Early warning systems and rapid response to the deteriorating patient in hospital: a realist evaluation

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ABSTRACT

Aim

To identify those contexts and mechanisms that enable or constrain the implementation of Rapid Response Systems on acute general hospital wards to recognise and respond to patient deterioration.

Background

Rapid Response Systems allow deteriorating patients to be recognised using Early Warning Systems, referred early via escalation protocols and managed at the bedside by competent staff.

Design

Realist Evaluation

Methods

The research design was an embedded multiple case study approach of four wards in two hospitals in Northern Ireland which followed the principles of Realist Evaluation. We used various mixed methods including individual and focus group interviews, observation of nursing practice between June - November 2010 and document analysis of Early Warning Systems audit data between May - October 2010 and hospital acute care training records over 4.5 years from 2003-2008. Data were analysed using NiVivo8 and SPPS.

Results

A cross case analysis highlighted similar patterns of factors which enabled or constrained successful recognition, referral and response to deteriorating patients in practice. Key enabling factors were the use of clinical judgement by experienced nurses and the empowerment of nurses as a result of organisational change associated with implementation of Early Warning System protocols. Key constraining factors were low staffing and inappropriate skill mix levels, rigid implementation of protocols and culturally-embedded suboptimal communication processes.

Conclusion

Successful implementation of Rapid Response Systems was dependent on adopting organisational and cultural changes that facilitated staff empowerment, flexible implementation of protocols and ongoing experiential learning.

Key Words:

realistic evaluation, early warning systems, rapid response systems, nursing, patient deterioration, enabling and constraining factors, patient recognition, escalation protocols.

SUMMARY STATEMENT

Why is this research needed?

- Research has provided limited clinical answers to explain why such a conceptually logical model as RRS does or does not work in practice.

- There is a need to understand those contexts and mechanisms that have an impact on achievement of desired RRS outcomes.

- No research to date has used a realist evaluation approach to test the RRS programme theory.

What are the key findings?

- The use of clinical judgement by experienced nurses enabled early recognition of patients.

- Implementation of EWS protocols facilitated successful organisational change.

- Low staffing levels, inappropriate skill mix, rigid implementation of protocols, cultural communication processes constrained RRS implementation.

How should the findings be used to influence policy/practice/research/education?

- Staff empowerment is central to organisational change initiatives.

- Education of staff needs to be ward-based and ongoing to facilitate learning.

- Flexible implementation of protocols facilitates use of clinical judgement by trained staff.

INTRODUCTION

The concept of the Rapid Response System (RRS) was developed by expert consensus opinion as a solution to address suboptimal ward-based care and reduce the number of preventable hospital deaths (DoH 2000). The framework provides a mechanism to improve recognition of and clinical response to, patients who deteriorate in hospital. It entails a systematic change in the way hospitals deliver care. Essential features of the RRS comprise four interrelated systems: an afferent arm which is the "physiological assessment" and "triggering" mechanism; an efferent arm which provides competent personnel and resources at the bedside and treatment if necessary; a governance/administrative structure to supply and organize resources; and a mechanism to evaluate crisis antecedents and promote hospital process improvement to prevent future events (DeVita *et al.* 2006). Implementing all components of the RRS should ensure that most deteriorating hospital patients are identified early through the use of Early Warning System (EWS) charts; referred early using protocolised graded response strategies; and managed by professionals with appropriate specialist knowledge and skills in acute care. The intention is to provide safe, effective and equitable acute care to all patients in hospital.

Background

RRSs have been adopted internationally despite the lack of high grade evidence to support their effectiveness (McGaughey *et al.* 2007; Chan *et al.* 2010, McNeill & Bryden 2013, Alam *et al.* 2014). Studies have been predominately retrospective, uncontrolled or historically controlled before-and-after studies (Moon *et al.* 2011, Howell *et al.* 2012, Al-Qahtani *et al.* 2013, Etter *et al.* 2014, Sefton *et al.* 2015). To date, only two randomised controlled trials (RCTs) have evaluated RSS (Priestly *et al.* 2004, MERIT *et al.* 2005). These studies have focused primarily on measuring patient outcomes (unanticipated ICU admission, death,

cardiac arrest) of the efferent arm of the RRS, with limited assessment of the context, processes or mechanisms leading to the outcomes ie the afferent arm. Consequently, research has provided limited clinical answers to explain why such a conceptually logical model as RRS does or does not work in practice. To address this gap in the evidence, we set out to explore the implementation and delivery of components of the RRS in two Northern Ireland hospitals to identify those contexts and mechanisms that enable and constrain the recognition, referral and management of deteriorating patients in practice using a realistic evaluation approach.

THE STUDY

Aim

To test the RRS programme theory against actual practice components of the RRS implemented to identify those contexts and mechanisms which have an impact on the successful achievement of desired outcomes in practice.

Design

Realistic Evaluation (RE) is a theory driven approach used to explore and explain programme systems and the relationship between context (C), mechanism (M) and the outcomes (O). RE assumes that all programmes have an underlying theory to explain how a particular intervention is 'meant' to work. The purpose of the RE approach is to identify the underlying programme theory and test hypothesised causal relationships between the CMO concepts by gathering data to clarify and refine the theory (Pawson & Tilley 1997).

Stage one involved: (a) describing the RRS theory by undertaking a realist review of the literature; (b) interviewing people who had introduced the RRS to understand how the programme was meant to work; and (c) generating hypotheses of how it was supposed to work (developing theoretical propositions). Stage two involved collecting data from multiple

sources (hospital staff and documents) to determine how it actually worked in practice. Stage three involved establishing causal relationships to explain how in different contexts (C) various mechanisms (M) are triggered to generate outcome (O) patterns (typically called CMO configurations).

We used a multiple case study of two hospital sites with embedded subgroups of two hospital wards on each site (Figure 1). The sites were large hospitals in Northern Ireland with a similar Intensive Care Unit (ICU) provision and at that time neither hospital had funding to implement a multidisciplinary Critical Care Outreach Service (CCOS) to support ward staff with critical care staff competent in managing patient deterioration (Supplementary information Table 1). The sites had implemented Early Warning Systems (EWS) across their acute wards and operated Acute Life Threatening Events- Recognition and Treatment (ALERT) training for staff (Smith *et al.* 2002). In each site, one medical and one surgical ward were selected to represent a high and low risk ward based on the number of unanticipated ICU admissions over the previous year from the hospital admission records. Recruiting subgroups based on type of ward and level of risk allowed us to capture broad variation in potential factors that may have contributed to its success or failure.

Participants

Stage 1 Interviews: We recruited a purposive sample of 14 medical and nursing policymakers with a key role in the strategic planning and implementation of RRS, medical and nursing staff who had championed the implementation of EWS and the ALERT training programmes and external experts (Minister of Health, ALERT expert) to explore how RRS was implemented in practice. Participants were personally invited for face to face interview by letter by JM. This was followed up by a phone call to ascertain agreement to participate.

Stage 2 Interviews: Individual face to face interviews were undertaken with a purposeful sample of 28 key informants (senior managers, managers, junior doctors, EWS and ALERT champions), who were invited by letter and followed up by phone call, to determine their views of the conjectured RRS theories and to compare these with their actual experiences. Five key informants (2 in case site 1 & 3 in case site 2) interviewed in Stage 1 also participated in key informant interviews in Stage 2 to clarify and explain the findings from Stage 1 further in relation to the conjectured RRS theoretical assumptions. Focus group interviews were conducted with 34 key informants (staff nurses, student nurses or health care assistants) who had not been interviewed in Stage 1 or Stage 2 individual interviews and agreed to participate following a letter of invitation distributed to all ward staff by ward managers (Table 1). Staff who opted-in by returning reply slips were followed up by phone call. Separate focus groups were undertaken for staff nurses, student nurses and health care assistants to overcome the negative impact of power differences between professionals (Stewart *et al* 2007).

Stage 2 non-participant observation: All ward staff were provided with a letter of invitation from ward managers to participate in the observation period. Those staff who opt-in were followed up by phone call and rostered to work on the observational days.

Data collection

The three stages of the RE process guided the data collection and analysis. The study protocol outlines the methods in full detail (McGaughey *et al.* 2010). A synopsis of the methods is presented here. The organisational structure reported here was in place in 2010 during data collection.

Stage 1: Developing Theoretical Propositions

To develop the theoretical propositions, we undertook a realist review of the literature; interviewed key senior policymakers and managers; and obtained key policy and training documents to provide contextual information.

Realist Review: The realist review was undertaken (McGaughey submitted for JAN publication) prior to the interviews to illustrate the underpinning theory of how RRS is supposed to work and reveal initial RRS theoretical propositions (Table 2). The findings were used to guide the interviews.

Interviews: The semi-structured interview schedule was structured using the theoretical propositions identified during the realist review and from the implementation and sustainability framework devised by Greenhalgh (2004). Digitally recorded interviews (lasting approximately one hour) were conducted between July - October 2008 in agreed venues, principally participants' offices.

Contextual documentation: We obtained information from the acute care training records over 4.5s period from 2003-2008 relating to numbers and categories of staff who were trained including inter-professional ratios for each course, grades of staff trained, number of staff trained per ward and in Directorates since the ALERT course was implemented in the hospital (Table 3). Data was analysed in SPSS (2008). In addition, photocopies of EWS policies were also obtained.

Stage 2: Testing Theoretical Propositions

Having established theoretical propositions of how the RRS was intended to work, stage two involved collecting data during interviews with hospital staff and observation of practice between June - November 2010, this time with a focus on whether the RRS was working as it should; and from EWS audits during May 2010 - October 2010 to provide contextual

information on trends in adherence.

Interviews: A semi-structured interview schedule was developed following analysis of Stage 1 findings and modified for individual and focus group interviews to contextualise the questions to obtain different key informant perspectives (See supplementary information file 1). Interviews were undertaken by JM and lasted approximately 30 minutes; they were digitally recorded and conducted in a private room

Nonparticipant Observation: Nonparticipant observation of healthcare staff recording EWS charts was undertaken by JM on each of the four wards for an average of 8 hours (33 hours) from fixed points to minimise intrusion (See Supplementary information table 2). An observation guide was developed that captured information on ward infrastructure, working conditions and organisational processes (Greenhalgh *et al.* 2004). Information regarding the study was provided for patients on posters displayed on the wards.

EWS Audit Documentation: With permission from Directorate managers, we obtained copies of the EWS audits that were conducted in the four wards to report on compliance rates, reasons for low compliance and action plans to improve compliance where data existed.

Ethics

Ethical approval was obtained from the Office of Research Ethics Committee Northern Ireland ((Ref: 08/NIR01/15). The study was conducted under the requirements of the Research Governance Framework approved by the hospital Trusts and Queens University Belfast. Informed consent was obtained from all individuals who agreed to participate in the interviews and observation period. Documentary evidence obtained from the case sites did not contain personal information which ensured that the names of individuals were not known to the researcher and remained confidential.

Data analysis

Stage 1 and 2: Data analysis

Interviews were digitally recorded and transcribed verbatim to ensure consistent and accurate recording of data. The Stage 1 transcripts and observation data were coded according to the seven key factors (external context and agencies; internal context and organisation readiness; communication; adaptors and adoption; innovation; implementation process and consequences) from the Greenhalgh framework (2004). The emergent themes from the Stage 2 transcripts were categorised in the key components of the RRS theoretical propositions. Coding and categorisation in Stage 1 and Stage 2 allowed indexing and retrieval in NVivo8 software (NVivo 2008).

Stage 3: Cross Case Comparison & Mid–range theory development

The synthesised data from the interviews, focus groups, observation and documentation were compared within and across sites and subgroups to provide an understanding of the similarities and differences. Cross case synthesis and triangulation of Stage 1 and 2 findings through a process of constant reflection and critique to compare competing explanations allowed us to refine CMO configurations (McEvoy & Richards 2003). These CMO configurations explained the causal mechanisms which produced outcomes in different contexts. Interpretation of these CMOs using an iterative and cyclical process facilitated theory refinement and the development of a mid-range theory to explain how and why the programme works in certain circumstances for certain individuals (Pawson & Tilley 1997).

Validity and Reliability

The realist review identified RRS theoretical propositions for testing and the Greenhalgh framework (2004) structured data collection and analysis to enhance validity and reliability. The interpretation of interview coding and categories were cross-checked by BB to enhance

reliability and reduce bias. Credibility was ascertained through the use of triangulation and respondent validation of Stage 1 findings with key policymakers in Stage 2. Documentary evidence of EWS and ALERT records provided an audit trail to enhance dependability and confirmability of findings. The emerging RRS conceptual themes were cross-checked the by the steering group members.

RESULTS

RRS Theoretical Propositions

The realist review and policymaker interviews identified key intervention components that were thought to lead to successful implementation and sustainability of the RRS afferent arm: early recognition of deterioration using EWS charts; early referral using graded response protocols; and education or ALERT training to improve the effectiveness of care offered by early responders. The initial impetus for these initiatives was reported to have arisen from concerned staff and managers in the hospitals but was not generally supported until patient safety directives were prioritised by the Department of Health (DoH) and a cultural change occurred. These changes to establish Clinical Governance in hospitals resulted in new structures and roles to improve and develop patient safety initiatives within existing budgets. Hospitals then implemented these aspects of the intervention as a Priority for Action (PfA) to reduce the annual number of cardiac arrest rates. To effectively implement the planned changes managers recognised the importance of raising awareness, effective ward leadership, EWS and ALERT training and continued support for staff. The implementation of EWS was perceived by policymakers as an opportunity to change the task orientated culture of observations to a structured patient assessment approach and change mind-sets to improve inter-professional understanding and referral with: (i) objective criteria; and (ii) communication using the Situation, Background, Assessment and Recommendation (SBAR)

tool (IHI 2016). In addition, ALERT champions perceived that the standardised educational package adopted by both hospitals provided staff with a structured assessment framework, improved confidence, knowledge, skills, communication and teamwork. Theoretical propositions developed from this evidence provided an understanding of how RRS was supposed to work in practice. However, policymaker interviews, ALERT audit data and research evidence (Odell *et al.* 2009, O'Leary *et al.* 2010, Azzopardi *et al.* 2011, Shearer *et al.* 2012, Radeschi *et al.* 2015) highlighted that traditional hierarchical referral cultures, routine observation culture, competing workloads, low staffing levels, low nursing confidence and a lack of communication and interdisciplinary teamwork were factors that constrained implementation of the underlying propositions in practice. These factors were tested in Stage 2 to develop further and refine CMO configurations and RRS theory to explain those factors that enabled or constrained the implementation of EWS or ALERT in practice.

Testing and refining RRS Theories

Early Recognition

In both sites there was a phased implementation of EWS charts and staff training to improve awareness, compliance and standardise the recording of observations on wards. The leadership role of the ward manager was perceived by hospital managers, senior nurses and champions as key to driving changes at ward level. However, hospital managers reported that the lack of change to the routine task of recording observations was associated with workload pressures due to continual resource issues to ensure adequate staffing levels for the level of patient dependency on general wards and the rigid application of recording observations implemented with clinical Governance in hospitals. As a result, staff employed several mechanisms to ensure workload was completed in this demanding and changing

organisational context. Experienced nurses would delegate the task of recording observations of patients' clinical status (heart rate, blood pressure etc.) to junior nurses, student nurses or health care assistants (HCAs) as part of the ward routine to enable them to care for the sickest patients on the ward. Managers felt this resulted in a continuing reliance by staff solely on electronic equipment (rather than holistic assessment) with limited interpretation of the clinical observations or knowledge of appropriate action. Staff nurses reported that the pressure to juggle time-rigid completion of observations with other ward priorities resulted in charts not always being completed accurately or at an exact time to comply with the instructions on the EWS charts. Consequently, staff reported they did not always record the time of measurements on clinical observation charts and this meant that EWS audits did not meet compliance rates set by the hospital. Managers and champions recognised that EWS training, human error, competing workloads and existing custom and practice in relation to patient observations were factors that had an impact on EWS chart compliance (Table 4).

Early Referral

A clearly defined trigger and response strategy was implemented in hospitals to standardise the decision making and referral process. In providing a mechanism for nurses to ensure patients were reviewed within the appropriate timeframe, the EWS protocol empowered nurses and gave them confidence to challenge response delays or refer to a senior level based on their interpretation of the situation. This cultural change provided nurses with clear guidelines and authority to support decisions; which managers perceived reduced the potential fear associated with contacting the doctor and provided a structure to the system which facilitated decisions to call for help. This was particularly evident for higher trigger scores. However, at low trigger scores the protocol was used flexibly by nursing staff to refer patients based on their clinical judgment. Clinical judgement was underpinned by pattern

recognition and intuition based on subjective criteria of knowing the patient, normal ward practices, the context (situation, time of day, availability of medical staff and whether doctors were familiar with the patient) or individual circumstances and clinical experience. Managers and staff nurses reported that the referral protocol was viewed as a guideline and recognised that clinical judgement and individual discretion were used when referring lower trigger scores. However, doctors and managers perceived that delays in referrals were associated with junior nurses' lack of confidence, waiting to recheck observations and not reporting a single deranged physiological parameter. In both sites, ward managers and staff nurses stated that agency staff and student nurses were mainly responsible for not reporting EWS scores, high parameters or deranged observations straight away (often students provided a list of observations just prior to handover).

An informal, cultural communication process was used by nurses during the daytime to refer patients to junior or senior medical staff as it was the most effective way to obtain a response. Nurses reported that communication reported to doctors was comprehensive. However, junior doctors stated that referral information was inconsistent (depending on the individual and experience) and often required having to prise information from nurses. Nurses did not use the SBAR communication tool during the day as there was limited use for a formal communication tool when there was no CCOS in place and ward doctors were familiar with patients. At night in both case sites referrals to doctors required an SBAR call to the Hospital at Night team. The use of SBAR at night required nurses to refer patients based on subjective criteria which was not compatible with a formal process requiring justification for help, was time consuming and elicited limited immediate response from doctors out of hours. Communication difficulties highlight the gaps in understanding each other's roles and responsibilities (McCrory *et al*. 2015, Michalec *et al*. 2015).

Early Response

In both sites ALERT training was adopted and driven by champions in existing human resources to ensure staff managed patient deterioration appropriately at the bedside within their level of competence. Managers felt that ALERT training improved inter-professional communication and nurses' knowledge, skills and confidence to provide basic pre-emptive management while waiting for help. However, doctors and nurses felt they primarily learnt from clinical ward experience. As a result, there was a recognised need by nurses for ongoing education on the wards, for placement opportunities to gain experience and to have a transparent educational role on the ward to facilitate ongoing learning and link course theory to practice. The nurse education role on wards at the time of the study was subsumed in a management role and as a result education was not viewed as a high priority, staff were not released for training due to staff shortages, there was limited competency based teaching on the wards and the primary educational focus was on attendance at mandatory training courses.

Policymakers and experts felt that in most cases deteriorating patients did trigger a referral and a clinical assessment was made by junior staff. However, in a small number of cases there continued to be problems ensuring an effective and timely response to patient deterioration. Hospital managers associated these delays with nurses' confidence in initiating the response, or doctors not complying or responding to the trigger mechanism. Nurses stated that their lack of confidence in obtaining a response from junior doctors out of hours meant they often decided not to refer but to manage the situation on the ward. Indeed, key informants reported that there was a degree of uncertainty over making a decision to manage or refer patients. This uncertainty was associated with determining whether the situation was manageable when the EWS score and clinical judgment conflicted. In both sites

organisational practices and beliefs encouraged junior medical staff to assess and manage patient care within their level of competence prior to calling for senior help. As a result the response in many cases was to manage situations on the wards within their own realm of competence and to re-evaluate. An ALERT expert reported that most of the time the decision to reassess was an appropriate response to a transient change. However, on a small number of occasions staff failed to rescue patients as a result of making an incorrect decision that there was no underlying problem or to re-evaluate. This was perhaps a result of the most junior medical and nursing staff being the predominant responders.

Clinical & Process Outcomes

Standardised recording practices, protocolised referrals and education were implemented to improve accuracy and completeness of observation recording in hospitals and to reduce the number of cardiac arrests. In both sites, audit records on EWS compliance and cardiac arrest rates were maintained and reported as part of the Clinical Governance process. Hospital managers, ward managers, senior nurses, ALERT champions and staff nurses felt that changing cultural attitudes to resuscitation had increased the number of pre-arrest calls and proactive Do Not Resuscitate (DNR) management plans had contributed to the reduction in the number of cardiac arrests. However, policymakers, experts and hospital managers recognised that it was difficult to attribute these figures to any one intervention due to the complex interplay of numerous factors in the healthcare environment and no records of DNR orders maintained in the hospitals at that time. Documentary evidence on cardiac arrest rates across hospitals were not reviewed in this study.

Analysis of EWS compliance records showed an increase in the accuracy and completeness of recording practices over the five-month data collection period (Table 5). Similarly, hospital managers reported that the EWS audits showed improved compliance rates, although they felt that charts continued to be inaccurate and incomplete as the frequency of observations to be recorded or actions taken for a triggered score were not documented. However, managers in both sites questioned the representativeness of the 100% EWS compliance rates captured by audit, as there continued to be incidents reported. Staff nurses perceived the EWS audit to be a burdensome waste of time and were not aware of feedback on compliance scores. They therefore viewed the audit process as a paper exercise of limited value in providing safe, high-quality care. Consequently, properly completed EWS charts were purposively selected each week to ensure a high compliance score in the audit and avoid further paperwork involving writing action plans to address non-compliance.

DISCUSSION

The RE found that RRS early recognition theoretical assumptions worked when experienced staff used the EWS protocols flexibly alongside contextual knowledge at low trigger scores to guide and inform their decision-making. Staff experience has been highlighted in this study and others as an important contributing factor to effective recognition and referral (Massey *et al.* 2014, Braaten 2015). However, when observations were undertaken by junior staff and HCAs, the early recognition and referral procedures did not work in practice (Ludikhuize *et al.* 2011, Mackintosh *et al.* 2012, Roberts *et al* 2014, Radeschi *et al.* 2015, Johnston *et al.* 2015). This was a result of junior nursing staff rigidly applying the trigger criteria with limited knowledge or skills in patient assessment. Rigid application of EWS increased the number of false positive calls and medical workload as a result of poor sensitivity and specificity of the tools in practice (Azzopardi *et al.* 2011, Mandell *et al.* 2015). This perpetuated a ritualistic and

mechanistic approach to the recording of observations which meant cues were often missed and physiological parameters were reported in isolation. As a result junior staff were less likely to recognise and refer EWS scores to senior staff (Azzopardi *et al*. 2011, Pattison & Eastham 2011). The existing literature suggests that junior staff may lack confidence and experience in integrating theoretical knowledge in the clinical context (DoH 2013) to safely make these decisions (Shearer *et al.* 2012; Massey *et al.* 2014).

Inadequate staffing levels and skill-mix on wards has been highlighted in this study and others as causal factors contributing to poor recognition and management of deteriorating ward patients (Donohue and Endacott 2010, Johnston *et al.* 2015) as a result of a lack of time to observe or follow up deteriorating patients (Hands *et al*. 2013, Jeddian *et al*. 2016). Research evidence highlights a strong association between mortality rates and improved staff ratios (NICE 2014, National Quality Board 2016).

Implementation of the EWS protocol in this study empowered experienced nurses to call for help and to refer patients appropriately based on the trigger criteria and clinical judgement. The use of clinical judgement was viewed by staff as an important part of professional decision making to ensure the most effective use of time and resources in managing patient care. Research evidence recognises the importance of intuitive knowledge and pattern recognition (Pattison & Eastham 2011, Mackintosh *et al*. 2012, Brady & Goldenhar 2014, Clifton *et al*. 2015). As a result, the flexible use of EWS protocols in practice will have an impact on the implementation and utility of the National Early Warning System (NEWS) (RCP 2012) to standardise assessment and response of acute illness in hospitals.

Referral processes tended to be informal. Staff referred to junior doctors on the ward rather than using the SBAR communication tool which they found to have limited response benefit when contacting doctors out of hours or doctors who were unfamiliar with the patient. SBAR has not been widely adopted or used by nurses as it requires justifying the need for help which nurses find difficult when concerned about a patient (Ludikhuize *et al.* 2011, Mackintosh *et al.* 2012, Smith *et al.* 2014, Bingham 2015). Evidence suggests that this hierarchical communication and traditional response systems often delay calls for help and compromises care (Calzacca *et al.* 2010, Azzopardi *et al.* 2011, Radeschi *et al.* 2015, Braaten 2015).

The early response theoretical assumptions worked when nurses and doctors were given acute care training to improve awareness, knowledge and confidence in the management of patient deterioration. With regards to competence it was recognised that it is the responsibility of each individual to know their own level. This resulted in difficulties for junior doctors and nurses knowing when to when to manage or call for help. Delays in referral or response to patient deterioration were attributed to nursing staff making informed decisions based on their clinical judgement to wait and repeat observations prior to referral, or junior staff making informed decisions to manage the patient on the ward within their own realm of competence. Often these decisions to reassess or manage patients on the ward were correct but on a small number of occasions resulted in failure to rescue patients.

Increased educational awareness changed the cultural response practices in the hospitals as staff called for help earlier and proactively managed patients who may not have benefited from further resuscitative or invasive procedures by discussing palliative care options. These changes in practice were attributed to the reduction in the number of cardiac arrests in the

hospitals. This evaluation and other studies highlight the difficulty of ascertaining whether reductions in cardiac arrest numbers were due to increased DNR orders or caused by improved outcomes due to timely treatment (Calzavacca *et al*. 2010, Oglesby *et al.* 2011, Downar *et al*. 2013, Pattison *et al.* 2015).

Limitations

The focus group interviews with staff nurses, student nurses and HCAs were restricted to two or three individuals at anytime due to ward staffing levels at the time of the study. This may have limited the group dynamics and generalisability of the findings. In addition, the observation of staff and ward practices may have resulted in variations of behaviours. To minimise the Hawthorne effect JM visited the ward on numerous occasions to familiarise with staff prior to the observation period.

CONCLUSION

The findings highlight that implementation and use of protocols to standardise care and inform decision making will never be straightforward because individual experience, sociocultural and contextual factors have an impact on clinical decisions. As a result, organisations need to provide true multidisciplinary education and ensure experienced staff record, report and manage patient deterioration. This will require an investment in human resources to address current staffing issues and recognition by policymakers that the provision of high-quality care costs. This is an important consideration given the findings of reports on the quality and provision of care in England (Berwick 2013, DoH 2013, Francis 2013) which characterise the importance of a good culture of care. Pawson and Tilley (1997) suggest that the provision of reasons and resources enables programme participants to change.

Since completion of this study the case site hospitals have implemented the National Early Warning System (NEWS) to standardise the recognition and referral process. Further training and educational initiatives have resulted in the development of EWS training alongside an online SBAR training package. CCOS have been implemented across both case sites to improve response and management of deterioration at the bedside. Acute care training in ALERT has continued despite limited human resources and funding. A recent review of acute care training in the management of patient deterioration has been undertaken regionally due to the variation in educational provision and funding across the hospitals (Education Commissioning Group 2017). However, multiprofessional educational opportunities continue to be restricted by block training of junior doctors to accommodate organisational rotation practices. The success and sustainability of RRS requires further organisational changes to improve staffing levels and interprofessional education to address the main factors constraining implementation in practice.

Author Contributions:

All authors have agreed on the final version and meet at least one of the following criteria (recommended by the ICMJE*):

1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;

2) drafting the article or revising it critically for important intellectual content.

* http://www.icmje.org/recommendations/

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Table 1: Participant sample and prior acute care training

Stage 1	Policymaker Individual Interviews (n=14)											
Interviews	**Case site 1**						**Case site 2**					
	Sample	**Prior training**					**Sample**	**Prior training**				
Individual		E W S	A L E R T	I L S	O T H E R	N V Q		E W S	A L E R T	I L S	O T H E R	N V Q
Medical & Nursing Hospital Managers, ALERT/EWS champions	5	2	4	1	3		5	1	2	2	2	
Managers	5	3	3	1	2		5	5	5		1	
Junior doctors	4		4	4			5		4	4	1	
Focus groups												
Nurses	12	9	7				11	5	6	1	1	
Student nurses	5						2	2				
HCAs	0						4					3

EWS, Early Warning System; ALERT, Acute Life-threatening Events: Recognition and Treatment;
(A)ILS, Advanced / Intermediate Life Support course and or Instructor; Other, Specialist nurse
training (ICU, Cardiology, Anaesthetics, Renal)or III Medical Patients Acute Care & Treatment course
(IMPACT); NVQ, National Vocational Training Level 2 or 3

Table 2: RRS Theoretical Propositions

RRS Component	Proposition
Early Recognition	Accurate, regular monitoring of vital signs on general hospital wards (Context) using a standardised EWS tool alongside subjective assessment (Intervention) improves recognition of patient deterioration (Outcome) by highlighting changes in physiological parameters to nurses (Mechanism).
Early Referral	Predefined trigger thresholds with graded protocolised response strategies (Intervention) empower nurses to refer patients (Mechanism) to an appropriate member of staff (Context) who will attend within specified response times (Outcome).
Early Response	Educational courses in caring for the acutely ill patient for all hospital staff at varying levels of competence (Intervention) improves early intervention (Outcome) as an appropriate member of staff with the required knowledge and skills (Mechanism) will address deranged physiology according to the level of patient need at the beside (Context).
Improved outcome	The use of a sensitive and specific EWS tool, with predefined triggers and graded response algorithm (Intervention) improves early recognition, referral and response to patient deterioration by staff (Mechanism) to reduce the incidence of cardiac arrests, unplanned ICU admissions and unexpected deaths (Outcomes) in hospitalised patients (Context).

Table 3: ALERT documentary analysis

ALERT documentation	Case site 1	Case site 2
Dates records reviewed	28.7.2003-29.5.2008	19.12.2003-5.2008
Total number trained	775 (15 per course)	599 (20 per course)
Number of courses	52	28
Number of nurses trained Number of junior doctors trained Others trained	510 (66%) 244 (31%) CNP (1%), lecturers (0.3%), specialist nurses (0.5%), F2 doctors (0.2%)	384 (64%) 124 (21%) physio (6.3), ward sister (4%), senior doctors (2.4%)
Number of wards across hospital	50	38
Wards x attendance at training	A&E (n=58),CCU(n=32),Cardiology (n=27), ICU (n=23),Theatres (n=22)	Medical wards (N=30, N=25, N=24, n=24), Maternity (n=26)
Courses block booked for doctors	13	6
Doctors participating in MDT ALERT training	26 out of 246	34 out of 140

ALERT, Acute Life-threatening Events: Recognition and Treatment; CNP, Clinical Nurse Practitioner, A&E, Accident and Emergency; MDT, Multidisciplinary team

Table 4: Refined RRS CMOs

Early Recognition			
Context +	Mechanism =	Outcome	CMO Qualitative evidence
EWS calling criteria poor sensitivity & specificity (-ve)	Experienced staff view EWS criteria as a guideline which is used alongside clinical judgment to refer patients at low trigger scores	• Reduces false positive triggers • Clinical deterioration recognised by clinical experience • Lack of consistency in application at lower trigger scores • Use of clinical judgment might delay referral	*".. you need to still be able to look at observations or even still look at your patient without having to use an Early Warning Chart to tell if your patient is unwell or not. ..It should be an in-hand system but it shouldn't be a 'the' system.."(Surgical ward staff nurses 02[07])*
Inadequate staffing levels and skill mix for patient acuity and workload (-ve)	Observations delegated to junior staff who have limited knowledge, skills and clinical experience	• EWS incomplete and inaccurate • Reliance on tool for recognition by junior staff • Less experienced staff lack clinical judgement to provide interpretive context for EWS scores	*"There is a level of intuition with staff but I think again that is something that not everyone has and some people have more of it than others."(Senior Nurse Manager Medicine 02[06])*
Rigid EWS audit to record observations at an exact frequency imposed within a demanding and changing ward context (-ve)	Staff omit recording frequency on chart as not able to comply with rigid recording practices	• Calculation errors • Underscoring of EWS • Poor EWS compliance rates as frequency not recorded on chart	*"...so I think that's where the downfall comes, sometimes looking at the score and forgetting the observations of the patient behind the score really". (Medical ward junior doctor 02[17])* *"..it's just an instinctive thing that you do and sometimes we can look at patients and know by their obs that they probably should have a PEWS higher than they do because you just know your patient's not right and they know they're not right, it's instinct."*

(Medical ward staff nurses 01[09])

"..what we found was, repeatedly, that their scores weren't being done correctly, they were missing some parameters, the higher the score the more chance there was that it wasn't added up correctly and that was a frequent finding that whenever they had totted them up they had got the wrong number and obviously that could change the response that was required. ..." (Senior Nurse A 01[03])

Early referral		
Context +	Mechanism =	Outcome
EWS protocol establishes clear hospital guidelines for referral criteria and response times (+ve)	Protocol provides criteria and empowers experienced nurses to refer patients to senior staff by providing objective data to ground clinical judgement.	• Organisational change shifted the balance of power /authority regarding referral timeframes • Increased confidence of experienced nurses to refer patients without fear of reprimand • Inexperienced, agency and HCA staff fail responsible for delays in referral
Rigid implementation of protocol by nurses to comply with hospital policy (-ve)	Nurses refer patients if EWS trigger score reached regardless of potential for false positive trigger calls	• Increased number of false positive calls • Wastes nurses' and doctors' time • Questions the validity of the tool • Infringes on professional acumen
SBAR recommended to structure referral calls for medical help (-ve/+ve)	Nurses use clinical	• SBAR not utilised as time consuming

"It would probably be your F1 because they're ward based but obviously you wouldn't undermine them, you would tell them but if you felt that maybe they weren't taking onboard then you would just bleep someone more senior"(Surgical ward sister 01 [19])

"I think that the structure of Mews or of any type of early warning system just makes the decisions easier for everybody involved especially for the people at the bottom up, it gives them the confidence to say,…'it's not me making the decision to call you, I have to call you because the system actually…', it gives you

Context	Mechanism	Outcome	
judgment and contextual cues to contact doctors who they know and who are familiar with the patient	with limited immediate response benefit • Patient referrals based on clinical judgement and hierarchical system		*another level of support..."(Senior Medical Manager Medicine 02[04])* *"..these things (EWS) don't have sensitivity, I'm sure they're going to people that are a complete waste of time and they're probably missing some of the patients that they should be seeing". (ALERT expert [12])* *"..that's something I know from our training when you did sort of disciplinary things, nurses were always were sort of told SBAR bit. I don't think I've ever had a phone call where anyone's used it". (Surgical junior doctor 02[24])* *"I think the important thing was the doctor and I have worked together for a while anyway so we probably know each other and then I was able to bring her to the patient and then she felt as well that there was something maybe just not 100% right although when you looked at the observations they were fine".(Surgical Ward Manager 01[01])*

Early Response

Context +	Mechanism =	Outcome	
Individuals are responsible for knowing when to manage or call for help when level of competence exceeded (-ve/+ve)	Nurses and doctors decide to manage patients on the ward when they are uncertain of obtaining a response, when there is a cultural expectation to manage, uncertain if the patient is deteriorating or uncertain if the situation is manageable	• Uncertainty regarding referral decision delays response • Patients are managed on wards and re-evaluated within the nurses and doctors realm of competence	*"I think the toughest thing is making a judgment call when you need senior help and when you can sit tight on something"(Medical junior doctor 02[22])* *"I think what has maybe happened is that the algorithm has broken down at the first or second stage so someone who is perhaps too junior has been involved and again not recognised, but felt confident enough for whatever reason to say, 'well look, they're ok, ...they make a clinical assessment and their judgement may not be perfect at that stage". (Medical ALERT Champion 02 [08])*
ALERT training in hospital for members of MDT to improve knowledge & skills (+ve)	ALERT courses are delivered to align with influx of doctors in separately for nurses and doctors to accommodate	• ALERT training increases awareness & improves confidence • Competence not assessed • Workload impacts on educational release • HCAs, agency & student nurses training in observations	

| | | unclear | *"..again we looked at the impact of ALERT on knowledge and that seemed to improve, we looked at the impact of knowledge on people's attitudes and they seemed to improved but whether they really translate into a clinical outcomes for a patient it's difficult to tell". (ALERT expert [12])* |
| | | | *"I ALERT is much more relevant and think it's unfortunate there isn't someone, there aren't key people on the wards, we don't have time to do it ....and I think that's the missing link. It's having that, the old clinical teachers"(Senior Nurse A 01[03])* |

Clinical and Process Outcomes

Context +	Mechanism =	Outcome	
Changes to cardiac arrest team calling criteria & patient review (+ve)	Ward staff call for help prior to clinical signs of cardiac arrest	• Increased number of pre-arrest calls • Increased number of DNR orders	*"I know that we had more patients who would be admitted to ICU now than we had previously because we are preventing the arrests from actually happening.... the girls know they don't have to wait until somebody has stopped breathing or the heart has stopped before they do call an arrest team or an anaesthetist".(Surgical ward Nurse Manager 01 [01])*
Weekly EWS compliance audit & action plans implemented as a top down process to reduce adverse events (-ve)	Ward staff selectively chose EWS charts that have been documented accurately on the ward to complete the weekly EWS compliance audit	• 100% compliance questioned by managers • Continued evidence of adverse incidents • Audit viewed as paper exercise by nursing staff	*"The care bundle is more of an audit to make sure these charts are being completed correctly and being actioned correctly....It's just all the information is recorded, it goes away to people in suits but it come back to us again and then we are supposed to reply back to them and in the meantime keep your patients safe". (Surgical ward Nurse Manager 01[01])*

Table 5: EWS compliance data across case sites

EWS	Case site 1		Case site 2	
	Medical 01	**Surgical 01**	**Medical 02**	**Surgical 02**
Data collection dates	May - Oct 10	May -Oct 10	May –Oct 10	Sept- Oct10
Time span	21 weeks	21 weeks	20 weeks	8 weeks
Initial compliance rate	20%	80%	100%	55%
Range	60-80%	85-100%%	85-100%	55-100%
Noncompliant areas	Frequency not recorded; Not recorded to frequency; no evidence of action	Frequency not recorded	Frequency not recorded; vital signs compliance; not totalled	Frequency not recorded; not recorded to frequency; no evidence of action; not totalled
Last compliance rate	100%	100%	85%	95%

Figure 1: Study Design