the passive e-alert was often described as being too easy to dismiss.	
Reconfiguration Mean survey score: 3.89	Clinicians often did not know who was responsible for the AKI e-alert. They would never consider providing feedback about the e-alert, and there	"I'm not sure if there is a feedback mechanism. If there is, I'm not aware of it." [F1 interview, Emergency Admissions, Trust 1]
	was no formal mechanism for doing so.	"[To provide feedback] I would ring IT and they would probably be very unhelpful and I would give up at that point." [ST2 interview, Internal Medicine/Care of the Elderly, Trust 1]

DISCUSSION

This is the first known mixed methods study to use Normalization Process Theory to investigate the implementation of AKI e-alerts,¹⁷ an area identified as being an international research priority.⁹ The findings of this study suggest that AKI e-alerts are somewhat embedded into routine practice in the English NHS Trusts studied, with several aspects of implementation indicative of positive or negative normalization. Given AKI e-alerts are now mandated across primary and secondary care in England and Wales,⁴ these findings suggest that more consideration was needed for how the AKI e-alert could be integrated into existing healthcare processes to influence both individual and collective behaviours. Furthermore, the findings highlight how other healthcare systems, where AKI e-alerts are not mandated, could implement AKI e-alerts in the future to improve their use.

The two aspects that particularly promoted normalization of the AKI e-alert were that the e-alert was seen to be a legitimate part of a clinician's role, and clinicians within the study mostly recognised the potential benefits of using the AKI e-alert. This demonstrates insight amongst clinicians that AKI is a significant risk to patient safety,² and consequently clinicians understand the importance of early AKI detection and treatment,²⁸ which have been historically poor.³ This finding also suggests that, when operated raising awareness of AKI and AKI e-alerting is insufficient, when operated as a single strategy, in addressing the problem of poor AKI care. Instead, attention should focus on other aspects of implementation that could be improved.

One such aspect that required improving was initiation to the e-alerts, such as via Trust-specific training, which was lacking or of insufficient quality. This was demonstrated by a lack of knowledge amongst clinicians about what differentiates the stages of AKI, and how the e-alerts were expected to be used. The definition of AKI has been refined considerably over the past decade, partly in an attempt to reduce variation in practice, 6,29 but our findings reflect previous studies which have identified gaps in AKI knowledge amongst medical staff. Although education is important in improving AKI care, there is a gap between the objective volume of delivery of AKI teaching and end-users' perception of its paucity. This dissonance might also be consistent with an alternative interpretation to our findings, which is that the existing definition of AKI lacks intuition and/or clinical credibility. Clinicians in our study reported using the terms minor, moderate, or severe, even when they knew the different stages as per the 2012 KDIGO guidelines as they felt it easier to communicate to others. This corresponds closely with our finding, that some clinicians had difficulty in recognising and prioritising AKI e-alerts. Little research has focussed on how staff are educated about AKI e-alerts, but some tentative links have been made between effective education and successful implementation.

Another area of implementation identified as needing improvement was the systematization of the AKI e-alerts through implementing feedback to end-users of the e-alerts. There was no system for providing feedback to clinicians, despite a wide range of safety literature identifying the importance of providing this to people involved in the process.³²⁻³⁴ NPT proposes that an intervention is normalized through agents' continuous actions which are enacted over a sustained period of time and space.³⁵ As approval ratings for AKI e-alerts have been reported to reduce over time, giving feedback to those involved in the safety behaviour could slow, pause or even reverse the decline,^{36,37} and can be a transformative process that can lead to improved performance.³⁸

Alert fatigue or disruptions to workflow have been identified as barriers to implementation,^{5,10} and there were examples of these identified in this study. Both e-alert systems produced opposing perspectives on how or whether the e-alerts influenced workflow. It was however common for those receiving the pop-up e-alert to dismiss it instantly and comment on its intrusiveness, whilst those who received the passive e-alert commented on it not being intrusive enough and being too easy to ignore. This suggests that there is no one-size-fits-all e-alert presentation, and instead they may require tailoring to either the individual or clinical unit. However, the causes of these differing perspectives were unclear and require further research.

It was also notable that collaborative working in response to the AKI e-alert were dismissed or downplayed by participants. Implementation of a complex intervention, or of a simple intervention into a complex environment, requires social activity that results in joint action; agents' continuous actions are enacted over a sustained period of time and space.³⁵ Using and incorporating the e-alert into practice was often perceived to be an individual action that did not result in or alter discussions amongst clinicians. Future research should investigate whether the individual nature of an intervention, such as AKI e-alerting, contributes to poorer implementation, and whether such interventions require more collaborative working to be built-in to improve optimality.

Limitations

Firstly, the study was conducted in clinical areas where AKI incidence is high, which may limit the generalisability of the findings; it is unknown whether the e-alert would be more useful (and whether it would be more or less poorly implemented) in clinical areas where AKI incidence is lower and thus clinicians have lower contact time with the AKI e-alert. Secondly, the study was conducted in one region, and so implementation of the AKI e-alert may have been influenced by local networks. Finally, it is unknown whether the e-alerts had a quantifiable impact on AKI outcomes or staff actions, and so it is not possible to draw conclusions about the effectiveness of the AKI e-alerts studied as a result of implementation. However, the identification of perceived differences between the NPT mechanisms, including sub-constructs that were successfully implemented, suggests that a more focused approach, aligned with Safety-II principles, could help to identify successful implementation. Investigating where AKI e-alerts have been successfully implemented on a larger scale would provide valuable lessons for future implementation of both AKI e-alerts and other e-alerts.

CONCLUSIONS

Clinicians recognised the value and importance of AKI e-alerts in their clinical practice, though not sufficiently for AKI e-alerts to be routinely engaged with. To further normalize and promote clinician engagement with AKI e-alerting systems, there is a need for tailored training on AKI and how to use e-alerts; feedback should, also, be routinely given to staff about their impact on outcomes. The findings of this study provide a potential explanation for conflicting data on the reported effectiveness of AKI e-alerting systems. The findings have the potential to inform future national improvements to the way in which AKI e-alerts are implemented in the NHS and could be transferred into other countries' healthcare systems where AKI e-alerts have either not yet been implemented or where this has been suboptimal.

Declarations

Ethical approval and consent to participate

All participants provided informed consent to participate. Interview participants provided written consent. Consent for observations was provided verbally by the lead consultant of each unit and individuals being observed. Survey respondents provided consent by returning the survey. The project was reviewed and Approved by the National Health Service's Health Research Authority (https://www.hra.nhs.uk/) [reference 16/HRA/2106]. HRA Approval brings together the HRA's assessment of governance and legal compliance with the independent ethical opinion by a Research Ethics Committee. HRA Approval is for all project based research involving the NHS and Health and Social Care that is being led from England.

Consent for publication

Not applicable

Availability of data and materials

The quantitative datasets used and/or analysed during the current study are available from the corresponding author on reasonable request. Participants were not asked to provide consent to share their transcripts beyond the research team. The study team would be happy to interrogate the data on behalf of others upon reasonable request to the corresponding author.

Competing interests

NSS received travel funding from Alexion Pharmaceuticals to attend ERA-EDTA 2018 congress. NSS is also a grant holder for a project 'Imaging in Chronic Kidney Disease', funded by GlaxoSmithKline. No other authors have competing interests to declare.

Funding and Acknowledgements

This work was supported by funds from Northern Counties Kidney Research Fund (www.nckrf.org.uk). The funder had no role in the design and conduct of the study, including the collection, management, analysis, interpretation of the data, preparation, review or approval of the manuscript, and decision to submit the manuscript for publication.

Author contributions

TF, MB, GM, CG, BY, NK, NSS, NSK conceived and designed the study. JS collected the data. JS, TF, GM and NSK analysed the data. JS and NSK drafted the manuscript, with all authors providing critical revisions and approval for the final version. JS and NSK agree to be accountable for all aspects of the work.

Acknowledgements

We would like to thank the NHS Trusts and departments for allowing us access, and the participants for giving their time.

References

 National Institute for Health and Care Excellence. Acute kidney injury: Prevention, detection and management of acute kidney injury up to the point of renal replacement therapy.
 National Institute for Health and Care Excellence; 2013.

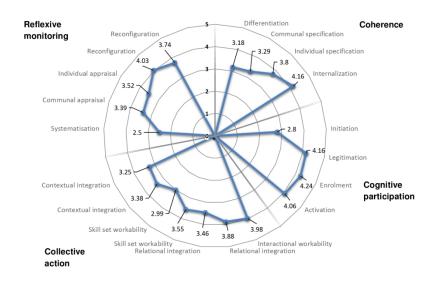
- 536 2. Kerr M, Bedford M, Matthews B, O'Donoghue D. The economic impact of acute kidney injury in England. *Nephrology Dialysis Transplantation*. 2014;29(7):1362-1368.
- 538 3. Stewart J, Findlay G, Smith N, Kelly K, Mason M. *Adding insult to injury: a review of the care*539 of patients who died in hospital with a primary diagnosis of acute kidney injury (acute renal failure). London: National Confidential Enquiry into Patient Outcome and Death; 2009.
- 541 4. Selby NM, Hill R, Fluck RJ. Standardizing the Early Identification of Acute Kidney Injury: The NHS England National Patient Safety Alert. *Nephron.* 2015;131(2):113-117.
- 543 5. Sawhney S, Fluck N, Marks A, et al. Acute kidney injury—how does automated detection perform? *Nephrology Dialysis Transplantation*. 2015;30(11):1853-1861.
- 545 6. KDIGO. KDIGO Clinical Practice Guideline for Acute Kidney Injury. *Kidney International Supplements*. 2012;2(1).
- 547 7. Selby NM. Electronic alerts for acute kidney injury. *Current Opinion in Nephrology and Hypertension.* 2013;22(6):637-642.
- 549 8. Kashani KB. Automated acute kidney injury alerts. *Kidney International*. 2018;94(3):484-490.
- 550 9. Lachance P, Villeneuve P-M, Rewa OG, et al. Association between e-alert implementation for detection of acute kidney injury and outcomes: a systematic review. *Nephrology Dialysis*552 *Transplantation*. 2017;32(2):265-272.
- 553 10. Kanagasundaram NS, Bevan MT, Sims AJ, Heed A, Price DA, Sheerin NS. Computerized 554 clinical decision support for the early recognition and management of acute kidney injury: a 555 qualitative evaluation of end-user experience. *Clinical Kidney Journal*. 2015;9(1):57-62.
- 556 11. Park S, Baek SH, Ahn S, et al. Impact of Electronic Acute Kidney Injury (AKI) Alerts With 557 Automated Nephrologist Consultation on Detection and Severity of AKI: A Quality 558 Improvement Study. *American Journal of Kidney Diseases*. 2018;71(1):9-19.
- Haase M, Kribben A, Zidek W, et al. Electronic Alerts for Acute Kidney Injury: A Systematic Review. *Deutsches Ärzteblatt International*. 2017;114(1-2):1-8.
- Selby NM, Crowley L, Fluck RJ, et al. Use of Electronic Results Reporting to Diagnose and
 Monitor AKI in Hospitalized Patients. *Clinical Journal of the American Society of Nephrology*.
 2012;7(4):533-540.
- 564 14. Colpaert K, Hoste EA, Steurbaut K, et al. Impact of real-time electronic alerting of acute kidney injury on therapeutic intervention and progression of RIFLE class*. *Critical Care Medicine*. 2012;40(4):1164-1170.
- 567 15. May C, Finch T. Implementing, Embedding, and Integrating Practices: An Outline of Normalization Process Theory. *Sociology.* 2009;43(3):535-554.
- May CR, Mair F, Finch T, et al. Development of a theory of implementation and integration:
 Normalization Process Theory. *Implementation Science*. 2009;4(1):29.
- 571 17. May CR, Cummings A, Girling M, et al. Using Normalization Process Theory in feasibility 572 studies and process evaluations of complex healthcare interventions: a systematic review. *Implementation Science*. 2018;13(1):80.
- Henderson EJ, Rubin GP. The utility of an online diagnostic decision support system (Isabel) in general practice: a process evaluation. *JRSM Short Reports*. 2013;4(5):1-11.
 - Hooker L, Small R, Humphreys C, Hegarty K, Taft A. Applying normalization process theory to understand implementation of a family violence screening and care model in maternal and child health nursing practice: a mixed method process evaluation of a randomised controlled trial. *Implementation science*. 2015;10(1):39.
 - 20. Kennedy A, Rogers A, Chew-Graham C, et al. Implementation of a self-management support approach (WISE) across a health system: a process evaluation explaining what did and did not work for organisations, clinicians and patients. *Implementation Science*. 2014;9(1):129.
 - Finch TL, Rapley T, Girling M, et al. Improving the normalization of complex interventions: measure development based on normalization process theory (NoMAD): study protocol. Implementation Science. 2013;8(1):43.

- Finch TL, Girling M, May CR, et al. NoMAD: Implementation measure based on Normalization
 Process Theory [Measurement instrument]. http://www.normalizationprocess.org.
 Published 2015. Accessed 12th April 2018.
- Rapley T, Girling M, Mair FS, et al. Improving the normalization of complex interventions:
 part 1 development of the NoMAD instrument for assessing implementation work based
 on normalization process theory (NPT). *BMC Medical Research Methodology*.
 2018;18(1):133.
- 593 24. Finch TL, Girling M, May CR, et al. Improving the normalization of complex interventions: 594 part 2 - validation of the NoMAD instrument for assessing implementation work based on 595 normalization process theory (NPT). *BMC Medical Research Methodology*. 2018;18(1):135.
 - Agency for Healthcare Research and Quality (AHRQ). Hospital Survey on Patient Safety
 Culture. https://www.ahrq.gov/sops/quality-patient-safety/patientsafet
- Gale N, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the
 analysis of qualitative data in multi-disciplinary health research. *BMC Medical Research Methodology*. 2013;13(1):117.
- Barbour RS. Checklists for improving rigour in qualitative research: a case of the tail wagging the dog? *BMJ.* 2001;322(7294):1115-1117.
 - 28. Kolhe NV, Staples D, Reilly T, et al. Impact of Compliance with a Care Bundle on Acute Kidney Injury Outcomes: A Prospective Observational Study. *PLoS ONE*. 2015;10(7):e0132279.
 - 29. Thomas ME, Blaine C, Dawnay A, et al. The definition of acute kidney injury and its use in practice. *Kidney International*. 2015;87(1):62-73.
- Muniraju TM, Lillicrap MH, Horrocks JL, Fisher JM, Clark RMW, Kanagasundaram NS.

 Diagnosis and management of acute kidney injury: deficiencies in the knowledge base of non-specialist, trainee medical staff. *Clinical Medicine*. 2012;12(3):216-221.
- Sykes L, Nipah R, Kalra P, Green D. A narrative review of the impact of interventions in acute kidney injury. *Journal of Nephrology.* 2017.
 - Benn J, Arnold G, Wei I, Riley C, Aleva F. Using quality indicators in anaesthesia: feeding back data to improve care. *British Journal of Anaesthesia*. 2012;109(1):80-91.
 - 615 33. Macrae C. The problem with incident reporting. *BMJ Quality & amp; Safety.* 2016;25(2):71-616 75.
- 81. Brún AD, Heavey E, Waring J, Dawson P, Scott J. PReSaFe: A model of barriers and facilitators to patients providing feedback on experiences of safety. *Health Expectations*.
 2017;20(4):771-778.
- 620 35. May C. Towards a general theory of implementation. *Implementation Science*. 2013;8(1):18.
- 36. Wilson FP, Shashaty M, Testani J, et al. Automated, electronic alerts for acute kidney injury:
 a single-blind, parallel-group, randomised controlled trial. *The Lancet*. 2015;385(9981):1966 1974.
- 624 37. Oh J, Bia JR, Ubaid-Ullah M, Testani JM, Wilson FP. Provider acceptance of an automated electronic alert for acute kidney injury. *Clinical Kidney Journal*. 2016.
 - 38. Karsh B-T, Holden RJ, Alper SJ, Or CKL. A human factors engineering paradigm for patient safety: designing to support the performance of the healthcare professional. *Quality and Safety in Health Care.* 2006;15(suppl 1):i59-i65.

Figure title & legend

- 631 Figure 1 title: Petal chart showing mean scores for the sixteen NPT sub-constructs
- Figure 1 legend: Likert scale of 1 (strongly disagree) to 5 (strongly agree).

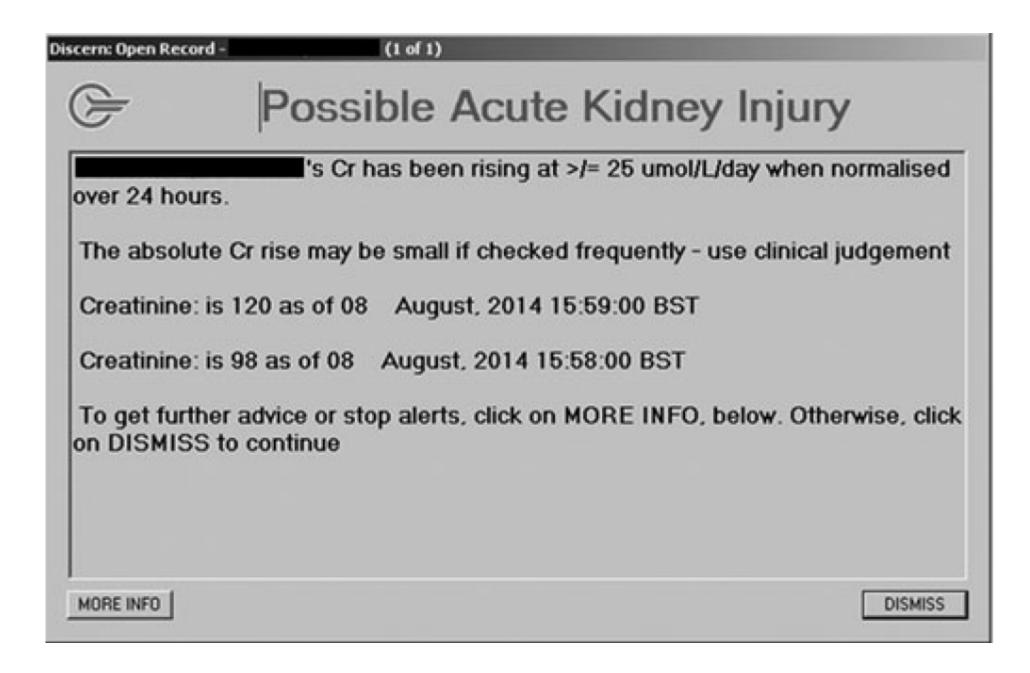


Petal chart showing mean scores for the sixteen NPT sub-constructs. Likert scale of 1 (strongly disagree) to 5 (strongly agree).

210x297mm (200 x 200 DPI)

1	
2	
3 4 5	
4	
2	
6 7	
/	
8	
9 10	
10	
11	
12	
13	
14	
14 15 16	
16	
16 17	
18	
19	
20	
21	
22	
23	
24	
25	
26	
26 27	
28	
29 30 31	
31	
32	
33	
34	
34 35	
36	
37	
38	
39	
40	
41	
42	
43	
43	
44	

06	
mmol/L	133 - 146
mmol/L	3.5 - 5.3
mmol/L	95 - 108
mmol/L	22 - 29
mmol/L	2.5 - 7.8
umol/L	49 - 90



Acute Kidney Injury Alert Study

Interview Questions

Themes:

- Coherence: Meaning-making sense of the technology and the work, differentiation, embedding
- Cognitive participation: Commitment-what is done to work with others
- Collective action: Effort-what is done whilst using this tool
- **Reflexive monitoring:** Comprehension- How the new technology affects them, others and patient care

Introduction

- Introduce myself and my role in the research
- Ensure information has been read and consent (x2) is signed and they retain a copy
- Ask the participant to briefly explain:
 - Who they are
 - O What they do (role) e.g. Dr (registrar etc.) nurse.
 - How long they have been on the ward
 - What other experience do they have, eg previous roles

Opening question

- Q Please describe your first/last encounter with the AKI alerts: this should provide a basis for further questions as it will point to aspects of his or her experience
 - O What sort of experience do you have of using AKI alerts?
- **Q** How do you currently use electronic alerts (not necessarily AKI) within the electronic record? Are some alerts more important than others? (if yes, what makes them so?)
- Q Use screen prints of each page to ask questions about user experience: ease of use, visual appearance, nuisance factors etc.
 - If appropriate make memos of facial expressions, hand gestures, non-verbals
 - Make memos in relation to comments for further questioning/investigation at the interview and/or subsequent participants.

List of potential (Not in order of importance) Normalization Process Theory-based questions as a reminder used on the basis of answers to the opening questions

Many descriptive and explanatory questions are used to elicit detail of actions, processes, outcomes and correlations. Some questions may overlap one or more theme.

Questions will develop given the kind of answer and may include questions not cited below.

Coherence Type Questions

- **Q** What do you understand as the purpose of the alerting tool? Is it important to the patient's safety? Why do you think the alerts have been implemented?
- **Q** Ideally, where do you think this tool should fit in to your daily work?

- **Q** How do others in your unit / clinical setting use the tool? From your own experience, is this specific to your clinical setting?
- **Q** From your perspective, how do AKI alerts compare to other alerts / computer tools
- **Q** How do you think you are expected to use the alert?
- Q What benefits/value do you think the alert provides?

Cognitive Participation type questions

- **Q** Who leads the use of this on your ward/unit? What does this role / task consist of for them? Does it include responsibility for AKI outcomes?
- **Q** How do the different professionals on the ward interact / use / respond to the alert? Do people have different roles / interactions with the alert depending on their profession / role?
- **Q** From your perspective, what would help staff to engage better with the alerting system?
- **Q** Have you shown others how to use it? If so, describe what you did and why. If not, why not?

Collective Action type questions

- **Q** Please describe what you do when you encounter the alert?
- Q Please explain how the tool helps/hinders working with others
- **Q** How does the alert affect how you work? Eg use of time and resources

Reflexive monitoring

- **Q** How does it make you feel when you see the alert?
- **Q** Would you say the alert is useful or not? Explain
- **Q** What do you think of the alert? (elicit a personal opinion)
- **Q** What do others say about it?
- **Q** To what extent do you and/or others have the ability to provide feedback / influence improvements to the system? What helps or hinders this ability?
- **Q** Has it altered the way you work/think about acute kidney injury?
- Q Does the alert effect change in medical management of the patient? Does this lead to a change in the patient's outcome?
- **Q** Is the alert worthwhile? Explain the answer
- **Q** Are there any improvements you would like to make to the system? Eg alert, interaction with alerts, validation, visual etc.

Remember to thank them for their time and effort

Survey Instructions

This survey is designed to help get a better understanding of how to apply and integrate new technologies and complex interventions in health care.

This survey asks questions about the implementation of acute kidney injury (AKI) electronic alerts into patients' medical records. We understand that people involved with AKI alerts have different roles, and that people may have more than one role. For this survey, please answer all the statements from the perspective of being an end-user of AKI alerts.

The survey is in 3 parts, Parts A-C:

- Part A asks some brief questions about yourself and your role.
- Part B asks general questions about patient safety and AKI alerts.
- Part C contains four sets of statements about AKI alerts. For each statement in Part C, there is the option to agree or disagree with what is being asked. However, if you feel that the statement is not relevant to you, you can answer 'not relevant'.

The survey is on both sides of paper. Answers to all questions are required, except where it is stated as being optional. The only optional questions are Q15b, Q16b, Q17b, and Q18b.

Please take the time to decide which answer best suits your experience for each statement and tick the appropriate circle.

If you would like to complete this version electronically (on mobile, tablet or desktop) please use the address below.

[address removed for publication]

Electronic alerts for acute kidney injury - end user survey

Part A. About vourself

Part A: About yourself	Survey number (admin only)
 Q1. How would you describe your professional job category? Medical doctor (go to Q2a) Surgical doctor (go to Q2a) Nurse (go to Q2b) Other (go to Q2c) 	
 Q2a. How would you describe your professional job level? Foundation-years doctor 1 (F1) Foundation-years doctor 2 (F2) Specialist trainee doctor (ST1 or ST2) Specialist trainee doctor (ST3, ST4 or ST5) Specialist trainee doctor (ST6 or ST7) Staff grade doctor Consultant Other (go to Q2d) 	
Please go to question 3 on the next page	
Q2b. How would you describe your professional job level? Dand 4 Band 5 Band 6 Band 7 Band 8a Band 8b Dand 8c Other (go to Q2d)	
Please go to question 3 on the next page	
Q2c. How would you describe your professional job category? For example healthcare assistant, nurse, doctor.	
Please go to question 2d below Q2d. How would you describe your professional job level? For example, your c grade / band	urrent

Please go to question 3 on the next page

Part A: About yourself (continued)

Q3. How many full years have you held your primary professional qualificat	ion?
Q4. Which NHS Trust do you currently work at?	
O Gateshead Health NHS Foundation Trust	
O Newcastle upon Tyne Hospitals NHS Foundation Trust	
O Northumbria Healthcare NHS Foundation Trust	
Other (please specify in box below)	
10	
Q5. How many full years have you worked in your current role at this NHS 1	
If your Trust has merged with another or changed its name, please include in you	ır answer all
the time you have worked with this Trust and its predecessors	
Q6. Which best describes the department / unit that you work in?	
O Internal Medicine / Care of the Elderly	
O Emergency Admissions	
O General / Vascular Surgery	
Other (please specify)	
O7 How many full years have you worked in your coment role in this denom	4man4 /
Q7. How many full years have you worked in your current role in this depar unit?	tment /
unit :	

Part A: About yourself (continued)

Q8. Have you received any formal or informal training in relation to acute kidney injury in the past 24 months?	
O No	
O Yes (please specify)	
Q9. Does your team, unit or NHS Trust have any initiatives other than acute kidney injury electronic alerts to improve acute kidney injury awareness? No	
O Yes (please specify)	

This is the end of Part A. Please turn over for Part B.

Part B: General questions about patient safety

Q10. Perceptions of patient safety in your work area / unit

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
It is just by chance that more serious mistakes do not happen around here	0	0	•	•	0
Patient safety is never sacrificed to get more work done	0	0	0	0	0
We have patient safety problems in this unit	0	0	•	•	•
Our procedures and systems are good at preventing errors from happening	0	•	•	•	0

Q11. Please give your work area / unit in this hospital an overall grade on patient safety

	Failing	Poor	Acceptable	Very good	Excellent
Patient safety grade	•	•	0	0	0

Part B: General questions about acute kidney injury alerts

Q12. When you see an acute kidney injury alert within the patient's record, how familiar does it feel?

	Still feels very new									Feels completely familiar
	1	2	3	4	5	6	7	8	9	10
Familiarity of AKI alert	0	0	0	0	0	0	0	•	0	0

Q13. Do you feel the acute kidney injury alert is currently a normal part of your work?

	Not at all									Completely
	1	2	3	4	5	6	7	8	9	10
Responding to the AKI alert is currently normal (present)	0	0	0	0	0	0	•	0	0	•

Q14. Do you feel the acute kidney injury alert will become a normal part of your work?

	Not at all									Completely
	1	2	3	4	5	6	7	8	9	10
Responding to the AKI alert will become normal (future)	•	0	0	0	0	0	0	0	0	•

This is the end of Part B. Please turn over for Part C1.

Part C1: Detailed questions about acute kidney injury alerts

Q15a. For each statement, please select one answer that best suits your experience.

	Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Not relevant
I can see how the AKI alert differs from usual ways of working	•	•	•	O	•	•
Staff in this organisation have a shared understanding of the purpose of the AKI alert		•	0	O	0	O
I understand how the AKI alert affects the nature of my own work	0	0	0	0	0	0
I can see the potential value of the AKI alert for my work	•	•		•	O	•

15b. Please elaborate on your answers provided in this part (optional)										

This is the end of Part C1. Please turn over for Part C2.

Part C2: Detailed questions about acute kidney injury alerts (continued)

Q16a. For each statement, please select one answer that best suits your experience.

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Not relevant
There are key people who drive the AKI alert forward and get others involved	0	0	•	O	•	O
I believe that responding to the AKI alert is a legitimate part of my role	90	0	0	0	O	O
I'm open to working with colleagues in new ways when responding to the AKI alert	0	0	0	O	0	O
I will continue to support the AKI alert	0	0	0/2	0	O	0

116b. Please elaborate on your answers provided in this part (optional)				

This is the end of Part C2. Please turn over for Part C3.

Part C3: Detailed questions about acute kidney injury alerts (continued)

Q17a. For each statement, please select one answer that best suits your experience.

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Not relevant
I can easily integrate the AKI alert into my existing work	0	O	0	O	0	O
The AKI alert disrupts working relationships	0	•	•	•	•	0
I have confidence in other people's ability to respond to the AKI alert	0	•	•	•	•	0
Work is assigned to those with skills appropriate to responding to the AKI alert	•	0	0	•	•	0
Sufficient training is provided to enable staff to implement the AKI alert	0	0	0	0	0	0
Sufficient resources are available for the AKI alert	0	0	0	G	0	0
Management adequately supports the AKI alert	•	•	•	0	•	0

Q17b.	Q17b. Please elaborate on your answers provided in this part (optional)					

This is the end of Part C3. Please turn over for Part C4.

Part C4: Detailed questions about acute kidney injury alerts

Q18a. For each statement, please select one answer that best suits your experience.

	Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Not relevant
I am aware of reports about the effects of the AKI alert	0	0	0	0	0	0
The staff agree that the AKI alert is worthwhile	0	O	0	•	0	O
I value the effects that the AKI alert has had on my work	0	0	•	•	0	•
Feedback about the AKI alert can be used to improve it in the future	0	0	0	O	•	•
I can modify how I work with the AKI alert	O	•	0	0	0	•

Q18b. Please elaborate	Q18b. Please elaborate on your answers provided in this part (optional)				

Please turn over

This is the end of the survey

Thank you for completing the survey; your participation is greatly appreciated. We understand that the nature of a survey may not allow you to fully express your thoughts and opinions about the acute kidney injury alerts. If you feel this is the case and would be interested in participating in an interview (if you have not already), please leave your name and email address below and we will be in touch shortly with more information. These will not be linked back to your survey responses. If you are not interested in hearing more about an interview, please leave the box blank.

Name	
Email address	

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on
			Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	
Occupation	3	What was their occupation at the time of the study?	
Gender	4	Was the researcher male or female?	
Experience and training	5	What experience or training did the researcher have?	
Relationship with			_L
participants			
Relationship established	6	Was a relationship established prior to study commencement?	
Participant knowledge of	7	What did the participants know about the researcher? e.g. personal	
the interviewer		goals, reasons for doing the research	
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator?	
		e.g. Bias, assumptions, reasons and interests in the research topic	
Domain 2: Study design			1
Theoretical framework			
Methodological orientation	9	What methodological orientation was stated to underpin the study? e.g.	
and Theory		grounded theory, discourse analysis, ethnography, phenomenology,	
		content analysis	
Participant selection	•		
Sampling	10	How were participants selected? e.g. purposive, convenience,	
		consecutive, snowball	
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail,	
		email	
Sample size	12	How many participants were in the study?	
Non-participation	13	How many people refused to participate or dropped out? Reasons?	
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	
Presence of non-	15	Was anyone else present besides the participants and researchers?	
participants			
Description of sample	16	What are the important characteristics of the sample? e.g. demographic	
		data, date	
Data collection	1		
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot	
		tested?	
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	
Field notes	20	Were field notes made during and/or after the inter view or focus group?	
Duration	21	What was the duration of the inter views or focus group?	
Data saturation	22	Was data saturation discussed?	
Transcripts returned	23	Were transcripts returned to participants for comment and/or w only - http://bmjopen.bmj.com/site/about/guideilnes.xhtml	

Topic	Item No.	Guide Questions/Description	Reported on
			Page No.
		correction?	
Domain 3: analysis and			
findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	
Description of the coding	25	Did authors provide a description of the coding tree?	
tree			
Derivation of themes	26	Were themes identified in advance or derived from the data?	
Software	27	What software, if applicable, was used to manage the data?	
Participant checking	28	Did participants provide feedback on the findings?	
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings?	
		Was each quotation identified? e.g. participant number	
Data and findings consistent	30	Was there consistency between the data presented and the findings?	
Clarity of major themes	31	Were major themes clearly presented in the findings?	
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.