Is there a role for patients and their relatives in monitoring, detecting and escalating clinical deterioration in hospital?

Abigail Kathleen Albutt

Submitted in accordance with the requirements for the degree of

Doctor of Philosophy

The University of Leeds

School of Psychology

January 2018

The candidate confirms that the work submitted is his/her own, except where work which has formed part of jointly-authored publications has been included. The contribution of the candidate and the other authors to this work has been explicitly indicated below. The candidate confirms that appropriate credit has been given within the thesis where reference has been made to the work of others.

The systematic review reported in Chapter 2 has been published:

Albutt, A. K., O'Hara, J. K., Conner, M. T., Fletcher, S. J., & Lawton, R. J. (2016). Is there a role for patients and their relatives in escalating clinical deterioration in hospital? *Health Expectations*. doi: 10.1111/hex.12496

All authors developed the concept for the systematic review. AA designed the study and conducted the searches, screening, data extraction and analysis with input from RL, JOH and MC. AA drafted the publication and thesis manuscript. All authors provided comments and approved the final version.

Acknowledgements

Firstly, I would like to express a huge thanks to my supervisors, Rebecca Lawton, Jane O'Hara and Mark Conner. Completing this PhD has been an extremely rewarding and enjoyable experience, and I am very grateful for the continued support and guidance you have given me. You've been an amazing supervision team and I feel privileged to have been supported by such experienced and knowledgeable researchers.

I'd like to say thank you to University of Leeds for funding this PhD, and a massive thank you to all the staff and patients who have taken part in my research. I am forever grateful for the time you have given to make this thesis possible.

Many people have helped and guided me through this PhD. Thank you to everyone in the Yorkshire Quality and Safety Research group who have taught me a lot about the complexities of applied health research, I have really enjoyed being part of the team. Thank you to Steve Fletcher, Rachel Harris, Alison Shaw and all the other clinical staff who have given their time so generously to help implement this research.

I am lucky to have made some great friends while doing this PhD. Thanks to all the PhD girls for the many chats, coffees and cakes that kept me going! And thank you to Ruth and Liz for being there for me and giving me much appreciated advice on all things.

I cannot thank my incredible family enough for being there for me through this experience. Mum- thank you for the endless love and support you show me in everything that I do, and for guiding me with your wisdom. Thank you to my Dad for the morals you have instilled in me and the mantras you have taught me. You have always encouraged me to be prepared and organised which has been so important when doing this PhD, after all "fail to plan, plan to fail". Thank you to my wonderful Nanny for always helping me find a simple solution when things felt overwhelming. Finally, thank you to my boyfriend Dave for all your love and encouragement. Thank you for making my dinner when I was too tired and for always putting a smile on my face with your jokes, but most of all thank you for encouraging me to challenge myself and improve- it is truly appreciated.

Abstract

Measures exist to improve early recognition of, and response to deteriorating patients in hospital. Yet, 11% of deaths in UK hospitals in 2005 were the result of patient deterioration going unrecognised or not being acted on (NPSA, 2007). The thesis aimed to investigate whether patients and relatives can aid health professionals in recognising clinical deterioration.

A systematic review was conducted which identified interventions that allow patients and relatives to escalate patient deterioration. However, there is not strong evidence for the clinical effectiveness of these interventions, and a limited understanding of patient and relative ability to recognise patient deterioration. In study 1, health professionals generated potentially feasible and acceptable methods of involving patients and/or relatives in recognising deterioration in hospital. Recording patients' views on changes in their wellness during routine observation was proposed. Focus groups were held in study 2 with healthcare assistants and patients to develop a questionnaire to capture patients' and relatives' ratings of patient wellness.

Study 3 piloted approaches to routinely collecting patient wellness ratings using the questionnaire on in-patient wards. Where the researcher attended observation to record patients' ratings, this was acceptable to most patients. However, there was limited uptake where patients and relatives were invited to complete the questionnaire themselves, and staff were invited to record patients' wellness ratings during observation. It may be necessary to encourage and support staff to adopt this change in practice. In study 4, the use of behaviour change techniques to encourage staff to routinely record patient-reported wellness in practice were effective on wards showing high previous levels of engagement with the observation system. The clinical effectiveness of routinely recording patient-reported wellness was also explored. Significant associations between patient-reported wellness, and early warning score and vital sign measurements were found, and these were stronger in more acutely unwell patients.

Evidence from the thesis suggests that routinely recording patient-reported wellness may be one feasible strategy that could aid health professionals in the early recognition of clinical deterioration.

Table of Contents

List of Tables

Chapter 2

Chapter 3

Chapter 4

Chapter 6

List of Figures

Chapter 2

List of Abbreviations

AA	Abigail Albutt
BCT	Behaviour change techniques
CCOT	Critical care outreach team
EWS	Early warning score
JOH	Jane O'Hara
MC	Mark Conner
MET	Medical emergency team
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
RRT	Rapid response team
RL	Rebecca Lawton
UK	United Kingdom
US	United States
WHO	World Health Organisation

Publications and presentations

Peer reviewed publications

Albutt, A. K., O'Hara, J. K., Conner, M. T., Fletcher, S. J., & Lawton, R. J. (2016). Is there a role for patients and their relatives in escalating clinical deterioration in hospital? *Health Expectations*. doi: 10.1111/hex.12496

Oral conference presentations

Albutt, A. K., O'Hara, J. K., Conner, M. T., and Lawton, R. J. (2017, May). Development and evaluation of a health services intervention to promote patient involvement in recognising clinical deterioration in hospital. Oral presentation at International Conference on Rapid Response systems and Medical Emergency Teams. Chicago, USA.

Albutt, A. K., O'Hara, J. K., Conner, M. T., and Lawton, R. J. (2016, November). Health professional's attitudes towards involving patients and their relatives in the detection of clinical deterioration in hospital. Oral presentation at Science of Improvement Conference. Harrogate, UK.

Albutt, A. K., O'Hara, J. K., Conner, M. T., and Lawton, R. J. (2015, December). Is there a role for patients and their relative in escalating clinical deterioration in hospital? A systematic review. Oral presentation at UK Society for Behavioural Medicine Annual Scientific Meeting. Newcastle, UK.

Conference poster presentations

Albutt, A. K., O'Hara, J. K., Conner, M. T., and Lawton, R. J. (2017, May). Is there a role for patients and their relative in escalating clinical deterioration in hospital? A systematic review. Oral presentation at International Conference on Rapid Response systems and Medical Emergency Teams. Chicago, USA.

Albutt, A. K., O'Hara, J. K., Conner, M. T., and Lawton, R. J. (2016, July). Health professional's attitudes towards involving patients and their relatives in the detection of clinical deterioration in hospital. Oral presentation at Health Services Research Symposium. Nottingham, UK.

Chapter 1

Introduction: Overview of the literature, thesis aims and objectives.

1.1 Chapter summary

This chapter presents an overview of literature exploring the quality and safety of healthcare, and discusses research efforts made to improve patient safety. The involvement of patients in healthcare to enhance quality and safety is then outlined, with reference to the potential for involving patients and relatives in monitoring, detecting and escalating clinical deterioration in hospital. The overall aim of the thesis was to generate rigorous evidence regarding the ability of patients and relatives to recognise signs of the patients' deteriorating condition, and aid health professionals in the early recognition of, and response to clinical deterioration. The research studies conducted in order to investigate and critically evaluate the role of patients and relatives in managing clinical deterioration are described in the thesis aims and objectives.

1.2 The quality and safety of patient care

In 1999, the Institute of Medicine released a seminal report called 'To Err is Human: Building a Safer Health System' (Kohn, Corrigan, & Donaldson, 1999). The report highlighted, for the first time, the prevalence of death and injury from medical error, and arguably launched the modern patient-safety movement (Wachter, 2010). This report, along with others that followed, such as 'An Organisation with a Memory' (Department of Health, 2000) and 'Crossing the Quality Chasm' (Institute of Medicine, 2001), put the quality and safety of patient care at the forefront of policy agendas, and prompted international and national campaigns to reduce patient harm from medical error within healthcare organisations (Lamont & Waring, 2015).

Research efforts have since progressed a number of patient safety issues (Pronovost, Miller & Watcher, 2006; Wachter, 2010). For instance, the introduction of the WHO Surgical Safety checklist, which aimed to decrease errors and increase communication in surgery, has significantly reduced surgical morbidity and mortality rates globally (Treadwell, Lucas & Tsou, 2013; Walker, Reshamwalla & Wilson, 2012). Other examples of improvements to patient safety include a reduction in hospital acquired infections through enhanced hand hygiene and screening for drug resistent organisams (Huskins et al., 2011; Salgado et al., 2013), and the introduction of incident reporting systems to understand how and why patients have been harmed at an organisaitonal level (Benn et al., 2009; Pham, Girard & Pronovost, 2013). Despite intense focus on patient safety research in recent years, preventable deaths as a result of medical error remains a widespread issue (Hogan et al, 2012). Medical error has been cited as the third leading cause of patient death in the US (Makary & Daniel, 2016), and evidence suggested that within a one year period, 4.8% (50/ 1052) of patient deaths in a large US teaching hospital were preventable (Provenzano et al., 2014). While in the UK, Hogan et al. (2012) identified that there were 11,859 preventable patient deaths in 2009 (5.2% of 1000 case record reviews). The main problems associated with preventable deaths were poor clinical monitoring, diagnostic errors and inadequate drug or fluid management (Hogan et al., 2012).

A series of recent, high profile government reports have highlighted nationwide failures within the National Health Service (NHS) to provide good quality, safe patient care (Berwick, 2013; Francis, 2013; Keogh, 2013). Evidence suggests that there is unwarranted variation within the quality of care provided (Agency for Healthcare Research and Quality, 2007), and the National Institute for Health and Care Excellence (NICE) was created in 1999 in part to address these unwarranted variations in care quality (Malhotra et al., 2015). Yet, research findings continue to highlight that not all patients receive the recommended quality of care (Appleby et al., 2011; NHS England, 2015; NHS Right to Care, 2016).

1.3 Improving quality and safety of patient care

Quality of care is considered a multi-faceted concept, and patient safety is thought to be one component of quality. There is no one universally accepted

definition of quality care (World Health Organisation, 2006), although NHS England (2016) propose a nationally agreed definition that encompasses safety, clinical effectiveness and patient-centeredness.

Quality improvement initiatives that aim to induce positive change by altering provider behaviour and organisation (Øvretveit, 2009) have become prominent within healthcare organisations. A key characteristic of quality improvement projects is that they are an improvement activity, rather than research designed to generate new knowledge (Portela, Pronovost, Woodcock, Carter & Dixon-Woods, 2015). These highly practical initiatives often proceed on the basis of provider intuition and anecdotal evidence (Shojania & Grimshaw, 2005). Many quality improvement strategies are based on scant evidence (Auerbach, Landefeld, & Shojania, 2007; Shojania, Duncan, McDonald, & Wachter, 2002), and do not undergo rigorous assessment to determine their efficacy. They are limited to measuring change in the key target, making it difficult to understand why change occurred (Dixon-Woods, Leslie, Tarrant, & Bion, 2013; Portela, Pronovost, Woodcock, Carter & Dixon-Woods, 2015).

Within the rapidly evolving field of healthcare, it is understandable that the impulse to address a problem may override the need for an evidence-base (Auerbach, Landefeld, & Shojania, 2007). Although, in not taking a scientific approach, quality improvement projects can result in negative outcomes rather than improvements, such as negative unintended consequences and side-effects, ineffective use of resources, and disengagement from staff (Auerbach, Landefeld, & Shojania, 2007; Marshall, Pronovost, & Dixon-Woods, 2013). The adoption of a more scientific approach to quality improvement has been proposed to better support healthcare organisations to provide high-quality, safe patient care (Marshall, Pronovost, & Dixon-Woods, 2013).

Improvement science, also referred to as implementation science, translational research and science of quality improvement is an emerging concept that applies rigorous research methods to understand what impacts upon quality improvement (The Health Foundation, 2011). It uses a highly pragmatic approach to produce local, practical learning using robust, well established research methods. The choice of methods used is often guided by the reality of implementing interventions in complicated, heterogeneous, real clinical practice (Marshall, Pronovost & Dixon-Woods, 2013). Importantly, improvement science

generates knowledge with external validity that is generalisable beyond the local context. It also contributes towards the use and development of explicit theories of how change happens, allowing interventions to be reproduced in new contexts (Marshall, Pronovost & Dixon-Woods, 2013).

1.4 Patient involvement in improving patient safety

Traditionally, models of healthcare in the UK have adopted a paternalistic approach where health professionals assumed sole responsibility for treatment decisions, with patients being passive recipients of care who rarely challenged their authority (Ali & Muhammad, 2014; Lawton & Armitage, 2012). However, in recent years this approach has shifted towards a model of care in which patients are empowered to be active partners in their healthcare, with treatment decisions ideally being made between health professionals, patients and their relatives (Greenhouse, Kuzminsky, Martin & Merryman, 2006; Lawton & Armitage, 2012). Involving patients in their healthcare is a top priority for the NHS, highlighted in the NHS constitution (Department of Health, 2015) and the NHS Five Year Forward View (NHS England, 2014). There has been a marked increase in patient involvement in numerous areas of patient safety. The main approaches to involving patients in improving safety include (1) collecting patient feedback retrospectively; (2) inviting patients to help plan broad service change; and (3) encouraging patients to identify risks when they are receiving care (The Health Foundation, 2013).

Lawton et al. (2017) trialled the Patient Reporting and Action for a Safe Environment (PRASE) intervention on 33 UK hospital wards in one of the largest patient safety trials ever conducted. The study explored how patient feedback on the safety of their care can be used to enhance patient safety at a ward level. They found that patients could contribute towards improving safety by providing feedback about the safety of their care, and identifying safety incidents. In terms of involving patients in improving the safety of services and wider systems, researchers in the UK interviewed 14 patients in the community and in care homes. They explored patients' perceptions of safety to identify ways to reduce safety incidents within organisational care transfers. Communication, responsiveness and avoidance of traditional safety risks were found to be

important to patients and informed new strategies to reduce safety incidents (Scott, Dawson & Jones, 2012).

The Clean Your Hands campaign is an example of patients being involved in safeguarding their individual safety (NPSA, 2010). Alcohol rub availability in hospitals was increased and patients were invited to question staff about their level of hand washing (NPSA, 2010). Involving patients in their safety in this way at an individual level in partnership with health professionals can be challenging (Jorm, Dunbar, Sudano & Travaglia, 2009; Lyons, 2007). Patients must be aware of patient safety issues that they could have a role in addressing without being made to feel fearful. Furthermore, the important contribution patients can make must be recognised without making them feel responsible and accountable (Lawton & Armitage, 2012).

Davis, Sevdalis and Vincent (2011) found that patients do not view their involvement in a range of patient safety-related behaviours uniformly. Patients were less willing to engage in behaviours which involved challenging health professionals. Asking staff about their hand washing (eg. Clean Your Hands campaign) may be considered as a challenging behaviour and this is reflected in research showing that the majority of patients (56%) reported they would be unlikely to question doctors on the cleanliness of their hands (Pittet et al., 2011). Encouragement from health professionals was found to increase patient-reported willingness to ask challenging questions (Davis et al., 2011). Conversely, a lack of health professional support for patient involvement in patient safety may be a significant barrier that should be addressed before the benefits of patient involvement can be achieved (Entwistle et al., 2005). Despite these challenges, there is a growing appreciation that patients can help to improve their own safety (Coulter & Ellins, 2006; Davis, Sevdalis, Jacklin & Vincnt, 2007; Giles, Lawton, Din & McEachan, 2013; McEachan et al., 2014) and there have been efforts to promote patient and relative engagement in the acute care setting (Berger et al., 2014; Jha et al., 2015).

1.5 Recognising and responding to the deteriorating patient

Clinical deterioration is marked by a period of clinical instability (National Confidential Enquiry into Patient Outcome and Death; NCEPOD, 2005) which

can occur at any time during a patient's illness but is more common following emergency admission to hospital, after surgery and during recovery from a critical illness (National Patient Safety Agency; NPSA, 2007). In-hospital clinical deterioration that is not promptly responded to can lead to numerous severe consequences for the patient including increased length of hospital stay, cardiac arrest, admission to the Intensive Care Unit, and increased morbidity and mortality (Brennan et al., 1991; Jones, Mitchell, Hillman & Story, 2013; Soar & Subbe, 2012; Stelfox, Bagshaw & Gao, 2014). Such serious adverse events may be prevented by recognising and responding to early signs of clinical deterioration (Jonsson, Jonsdottir, Moller & Baldursdottir, 2011; Kyriacos, Jelsma & Jordan, 2011).

To aid the recognition of and response to clinical deterioration, Early Warning Score (EWS) systems and Critical Care Outreach teams (CCOT) have been introduced in numerous countries including the UK, USA and Australia (O'Dell, Victor & Oliver, 2009). EWS are based on routine physiological measurement of patients' vital signs including their heart rate, respiratory rate, blood pressure, temperature and conscious level from which a score is calculated and recorded. In more recent times, the electronic physiological measurement of patients' vital signs has been introduced and investigated (Nwulu, Westwood, Edwards, Kelliher & Coleman, 2012; Schmidt et al., 2014). Using EWS, health professionals can monitor and detect changes in patients' vital signs (Kyriacos, Jelsma & Jordan, 2011). When a patient's EWS is outside of the normal range, this can be indicative of clinical deterioration and can prompt health professionals to escalate patient care and trigger a CCOT. CCOT, also referred to as Rapid Response Teams (RRT) or Medical Emergency Teams (MET) typically consist of medical and nursing staff with critical care skills who provide timely treatment to support the deteriorating patient on the ward (Alam et al., 2014). However, evidence for the efficacy of these systems at reducing in-hospital mortality among other serious adverse events is equivocal (Bokhari et al., 2010; Chan, Jain, Nallmothu, Berg & Sasson, 2010; De Meester et al., 2012; Jones, DeVita & Bellomo, 2011; Patel, Jones, Jiggins & Williams, 2011; Paterson et al., 2006).

Although EWS and CCOT systems are in place, the management of critical illness remains a problem as some patients who are deteriorating continue to go unrecognised and appropriate, timely action is not always taken. For instance,

detailed analysis of deaths reported to the National Patient Safety Agency National Reporting and Learning System in 2005 demonstrated that more than 11% of the 576 deaths related to patient deterioration not being recognised or responded to (National Patient Safety Agency, 2007). In order to prevent deterioration using the escalation protocol, health professionals must document and interpret observations, communicate these effectively to colleagues and appropriately manage and respond to the patients' clinical condition. However, evidence suggests that health professionals do not always adhere to the escalation protocol (Adelsteine et al., 2011; Hands et al., 2013; Petersen, Mackel, Antonsen & Rasmussen, 2014; Shearer et al., 2012).

Franklin and Mathew (1994) found over a 20 month period that deterioration had been documented within the preceding 6 hours for 66% of adult inpatient cardiac arrests. However, it was identified that nurses did not communicate this to doctors and doctors did not respond appropriately to the patients' deteriorating condition. Similarly, researchers investigating all serious adverse events in a hospital over a 6 month period showed that health professionals failed to follow at least one stage of the escalation protocol prior to 92% of the 132 serious adverse events, with most non-adherence occurring when patients' EWS indicated that their care should be escalated. (Petersen, Mackel, Antonsen & Rasmussen, 2014). Further research supports findings that health professionals recognise clinical deterioration but fail to respond appropriately (Boniatti et al., 2014; Tirkkonen et al., 2013; Trinkel & Flabouris, 2011). Common reasons cited by health professionals for failing to escalate a patient's care and trigger a CCOT include insufficient knowledge of the EWS and CCOT system, communication failures and concern about a negative reaction from colleagues for activating the CCOT (Shearer et al., 2012).

In light of the evidence, one way to enhance the efficacy of the EWS and CCOT system, and reduce preventable clinical deterioration may be to engage patients and their relatives in recognising and responding to patient deterioration (O'Dell, Victor & Oliver, 2009). Involving patients and relatives in the management of deterioration may be appropriate for a number of reasons. Evidence demonstrates that nurses commonly detect patient deterioration using intuitive reasoning that is mediated by their knowledge of the patient (O'Dell, Victor &

Oliver, 2009). It is intuitive to think that patients (and to some extent their relatives) have knowledge of the patient and their norms, and may sense if the patient's clinical condition is deteriorating. This has been especially well documented in paediatric deterioration where parents' recognised signs that their child was deteriorating before health professionals, for instance in the cases of 18 month old Josie King (Greenhouse, Kuzminsky, Martin & Merryman, 2006) and 15 year old Lewis Blackman (Raymond et al., 2009). In these cases, health professionals did not respond appropriately to escalate the patients' care resulting in the unexpected deaths of these children. Furthermore, patients themselves are at the centre of the care process, and so there is a large incentive for them to help ensure they receive quality care. They also observe the whole care process making them a valuable, largely untapped resource for quality and safety improvement (Davis, Sevdalis, Jacklin & Vincnt, 2007; Trier, Valderas, Wensing, Martin & Egebart, 2015). Considering patients ' and relatives' views on changes in the patients' health may provide another barrier to unrecognised preventable deterioration, alongside the EWS and CCOT systems that are in place.

1.6 Thesis aims

This chapter has provided a broad literature review on the involvement of patients in their care to enhance patient safety, and the potential for patients and relatives to aid health professionals in the early detection and escalation of clinical deterioration. A number of unanswered questions remain, which this thesis aims to address:

1. *How have patients and relatives previously been involved in monitoring, detecting and escalating clinical deterioration in hospital?*

   This thesis aims to further our understanding of how patients and relatives have previously been involved in escalating clinical deterioration in hospital to identify the strengths, limitations and gaps within the current literature.

2. *From a health professional perspective, can patients and relatives aid health professionals in the detection and escalation of deteriorating patients, and how might they be involved?*

This thesis aims to further our understanding of health professionals' perspectives on whether patients and relatives can aid them in the early detection and escalation of deteriorating patients. It aims to generate ideas about how patients and relatives might be involved in the management of clinical deterioration in the context of a resource-limited UK health service.

3. *Are there feasible and acceptable approaches to using the Patient Wellness Questionnaire to routinely collect patients', relatives' and healthcare assistants' views on changes in patient wellness in practice?*

This thesis aims to further our understanding of the feasibility and acceptability of involving patients and relatives in the recognition of clinical deterioration in practice by routinely recording their views on changes in patient wellness. Two approaches to collecting this information from patients, relatives and healthcare assistants were trialled. Firstly, these groups were invited to routinely record their views themselves. Secondly, the researcher attended routine observation and visiting hours to record their views.

4. *Does routinely recording patient-reported changes in wellness provide novel information to suggest the patient is deteriorating?*

This thesis aims to further our understanding of whether recording patients views on changes in their wellness during routine observation provides health professionals with novel information to suggest the patients' clinical condition is deteriorating. The relationship between patient-reported wellness and routinely recorded clinical measures of patient health, such as the EWS is explored. This allows us to gain insight in to the clinical effectiveness of routinely recording patient-reported wellness, and to understand whether patients can recognise signs of genuine clinical deterioration.

1.7 Thesis overview

A systematic review and four research studies were conducted in order to address the above research questions. A systematic review explored approaches used in healthcare to engage patients and relatives in escalating in-hospital clinical deterioration. Health professionals were then interviewed to

generate potentially feasible and acceptable approaches to involving patients and relatives in the management of the deteriorating patient in practice, and the concept for a health services intervention to promote patient involvement in recognising in-hospital clinical deterioration was identified (study 1). A series of small-scale studies tested the feasibility of the intervention procedures from a patient perspective, and iteratively refined the design of the intervention (studies 2 and 3). The clinical effectiveness of the intervention to aid health professionals in recognising and responding to in-hospital clinical deterioration was then investigated (study 4).

Chapter 2 reports a systematic review: 'Is there a role for patients and their relatives in escalating clinical deterioration in hospital? A systematic review' (thesis aim 1). A search strategy was applied across four electronic databases and two web search engines to identify peer reviewed, academic literature and non-peer reviewed, grey literature. Articles which investigated the implementation or use of systems involving patients and relatives in the detection of clinical patient deterioration and escalation of patient care were reviewed. Reference list and citation searches were also performed to identify articles. Data were extracted according to pre-defined criteria. Narrative data synthesis was carried out to a) identify and describe systems involving patients and relatives in the process of escalating in-hospital clinical deterioration; b) describe how these systems have been implemented; and c) assess the effectiveness of these systems at preventing in-hospital clinical deterioration. The findings of the systematic review informed the development of subsequent research studies described within the thesis.

Chapter 3 reports on study 1: 'Health professionals' attitudes towards involving patients and their relatives in the detection of clinical deterioration in hospital' (thesis aim 2). Using a purposive, qualitative design, health professionals working across different specialities and professions participated in semi-structured interviews. Their experiences and views were examined to determine the potential for involving patients and relatives in recognising clinical deterioration to improve the early recognition of, and response to, deteriorating adult patients. Findings of the systematic review described in Chapter 2 suggested a paucity of evidence exploring the extent to which patients and relatives can recognise signs of the patients' deteriorating condition, and

contribute towards the early recognition of clinical deterioration in hospital. Data were analysed thematically, using an inductive, semantic approach. The health professionals interviewed generated a potentially appropriate approach to engage patients and relatives in recognising clinical deterioration in hospital, which formed the concept for a health services intervention implemented in subsequent studies.

Chapter 4 outlines studies 2 and 3: ‘Development and feasibility testing of a health services intervention to promote patient and relative involvement in recognising clinical deterioration in hospital’ (thesis aim 3). This reports an intervention development and feasibility testing phase. Focus groups with healthcare staff and patient representatives were used to develop a two-item questionnaire to prompt patients and relatives for their views on changes in the patients’ wellness while in hospital. A pilot study was conducted to explore feasible and acceptable approaches to using the questionnaire to routinely collect patients’ and relatives’ views on changes in patient wellness in practice. Chapter 5 reports on the researcher’s personal reflections of contextual factors observed within, and across the sampled wards, that appeared to help or hinder implementation of the intervention.

Chapter 6 describes study 4: ‘Are patients' views on changes in their health and wellness predictive of clinical deterioration in their condition?’ (thesis aim 4). During the four week study period, healthcare staff were invited to ask patients the two-item Patient Wellness Questionnaire during each observation as part of routine care, and record the patients’ responses (referred to as patient wellness ratings). Multi-level modelling was undertaken to determine the relationship between the patient wellness ratings and objective early warning score recorded during the same observation, to identify factors that moderate the relationship, and explore whether patient wellness ratings predict subsequent early warning scores. The study assessed the extent to which patients can recognise changes in their condition that signal clinical deterioration.

The final chapter, Chapter 7 presents a general discussion. It starts by reiterating the aims of the thesis and the research studies conducted in order to address these aims. Key findings of a systematic review and four research studies described within the thesis are then outlined. A number of reflections about involving patients and relatives in the management of deterioration in hospital

are made, and limitations of the research studies conducted are considered. Lastly, suggestions about the direction of future research, and practical implications associated with conducting the applied health research outlined in this these are given.

Chapter 2

Is there a role for patients and their relatives in escalating clinical deterioration in hospital? A systematic review.

2.1 Chapter summary

This chapter reports a systematic review of studies exploring how patients and relatives have previously been involved in escalating clinical deterioration in hospital. Peer reviewed academic articles, and grey literature articles that describe the implementation and effectiveness of systems involving patients and relatives in the process of escalating in-hospital clinical deterioration were reviewed. The findings of this review are discussed along with implications and recommendations for healthcare services. The findings informed subsequent research studies within this thesis.

2.2 Background

Clinical deterioration, a period of clinical instability in a patients' condition (National Confidential Enquiry into Patient Outcome and Death; NCEPOD, 2005) can result in poor clinical outcomes for patients (Jones, Mitchell, Hillman & Story, 2013; Soar & Subbe, 2012; Stelfox, Bagshaw & Gao, 2014). Recognising early signs of clinical deterioration and responding in an appropriate and timely manner can prevent serious adverse events (Jonsson, Jonsdottir, Moller & Baldursdottir, 2011; Kyriacos, Jelsma & Jordan, 2011). Systems exist to prevent clinical deterioration in hospital. For instance, nursing staff routinely monitor and record patients' vital signs. Vitals sign measurements outside of the normal range can be indicative of deterioration in the patients' condition, and can prompt staff to call for a team of health professionals with critical care skills who provide timely treatment to support the deteriorating patient on the ward (Alam et al., 2014). In the UK health service, this team of health professionals is referred to as a Critical Care Outreach Team (CCOT). In other countries, such as the US

and Australia, these teams are called Rapid Response Teams (RRT) or Medical Emergency Teams (MET).

Despite these systems, some patients who are deteriorating continue to go unrecognised and appropriate, timely action is not always taken. Indeed, a recent report Time to Intervene, suggests that a third of 454 in-hospital cardiac arrests were avoidable with proper assessment and intervention (NCEPOD, 2012). In recent years, the role that patients could play in improving the quality and safety of healthcare has been highlighted (Berger, Flickinger, Pfoh, Martinez & Dy, 2014). Detecting clinical deterioration and escalating care is one area where patients and their relatives could be involved. As previously discussed in Chapter 1, evidence demonstrates that nurses use intuitive reasoning that is mediated by their knowledge of the patient to identify deteriorating patients (O'Dell, Victor & Oliver, 2009). Patients, and in some instances their relatives have knowledge of the patients' normal health and wellbeing, and anecdotal evidence suggests that they may sense if the patient's clinical condition is deteriorating. This has been especially well documented in paediatric deterioration, for instance in the cases of 15 year old Lewis Blackman (Raymond et al., 2009). Relatives' recognised signs that the patient was deteriorating before health professionals and raised the alarm. Despite this, health professionals did not respond appropriately to escalate the patient's care resulting in the unexpected death of this child. Such high profile cases have led some hospitals to allow the opportunity for patients and relatives to bypass health professionals on the ward and activate the RRT themselves when they suspect deterioration. This service is referred to as patient and relative led escalation.

There is a growing acceptance of patient and relative led escalation in healthcare services and it has been implemented in a number of institutions. Therefore, it is important to understand how patients and their relatives recognise and escalate deterioration using these systems, and whether these systems are effective at preventing deterioration, to indicate how patients and their relatives can contribute towards improving the management of clinical deterioration in hospital. This paper aims to systematically review citations that (1) identify and describe systems involving patients and relatives in the process of escalating in-hospital clinical deterioration; (2) describe how these systems have been

implemented; and (3) investigate the effectiveness of these systems at preventing in-hospital clinical deterioration. This topic will be summarised with regards to the available peer reviewed, academic literature and non-peer reviewed, grey literature. A decision was made to include grey literature to examine what is happening in practice, and also because practitioners may not have the same incentive as academics to publish in peer-reviewed journals (Mahood, Van Eerd & Irvin, 2012). The implications of engaging patients and relatives in the escalation of clinical deterioration will also be outlined.

2.3 Methods

2.3.1 Search strategy

This systematic review was guided by the Preferred Reporting Items for Systematic Reviews and Meta-analyses statement (see Appendix 1) and the protocol was published on PROSPERO (Registration number: CRD42015019246). Search terms used included combinations of 'patient, family OR relative activated' AND 'rapid response team, medical emergency team, critical care outreach OR condition help' AND 'patient deterioration'. The search strategy was applied to PsycINFO, Medline, Cumulative Index to Nursing and Allied Health Literature (CINAHL) and Cochrane Library in February 2015. Searches were limited to retrieve articles published in the years following 1990. This time restriction was used because the first RRT were developed in Australia around this time (Lee, Bishop, Hillman & Daffurn, 1995).

Grey literature was operationally defined as magazine articles, academic dissertations, institutional reports, consultant reports, book chapters and conference proceedings (Mahood et al., 2014). Web search engines (Google and Google Scholar) were selected and searched as it has been recommended to use these when conducting grey literature searches for systematic reviews (Dobbins, Robeson, Jetha & DesMeules, 2008; Giustini, 2012; Hammerstrom, Wade & Jorgenson, 2010). The web search engines could not accommodate the full search strategy, however simpler searches were possible. Terms were searched for in the titles of pages and anywhere else in the text. This search strategy produced predictably large numbers of results. Subsequently, the first 100 results of each grey literature search in Google and Google Scholar were

reviewed for relevance (Carr et al., 2011). The academic and grey literature search strategies and full results are detailed in Appendix 2 and 3.

2.3.2 Eligibility criteria and study selection

The eligibility criteria applied to academic literature are defined in Table 2.1. For grey literature, the eligibility criteria used were the same as that applied to academic literature except it was not necessary for grey literature to use comparison groups or outcome measures. The titles and abstracts of identified citations were screened against the inclusion criteria and the full texts of potentially relevant citations were obtained and reviewed for inclusion by one reviewer. A random sample of 20% of the citation titles and abstracts were screened independently against inclusion criteria by three second reviewers (RL, JOH, MC). To resolve any discrepancies in citation inclusion, a discussion was held between the reviewers to reach a consensus. After discussion, the eligibility criteria for grey literature was altered. When screening citations against the new grey literature eligibility criteria, 100% consensus was reached for citation inclusion.

2.3.3 Assessment of study quality

Study quality was assessed using the Quality Assessment Tool for Studies with Diverse Designs (QATSDD; Sirriyeh, Lawton, Gardner & Armitage, 2012). The QATSDD is a validated quality assessment tool, comprising of 14 items on a four point scale that can be applied to a methodologically diverse group of academic articles. The studies were scored to indicate the quality of the individual studies and the overall scope of research. First, one reviewer conducted quality assessments for all studies, and then, three reviewers conducted a second quality assessment of all studies (RL, JOH, MC). There was a strong and significant correlation between the first and second reviewers' quality assessments, $r = .73$, $p = .039$.

2.3.4 Data extraction and synthesis

Data were extracted according to pre-defined criteria by a single reviewer for citations that were accepted in to the review after full text screening. The accuracy and completeness of data extraction was independently assessed by three second reviewers (RL, JOH, MC). Owing to the heterogeneous designs of the included studies, narrative data synthesis was carried out on the academic

and grey literature using guidance from Popay et al. (2006). Narrative data synthesis is an approach in which the findings from multiple studies are summarised and synthesised principally using words (Popay et al., 2006), as opposed to numbers. Preliminary descriptions of the results of each of the citations were developed using textual descriptions, groupings and tabulations, and then an understanding of the relationship between individual study characteristics and their findings was explored (Popay et al., 2006).

Table 2.1 Eligibility criteria for the inclusion of academic articles in the review

PICOS	Eligibility criteria
Population	Adult and paediatric patients hospitalised in developed countries and their relatives or carers.
Intervention	Implementation or use of systems involving patients and relatives in the detection of clinical patient deterioration and escalation of patient care. Systems implemented alone or within a complex intervention.
Comparison	Detection and escalation by patients and relatives can be compared to detection and escalation by any other group.
Outcome	Patient and relative detection and escalation could be used to address any clinical and non-clinical outcome.
Study design	Peer reviewed reports of empirical, academic research were included. Non-peer reviewed articles and grey literature were also included. Opinion pieces were excluded. Articles using any study design, published after the year 1990 were included. Only studies published in English were included because of limited resources for translation.

2.4 Results

A total of 6,188 potential citations were identified after de-duplication. After title and abstract screening, 89 citations potentially fulfilled the eligibility criteria. The full-texts of these citations were acquired and reviewed. Of these, 9 academic articles from the academic literature search and 36 websites from the grey

literature search fulfilled the eligibility criteria and were included in the review (See Figure 2.1).

2.4.1 Academic literature

Patient and relative led escalation was most often researched in the USA, within single centres (eight of nine articles), and to address paediatric deterioration (six of nine articles). All studies used a descriptive design with some taking a cross-sectional, qualitative approach to data collection and others taking a quantitative approach. All nine studies measured at least one non-clinical outcome. These were the number of patient and relative activated RRT and their reasons for activating it (Bogert et al, 2010; Greenhouse et al., 2006; Hueckel et al.,2012; McCawley et al., 2013; O'Dell et al., 2010), number of RRT activations where family concern was noted (Brady et al., 2014; Ray et al., 2009), percentage of patients and relatives who received education about the service (Hueckel et al.,2012; McCawley et al., 2013), and a survey to test patient and family understanding (Hueckel et al.,2012; McCawley et al., 2013; O'Dell et al., 2010). and staff understanding (O'Dell et al., 2010). Three studies also measured clinical outcomes; transfer of the patient to higher level care after RRT assessment (Brady et al., 2014; Gerdik et al., 2010), number of non-Intensive Care Unit adverse events (Gerdik et al., 2010) and mean number of days between cardiac arrests (O'Dell et al., 2010) since the introduction of patient and relative activated RRT (See Appendix 4 for a summary of academic study characteristics).

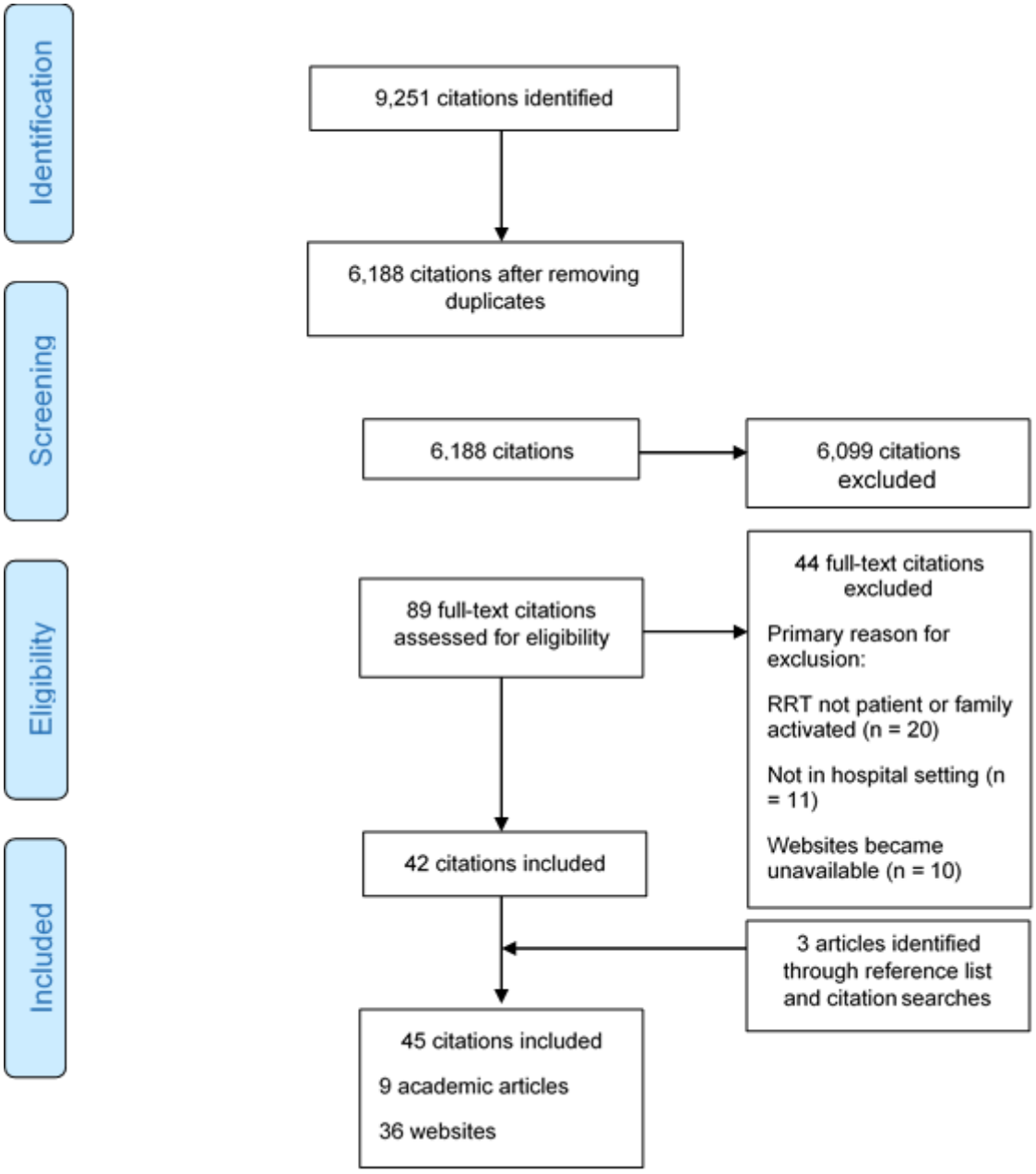


Figure 2.1 Flow chart summarising search strategy

2.4.2 Grey literature

Thirty-three of the websites were written in the USA, one was written in the UK, one in Canada and one in Australia. Twenty-six of the websites were patients and relative facing, 7 were health professional facing and 3 were both patient and relative and health professional facing. The patient and relative facing websites either provided a description of patient and relative activated RRT, along with information about its origins and purpose, or they provided instructions of why, when and how patients and relatives can activate the RRT at a particular

healthcare organisation. The health professional facing websites provided guidance and tools to assist healthcare organisations to develop and implement patient and relative activated RRT. A small number of the health professional facing websites also presented findings of previously implemented patient and relative activated RRT interventions. Findings included information about how many times patients and relatives activated the RRT (See Appendix 5 for a summary of grey literature website characteristics).

2.4.3 How have patients and relatives been involved in the detection and escalation of in-hospital clinical deterioration?

The reviewed citations indicate that implemented systems centre on enabling patients and relatives to escalate care for suspected clinical deterioration, placing little focus on how patients and relatives might detect deterioration. While the aims of these systems are consistent; to summon health professionals to assess the patient's clinical condition and treatment needs in a timely manner, institutions appear to subscribe to different patient and relative led escalation protocols and invite different patient groups to engage in this service.

2.4.3.1 Direct or indirect escalation of care

In five of the nine published academic articles, the healthcare organisation implemented an indirect pathway of patient and relative led escalation, referred to as Condition Help (Bogert, Ferrell & Rutlegde, 2010; Dean et al., 2008; Greenhouse, Kuzminsky, Martin & Merryman, 2006; Hueckel, Mericle, Frush, Martin & Champagne, 2012; McCawley, Gannotta, Champagne & Wood, 2013). Here, patients and relatives activated a Condition Help team which had distinct staff members from the RRT. The Condition Help team triaged the patient to determine whether the RRT was required. In this way, patients and relatives indirectly escalated care through the Condition Help team. In one UK based study, Condition Help was referred to as Call 4 Concern, although the concept was the same (O'Dell, Gerber & Gager, 2010). In three of the nine studies, the healthcare organisation implemented a direct pathway of patient and relative led escalation (Brady et al., 2014; Gerdik et al., 2010; Ray et al., 2009). With this patient and relative led escalation protocol, the same RRT who respond to clinicians' activations could be activated directly by patients and relatives, with no triage step. The implementation of the indirect pathway, Condition Help, was

more common in the academic literature. This finding is consistent with the included grey literature websites whereby numerous websites described what Condition Help is, the origins of the service and how the service can be used.

2.4.3.2 Composition of the RRT

A further distinction identified between studies was the different types and numbers of health professionals used to comprise the Condition Help teams and RRT. This ranged from a nurse, nurse manager, respiratory therapist, resident physician and critical-care fellow in one study (Brady et al., 2014), to a respiratory therapist and critical care nurse in a second study (Gerdik et al., 2010). Although different patient and relative led escalation protocols were used, studies exploring patient and relative satisfaction found that they had favourable opinions towards the service (Gerdik et al., 2010; Greenhouse et al., 2006; O'Dell et al., 2010).

2.4.3.3 Escalation of paediatric or adult clinical deterioration

The academic literature has focused more on investigating patient and relative led escalation for paediatric compared to adult deterioration. Early studies explored the development and implementation of patient and relative led escalation for paediatric deterioration, suggesting that this service was initially available to prevent clinical deterioration in hospitalised children (Ray et al., 2009; Dean et al., 2008). In line with this, evidence indicates that children's clinical conditions can deteriorate at a faster rate than adults (McCaskey, 2007). However, later studies did investigate patient and relative led escalation with adult patients (Gerdik et al., 2010).

2.4.4 How have patient and relative led escalation systems been implemented in hospitals?

2.4.4.1 Education for health professionals, patients and relatives

In all reviewed studies, health professionals, patients and relatives received education about patient and relative led escalation prior to its implementation. Investigating the education of staff, patients and relatives was a secondary objective for the majority of studies reviewed. However, the primary aim of two studies related to improving staff, patient and relative education on, and awareness of, Condition Help (McCawley et al., 2013; Hueckel et al., 2012). Health professionals were frequently educated in group sessions where they

received information about what the service was and how to educate patients and relatives so they can use it appropriately. Staff had to demonstrate a certain level of understanding about the service before they could educate patients and relatives about it. The grey literature search revealed that guidance was available for healthcare organisations considering implementing patient and relative led escalation. From the academic literature, it was not clear whether healthcare organisations made use of these guidelines. Patients and relatives were often first informed about patient and relative led escalation by the admitting nurse using a formalised teaching script. Posters and leaflets were also provided in patients' rooms to remind them and their relatives of the information they received from the admitting nurse. This was reflected in the grey literature websites where numerous patient and relative facing educational leaflets, posters and videos were identified.

2.4.4.2 Use of small-scale pilot studies

Six of the studies reviewed made reference to the use of a small-scale pilot study where patient and relative led escalation was implemented on a small number of hospital wards for a short time period. During the pilot phase, health professionals, patients and relatives provided feedback, including potential barriers to their engaging in the service (Ray et al., 2009). Barriers identified for health professionals included concerns that patients and families would summon the RRT for frivolous or non-emergent reasons. Barriers for patients and relatives were not explicitly stated. Parts of the service were revised prior to whole hospital implementation based on the feedback received (Gerdik et al., 2010).

2.4.5 How effective are patient and relative led escalation systems at preventing clinical deterioration?

2.4.5.1 Clinical outcomes

The patient and relative led escalation protocols introduced across studies aimed to summon health professionals to assess the patient's clinical condition and treatment needs in a timely manner, treat patients accordingly, and subsequently prevent clinical deterioration. Gerdik et al. (2010) found a significant increase in transfers to higher level care and a non-significant decrease in the number of non- Intensive Care Unit adverse events when comparing the phase before RRT implementation and the phase after RRT and patient and relative led escalation

implementation. Also, Ray et al. (2009) identified an increase in the median number of days between cardiac arrests from 34 days to 104 days after implementation of a RRT.

It should be noted that during the studies, traditional clinician led escalation protocols continued to occur alongside the newly introduced patient and relative led escalation service, both of which may have influenced the measured clinical outcomes, accounting for the reported changes. Effects of clinician and patient and relative led escalation on clinical outcomes were separated in one study. Here, Brady et al. (2014) found that 24% of 40 patient and relative activated RRT resulted in the transfer of the patient to the Intensive Care Unit compared to 60% of 1,156 clinician activated RRT. Although patient and relative activation less often resulted in Intensive Care Unit transfer compared to clinician activation, patients and relatives may have escalated a subset of deteriorating patients missed by health professionals (Brady et al., 2014).

2.4.5.2 Non-clinical outcomes

Measures of non-clinical outcomes centred on the number of patient and relative activated RRT and their reasons for activating it. The majority of studies reported the number of patient and relative activated RRT to monitor the potential for the patient activation intervention to overwhelm available resources. However, the average number of patient and relative activated RRT reported across studies was 23 over an average time period of 1.5 years. The number of activations reported in each study are context dependent as the service was implemented on a different number of wards for different lengths of time between studies. Brady et al. (2014) presented the number of patient and relative activated RRT as a percentage of all RRT activations at 2.9%, supporting findings that the number of activations do not pose a substantial burden to the RRT.

The reasons patients and relatives activated a RRT were often cited as appropriate, meeting the pre-defined criteria for RRT activation. A small number of studies reported that some patient and relative activated RRT were considered problematic and demanding by health professionals (Bogert et al., 2010). All studies made reference to communication breakdown between health professioanls, patients and relatives as contributing towards the reason for some, if not all, patient and relative activations. Here, reasons for RRT activation

were not suspected patient deterioration but instead included concerns about the patients' plan of care, their medication and pain control, their dietary status, and their discharge (Dean et al., 2008). Six of the included grey literature websites reported research findings, providing information on the number of patient and relative RRT activations and reasons for these activations. Consistent with academic findings, the grey literature stated that patients and relatives reasons for activating the RRT were genuine and appropriate.

2.4.6 Quality assessment

The overall quality of the studies was fairly low. QATSDD scores ranged from 16% to 57%, with an average score of 31%. Few studies explicitly stated the study aims or objectives, and no studies justified their sample size or methods of data collection. Few studies provided descriptions of the analytic process or justification for the chosen analysis approach. One study made reference to the use of theory when implementing patient and relative led escalation. Theory was not used in any study to underpin the design and content of patient and relative led escalation. Research settings, procedures for data collection and recruitment data were adequately described in most studies.

2.5 Discussion

The current systematic review explores how patients and their relatives have been engaged in escalating in-hospital clinical deterioration. Since the systematic review was conducted as part of this thesis, Gill, Leslie and Marshall (2016) have also carried out a systematic review of studies exploring patient and relative led escalation initiatives. The review conducted within this thesis adds to that conducted by Gill et al. (2016) because it includes a synthesis of the grey literature and critiques the ability of included studies to demonstrate the clinical effectiveness of patient and relative led escalation. Furthermore, Mackintosh et al. (2017) have published a protocol for a Cochrane review of Interventions to increase patient and family involvement in escalation of care for acute illness in community health and hospital settings. The review conducted within this thesis may contribute towards understanding of patient and relative involvement in a hospital setting in the Cochrane review. A discussion of the findings of the review within this thesis are now outlined.

2.5.1 Research designs and methods used

Patient and relative led escalation is proposed as an intervention to reduce preventable deterioration within the reviewed studies. However, few studies were designed to establish the clinical effectiveness of this intervention, perhaps because to do so would require very large samples of patients to assess reductions in relatively rare events, for example cardiac arrests. Those studies that did employ clinical outcome measures were poorly designed in that the effects of patient and relative led escalation on clinical outcome measures were not isolated from the effects of clinician led escalation. Thus, any reported changes in clinical outcome measures could not be attributed solely to patient and relative led escalation. It is entirely possible that when patient and relative led escalation is implemented, this may lead to increased vigilance and hence escalation amongst health professionals resulting in improved clinical outcomes.

The majority of studies used non-clinical outcome measures to investigate issues of feasibility and acceptability surrounding patient and relative led escalation, exploring its impact on health professionals and their available resources. This reflects the infancy of research in this area and is entirely appropriate. Evaluating an intervention in a large scale trial first requires confidence that the intervention is acceptable to users and that it does not have associated unintended (negative) consequences. Studies exploring patient and relative satisfaction found that they had favourable opinions towards the service (Gerdik et al., 2010; Greenhouse et al., 2006; O'Dell et al., 2010). However, studies did not measure patient and relative satisfaction prior to introduction of the service for comparison.

Studies had a lack of theoretical underpinning making it difficult to gain insight into the active components of the interventions (Siemonsma, Schroder, Dekker & Lettinga, 2008). The low number of patient and relative activated RRTs reported in the academic and grey literature were interpreted as positive findings, showing that resources did not become overwhelmed. However, this may reflect an unwillingness by patients and relatives to participate in a behaviour that might be perceived as challenging health professionals (Davis et al., 2007). It will be important for future studies to explore possible mediating variables between the implementation of a patient and relative led escalation system and the outcome measures sampled, in order to better understand the mechanisms for any

identified relationships. It is being increasingly recognised that specifying theory of change for an intervention is important for both implementation and replicability (Davidoff et al., 2015).

Communication failure between health professionals, patients and relatives was cited as a reason for patient and relative led escalation in all studies. The types of communication failure reported were unrelated to communication between staff, patients and relatives about concerns over a patient's deteriorating clinical condition. Instead, reported communication failures that prompted patient and relative led escalation related to other issues that increased the possibility of patient safety events and negatively affected patient and family experience, such as a dismissive interaction between staff and family. This finding is consistent with previous research which found that clinician activated RRTs not only identify deteriorating patients, but they also identify previously unknown systems issues, adverse events and preventable adverse events (Amaral et al., 2015; Kaplan et al., 2009). Highlighting previously unknown communication issues was a valuable unintended outcome of patient and relative led escalation. Indeed, accessing help from health professionals who are independent from the ward/unit caring for the patient may be a vital function of this intervention. However, it could be argued that activating a RRT may not be the most appropriate or cost-effective method of resolving concerns that are non-life threatening.

2.5.2 Lack of evidence investigating the detection of clinical deterioration

The current systematic review has highlighted that patient and relative led escalation systems implemented in the reviewed studies do not consider the extent to which patients and relatives can monitor changes in the patients' clinical condition and detect if they are deteriorating. Yet, to improve the management of clinical patient deterioration in hospital, patient and relative led escalation depends wholly on patients and relatives' ability to effectively detect patient deterioration. Little is known about patients and relatives ability to recognise signs of the patients deteriorating condition.

Of the available literature, one study revealed that patients and relatives felt unable to actively contribute to the management of their acute illness as their

ability to recognise changes in their clinical condition was limited (Rainey, Ehrich, Mackintosh & Sandall, 2013). Patients stated that they used the presence of new symptoms to indicate that their clinical condition was worsening. However, even when new symptoms were present, some patients were unsure of their significance and often did not interpret this as an indication that their condition was deteriorating (Rainey et al., 2013). In line with this finding, researchers have developed a patient education intervention aimed at enhancing the self-efficacy of hospitalised patients to recognise and report symptoms of deteriorating conditions. It was found that participants who received the intervention had significantly higher self-efficacy to recognise and report symptoms post-intervention compared to controls (See, Chan, Huggan, Tay & Liaw, 2014).

2.5.3 Review limitations

Despite an inclusive search strategy, only two web search engines were used to search for a proportion of the grey literature. It is possible that relevant grey literature articles were not identified if they were stored on other databases that were not searched. The evidence included in the review lacked detail. Poor reporting may have resulted in an unduly negative assessment of the evidence. It is important that future research in this area is of high quality, and is reported in sufficient detail so that methods can be replicated and refined.

2.5.4 Implications and recommendations

Patients and their relatives are likely to possess unique expertise on the patients' status. Intuitively, it makes sense for patients and relatives to contribute towards the management of the deteriorating patient. However, in a complex organisation, it is difficult to engage patients and relatives in a way that is feasible and acceptable, to allow the expertise of both patient and provider to be utilised. Patient and relative led escalation has been implemented in a number of hospitals despite a lack of empirical evidence to suggest that it is the most effective means of engaging patients and relatives to reduce preventable deterioration.

The reviewed evidence did not investigate the extent to which patients and relatives can effectively detect patient deterioration. The available research on this topic points to a need to improve patients' and relatives' ability to detect changes in the patients' clinical condition indicative of deterioration. This

warrants further investigation as it has important implications for the utility of patient and relative led escalation which rests on the assumption that patients and relatives can effectively detect clinical deterioration. Furthermore, patients and relatives often escalated patient care to resolve communication issues with health professionals that were unrelated to suspected clinical deterioration. It is recommended that healthcare organisations consider an alternative escalation route to allow patients and relatives to receive a timely response to concerns that are not life threatening, but relate to communication issues with health professionals.

2.6 Conclusions

Healthcare providers have leapt into involving patients and relatives in the management of patient deterioration and now a more measured approach is required to investigate the assumptions on which patient and relative led escalation is based. The reviewed evidence suggests that introducing patient and relative led escalation did not overwhelm staff and their available resources, however it was difficult to establish the clinical effectiveness of the intervention. More high quality research and reporting is required to explore how the expertise of patients and relatives may be most effectively used, in conjunction with healthcare providers, to reduce preventable patient deterioration.

Chapter 3

Health professionals' attitudes towards involving patients and their relatives in the management of clinical deterioration in hospital.

3.1 Chapter summary

The study discussed in this chapter (study 1) explores health professionals' views on the potential for involving patients and relatives in recognising clinical deterioration to improve the early recognition of, and response to, deteriorating patients. A purposive, qualitative design, was used to recruit health professionals working across different specialities and professions. Data were analysed thematically, using an inductive, semantic approach. The health professionals interviewed generated a potentially appropriate approach to engage patients and relatives in recognising clinical deterioration in hospital, which formed the concept for a health services intervention implemented in subsequent studies (studies 2, 3 and 4). Barriers to patient and relative involvement in the management of deterioration were identified, and may need to be addressed to allow potential improvements in the safety of deteriorating patients to be realised.

3.2 Background

Increasing numbers of healthcare organisations globally are investing in services that invite patients and their relatives to escalate clinical deterioration by activating a rapid response team (RRT) to improve early recognition of, and response to, clinical deterioration and subsequent patient outcomes. In particular, patient and relative led escalation is becoming more prevalent in the US. A recent study that aimed to determine the characteristics of RRTs in hospitals in the US found that 69% of 103 institutions had introduced patient and relative led escalation (Chen, Kemper, Odetola, Cheifetz & Turner, 2012). In terms of the available evidence, a systematic review identified a small number of empirical studies which investigated issues of feasibility and acceptability

surrounding patient and relative led escalation by exploring its impact on health professionals and their available resources. Although the reviewed evidence indicates that introducing the service does not overwhelm available resources, patients and relatives often activated the RRT for non-emergencies, and it was difficult to establish the clinical effectiveness of the service (Albutt, O'Hara, Conner, Fletcher & Lawton, 2016).

The first stage of developing a complex intervention is to conduct a systematic review of the existing evidence on similar interventions to understand what is already known and what methods of evaluation have been used (Medical Research Council (MRC); Craig et al., 2008). A theoretical understanding of the likely process of change should then be developed; that being the mechanisms implicated in the relationship between the intervention and outcome measures. This is achieved by drawing on existing evidence and theory, and by conducting new research, such as interviews with stakeholders who will engage with the intervention if it is introduced in practice (Craig et al., 2008). Stakeholders can provide a unique contribution to research as they have personal experience of healthcare services, whether that be from the perspective of healthcare providers or service users (Caron-Flinterman, Broerse & Bunders, 2005; Faulkner &Thomas, 2002). Inviting stakeholders to participate in the design of a complex intervention ensures that it is designed to meet end users' needs (Fudge, Wolfe & McKevitt, 2008), and is embedded within the culture of the organisation in which it will ultimately be used.

Albutt et al. (2016) found that no empirical study systematically reviewed evidence investigating similar interventions or identified a theoretical understanding of the likely process of change when developing patient and relative led escalation interventions. Inviting patients and relatives to activate a RRT may not represent the optimal method of involving patients and relatives in the management of deterioration, particularly in the context of deteriorating adult patients. Indeed, Guinane, Hutchinson and Bucknall (2017) interviewed adult patients who deteriorated in hospital and required treatment by a RRT. Patients felt escalating their care was not their responsibility and expressed concerns about overriding health professionals by activating patient and relative led escalation. To begin to determine the optimal method of involvement, following

the MRC framework, a systematic review of studies exploring patient and relative led escalation was conducted (Albutt et al., 2016; see Chapter 2 for complete systematic review). The focus of the thesis then turned to obtaining the perspectives of health professionals; key stakeholders involved in the delivery of the intervention.

Paciotti et al. (2014) conducted semi-structured interviews with doctors in the US who would be involved in the delivery of a family led escalation intervention if it were to be implemented at the children's hospital where they worked. Their views were sought on (1) the contribution that families can make to aid the identification of deteriorating children and (2) enabling families to independently activate a RRT. It was found that although doctors valued input from families, they believed that families should not be invited to activate the RRT directly. They expressed a number of concerns which prevented them from supporting family activated RRTs. These included the misuse of limited Intensive Care Unit resources, asking family members to make assessments without clinical training, damaging therapeutic relationships and burdening families with responsibility. Doctors also stated that evidence demonstrating a relationship between family activated RRTs and improved patient outcomes was needed. These findings suggest that there may be barriers to the uptake of family activated RRT interventions by doctors. To the researcher's knowledge, Paciotti et al. (2014) have conducted the only study exploring health professional's views on involving families in the management of deterioration through family led escalation. However, this study is limited in that only doctors were interviewed, and thus the conclusions drawn in this study may not represent the views other types of health professionals have on family led escalation. Furthermore, the views of doctors working in US hospitals may not be generalisable to those of health professionals based in UK hospitals. Therefore, this single study provides insufficient evidence about health professional's views on involving patients and relatives in the management of deterioration.

To address the evidence gap, semi-structured interviews were conducted with UK based health professionals working across different specialities and grades. The study aimed to gain their perspectives on:

(1) What types of information patients and/or relatives might be able to provide to aid health professionals in recognising and responding to deteriorating patients.

(2) The extent to which patients and/or relatives can aid health professionals in the recognition of, and response to, deteriorating patients.

(3) How patients and/or relatives might be involved in the management of the deteriorating patient in the context of a busy healthcare service with limited resources.

This research expands discussion beyond patient and relative led escalation interventions to understand whether there are alternative methods that may be feasible, acceptable and effective from the perspective of health professionals.

3.3 Methods

3.3.1 Ethical approval

Ethical approval for this study was granted by University of Leeds Faculty Research Ethics Committee (Reference: 15-0043). All data was handled in a robust and transparent manner, applying confidentiality and security where appropriate.

3.3.2 Setting

The study was conducted at a large teaching hospital in the North of England. A rapid response system is implemented on all non-intensive care medical and surgical wards in the hospital. The rapid response system includes an afferent limb and an efferent limb. In the afferent limb, observational charts are used to record and monitor patients' vital signs. There are pre-determined criteria based on patients' vital signs which indicate the need to call for assistance. In the efferent limb, a critical care outreach team (CCOT) is available to be called by any staff member for assistance with any clinical concern. This team is composed of critical care nurses who have extensive experience working within the Intensive Care Unit. Currently, it is not possible for patients or relatives to call the critical care outreach team for assistance.

3.3.3 Participants

Health professionals caring for adult patients over the age of 18 on medical and surgical, non-intensive and intensive care units were eligible to participate. Participants must have had previous experience caring for patients whose clinical conditions had deteriorated. A purposive, snowball sampling strategy was used to recruit participants across specialities to include those working on base wards who recognise clinical deterioration and escalate patient care, and those working in Intensive Care who respond to an identified patient who is deteriorating. Equal representation from nursing and medical staff in the sample was sought. At least two participants from each level of profession were recruited (medical profession; Foundation Year Junior Doctor, Registrar, Consultant and nursing profession; Healthcare Assistant, Student Nurse, Staff Nurse, Ward Sister, Matron).

3.3.4 Procedure

The Director of Critical Care and a Consultant on the Renal Unit at the hospital were first approached and invited to participate in the study. Their research interests included engaging patients and relatives in managing deterioration, and they had previously provided the researcher with clinical guidance. These clinical contacts then suggested colleagues who might be interested in participating, and in turn these colleagues suggested further potential participants. Potential participants were first approached by the researcher via email, or in person on the ward, where they received an information sheet. The information sheet outlined the purpose of the study, what participants would be required to do, how the data might be used in the future and how to withdraw from the study. For those interested in participating, a convenient date and time was set for the interview to take place. This was at least 24 hours after potential participants were first approached to allow them time to consider whether they would like to take part.

Participants provided written informed consent immediately prior to the interview. A semi-structured interview schedule was developed, primarily using open-ended questions, to access health professionals' attitudes toward the role of patients and relatives in detecting and escalating deterioration in hospital. The interview schedule was developed through consultation with an expert group, namely the Yorkshire Quality and Safety Research Group. Examples of the questions asked during the interview include, 'do you think patients and/or

relatives know if the patients' condition is deteriorating? If so, how do patients and/or relatives express this feeling to staff?' and 'do you think patients and/or relatives can provide information to help staff to identify a deteriorating patient? If so, what kind of information do you think they could provide?' (See Appendix 6 for the complete interview schedule). Each interview was audio-recorded, transcribed verbatim by the researcher, and imported in to QSR NVivo 10 software to be analysed. Data collection was complete once thematic saturation was reached when no new codes were created as a result of three additional interviews (Bowen, 2008).

3.3.5 Analysis

3.3.5.1 Theoretical and epistemological approach

Themes were identified in the thematic analysis (TA) using an inductive approach. Here, coding and theme identification were directed by the content of the interviews, as opposed to being directed by a pre-existing coding frame determined by existing concepts or ideas. (Braun & Clarke, 2006; Hayes, 2000; Patton, 1990). An inductive approach was chosen because there is little prior research in the area, and thus interview data could not be coded to answer specific research questions based in previous literature and theory. Instead, the research questions were broad and exploratory, and evolved through the process of coding (Braun & Clarke, 2006). Furthermore, themes were identified at the semantic level, within the surface meaning of participants' responses. TA at the semantic level complemented the research questions which sought to gain participants explicit attitudes and opinions. The researcher did not seek to examine the underlying ideas or assumptions that may shape or inform participants' explicit attitudes, and therefore chose not to conduct TA at the latent level (Boyatzis, 1998; Braun & Clarke, 2006).

Although the inductive approach to TA may be data-driven, and not directed by the researcher's theoretical or analytic preconceptions, it is not possible to conduct TA without an epistemological stance. In the current study, TA was conducted within an essentialist or realist paradigm. Essentialism or realism assumes that there is a unidirectional relationship between meaning, experience and language in that language enables people to articulate meaning and experience (Braun & Clarke, 2006). Using this paradigm, the researcher was

interested in reporting the reality of participants and how they attach meaning to this reality using language.

3.3.5.2 Data analysis

The researcher became familiar with the data by transcribing the interviews verbatim and carefully reading the transcripts. Meaningful units of text that addressed the research questions were then identified. Units of text that related to similar ideas were grouped together in to named categories that formed provisional codes. The entire data set were then systematically reviewed to confirm that each code had a suitable name, definition and comprehensive set of units of text to support it. Second researchers (RL, JOH) independently recoded 20% of the total number of transcripts to reduce subjectivity in the analysis and ensure inter-rater reliability. The coders then reviewed their coding and resolved any discrepancies through discussion until consensus was reached. Once a definitive set of codes had been established, these were organised in to provisional key themes and quotations that represented these themes were identified. Determining the names and organisation of key themes was an iterative process whereby provisional key themes were discussed with the supervision team and wider research team (Yorkshire Quality and Safety Research Group). Theme headings and organisation were then refined based on these discussions, and the changes reported back to the teams for further feedback.

3.4 Results

3.4.1 Participants

A total of 27 health professionals were invited to participate in the study. Of these, 21 health professionals provided informed consent and participated in the interview. The high participation rate may be because potential participants were recommended by a colleague who was often more senior (See Table 3.1 for participant professions and specialities).

Table 3.1 Profession and speciality of participants

Pseudonym	Profession	Speciality/ current rotation
HCA2	Healthcare assistant	Cardiology
S1	Student nurse	Cardiology
M2	Matron	Elderly medicine
R2	Registrar	Elderly medicine
M1	Matron	General surgery (Acute care)
S2	Student nurse	General surgery (Acute care)
HCA1	Healthcare assistant	General surgery (Urology & Vascular)
C1	Consultant	Intensive Care
C3	Consultant	Intensive Care
D1	Anaesthetist	Intensive Care
JD1	Junior doctor (F2)	Intensive Care
WS1	Ward sister	Intensive Care
SN1	Staff nurse	Intensive Care
CCO1	Critical care outreach nurse	Intensive Care
R1	Registrar	Maternity
MW1	Midwife	Maternity
C2	Consultant	Nephrology
J2	Junior doctor (F1)	Nephrology
J3	Junior doctor (F1)	Nephrology
J4	Junior doctor (F2)	Nephrology
J5	Junior doctor (F2)	Nephrology

3.4.2 Thematic analysis

The following themes were identified within the analysis, and have been organised to address the specific research questions of the study. Cross-cutting themes that address multiple research questions will also be outlined.

3.4.2.1 Research question 1: What types of information might patients and/ or relatives be able to provide to aid health professionals in recognising and responding to deteriorating patients?

3.4.2.1.1 Theme 1: Knowing the patient

Participants felt that the more contact a person has with the patient, the more they come to know that patient. They talked about the importance of knowing the patient to be better able to recognise subjective changes in their wellness that may indicate deteriorating health. Subjective indictors of deterioration are subtle cues that arouse suspicion that the patient may be deteriorating, but are difficult to quantify. This is opposed to routinely monitored, quantifiable, objective indicators of deterioration. Health professionals are likely to have had no previous contact with patients prior to their hospital admission, and as such it is not always possible for them to have personal knowledge of the patient. Due to constraining organisational factors, such as low staffing levels, and the nature of shift based work, staff may only have intermittent contact with the patient during their hospital stay.

> "We may have expert knowledge in clinical care but we're not the experts in individuals because the individual and their family are. You know we have a passing contact with them but you've no previous contact" (Matron 2).

Undoubtedly, patients know themselves, and their close relatives may spend time with them in their day to day life outside of hospital, and while they are in hospital. Subsequently, patients (and to some extent) relatives have personal information about the patient and have developed knowledge about their normal health and wellbeing, enhancing their ability to identify subjective indictors of deterioration. Participants described the ways in which patients and relatives could subjectively identify that the patient was becoming more unwell. Firstly, participants referred to a number of signs and symptoms that patients and relatives have an enhanced ability to recognise changes in. These included

looking or feeling breathless, having a racing heart, and having a temperature or fever. Heart rate and temperate are vital signs measured as part of patient observation. However, patients may recognise changes in these symptoms before abnormalities are detected by vital sign measures. Secondly, participants talked about patients' and relatives' ability to recognise changes in the patients' capabilities. Here, participants referred to recognising changes in the patients' mobility, their ability to talk and hold a conversation, to eat and drink, and to go to the toilet.

> "They might be able to provide information on, you know, stuff and probably would need prompting on this but you know, are they eating? Are they talking to you as normal? Do they seem as bright as usual?" (Consultant 3).

Thirdly, participants referred to changes in a patients' physical appearance that patients and relatives are well placed to recognise. These included changes in facial colour, looking cold, or sweaty and flushed, or looking swollen. In the following quote, the participant speaks about the changes in symptoms and physical appearance that patients and relatives notice, and also mentions that patients are likely to tell their relatives about these.

> "Patients notice when you get tissue edema, that's when the patient starts to swell up. The patients notice that because obviously they know what they like normally. They'll spot thing, you know, when the patient's hands are cold, their colours changed all this kind of thing. I think they're aware of that and then obviously they talk to their loved one then they'll be able to elicit symptoms, they know what the patient is complaining about" (Consultant 1).

It may be that patients are more likely to tell their relatives, rather than health professionals, about changes in capabilities, symptoms and appearance that are concerning them: "There's a lot of things that the patient will tell the family that they don't tell the doctors for whatever reason" (Junior doctor 3).

Participants also emphasised that relatives are better placed than health professionals to recognise psychological and behavioural changes in the patient, as they are more aware of the patient's psychological and behavioural norms.

For instance, participants talked about it being possible for health professionals to accept cognitive impairments in patients as normal because of their old age or diagnosis. However, relatives may highlight that such cognitive impairments are not normal for the patient, possibly indicating deteriorating health and the need for intervention.

> "I think they *[relatives]* can tell you a lot. With the patient to start with, if their conscious level or if they become confused and this is acute. With different age groups people *[health professionals]* accept, they think 'oh you know, you're over 70 or you're over 60, you can be confused and it can be normal' and it isn't normal" (Ward sister 1).

> "If you're looking at people with cognitive impairment, there's a lot of acceptance that this is that persons norm, they are like this because they have dementia whereas actually no, it's not the dementia that's causing that, it's the illness. And those people that, for me, are not experts or knowledgeable in people with cognitive impairment ignore those signs and symptoms and therefore interventions don't happen until somewhere down the line, whereas actually if we'd have recognised those earlier then…" (Matron 2).

Participants discussed the significance of identifying subjective changes in wellness in order to recognise that a patient's condition may be worsening. Compared to objective indicators, taking account of patients' subjective experiences of the illness may give health professionals a more organic insight in to their progress or decline: "A person is not a set of numbers. So all of your numbers may sit within the norm but it's about how you feel, you know, and those numbers are never going to tell me how you feel. Only you can do that" (Matron 2).

Furthermore, participants felt that subjective indicators of deterioration are particularly significant because these can precede clinical, objective indicators of deterioration. Recognising and responding to subjective changes in wellness may allow for earlier intervention and improved patient outcomes. Further deterioration may be prevented as intervention is not delayed until clinical indicators of deterioration are demonstrated in the observation chart.

> “Patients who on paper, their observations look really good can still be very unwell but clinically it’s not been picked up yet. Down the line you start to see it. But when you actually see the patient, from an experience point of view, you can see that they’re deteriorating. It’s just it’s not detected by their observations yet” (Critical care outreach sister 1).

> “Like people say, nursing and medicine is a science and it is. But I sometimes think there is an art around it. Because sometimes before the signs can really indicate that people were deteriorating, sometimes you can pick up that people just don’t seem right. It might be that they’re withdrawing a bit, it might be that they don’t seem as if they’ve answered a question properly, so it’s being alert like I said earlier....I think it can be just someone sort of saying ‘I just don’t feel myself today, I don’t know what it is’. I mean sometimes it might materialise in to nothing which is great but sometimes it could be like a precursor before something does start to go wrong” (Matron 1).

Nevertheless, participants highlighted that it can be challenging for relatives to use subjective cues to recognise that the patient has deteriorated slightly: “I think as humans we’re all very aware of when someone looks unwell. It doesn’t take a huge amount of skill to tell someone is very sick. But actually, to notice a difference between like you say from somebody who has just deteriorated a fraction…” (Junior doctor 4). Here, the participant states that while it can be clear that a patient is unwell based on subjective signs, it is more difficult to recognise subtle changes in subjective signs that indicate a slight deterioration in the patient.

3.4.2.2 Research question 2: To what extent can patients and/ or relatives aid health professionals in the recognition of, and response to, clinical deterioration?

3.4.2.2.1 Theme 2: Patients viewed as experts in themselves

In terms of the potential role for patients in aiding early detection of deterioration, participants felt that patients’ views on changes in their health and wellness were credible. Patients were perceived as being experts in their own bodies, with an awareness of their baseline wellness: “I think patients know their own bodies. They know whether they are feeling okay and this is what they are always like or

whether actually they are really feeling not great" (Registrar 1). Participants also talked about patients having a personal experience of their illness, something which neither health professionals nor relatives have. Thus, it is valuable for patients to express to staff their subjective experience of the illness, to provide them with further information that could guide clinical decision making.

> "Their personal experience of their symptoms is unique to them, isn't it, so they obviously tell you. You have no idea what their chest pain is like, or how just generally unwell they feel. So for them to express that, it's definitely useful" (Junior doctor 4).
>
> "I think it's really important to listen, so if a patient is in pain that's a very subjective thing. I can't say if someone's in pain or not, so you have to really take in what they say" (Junior doctor 1).

Some participants felt that the judgements patients make about their wellness are predictive of future health outcomes. As highlighted in the following quotes, participants spoke particularly about patients abilities to predict serious adverse events, including their own transfer to higher level care, or death. One participant mentioned how patients use their previous experiences of acute illness, and knowledge about the treatment they received, to predict health outcomes if they again experience those signs and symptoms associated with the acute illness.

> "Sometimes certainly you'll get patients say to you, you know, I feel awful or I think I'm getting worse or I think I'm going to die. That often does, anecdotally, and I don't know if there's evidence behind it, but certainly from personal experience when a patient does express that they're feeling that unwell it is often indicative of how unwell they are or how unwell they're going to get" (Consultant 3).
>
> "It's always the red flag in the back of your mind when the patient says to you 'I think I'm going to die doctor'. That is a massive like, you know they're probably going to if they say stuff like that to you. There's also something about patients who turn around and say to you 'last time I had this happen I ended up on ITU (Intensive Therapy Unit). That is a big thing that keeps in the back of your mind" (Registrar 1).

Consistent with the idea that patients use their previous experiences of acute illness to predict future health outcomes, some participants talked about patients

with chronic illness and their families being particularly able to recognise signs and symptoms to suggest their condition may be deteriorating. Chronically unwell patients are likely to have previously experienced acute illness as a result of their chronic illness, unlike those without chronic illness who may be experiencing an acute illness for the first time.

> "If it's an acute illness and this hasn't necessarily been attached to some kind of chronic state then it's a little bit more difficult because a relative being unwell, if that's not a usual state for them, then it's distressing. Asking relatives to what degree they're not well on the basis of not knowing what 'not well' is, I think it's a difficult thing to do. When people have lived with chronic illness they recognise the effects that that's had on themselves or their relatives and so can make judgements based on changes in that. So I think if you've got a fit and well person coming in, any deterioration in state or function probably is difficult for them to gage as to how serious or how much that means. So I think probably those who do have chronic conditions and families who are living with people who have chronic conditions might be in a better position to give information" (Consultant 3).

Some participants felt that if certain patient groups may be more able to make accurate judgements about changes in wellness that reflect true physiological deterioration, identifying these groups would be useful: "I mean it's certainly very interesting and it's definitely useful if you are able to identify particular areas where patients and their relatives are particularly better at early detection of deterioration" (Registrar 2).

While what patients say about their health and wellness was viewed as valuable, participants highlighted circumstances that should be acknowledged when considering the role of patients in managing patient deterioration. The majority of participants stated that patients must have a certain level of capacity to make judgements about their wellness, and to express these to staff. Patients who are unconscious, have cognitive impairments or are disorientated cannot effectively communicate with health professionals, and thus cannot have a role in managing their deteriorating condition. Furthermore, participants highlighted that from their experience, it is possible for a patient's condition to clinically deteriorate (indicated by vital sign monitoring), without the patient feeling subjectively unwell.

> “Sometimes patients are feeling remarkably well even when you know that they’re quite poorly. It depends on the individual” (Critical care outreach sister 1).
>
> “Sometimes you can get people who say ‘yeah I’m fine, completely fine’ and their blood pressure will be absolutely terrible and they’ll have a high temperature” (Student nurse 1).
>
> “So patients will sometimes be sitting there saying ‘oh I feel alright, there’s a bit of pain in my tummy’ but they will be sitting there saying ‘I’ve got a bit of pain in my tummy’, rather than rolling around. But you check their heart rate and it’s really high, and you scan their tummy and they’ve got a litre of blood in there” (Registrar 2).

Conversely, one participant explained that a patient can feel subjectively unwell without their condition clinically deteriorating: “So there’s a rather small suite of ways in which a patient would subjectively feel that they are unwell. And that may or may not relate to a true physiological deterioration. Often it will, sometimes it won’t...Pain is a good example, of course. People can get pain without any deterioration. You can have a headache but you’re well still” (Consultant 2).

3.4.2.2.2 Theme 3: Relatives can be a help or hindrance

Participants discussed the extent to which relatives can make accurate judgements about changes in patient wellness. Factors that can limit the accuracy of relatives’ judgements about patient wellness, and result in relatives interfering with the work of health professionals were also considered. Participants’ perceptions of the strength of partnerships between health professionals and relatives appeared to influence their views on the potential for involving relatives in the management of deterioration.

Participants felt that relatives can, at times, aid health professionals to recognise deteriorating patients. When a relative is concerned about the wellness of a family member, this can be predictive of genuine patient deterioration: “We see patients who have been clearly deteriorating for a number of days, and you speak to the family and they’ve been trying to raise concerns all that time, so you suspect there’s a missed opportunity there” (Consultant 1). Here, the participant states that signs and symptoms of deterioration that health professionals may have missed can been picked up by relatives. Despite relatives raising their

concerns and identifying opportunities for intervention, staff may not recognise these opportunities or respond appropriately to prevent further deterioration.

Participants suggested that partnerships between health professionals and relatives can be at times strained, and relatives can hinder the work of health professionals. One participant said relatives' time on the ward should be restricted, despite it being necessary for relatives to be with the patient to recognise deterioration: "A few years ago they opened up visiting to any time and it was pretty much a disaster because the presence of relatives interacting with professionals all the time just meant that we couldn't get on with our work. And so we went back to the old system of restricted visiting hours. So to have family members much more involved in deterioration almost implies that they have to be there much more often and I'm not for that" (Consultant 2).

3.4.2.2.3 Subtheme 1: Lack of shared knowledge and understanding

Relatives may misjudge the seriousness of signs and symptoms because they lack medical training and clinical knowledge. Some signs and symptoms may appear worrying to a lay person, but health professionals would not be concerned because they know these do not necessarily indicate that the patient is deteriorating. Delirium was proposed as an example of this: "So one day the patient may be completely compos mentis and be okay, they're sick, they've got a reason why they're in hospital, but that's actually on the mend and their delirium is settled one day. And the next day because of the nature of the delirium, they're completely trying to climb out of bed, they are completely confused, wondersome, you know, at risk of falling and can't hold a conversation with their relative and so relatives obviously take that to mean they're really sick again but actually that's the nature of delirium" (Registrar 2).

Participants felt that relatives do not understand the job of a health professional, and the pressure they experience working in a resource limited health service. As a result they can become frustrated with staff, which can cause friction in staff-relative relationships. The following quotes highlight ways in which participants felt relatives do not understand the job.

> "We get a lot of families mollycoddling you could say. Where they just, mm, they're a bit would like to wrap them in cotton wool, whereas, I'm not going to say we're not like that because we are but we have to try get

them moving which may cause them quite a bit of discomfort but that's what we have to do whereas the families are like 'no that hurts' ...We get quite a lot of frustrated relatives because they don't think their relative that's the patient is being listened to but they are. We've already looked in to it the majority of the time. If we haven't then we do go and look at what they're trying to tell us. But we do get quite a lot of frustration put on to us which I can understand because they're guna feel helpless because they can't do anything while they're here" (Healthcare assistant 1).

"Relatives don't know what your, necessarily what things you've put in place to try and do certain things. ...I think it's hard because we are pulled in a lot of different directions when you're in clinical practice and a lot of prioritisation has to happen. I can only be one person when I'm on call and I can't be in more than one place at one time. And I often take on board, I have a nurse ring me or an SHO ring me to say this patient's really sick can you come and help me. But then I've also got someone in resus that's really sick and I need to sort that out and then I can see that relatives feel that their relative is the sickest person in the hospital and therefore I should be there doing that. They don't have that broader overview of that fact that there's only one person that can come along....'Yes the doctor is aware and they know they need to come but at the moment they are dealing with'" (Registrar 1).

As shown in the above quotes, families may lack medical knowledge and thus can become resistant towards health professionals efforts to improve a patient's condition because they do not understand how it will aid recovery. Also, families may not know or understand what clinical decisions have been made, resulting in their feeling frustration with issues that may have already been considered and addressed by health professionals. Understandably, families are focused on the wellbeing of their relative, and want to feel they are a priority while in hospital. As health professionals need to care for many patients, and prioritise those who most urgently need care, it is not possible for all patients to be priority at all times. Subsequently, relatives can become overprotective of the patient, and over-assertive when communicating their concerns with staff. Interestingly, participants talked only about emotional responses limiting relatives, and not patients, involvement in the management of deterioration.

> “I think a lot of the time your own emotions cloud your judgement. ...Sometimes some *[relatives]* are just overly protective of them. If they’ve got a little sweat on their brow then something’s wrong with them and they’re really ill. They might have a little temperature but we can bring that down straight away. There’s no worry about that. (Healthcare assistant 1)”.

3.4.2.2.4 Subtheme 2: Mistrust and a lack of respect weakens partnerships

Some participants felt that health professionals do not respect the views of relatives as much as they should. On this topic, one participant said: So I think the whole area of this research *[greater involvement for patients and relatives in recognising deterioration]* in theory is going to have an attraction but in practice it could be difficult because of staffing, and there’s cultural stuff there as well. I don’t feel we’re as nice to relatives as we should be. We don’t respect relatives as much as we should. They hold the key often in history and information and we don’t seem to want to get it because we don’t respect them enough” (Consultant 2). To ensure relatives are informed and feel that their concerns have been addressed, this may require extensive and continuous communication from health professionals. The high levels of emotion experienced by relatives and their lack of medical knowledge are likely to make such conversations more difficult. Respect between health professionals and relatives may be eroded as health professionals may not have the resources to communicate with patients and relatives, and ensure they feel listened to. Indeed, participants felt health professionals have become overstretched as a result of low staffing levels, particularly nursing staff. Understaffing reduces the time they have to engage in the patient centred aspects of care, such as communicating and listening.

> “If a ward is say understaffed or stretched with nurses and a couple of patients need specialling *[1:1 nursing for patients who lack mental capacity or are at high risk of falling]* then...I think on wards like surgical wards, medical wards, it doesn’t always happen *[communication with patients and relatives]* because it’s so busy, people are really overstretched. I don’t think it’s a neglect thing I think it’s just a time thing with staffing (Junior doctor 1).

Another participant spoke of the lack of trust between health professionals and relatives which may need to be addressed to enable effective partnership between them. The participant talks specifically about how a lack of trust between health professionals and relatives can mean interventions designed to improve communication between them are not carried out as planned at ward level: “Culturally we’ve got a long way to go to sort of have proper partnerships with carers...we’re trying to get more dialogue going between carers *[and health professionals]*. Like we’re doing a lot of work in this hospital with dementia and people with cognitive issues, and it’s key that you know everything about the patient. And it’s great because people like me talk about it and seems like fantastic but when you get down on to the wards it’s not always happening because people *[health professionals]*, I think they feel that the carers are watching out for them and watching to see if they’re doing it properly and get very defensive and it’s trying to get people so they trust each other. And I think that’s part of the culture that there’s a trust there” (Matron 1). In order for healthcare interventions that require partnership between relatives and staff to be successful, it may first be important to address the lack of respect and trust that can exist between them. Furthermore, through improving partnerships between health professionals and relatives, health professionals may feel there can be a greater role for relatives in recognising deterioration.

3.4.2.3 Research question 3: How might patients and/ or relatives be involved in the management of the deteriorating patient in the context of a busy health service with limited resources?

3.4.2.3.1 Theme 4: Facilitators of patient (and relative) involvement in practice

Participants generated ideas about potential approaches to involve patients and relatives in recognising clinically deteriorating adult patients that may be feasible and acceptable in the context of a resource limited health service.

3.4.2.3.2 Subtheme 1: Striking a balance when involving patients

Participants stated that patients and their relatives may contribute towards the management of deteriorating patients where there is gradual deterioration that may precede a serious adverse event. However, at the point of acute deterioration, the utility of patient and relative input was questioned: “It depends on the acuteness of the deterioration of the person. If it’s a gradual deterioration

then yeah, in the initial stages where the patient is deteriorating, I think that's fine. But then personally I think we need to, it's better that relatives have been removed from that immediate area so you can actually care for the individual, treat the individual and then bring the family back in to it to answer the questions" (Ward sister 1).

Some participants proposed that patients and relatives could become more involved in managing patient deterioration if they were aware, and vigilant of, signs and symptoms that indicate someone's condition is worsening. They felt this could be achieved through educating patients and their relatives about objective and subjective signs and symptoms: "I think they *[patients and relatives]* could be provided with information in terms of what we *[health professionals]* need to know, what they can do to help us help them if you catch my drift. If we provide them with 'this is what temperature you'd normally feel like day to day, you wouldn't feel cold (Student nurse 2)'". If patients and relatives were to receive education about signs and symptoms, the participant emphasised that there would be a balance to strike in the amount of information they were given: "We don't want to overload them because sometimes it's like scaremongering isn't it, you don't want to give them too much so that they get overly anxious but then you don't want to not give them enough, so it's finding that happy medium" (Student nurse 2). Nevertheless, there were mixed views on educating patients. Without being prompted by the researcher, some participants spoke about it being inappropriate to educate patients about subjective signs and symptoms, or the objective measures that form the early warning score chart. One participant felt it may be inappropriate because of the financial cost of providing education for patients and relatives. Furthermore, educating patients and relatives about signs and symptoms to increase their ability to recognise deterioration may threaten the professional identity of health professionals. It may be that patient and relative input in recognising deterioration should rely on abilities they already possess, such as having intuitive feelings that 'things are just not quite right'.

> "It just depends on whether they have the knowledge because the only way I'd say you could manage that was if we did give them the education but then it would be a huge resource. Some people could argue, not me,

but some people could argue that that's just a massive drain on money when that's our job. It's our job to support them" (Healthcare assistant 1).

"I don't think it would be appropriate for us to teach family members about NEWS charts so it would come down to their feeling that things are just not quite right" (Consultant 2).

3.4.2.3.3 Routinizing conversations about patient wellness

There appeared to be greater consensus among participants that routinely prompting patients and relatives for their perspectives on the patients' condition is an acceptable method of engaging them in recognising deterioration. It was suggested that patients could be prompted during routine observations: "I think if it became integrated in to care when you're doing physical observations, and 'How do you feel?' 'Do you still..' 'Do you feel well?'. Any sort of phrased question that can prompt a response in that way to explain how they're feeling in their self I think is useful" (Midwife 1). It was seen as particularly useful if routinely prompting and recording patient and relative views improved time efficiency: "Sometimes when we're actively trying to speak to relatives, you spend quite a long time trying to get phone numbers and trying to say to relatives 'Are you coming in? Can we speak to you?'. You know all that takes like, I've been running around for 20 minutes before just trying to get hold of a relative. So there is something to be said that some of it might be time saving" (Registrar 1).

Participants acknowledged the importance of speaking to patients, and of seeking out their relatives to have a conversation if the patient isn't able to themselves. However, they felt that health professionals only have enough time to complete the required tasks of the job and lack time to engage in patient centred aspects of care, such as communicating with patients and relatives, and listening to them. A task focused approach to patient care can result in care becoming rigid and impersonal: "I think we could talk to them *[patients]* more. I think there's probably not a lot of dialogue that goes on. We're all busy in our own little worlds and it would be nice to have the time to find out what's normal for that patient, and sort of say, we're planning to do this today and this is what's happening" (Matron 1). One participant felt that routinely prompting patients may address the lack of day-to-day discussion that should be occurring between health professionals and patients about the patients' health and wellness: "They

[patients and relatives] give us an awful lot of information when they first come in. But we don't go into that level of detail on a day-to-day basis, it's kind of a summary of. And whether or not it's, some of it's as basic as 'how are you feeling today?' because you've got to put it in a term that the patient can respond to. And I think if you start with that kind of open ended question then you may open it up in to 'well I'm not so good today'. 'Why, what's different today?'" (Matron 2).

In terms of how best to prompt patients, participants said that patients and relatives use both vague, general statements, such as 'They just don't seem themselves', and changes in specific signs or symptoms, such as 'He seems to be more breathless' to express their concerns to staff that the patients' condition is worsening. Participants were uncertain, and had differing views about the types of prompts health professionals should use to elicit patients' and relatives' perspectives, particularly whether they should be prompted for information about general improvement or decline in wellness, or information about changes in specific signs and symptoms.

> "Okay so they can give you useful information, definitely, and what kinds?…about their symptoms, whether it's getting better or worse. Okay so like a broad, general questionnaire I think is probably the most, probably very useful, but then there are lots of specifics to it… the deteriorating patient…can really tell you about, say their specific, what could specifically they tell you? I don't know to be honest" (Junior doctor 4).

> "In terms of specifics, I don't know, it's difficult. I think you've got lots of emotion at the time when relatives come in. I think if prompted they might be able to provide more information but just asked open questions I think some of them probably can't… I think they might be able to provide information on, you know, stuff and probably would need prompting on this but are they eating? Are they talking to you as normal? Do they seem as bright as usual? (Consultant 3)"

Participants did acknowledge that it can be a challenge for health professionals to interpret and quantify subjective views about changes in patient wellness: "They *[relatives]* might say 'oh they're looking a bit better today or a bit brighter'. But how you quantify that, I'm not sure because we're used to dealing in the more

objective parameters giving you indication of how that patient is doing from various different standpoints. So to ask a relative what is a subjective question, erm I think it's difficult." (Consultant 3). This participant highlights that there is a lack of clarity on how to quantify relative's subjective judgements of patient wellness, and also how to interpret and combine their judgements with routinely used, objective measures to identify deterioration.

3.5 Discussion

This study sought to explore health professional's experiential accounts of the contribution patients and relatives could make to improve early recognition of, and response to, patient deterioration. It is believed to be the first empirical study to explore this topic. Previous approaches to patient and relative involvement have included allowing patients and relatives to activate a RRT if they suspect the patient is deteriorating, and have not received a satisfactory response from the ward team. The available evidence demonstrated that doctors were resistant to patient and relative led escalation, and described significant barriers to the approach (Paciotti et al., 2014). Health professionals interviewed in the current study were open to discussing the contribution patients and relatives could make to improve recognition of deterioration, and generated alternative approaches to patient and relative led escalation rooted in their reality of the care they provide. Participants did identify barriers to involvement that may need to be addressed to allow possible improvements in the safety of deteriorating patients to be realised.

The roles that patients and relatives could have in managing deteriorating patients were questioned to different extents by health professionals. For the most part, barriers to patient involvement centred on issues of practicality, for instance, patients must be conscious in order to have a role in the management of deterioration. Barriers to relative involvement related to more abstract issues, including the difficulties in creating partnerships with relatives, and suggested a more limited role for them in recognising deterioration. Participants highlighted that health professionals can lack respect for relatives. Interactions between health professionals and relatives are often complex and sensitive, requiring continual effort to achieve shared understanding. In a time pressured, resource limited health service, it may not always be possible to achieve shared

understanding. Misunderstanding and resulting frustration may erode respect between health professionals and relatives. It will be important to further explore why health professionals can lack respect for relatives, as this could have a bearing on the perceived utility of relatives in recognising deterioration. Interventions to enhance partnerships between health professionals and relatives could begin to address some of the perceived barriers to relative involvement, for instance, the view that relatives do not understand the job of a health professional. Greater partnership could in turn alter health professional perceptions about the extent to which relatives can contribute towards improving the detection of deterioration.

Participants acknowledged that interactions between health professionals and patients are also complex and sensitive, yet compared to relatives, they viewed patients as having greater potential to contribute towards the management of deterioration. This was highlighted as feasible and acceptable ways to involve patients and relatives in practice centred on patient involvement; that being routinely prompting patients for their views on changes in wellness during observations.

Participants agreed that health professionals should be regularly eliciting information from patients about their health and wellness. Yet in practice, due to organisational constraints, these discussions may be ad hoc, or may not occur at all. This exemplifies the concept of work as imagined and work as done. Work as done refers to the practical and pragmatic way that tasks are achieved ‘at the sharp end’. Here, health professionals work under complex, resource-limited circumstances, and adjustments are continually made to achieve desired outcomes (Ball & Frerk, 2015). This reflects participants’ accounts of communication between health professionals and patients in practice, within a resource limited health service. In contrast, work as imagined does not consider the varying conditions health professionals work under, and assumes there are limited correct ways to achieve an outcome (Ball & Frerk, 2015). This reflects participants’ perceptions about how health professionals should communicate with patients. Health professionals should continually discuss with patients their views on changes in their wellness and the treatment they are receiving. Routinizing conversations that elicit communication about changes in patient wellness may encourage more dialogue between the nursing staff taking

observations and patients. It may serve to help nursing staff reconcile their perceptions of idealised communication with patients, and the reality of how they communicate with patients in practice.

3.5.1 Implications and recommendations for an intervention to involve patients in the management of clinical deterioration

If as suggested by some health professionals, it may be feasible for patients to become involved in recognising deterioration by recording their views on changes in their health and wellness in the observation chart, consideration about how to prompt patients for this information is required. Participants were unsure as to how to prompt patients for their views on changes in wellness, particularly, whether patients should be asked about their general health and wellness, or specific aspects of their wellness. In current healthcare practice, health professionals may consider patients' subjective views on their wellness in an ad hoc manner. It is only when their subjective views are prompted for, and recorded, as part of routine care that it becomes necessary to determine how to ask patients about their wellness, and to quantify and interpret their responses. Further research is required to explore appropriate questions to prompt patients for their views on changes in their wellness. Health professionals and patients are the key stakeholders with whom the intervention may eventually be used. Appropriate questions ought to be identified through a shared process of development between the researcher, health professionals and patients.

3.5.2 Limitations

The findings reported here are based on single interviews with a small sample of health professionals working within one hospital in the North of England. As such, the findings of this study may not be generalisable to healthcare systems in other countries. Also, it should be noted that snowball sampling was used whereby participants suggested further colleagues to approach about participation in the study, creating the potential for bias. Nevertheless, a purposive sampling strategy was used alongside to recruit a variety of health professionals in terms of speciality, grade and years in practice and as a result is thought to be a representative sample.

3.6 Conclusions

The findings presented here demonstrate that health professionals believe there is a role for patients and relatives in identifying clinical deterioration in hospital, although a number of barriers to their involvement were highlighted that need consideration. For relatives to become more involved in recognising deterioration in adult patients, improved partnerships between health professionals and relatives may first be required. Potentially feasible and acceptable methods of involving patients in recognising deterioration were suggested. It will now be important to explore how suggested methods of patient involvement may be implemented in practice, and whether involving patients in this way is feasible and acceptable in practice. Enabling patients to become more involved in the management of deterioration, by recording their views on wellness during routine observation, may be one strategy that could aid health professionals in recognising and responding to deteriorating patients in a timely manner.

Chapter 4

Development and feasibility testing of a health services intervention to promote patient and relative involvement in recognising clinical deterioration in hospital.

4.1 Chapter summary

The concept for a health services intervention to promote patient and relative involvement in recognising clinical deterioration in hospital was suggested by health professionals during interviews described in Chapter 3. This chapter reports a series of small scale studies to develop intervention components and investigate the feasibility and acceptability of the intervention from the perspective of patients, key stakeholders in the intervention. Focus groups were held with healthcare staff and patient representatives to develop a two-item questionnaire to routinely prompt patients and relatives for their views on changes in the patients' wellness while in hospital (study 2). A pilot study was then conducted on in-patient wards to explore feasible and acceptable approaches to routinely collect patient and relative views on changes in patient wellness in practice using the questionnaire (study 3). Implications of sub-optimal vital sign monitoring for the current intervention, and recommendations for future research are discussed.

4.2 Background

The concept for a health services intervention to promote patient involvement in recognising and responding to in-hospital clinical deterioration was based on findings from an interview study with health professionals (outlined in Chapter 3). In the study, health professionals talked about the contribution patients and relatives could make to improve early recognition of, and response to, patient deterioration. Approaches to involvement generated by participants centred on involving patients in the recognition of, rather than the escalation of deterioration. Recording patients' views on changes in their wellness during routine clinical

observation was identified as a potentially feasible approach to involving patients in recognising deterioration in practice, and formed the concept for a health services intervention to promote patient involvement in recognising clinical deterioration in hospital. Although the health professionals interviewed in study 1 believed there was a limited role for relatives in the management of deterioration, anecdotal evidence suggests relatives may sense when a patients' condition is deteriorating. Therefore, exploring the potential to routinely record relatives views on changes in patient wellness felt warranted.

For healthcare assistants and nurses to record patients' views on changes in their wellness during routine clinical observation, patients must be prompted for their views. The health professionals interviewed were uncertain, and had differing ideas about the prompts healthcare staff should use to elicit patients' views on changes in their wellness, particularly whether they should be prompted for information about general improvement or decline in wellness, or about changes in specific signs and symptoms. To inform the development of a questionnaire to capture patients' views on changes in their wellness, the findings of existing literature exploring self-ratings of health as predictors for mortality were considered. Mossey and Shapiro (1982) conducted the first study clearly highlighting the relationship between people's self-assessments of their health and mortality. In a large sample of 3,128 elderly adults, it was found that self-ratings of health were better predictors of seven year survival rate compared to patient medical records or self-reporting of medical conditions. A systematic review of 27 studies using community samples has since identified large effect sizes demonstrating that self-ratings of health can reliably predict survival in populations where known health risk factors have been controlled for (Idler & Benyamini, 1997).

In order to measure self-rated health in these population-based longitudinal studies, the following simple, global measure is most commonly used; How in general would you rate your health? With the following five response options; Very poor - poor - fair - good - very good (Benyamini, 2011; Rakowski, Mor & Hiris, 1991; Schoenfeld et al., 1994; Wu et al., 2013). The practical advantages of using a single item measure to obtain people's perceptions of their health status include the ease of administration and reduced likelihood of participant fatigue (Benyamini, 2011). Benyamini (2011) suggests that self-rated health,

measured using a single global item, predicts future health outcomes because it is a holistic evaluation of health. Self-rated health is an interpretation of experienced diseases and symptoms, and may be based on the objective characteristics of the illness or on the person's subjective experience of it (Karademas, Kynigopoulou, Aghathangelou, & Anestis, 2011; Karademas, Zarogiannos, & Karamvakalis, 2010). It may be that this global item is better able to capture overall subjective assessments of health compared to detailed multi-item scales. Benyamini (2011) proposes that this could be because people are likely to have a sense of whether they are healthy or not and this information is easily accessible. Specific aspects of illness often measured by multi-item scales may be less psychologically meaningful and subsequently less accessible.

As outlined by the Medical Research Council (Craig et al., 2008), when developing a complex intervention it is first important to identify the existing evidence base by investigating what is already known about similar interventions and the methods used to evaluate these. The mechanisms implicated in the relationship between the intervention and outcome measures should then be explored (Craig et al., 2008). Chapters 2 and 3 of the thesis address these stages of developing a complex intervention. Modelling the processes and outcomes of the intervention prior to full scale evaluation is proposed to be the final stage of developing a complex intervention (Craig et al., 2008). Therefore, a series of studies, outlined in the current chapter, were conducted to test the feasibility of the procedures and iteratively refine the design of the intervention aimed at promoting patient and relative involvement in the recognition of clinical deterioration. First, a short two-item questionnaire was developed, in collaboration with healthcare assistants and patient representatives, to prompt patients, relatives and healthcare staff for their views on changes in the patients' wellness. Second, feasible and acceptable approaches to using the questionnaire to routinely collect patients', relatives' and healthcare assistants' views on changes in patient wellness in practice were explored.

4.3 Identifying intervention components

4.3.1 Aims

No previously developed measure that serves to capture patients' perceptions of changes in their wellness while in hospital was identified. Therefore, this study

aimed to identify suitable questions for healthcare staff to ask patients during clinical observations to prompt them for their views on changes in their wellness.

4.3.2 Methods

4.3.2.1 Ethical approval

Ethical approval for this study was granted by University of Leeds Faculty Research Ethics Committee (Reference: 15-0355). All data was handled in a robust and transparent manner, applying confidentiality and security where appropriate.

4.3.2.2 Participants

Two focus groups were held; one with three healthcare assistants (who predominantly conduct clinical observations), and the other with five members of the Yorkshire Quality and Safety Research Group patient panel. These are members of the public that volunteer as research advisors, providing feedback from the public and patient perspective on the design and conduct of research studies. These two groups were chosen as they represent the views of patients and the people caring for them, two populations that the intervention will be developed for use with.

4.3.2.3 Procedure

During the focus groups, potential question and response options that could measure patient views on changes in patient wellness were presented and discussed. The potential question and response options were created based on findings from interviews with health professionals, and questions used in the self-reported health literature (Benyamini, 2003; Frankenberg & Jones, 2004; Idler & Benyamini, 1997). Two health professionals interviewed in the study described in Chapter 3 suggested questions that healthcare staff could ask patients during routine care to elicit their views on their wellness. These questions included ‘how are you feeling today?’ and ‘how do you feel?’. In terms of the self-reported health literature, the question item commonly used to measure self-rated health is ‘How in general would you rate your health?’ with the following Likert scale response options: ‘Very good, good, fair, poor, very poor’ (Idler & Benyamini, 1997).

In the focus group with patient representatives, participants imagined that they were a patient in hospital and the nurse was asking them about changes in

their wellness using the questions options a few times a day during their stay. In this context, participants were asked to discuss what they felt each question was asking them, how difficult the question was to answer, how appropriate the question was and how willing they would be to answer it. In the focus group with healthcare staff, they discussed the same points but from the perspectives of their patients, for example, whether they thought patients would be willing to answer the question options. The focus groups were audio-recorded and transcribed verbatim.

4.3.3 Results

4.3.3.1 Patient representative focus group

During the focus group, participants stated that the questionnaire should be simple and brief to account for patients' differing ages, reading abilities, education levels and languages. Participants felt it was appropriate to adapt the questionnaire for use with relatives, but noted the importance of using specific questions about the patients' health and wellness as to not elicit a 'flood of complaints' from relatives. Routinely asking patients about changes in their health and wellness was thought to be particularly helpful to encourage shy and stoical patients to speak up about how they are feeling. The questions and response options presented to participants are outlined, along with their comments in Table 4.1.

Table 4.1 Patient representatives' comments on the question and response options

Question options	**Participants comments**
How in general would you rate your wellness/condition/health?	Patients might not understand what wellness means and would not understand what condition means. Patients would understand what health means.
How are you feeling? How well are you feeling?	Patients may think the question 'How are you feeling?' is asking them about how they are feeling emotionally, not physically. 'How well are you feeling?' may be more likely to prompt patients to think about how they are feeling physically.
How worried are you about your wellness/condition/health?	Worry is a negative word and patients might not like to answer a question like this. The question 'how well are you feeling?' might encompass worry and so it may not be necessary to ask about worry specifically. If using this question would be useful to include a text box with this question so patients could elaborate on why they are worried.
How well are you feeling compared to the last time you answered this question?	This is the best question and patients should be asked this.
Response options	**Participants comments**
1 **2** **3** **4** **5** Very poor Poor Fair Good Very good **1** **2** **3** **4** **5** Much better Better No change Worse Much worse	Word response options should be used alongside the numbers. Patients would not know what the numbers meant if they were not also described in words.

4.3.3.2 Healthcare assistant focus group

Healthcare assistant participants talked about the importance of making the questionnaire simple and concise. This was important so that patients could understand the questions and be physically capable of answering them, but also to ensure that time pressured healthcare staff have the resources to ask patients these questions and interpret their responses. Participants felt that a two-item questionnaire to prompt patients for their views on changes in their wellness during routine observation would be appropriate. Participants spoke about the acceptability of introducing a change in practice by routinely asking patients about changes in their health and wellness, and recording patients' responses. It was felt that this change in practice would be successfully adopted by healthcare staff because they already ask patients about changes in their health and wellness as part of usual care. Please see Table 4.2. for healthcare assistants' comments on the question and response options presented.

Table 4.2 Healthcare assistants' comments on the question and response options

Question options	Participants comments
How in general would you rate your wellness/condition/health?	A lot of patients aren't aware of their condition so this would not be an appropriate term to use.
How are you feeling? How well are you feeling?	'How are you feeling?' is a more useful question than 'how well are you feeling?' The latter question may prompt just patients to say they are feeling poorly. A lot of patients can't put their finger on how they are feeling and be able to tell you. Patients often use vague, general statements such as 'oh, I feel a bit rubbish'. 'How are you feeling?' covers all aspects of health and wellness.
How worried are you about your wellness/condition/health?	Doctors ask patients if they are feeling worried but being asked this might be daunting for patients in hospital if they do not know what is happening and this could set off anxiety. Should phrase the question 'Are you worried about your health?' with Yes and No response options, rather than 'how worried are you about your health?'. This gives patients the opportunity to say they are not worried, and doesn't suggest that they should be worried about their health.
How well are you feeling compared to the last time you answered this question?	'How are you feeling since we last asked you?' is the simplest and easiest to understand question to ask patients.

Table 4.2 continued Healthcare assistants' comments on the question and response options

Response options					Participants comments
1	**2**	**3**	**4**	**5**	Using word and number response options is more appropriate than number response options alone.
Very poor	Poor	Fair	Good	Very good	
1	**2**	**3**	**4**	**5**	
Much better	Better	No change	Worse	Much worse	

Based on discussions during the focus groups with patient representatives and healthcare assistants, two versions of a questionnaire were developed to measure patient perspectives on changes in their wellness. These are referred to as 'Patient Wellness Questionnaire' versions. The Patient Wellness Questionnaire versions use different wording and response options to ask patients to give a rating of their current wellness, how their wellness has changed from an earlier time point or whether they are worried about changes in their wellness.

The questionnaire versions were adapted for use with relatives and healthcare staff who conduct patient observations to gain their perspectives on changes in the patients' health and wellness. Table 4.3. displays the Patient Wellness Questionnaire versions used in the pilot study. Versions *A, B,* and then *C* were piloted on different in-patient wards. Versions *A* and *C* were developed based on the focus group discussions. The questions in Version *B* were identified as potentially suitable during the focus group study. The use of a visual analogue scale as a response option in Version *B* was not discussed during the focus groups because the EQ-5D, the questionnaire from which the visual analogue originates was identified in the literature after the focus groups had taken place. The EQ-5D is a questionnaire used to measure health-related quality of life as completed by the respondent (Gusi, Olivares & Rajendram, 2010). Studies have demonstrated that the EQ-5D has moderate to high validity to measure health-related quality of life in clinical and general populations (Conner-Spady et al.,

2015; Hong-Mei Wang et al., 2012; Seon-Ha, Min-Woo, Jong-Won & Jong, 2015). Through discussion between the researcher and their supervisory team, it was decided that the 10 point visual analogue scale adapted from the EQ-5D may be a suitable response item to use in the Patient Wellness Questionnaire.

Health professionals interviewed in the study described in Chapter 3 focused on involving patients in the management of deterioration. There are high profile examples where relatives have recognised signs of the patient's deteriorating condition before healthcare staff (Raymond et al., 2009), suggesting relatives may have insight to recognise significant changes in the patients' health. It may be that relatives could also be involved in the management of deterioration by routinely recording their views on changes in the patients' wellness. Health professionals' perspectives of changes in patient wellness can act as a variable that is known to predict patient deterioration. For changes in patient-reported wellness to be of interest, it is important that this adds predictive value beyond already known risk factors for patient deterioration, for instance nurse worry for the patient. A pilot study exploring the feasibility and acceptability of routinely recording patients', relatives' and health professionals' views on changes in patient wellness is outlined in the following section named 'Piloting the intervention'.

Table 4.3 Patient Wellness Questionnaire versions

Version A

How are you feeling?

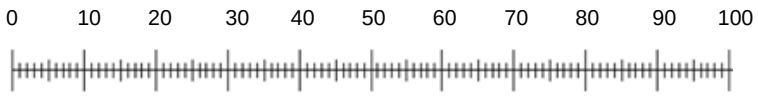
1	2	3	4	5
Very poor	Poor	Fair	Good	Very good

Are you worried about how you are feeling?

Yes	No	Don't know
☐	☐	☐

Version B

How are you feeling?



The worst health you can imagine

The best health you can imagine

How are you feeling compared to the last time we asked you?

1	2	3	4	5
Much worse	Worse	No change	Better	Much better

Version C

How are you feeling?

1	2	3	4	5
Very poor	Poor	Fair	Good	Very good

How are you feeling compared to the last time we asked you?

1	2	3	4	5
Much worse	Worse	No change	Better	Much better

4.4 Piloting the intervention

4.4.1 Aims

In this study, the Patient Wellness Questionnaire versions were piloted with patients receiving care on in-patient wards, their relatives and healthcare assistants who conduct patient observation.

The pilot study aimed to:

(1) Identify a feasible and acceptable approach to using the Patient Wellness Questionnaire to routinely collect patients', relatives' and healthcare assistants' views on changes in patient wellness.

(2) Explore which version of the Patient Wellness Questionnaire is the most appropriate to routinely prompt participants for their views on the patients' wellness. Appropriateness will be determined by acceptability of the questions to participants and the amount of variation in their responses to the questions.

4.4.2 Methods

4.4.2.1 Ethical approval

Ethical approval for this study was granted by the NHS Health Research Authority North West Research Ethics Committee (Reference: 16/NW/0472). All data was handled in a robust and transparent manner, applying confidentiality and security where appropriate and operating to high ethical and quality standards as outlined by the Health Research Authority's framework for Information Governance.

4.4.2.2 Setting and participants

The pilot study was conducted on four wards at a teaching hospital in the North of England. The wards were purposively sampled based on cardiac arrest call audit data that was accessed through the director of Intensive Care at the hospital, a clinical contact who provided guidance to the researcher. Cardiac arrest is generally an unwanted outcome (as evidenced by the lack of a Do-Not-Attempt-Resuscitation order) and can represent a failure to recognise and respond to clinical deterioration in an appropriate and timely manner (Churpek, Yuen & Edelson, 2013). Although in some instances, clinical deterioration preceding a cardiac arrest can be unpreventable, cardiac arrest is identified as

an avoidable adverse outcome associated with unrecognised patient deterioration (NICE, 2011). The number of cardiac arrest calls was used to indicate the prevalence of unrecognised patient deterioration on wards, to highlight wards that might benefit most from an intervention to improve early recognition of deterioration. Two medical and surgical wards with the highest numbers of cardiac arrest calls of all inpatient wards in the hospital (excluding paediatrics and cardiology) between April 2014 and April 2015 were selected. The number of cardiac arrest calls recorded on the sampled medical and surgical wards were 23 and 15, and 11 and 10, respectively. Patients receiving care on the sampled wards, their relatives and healthcare assistants working on these wards were invited to participate in the pilot study.

4.4.2.3 Procedure

The study was introduced to the nursing team during nursing shift handovers. Through discussion with the nurse in charge, patients who had capacity were identified and first approached by a member of nursing staff who asked them for verbal approval for the researcher to approach them about study participation. Potential patient participants were then approached by the researcher at their bedside at convenient times to fit around planned treatment or care. Potential relative participants were approached by the researcher at visiting hours. Potential healthcare assistant participants were approached after shift handover or during their lunch break. The study was introduced to potential participants and information sheets were provided. If willing to participate, the researcher collected written informed consent.

Patients and relatives participated in the study for up to seven days (based on average length of hospital stay for all causes (NHS Confederation, 2016)). If patient participants were discharged from hospital before seven days then they and their relatives participated in the study until they were discharged. Healthcare assistants participated in the study until every patient participant on their ward had finished participating in the study. Patients who staff predicted would be in hospital for at least three more days were recruited to ensure sufficient patient wellness ratings could be collected.

Two approaches to routinely collecting patients', relatives' and healthcare assistants' views on changes in patient wellness were explored. Initially,

participants were asked to record answers to the patient wellness questions themselves after routine observations (patients and healthcare assistants), or at visiting hour (relatives). As the pilot study progressed using this approach to data collection, it was established that participants were not routinely recording their patient wellness ratings, and sufficient data were not being collected to allow the analysis to be performed. At this point, the method of data collection was altered. The researcher attended day time routine observations and visiting hours to ask participants the Patient Wellness Questionnaire and record their responses. Although altering the data collection method allowed sufficient patient wellness data to be collected from patients, there was substantial missing data on healthcare assistants and relatives patient wellness ratings.

4.4.2.3.1 Participant recorded patient wellness ratings

Where patient wellness ratings were recorded by participants themselves, this method is referred to as participant recorded patient wellness ratings. Here, patient, relative and healthcare assistant participants were each given a patient wellness booklet containing repeated sets of patient wellness questions. Patient and healthcare assistant participants were asked to record their answers to one set of patient wellness questions in their booklet after each clinical observation, along with the time and date. Relatives were asked to record their answers to one set of patient wellness questions in their booklet, along with the time and date, each time they visited the patient during the study period. Healthcare assistants prompted half the patients to complete the patient wellness questions while they carried out the clinical observation, while the other half of patients were prompted by their relatives during visiting hours. This was to explore whether being prompted by healthcare staff or relatives was more effective at reminding or encouraging patients to routinely complete the Patient Wellness Questionnaire. The mean percentage of patient wellness ratings recorded by patient participants out of the total number of opportunities was low at 14%.

4.4.2.3.2 Researcher recorded patient wellness ratings

Where patient wellness ratings were recorded by the researcher, this method is referred to as researcher recorded patient wellness ratings. Here, the researcher attended day time clinical observations at 10am, 2pm and 6pm for each patient participant. They asked patients' and the healthcare assistant conducting the

clinical observation for their patient wellness ratings and recorded these. The researcher also attended visiting hours to ask relative participants for their patient wellness ratings, recording these. The mean percentage of patient wellness ratings recorded by the researcher out of the total number of opportunities was high at 95%.

Patient participants were asked to give feedback about whether the questions were understandable, appropriate, and suitable for patients to answer during clinical observation. Patient participants were also asked in greater detail about the nature of perceived changes in their wellness. Topic guides used in previous research exploring the involvement of patients and relatives in managing complications in maternity were used to guide the content of the feedback questions in the current study (Mackintosh, Rainey & Sandall, 2010; Rainey, Ehrich, Mackintosh & Sandall, 2013) (See Appendix 9 for patient participant study feedback questions).

4.4.2.4 Data analysis

Patient wellness ratings were converted in to Z scores ($M = 0$, $SD = 1$) to analyse the within and between participant variability in patient wellness ratings. Descriptive statistics, including the ranges, means and standard deviations of ratings were calculated. Analysis was conducted to establish variability in participant's patient wellness ratings over all study days and individual study days, and based on ward type (medical or surgical), gender, ethnicity and age. The analysis of patients' feedback responses focused on manifest content; the visible, countable content of the text, as opposed to the underlying meaning of the text (Kondracki, Wellman, & Amundson, 2002). The researcher identified occurrences of similar words or content between participants' feedback responses, and counted the number of participants that gave the same response to a feedback question. Counting highlighted patterns in participants' feedback responses.

4.5 Results

Fifty-nine patients were approached to participate in the study. Of these, 30 patients were recruited, 1 withdrew because they felt too unwell and 29 declined participation. Participants reasons for declining participation were: feeling too

unwell (*N* = 9), feeling too tired (*N* = 5), not wanting to give informed consent (*N* = 2), expecting visitors (*N* = 1), no reason given (*N* = 12). Twenty-eight healthcare assistants were approached to participate in the study. Of these, 12 were recruited and 16 healthcare assistants declined participation because they were too busy to participate (*N* = 5), or were bank staff who worked on the ward temporarily (*N* = 6). Three healthcare assistants who declined participation because they were bank staff also said they did not know the patients so could not participate. Twenty-four relatives were approached to participate in the study and 5 of these were recruited. Nineteen relatives declined participation in the study. Reasons for this included: they do not visit their relative in hospital often (*N* = 4), they just wanted to speak to their relative (*N* = 3) or they were too stressed to participate (*N* = 1). Eleven relatives gave no reason for declining participation in the study.

The characteristics of ratings patients gave about their wellness during routine observation are discussed below in the 'Characteristics of patient wellness ratings' section. Healthcare assistant and relative participants were also asked to rate patient wellness during routine observation and visiting hours. Due to there being substantial missing data on healthcare assistants' ratings of patient wellness, descriptive statistics could not be calculated to explore variability in their ratings. At least one patient wellness rating from a healthcare assistant perspective was recorded during routine observation for 17 of the 30 patients in the study. For these 17 patients, the mean percentage of recorded patient wellness ratings given by healthcare assistants out of the total number of opportunities was 51%. The total number of opportunities was calculated by considering the number of routine observations the patient had while they were participating in the study. Where a healthcare assistant rating of wellness was recorded during observation, 15% of the time healthcare assistants gave a rating of how well they thought the patient was, but did not give a rating of the change in patient wellness. In these instances, they could not make a judgement about any changes in the patients' wellness because they had not cared for the patient before, and this was their first time meeting the patient. In terms of relative participants, patient wellness ratings were collected from 2 of the 5 recruited relatives. Again due to a lack of data on relatives' ratings of patient wellness, descriptive statistics could not be calculated to explore variability in their ratings.

On one of the sampled wards, participants were asked to record their own patient wellness ratings after clinical observations or during visiting hours. The low number of patient wellness ratings recorded when asking patients to record their wellness ratings themselves suggested it was necessary to use a different approach to collect the data. Therefore, on the remaining three wards, the researcher attended clinical observations and recorded patients' wellness ratings. No patient participants could be approached to participate in the study on one of the sampled wards suggesting it was not possible to record patients' views on changes in their wellness during clinical observation here. This was a Medical Assessment Unit where the average length of stay for patients is a few hours and it is likely that only one routine clinical observation will be carried out in this time. See Table 4.4 for characteristics of the patients recruited from the three other sampled wards.

Table 4.4 Summary of patient participant characteristics

Patient characteristics		**Ward W (*N* = 8)**	**Ward X (*N* = 7)**	**Ward Y (*N* = 15)**
		N	***N***	***N***
Age	>60 years old	5	2	7
	< 60 years old	3	5	8
Gender	Male	8	5	9
	Female	0	2	6
Ethnicity	White British	7	6	14
	Asian Bangladeshi	1	0	0
	Asian Pakistani	0	1	1

4.5.1 Characteristics of patient wellness ratings

4.5.1.1 Participant recorded patient wellness ratings

Where patients were asked to record their answers to *Version A* of the Patient Wellness Questionnaire after each clinical observation, the mean was .01 (*SD* = .57, *Mdn* = .1, range: -.82 to .75). Analysis revealed there was variation in patient wellness ratings in both age groups. There was greater variation in patient wellness ratings given by younger patients aged 60 or under (*M* = -.17, *SD* = .82, *Mdn* = -.46, range: -.82 to .75) compared to patients 60 or over (*M* = .19, *SD* = .18, *Mdn* = .14, range: .05 to .40), and younger patients reported poorer wellness than older patients. Although this was a mixed gender ward, all patients in the sample using this method were males. Female patients approached to participate in the study declined.

4.5.1.2 Researcher recorded patient wellness ratings

The characteristics of patient wellness ratings in response to *Version B and C* of the Patient Wellness Questionnaire are discussed. There was variation in the wellness ratings patient participants gave in response to *Version B* (*M* = .58, *SD* = .49, *Mdn* = .44, range: .01 to 1.36) and *Version C* (*M* = -.27, *SD* = .28, *Mdn* = -.32, range: -.78 to .34) of the Patient Wellness Questionnaire. Table 4.5 outlines the variation in patient wellness ratings on individual and all study days. The ratings patients gave for their health and wellness varied on each day, with ratings indicating poorer health as the days progressed.

Table 4.5 Variation in patient wellness ratings by study day

Day	*M*	*SD*	Min	Max	*Mdn*
All days	.01	.54	-.78	1.36	-.12
Day 1	.11	.86	-.87	2.79	-.13
Day 2	.05	.55	-.87	1.3	.03
Day 3	-.15	.72	-1.73	.72	.03

There was variation in patient wellness ratings for age, gender and ward type. In terms of age, there was greater variation in patient wellness ratings given by older patients aged 60 or over (*M* = -.01, *SD* = .51, *Mdn* = -.32, range: -.42 to 1.12) compared to patients 60 or younger (*M* = -.09, *SD* = .43, *Mdn* = -.12, range: -.78 to .6). Patient wellness ratings reported by male participants (*M* = .09, *SD* = .6, *Mdn* = -.02, range: -.78 to 1.36) had greater variability than those reported by females (*M* = -.14, *SD* = .39, *Mdn* = -.23, range: -.64 to .44). Participants receiving care on medical wards (*M* = .58, *SD* = .49, *Mdn* = .44, range: .01 to 1.36) reported greater variability in patient wellness ratings compared to those on surgical wards (*M* = -.27, *SD* = .28, *Mdn* = -.32, range: -.78 to .34). The full range of response options on a 5 point scale were used by participants to rate their wellness when they were asked *versions A* and *C* of the Patient Wellness Questionnaire. *Version B* of the questionnaire had a 10 point scale for participants to rate how well they were feeling, and participants did not use the full range of response options to rate their wellness. Patients reported the poorest wellness in response to *Version C* (*M* = -.27) of the questionnaire, followed by *Version A* (*M* =.01) and then *Version B* (*M* = .58).

4.5.2 Qualitative content analysis

Feedback responses were collected from 17 patient participants. It was not possible to obtain feedback from all patients because some moved to different wards that were not participating in the study, or were discharged from hospital before the researcher was able to obtain their feedback responses. Patient participants gave feedback on the version of the questionnaire they had completed during the study (*Version A*, *N* = 5; *Version B*, *N* = 6; *Version C*, *N* = 6). Patients were asked to rate on a five point scale (strongly agreed to strongly disagreed) their agreement with the following statements in relation to the Patient Wellness Questionnaire version they were asked while participating in the study: ‘I understood what the questions were asking me’ and ‘I was comfortable answering the questions’. Table 4.6 details the frequencies of participants responses.

Table 4.6 Frequency of patient participants' responses to feedback questions

Patient wellness questionnaire version	Feedback question	Participant response					
		Strongly agree	**Agree**	**Neither agree nor disagree**	**Disagree**	**Strongly disagree**	***N***
Version A	I understood what the questions were asking me	4	1	0	0	0	5
	I was comfortable answering the questions	4	1	0	0	0	5
Version B	I understood what the questions were asking me	6	0	0	0	0	6
	I was comfortable answering the questions	6	0	0	0	0	6
Version C	I understood what the questions were asking me	6	0	0	0	0	6
	I was comfortable answering the questions	6	0	0	0	0	6

A number of patient participants elaborated on their understanding of what the patient wellness questions were asking them about. Response topics and frequencies are organised in to a categorisation matrix and presented in Table 4.7.

Table 4.7 Categorization matrix exploring the content validity of patient wellness questions

Feedback question	My general wellbeing	My mental health	Progress in my health	Adequacy of my treatment	***N* of patient respondents**
What are the questions are asking you about?	6	3	4	2	15

Patients' responses to feedback questions exploring the feasibility, acceptability and effectiveness of the intervention are displayed as word frequency counts in Table 4.8. To elaborate on the qualitative data collected from patients during the feedback exercise, the majority of participants felt that it was acceptable to be asked patient wellness questions as frequently as every observation. Although, one participant felt it would be more appropriate to answer the questions once at the end of each day. They talked about their ability to give accurate answers to patient wellness questions, where being in pain made it difficult to think clearly about their wellness. Patients' perspectives on the utility of the intervention were mostly positive. Those that felt recording patients' views on changes in their wellness during clinical observation would aid health professionals in recognition deterioration said that it relied on them seeing patients' ratings. Some were doubtful that health professionals would look at their ratings of their wellness. Reasons for this included; health professionals lack time to consider what patients say about how they are feeling, recording patients' views on their wellness creates further paperwork, health professionals may not be responsive to new interventions, and health professionals are sufficiently trained to recognise deterioration without input from patients.

Table 4.8 Word frequency counts for patient participants' responses to feedback questions

Feedback question	Yes	No	Don't know	*N* of patient respondents
Was it acceptable be asked the patient wellness questions as frequent as every observation?	15	2	0	17
Will your answers to the patient wellness questions help staff recognise if you are getting more unwell?	10	4	3	17
During your stay in hospital, were you aware of any changes in your health or wellness?	11	2	1	14
Were you concerned about the changes in your health or wellness?	5	5	1	11

4.6 Discussion

This study aimed to develop and evaluate the feasibility and acceptability of a health services intervention to promote patent and relative involvement in recognising patient deterioration. Approaches to involvement generated by health professionals in a study discussed in Chapter 3 centred on involving patients in the recognition of, rather than the escalation of deterioration; that being recording patients' views on changes in their wellness during clinical

observation. In the current study, a two-item questionnaire was developed to prompt patients and relatives for their views on changes in their wellness. The feasibility and acceptability of using the questionnaire to record patients' ratings of their wellness during routine clinical observation and relatives' ratings of patient wellness during visiting hours was then explored.

There was a lack of uptake when patients were required to record changes in their wellness themselves after routine observation. Asking patients to record their answers to the Patient Wellness Questionnaire after each observation was not a feasible method to routinely collect data about patients' views on change in their wellness. This is reflected in the low percentage of patient wellness ratings recorded using the method. Chapter 5 outlines contextual factors that are thought to have influenced the feasibility of using patient recorded patient wellness ratings as a data collection method.

Subsequently, the researcher attended day time patient observations for each patient participant, asking for their wellness ratings and recording these. Using this method, it was found that most patients are willing and able to give information about changes in their wellness during routine observations. Although, some patients were too unwell to complete the consent process to participate, and some who could have consented did not want to participate. This data collection method is not sustainable in practice, but it was first important to ensure sufficient data were collected to answer the research questions. Inviting healthcare assistants and nurses who conduct clinical observations to ask patients about their wellness and record their responses, along with objective vital sign measures, may be a sustainable approach to routinely collecting this information from patients. Furthermore, it was difficult to routinely record relatives views on changes in patient wellness during visiting hours. A small number of relatives approached to participate in the study agreed to take part, and the most common reason for declining was that they did not visit the relative in hospital often which may have affected their ability to notice changes in their wellness.

4.6.1 Positive unintended consequences of routinely recording patient-reported wellness

Encouraging ward staff to genuinely engage with patients is vital to improve detection of acute illness (Rainey, Ehrich, Mackintosh & Sandall, 2013). Routinizing conversations that elicit communication about changes in patient

wellness may also encourage more open dialogue between ward staff and patients. Indeed, the current study identified that routinely asking patients about changes in their wellness uncovered concerns patients had that related to communication failure with health professionals, for instance requests for pain relief that had not been acted on by staff. This finding is consistent with that of a systematic review of studies exploring patient and relative led escalation systems (outlined in Chapter 2). Here, it was found that communication failure between health professionals, patients and relatives was cited in all studies as a reason why patients and relatives activated a rapid response team (RRT). Often, the types of communication failure reported were unrelated to a patient's deteriorating clinical condition.

This study suggests that routinely asking patients about changes in their wellness may have the positive unintended consequence of highlighting non-life threatening, but important patient concerns. Similar non-life threatening concerns that prompted patient and relative led escalation related to issues that increased the possibility of patient safety events and negatively affected patient and family experience (Brady et al., 2014). Yet, escalating non-life threatening concerns to a RRT may not be the most appropriate or cost-effective method to address these issues (Albutt, O'Hara, Conner, Fletcher & Lawton, 2016). If prompting patients for their views on changes in their wellness during routine observation also uncovers non-life threatening patient concerns, encouraging ward staff to address these concerns at observation may be a more appropriate approach.

4.6.2 Patients' ability to effectively detect signs of clinical deterioration in their condition

As discussed in Chapter 2, responding appropriately to deterioration using patient led escalation protocols depends on the ability of patients to effectively detect deterioration, and little is known about their ability to recognise signs of their deteriorating condition. This study found that the ratings patients gave about their wellness in response to the Patient Wellness Questionnaire varied overtime. Finding variability in patients' ratings of their wellness adds knowledge to our limited understanding of their ability to recognise changes in their health, and suggests that patients can subjectively perceive changes in their wellness overtime. It is not yet known whether patient-reported changes in wellness are

associated with objective, clinical measures of patient health, such as the EWS, to signal genuine deterioration in their condition. It should be noted that evidence for the efficacy of early warning score systems at reducing in-hospital mortality and morbidity is equivocal (Alam et al., 2014; De Meester et al., 2013; Patel, Jones, Jiggins & Williams, 2011). Therefore, it will be important for future research to investigate whether patients' ratings of their wellness are associated with the EWS, as well as other clinical measures and outcomes, or provide novel information to indicate a patient is deteriorating. *Version B* of the Patient Wellness Questionnaire produced the greatest variability in patient wellness ratings, and may be the most appropriate version of the questionnaire to use to gather patient-reported wellness in future research.

4.6.3 Implications of sub-optimal vital sign monitoring for routinely recording patient-reported wellness

Studies have revealed incomplete and infrequent monitoring of patients' vital signs on general wards (Cardona-Morrell et al., 2015; De Meester, Bogaert, Clarke & Bossaert, 2012; ; Leuvan & Mitchell, 2008; Ludikhuize, Smorenburg, De Rooij, & De Jonge, 2012). For instance, Clifton et al. (2015) analysed 16,795 observation sets from 200 postsurgical patients in a large UK teaching hospital and found only 65% of the observation sets were complete and had correctly calculated aggregated scores. Similarly, Chua, Mackey & Liaw (2013) interviewed 15 nurses and identified that timely monitoring and recording of vital signs did not always occur, with nurse participants attributing this to the difficulty of balancing workload with frequent vital sign monitoring. Poor quality vital sign monitoring is said to be the result of nurses' heavy workload in a number of studies (Hogan, 2006; James, Butler-Williams, Hunt & Cox, 2010; Wheatley, 2006). Furthermore, the nature of vital sign monitoring is repetitive and tedious, and it appears to be an easy, yet time consuming task (Beaumont, Luettel & Thomson, 2008; Rose & Clarke, 2010). As a result, nursing staff may neglect to see the importance of vital sign monitoring to identify deteriorating patients, highlighted by the increasing delegation of vital sign monitoring to unqualified staff (Mok, Wang & Liaw, 2015).

Incomplete and infrequent vital sign monitoring can hinder health professionals' ability to identify clinical deterioration, and could have implications for the current intervention to promote patient involvement in recognising deterioration. Inviting

healthcare assistants and nurses to record patients' views on changes in their wellness during routine observation creates an extra task to complete after vital sign monitoring. The above evidence suggests that nurses and healthcare assistants who have disregarded the importance of vital sign monitoring may be resistant to recording patient wellness ratings during routine observation. Negative attitudes towards vital sign monitoring, and heavy workload may account for the finding in the current study that healthcare assistants often did not rate the patients' wellness during routine observation. It may be important to understand and alter nurses' attitudes towards routine observations, and to encourage them to involve patients in recognising deterioration by routinely recording their views on changes in their wellness during observation.

4.6.4 Limitations

The findings reported here are based on data collected from patients receiving care on a small number of acute care wards within one hospital in the North of England. As such, the findings of these studies may not be generalisable to healthcare systems in other countries. Furthermore, it should be noted that the patient sample were predominantly British males, despite the sampled wards being mixed gender wards. Again, this may limit the generalisability of the findings to patients of different ethnicities. Nevertheless, patients were recruited from both medical and surgical wards and thus the conclusions drawn are relevant to both types of acute ward.

4.7 Conclusions

The findings presented here demonstrate that health professionals believe there is a role for patients in identifying clinical deterioration in hospital. This research indicates that from a patient perspective, it is feasible and acceptable to involve patients in the management of deterioration in practice by routinely recording their views on changes in their wellness during observation. It will now be important to identify approaches to collecting patient wellness ratings during routine observation that are sustainable in practice, and to begin to explore whether changes in patient-reported wellness are indicative of genuine patient deterioration. Encouraging nursing staff to have conversations with patients about their views on changes in their wellness as part of routine care may improve the early recognition of deterioration, and serve to uncover concerns

patients have that are unrelated to suspected deterioration but require a response, both of which may reduce the incidence of patient safety events.

Chapter 5

Contextual factors influencing the implementation of an intervention to promote patient and relative involvement in recognising clinical deterioration in hospital.

5.1 Chapter overview

This chapter discusses the researcher's reflections of contextual factors observed when conducting the applied health research study (study 3) described in Chapter 4. In study 3, an intervention to promote patient and relative involvement in recognising deterioration in hospital was implemented on four in-patient wards. Contextual factors observed by the researcher that appeared to facilitate or impede the implementation of the intervention are outlined in this chapter, along with hypotheses about why these factors may have influenced intervention implementation.

5.2 Background

Growing evidence states that it is important to consider the context within which health services interventions are implemented (McDonald, 2013). Contextual factors represent the local conditions that the intervention must become integrated within if it is to be feasible in practice (May, Johnson & Finch, 2016). Increasingly, research studies are exploring contextual confounders that act as barriers or facilitators to health services interventions (Mockford et al., 2015; Huis, van, Achterberg, de Bruin, Grol, Schoonhover & Hulscher, 2012; Gravel, Legare & Graham, 2006). For example, Mockford et al. (2015) investigated facilitators and barriers to the implementation of do not resuscitate orders, concluding that the context within which do not resuscitate orders are made influences decision-making and implementation. The following describes contextual factors observed by the researcher within the individual sampled wards, and across the wards when conducting the applied health research study (study 3) described in Chapter 4. These contextual factors appeared to help or

hinder the implementation of an intervention to promote patient and relative involvement in recognising clinical deterioration in hospital. Understanding factors that helped or hindered implementation of the intervention in a pilot study will be useful to guide and support implementation of the intervention on a larger scale in the future.

The wards involved in the study were purposively sampled based on cardiac arrest call audit data that was accessed through the director of Intensive Care at the hospital, a clinical contact who provided guidance to the researcher. The number of cardiac arrest calls was used to indicate the prevalence of unrecognised patient deterioration on wards, to highlight wards that might benefit most from an intervention to improve early recognition of deterioration. Two medical and surgical wards with the highest numbers of cardiac arrest calls of all inpatient wards in the hospital (excluding paediatrics and cardiology) between April 2014 and April 2015 were selected. The sampled wards have been assigned a pseudo letter to protect their anonymity.

Two approaches to routinely collecting patients', relatives' and healthcare assistants' views on changes in patient wellness were explored in the study described in Chapter 4. Initially, participants were asked to record answers to the patient wellness questions themselves after routine observations (patients and healthcare assistants), or at visiting hour (relatives). Participants were given a booklet containing Patient Wellness Questionnaires for them to complete. This approach to data collection was used on Ward W. As the pilot study progressed using this approach to data collection, it was established that participants were not routinely recording their patient wellness ratings, and sufficient data was not being collected to allow the analysis to be performed. At this point, the method of data collection was altered. The researcher attended day time routine observations and visiting hours to ask participants the Patient Wellness Questionnaire and record their responses. This approach to data collection was used on wards X and Y. No patient participants were suitable to be approached to participate in the study on Ward Z and as such, neither method of data collection was tested on this ward.

5.3 Ward W

Ward W is a vascular surgery unit that treats patients with arterial, venous and lymphatic disease which affect circulation. Lifestyle factors can contribute toward the development and severity of these disease. Where it is not possible to improve circulation in any other way, affected limbs may be amputated. Ward W was the surgical ward with the second highest number of cardiac arrests, with 11 patients suffering a cardiac arrest while on the ward between 2014 and 2015.

Some patients were receiving treatment on Ward W for health problems that had developed, in part, as a result of their own health behaviour. From my conservations with patients and ward staff, it appeared that alcohol and drug abuse, smoking, and poor management of diabetes were the most prevalent lifestyle factors that contributed towards these patients' health problems. There were some challenging patients on the ward. Nursing staff discouraged me from approaching some patients who fulfilled the inclusion criteria for the study because they were illicit drug users who could be violent. Drug paraphernalia had been found on the ward and one patient, who was under the influence of illegal drugs while being treated on the ward, was aggressive towards staff and other patients. The average length of stay on Ward W is 3 weeks, thus patients were often being cared for on the ward for long periods of time. Furthermore, repeat admissions to the ward were common and as a result staff came to know these patients.

I found it difficult to recruit healthcare assistants to the study on Ward W. These staff were often too busy, and did not have time to speak to me. One healthcare assistant who did not want to participate in the study themselves, took charge of other healthcare assistants and blocked my attempts to speak to them by assigning them tasks when I approached. It may be that staff felt threatened by the Patient Wellness Questionnaire. Some patients did use the Patient Wellness Questionnaire booklet to document perceived staff failings in the comment box during their hospital stay, rather than comment on any worries about their wellness. When approaching healthcare assistants to take part in the study, I learned that the ward relied on bank staff to provide temporary cover for shortfalls in healthcare assistants. Both bank staff and part time healthcare assistants declined participation in the study because they did not work on the ward full

time. The staff perspective of patient wellness was not documented when bank and part time staff who were not part of the study completed observations for patients who were in the study. There was a substantial lack of data recorded on healthcare assistants' ratings of patient wellness.

From speaking with patients and observing interactions between staff on the ward, I sensed that there was friction between particular patients, nursing staff and healthcare assistants. When taking part in the feedback exercise, these particular patients made some negative comments about staff attitude and the care they received. It was unknown which staff members they were referring to. Shortly after, in the staff room, certain nursing staff and healthcare assistants were talking between themselves and spoke negatively about these patients in terms of their character and behaviour. Interestingly, comments related to frustration about how frequently one patient was admitted to the ward, and questions about whether these repeat admissions were necessary. The patients who staff made negative comments about were vocal about being part of the study, prompting staff to complete the Patient Wellness Questionnaire for them and other patients in their bay who were part of the study. I was concerned that the study may have exacerbated negative feelings between these patients and staff, especially because these particular patients wanted to be part of the study and yet the healthcare assistants did not.

In the pilot study, the use of Patient Wellness Questionnaire booklets as a research method to gather the data on patient, relative and staff perspectives of changes in patient wellness was explored. The researcher was interested in whether this method of data collection was feasible in practice. Each patient and relative participant was given their own booklet containing all of the Patient Wellness Questionnaires they would be asked to complete in the study period. Each patient in the study had a Patient Wellness Questionnaire booklet to be completed by healthcare assistants after taking the patient's observations (kept with the drug charts at the end of the patient's bed). With this method, all participants were required to complete the questionnaires themselves.

After a month on Ward W using this research method, it appeared that it may not be feasible to collect the data by relying on participants completing the questionnaires in the Patient Wellness Questionnaire booklets themselves. The main problems I found with this method were firstly, that booklets would regularly

be lost from the patients' bedside, and thus any patient wellness ratings collected up until that point in the booklet were lost. Secondly, booklets kept at the end of the patients' bed for healthcare assistants to complete were often pushed to the bottom of the draw and forgotten about. One healthcare assistant suggested that the booklets be clipped in the drug chart folder as to be more visible. Although this did stop the booklets for healthcare assistants to complete from being lost, it did not encourage them to complete the questionnaire. Thirdly, it was important that participants wrote the date and time when they completed the Patient Wellness Questionnaire. In the following study (described in Chapter 6), patient wellness ratings were compared to early warning scores recorded at the corresponding time point. Therefore, in the pilot study it was important to identify a method of data collection that allowed for patient wellness ratings and the early warning scores at the corresponding time point to be identified. Yet, often patients did not write down the time and date when they completed the Patient Wellness Questionnaire. Also, the clocks in all bays were showing the wrong date and time, thus for patients who did write the date and time, it may have been incorrect or relied on them remembering by how many days and minutes the clock was wrong.

To address these issues, the method of data collection was modified. Instead of relying on patients, relatives and healthcare assistants to complete the Patient Wellness Questionnaire themselves using the booklet, the researcher attended each daytime observation (these were at roughly 10am, 2pm and 6pm) and visiting hours to ask patients, healthcare assistants and relatives the Patient Wellness Questionnaire and record their responses. This method of data collection was adopted after trialling the participant recorded patient wellness rating method on Ward W for one month. Having the researcher attended each daytime observation and visiting hours to ask patients, healthcare assistants and relatives the Patient Wellness Questionnaire and record their responses is not a method of data collection that is feasible in practice. However, it was important to obtain sufficient data on recording participants' views on changes in patient wellness using the patient wellness questions. Future research could explore processes for implementation in practice. This method of data collection did allow a greater amount of patient wellness data to be collected, however, the study no longer encouraged conversations between healthcare assistants and patients

about patient wellness. The researcher now asked healthcare assistants and patients the patient wellness questions.

5.4 Ward X

Ward X is a renal medical ward that treats patients with kidney disease who require inpatient care. This was the medical ward with the fourth highest number of cardiac arrests, with 15 cardiac arrests occurring on the ward between 2014 and 2015. Patients on Ward X receive renal replacement therapies (dialysis), and may also be receiving follow-up care after a kidney transplant. As with Ward W, lifestyle factors can contribute toward the development and severity of kidney disease. While conducting the pilot study on Ward X, the senior ward sister suggested that Ward X may benefit from increased patient and relative involvement in recognising deterioration, providing further justification for the use of Ward X as a pilot site. To gain access to Ward X, I first approached a consultant to discuss the study. He was particularly interested in how much input was required from staff and warned that there was low morale amongst nursing staff on the ward, therefore it might not be possible to use the ward as a pilot site. Despite this, the senior ward sister kindly allowed me to conduct the pilot study on the ward.

I attended the nursing handover every couple of days while recruiting on Ward X to introduce myself, and the study, to nursing staff and healthcare assistants. Attending handover was a useful opportunity to raise awareness of the study amongst staff, and allowed me to approach all healthcare assistants working that day at once to ask them if they would like to participate in the study. I felt healthcare assistants on Ward X were more receptive to participating in the research compared to Wards W. This may be because the new method of data collection was less burdensome on healthcare assistants. Instead of having to complete the Patient Wellness Questionnaire themselves using the booklet, I asked healthcare assistants the patient wellness questions and recorded their answers. I often found that they would be completing observations while I asked them the patient wellness questions, and thus using this research method they did not have to break off from their tasks. Although this research method allowed healthcare assistants to continue doing patient observations, this meant they gave their perspective on changes in patients' wellness within ear shot of the

patient. It may be that healthcare assistants would not give an honest opinion if they felt the patient's health had worsened so as to not worry the patient.

As with Ward W, the large majority of healthcare assistants working on the ward were bank staff. While talking to one healthcare assistant about the study, she told me the ward were severely short staffed and there were many more bank healthcare assistants than there were permanent. I found that there was no continuity of healthcare assistants as bank staff would often work just one day on Ward X before moving to a different ward. For this reason, 3 healthcare assistants declined participation in the study because they felt they couldn't make judgements on changes in the patients' wellness because they did not know the patients. Having a large number of bank staff made it difficult to collect data on healthcare assistants' views of changes in patient wellness at each observation. First, because collecting the data relied on the large number of healthcare assistants that do a patients observations over a number of days agreeing to participate in the study. Second, where healthcare assistants did agree to participate, they often said they could not make a judgement on changes in patient wellness after an observation as it was the first time they had met the patient. Furthermore, at times the healthcare assistants who wanted to participate in the study were working in a different bay from the patients who wanted to be part of the study. In these instances, the healthcare assistant perspective was not captured after observations.

5.5 Ward Y

Ward Y is a surgical Progressive Care Unit that is used as an intermediary step between the Intensive Care Unit and surgical wards. This was the surgical ward with the third highest number of cardiac arrests, with 10 cardiac arrests occurring on the ward between 2014 and 2015. Patients admitted to Ward Y require a high level of skilled nursing care and surveillance, and are too unwell to be cared for on a surgical ward. However, these patients are more stable than those admitted to the Intensive Care Unit (Stacy, 2011). Patients are down streamed from Ward Y to a surgical ward once their condition improves. Patients being cared for on Ward Y have recently undergone major surgery.

The average length of stay on Ward Y is 5 days. Patients who were being cared for on the ward for a long length of time were often too unwell to participate in

the study. Nursing staff directed me to potential participants who had capacity, and who they felt were well enough to take part. However, after being recruited, often these patients were soon moved to a typical surgical ward because their condition improved, making it difficult to retain participants in the study on Ward Y.

As with Ward X, I attended the nursing handover every couple of days while recruiting on the ward to introduce myself, and the study, to nursing staff and healthcare assistants. During a nursing handover, a member of staff raised concerns about the relatives of one patient being rude and nasty to staff members caring for the patient. The relatives felt the patient's care was unsatisfactory as they had been 'left in a state' because their stoma bag had leaked. The staff member raising the concern said there had been difficulty fitting the stoma bag, and that the relatives were then scanning to find faults with the patient's care. Where there has already been conflict between relatives and nursing staff, it may be that this intervention could worsen mistrust, as observed on Ward W where staff became aware that the patient was using the patient wellness booklet to document perceived staff failings. Patients and relatives on Ward Y were not using the patient wellness booklets to record their views on changes in patient wellness, but nevertheless, I felt it was inappropriate to approach this patient and their relatives about the study to avoid the potential for exacerbating problems.

On all wards I found that the majority of patients who were recruited to the study were mostly well and shortly to be down streamed or discharged from hospital. It was not possible to recruit more unwell patients whose conditions may be more likely to deteriorate because they were not well enough to follow the process of gaining informed consent. Healthcare assistants and nursing staff often asked patients how they were feeling as part of usual care. Therefore, these more unwell patients may have had the capacity to talk to healthcare staff about how they are feeling during routine observation in the study. The ratings one patient gave of their wellness in response to the patient wellness questions indicated that their wellness was declining. After giving one set of ratings indicating a decline in their health, they withdrew from the study and said they felt too unwell to participate. It may be that this patient participant withdrew from the study because it was the researcher, an extra person outside the direct care team, who

was asking them about their wellness. If a member of healthcare staff, rather than the researcher, were asking patients about their wellness during observation, this may be less onerous for the patient.

5.6 Ward Z

Ward Z is a Medical Assessment Unit, and was sampled because cardiac arrest call audit data indicated it was the medical ward with the second highest number of cardiac arrests between 2014 and 2015. Patients are usually admitted to Ward Z from Accident and Emergency or are sent to hospital by their General Practitioner where they are first assessed on the ward. The role of Ward Z is to provide timely evaluation of patients and initiate treatment. Patients are often discharged home but if they require further treatment then they are transferred to the appropriate ward. However, the intervention did require patients to answer questions about changes in their wellness during routine monitoring over a number of days. I found that as Ward Z was an assessment unit, the length of patient stay was very short with the majority of patients being treated on the ward for no longer than a few hours. It was likely that only one routine clinical observation was carried out in this time. If patients were treated on the ward for a longer time period, these were outliers with contagious diseases staying in side rooms who were often too unwell to participate. No patient participants were recruited on Ward Z suggesting it was not possible to record patients' views on changes in their wellness during clinical observation here. For these reasons, the intervention was felt to be inappropriate for Ward Z and attempts to approach and recruit participants on this ward were stopped after a week.

5.7 Summary of considerations for implementing an intervention to routinely record patient-reported wellness in practice

When determining the type of ward this intervention may be suitable for, it will be important to consider the average length of patient stay. Piloting the intervention on a Medical Assessment Unit, where patients are usually treated for no longer than a few hours indicated that the utility of this intervention may be limited for wards where the average length of patient stay is very short. Only one observation may be conducted for patients while they are treated on such wards.

In order to capture a change in patient-reported wellness that could potentially aid health professionals in recognising clinical deterioration, it may be necessary to record patient wellness ratings during a number of observations. It is likely that a different approach to involving patients in the management of deterioration would be needed on short stay wards, and warrants investigation in future research.

Asking patients to complete the Patient Wellness Questionnaire themselves (where possible) after observation appeared to be infeasible. A number of factors were identified that impacted the feasibility of asking patients to record their own patient wellness ratings. These included patients' level of sight and writing ability to allow them to read the patient wellness questions and write down their patient wellness ratings, patients' difficulty in remembering to answer the Patient Wellness Questionnaire, and whether they had access to correct information about the date and time to record when they answered the patient wellness questions. It may be important to consider other approaches to routinely recording patients' views on changes in their wellness using the Patient Wellness Questionnaire.

Healthcare assistants and nursing staff often asked patients how they were feeling as part of usual care, and health professionals interviewed in study 1 suggested that staff could routinely ask patients about their wellness during observation, an idea supported by healthcare assistants during a focus group in study 2. Yet, there was little uptake where staff were invited to routinely ask patients about their wellness using the Patient Wellness Questionnaire, and record their responses during observation in the pilot study. It may be that healthcare assistants and nursing staff need support in order to begin performing this additional activity. Extensive literature indicates that targeted behaviour change techniques can be effective to encourage and support health professionals in adopting new evidence-based practices (Davey 2013; Dombrowski et al., 2016; Ivers et al., 2012). It may be important to consider ways to support health professionals to adopt a change in practice, for instance by using targeted behaviour change techniques to encourage healthcare assistants and nursing staff to ask patients the Patient Wellness Questionnaire and record their responses during routine observation.

Chapter 6

Are patients' views on changes in their wellness associated with clinical deterioration in their condition?

6.1 Chapter summary

In the study reported in this chapter (study 4), a potentially sustainable approach to collecting patients' views on changes in their wellness (patient wellness ratings) during routine observation was implemented. Nursing staff and healthcare assistants working on four in-patient wards were invited to ask patients the Patient Wellness Questionnaire and record patients' wellness ratings during routine observation. The efficacy of using targeted behaviour change techniques to encourage nursing staff and healthcare assistants to adopt this change in practice was also explored. Furthermore, the relationship between patient-reported wellness and early warning scores (EWS), an objective indicator of clinical deterioration, was explored to assess the extent to which patients can recognise genuine deterioration in their condition. The relationship between patient-reported wellness and the vital sign measurements that make up the EWS was also explored. An understanding of the clinical value of routinely recording patient-reported wellness began to be developed within this study. The findings are discussed along with implications and recommendations for healthcare services.

6.2 Background

A series of studies, outlined in Chapter 4, were conducted to explore the feasibility of approaches to routinely collecting information from patients, relatives and healthcare staff about changes in patients' health and wellness. In collaboration with patient representatives and healthcare assistants, versions of a questionnaire, referred to as the Patient Wellness Questionnaire, were developed to prompt these groups for their views on changes in patient wellness. As previously described in Chapter 4, variability in patients' ratings of their

wellness suggest that the Patient Wellness Questionnaire has the sensitivity to measure patient-reported changes in wellness. Furthermore, most patient participants were willing and able to give information about changes in their wellness during routine observations when asked the Patient Wellness Questionnaire by the researcher who recorded their responses. Although, it should be acknowledged that some patients were too unwell to complete the consent process to participate, and some who could have consented did not want to participate.

Where the researcher recorded patient wellness ratings at observations, this allowed sufficient data to be collected to ensure that the feasibility and acceptability of the intervention could be explored from the perspectives of patients. However, this approach to routinely recording patient-reported wellness is not sustainable in practice. Inviting healthcare staff to record patient wellness ratings during routine observation may be sustainable. This was an idea supported by healthcare assistants during focus group discussion described in Chapter 4. They felt that staff would be willing to routinely ask patients about their wellness, and record their responses because they already speak to patients about their views on their health and wellness as part of usual care. The current study explored whether patient-reported changes in wellness recorded at routine observation are associated with, or predictive of, genuine patient deterioration.

In terms of previous literature relating to the current study, research conducted in Denmark found that routine blood tests were associated with short-term mortality in patients in an Emergency Department (Kristensen et al., 2017). Further research conducted in the UK explored the combined use of blood test results and EWS taken within 24 hours of emergency hospital admission to predict the risk of in-hospital mortality (Mohammed et al., 2013). Findings based on 23,248 emergency hospital admissions identified that EWS, albumin, sodium, white cell count and urea were significant ($p < 0.001$) predictors of death. The use of routine blood test results and EWS taken within 24 hours of admission provided good discrimination to aid identification of deteriorating patients (Mohammed et al., 2013).

In another study, nurses were invited to routinely rate their level of worry for a patient's condition at least one per shift or at any time using a clinical assessment tool (Douw, Huisman-de Waal, van Zanten, van der Hoeven & Schoonhoven,

2016). They found that adding the EWS to indicators in the clinical assessment tool for nurse worry improved the prediction of unplanned intensive care admissions and unexpected mortality (Douw et al., 2016). The current study is the first to explore whether routinely recorded patient-reported changes in wellness have the potential to be a valuable indicator of clinical deterioration when used in addition to the EWS.

As highlighted in the systematic review described in Chapter 2, patient and relative led escalation systems implemented in the reviewed studies do not consider the extent to which patients and relatives can effectively monitor changes in their condition, and there is scant evidence exploring the ability of patients and relatives to recognise signs of the patients' deteriorating condition. In order to better understand the clinical effectiveness of involving patients in the management of deterioration, it will be important to close this evidence gap. As Douw et al. (2016) found when considering nurse level of worry, it may be that considering routinely recorded patient-reported changes in wellness, alongside patients' vital signs could improve the ability of the EWS to predict outcomes associated with patient deterioration. Gaining a greater understanding of the relationship between patient-reported wellness and objective measures of health, such as the EWS will shed light on the ability of patients to recognise genuine deterioration in their condition, and the utility of involving patients in the management of deterioration to improve early recognition and timely response.

6.2.1 Use of behaviour change techniques to encourage changes in health professional behaviour

To investigate the relationship between patient-reported changes in wellness and objective indicators of clinical deterioration (for example, the EWS), healthcare staff will be required to perform a new behaviour as part of routine patient care; that being to ask patients the Patient Wellness Questionnaire and record their wellness ratings during observations. Identifying effective ways to encourage health professionals to embed clinical evidence in to their daily practice is vital (Johnson & May, 2015). There is a substantial literature exploring the use of behaviour change techniques (BCTs) to encourage the adoption of evidence-based practice in health professionals. BCTs are defined as an "observable, replicable, and irreducible component of an intervention designed to alter or redirect causal processes that regulate behaviour" (Michie et al., 2013,

p. 82). Researchers have used theories of behaviour to identify behavioural determinants, and develop a taxonomy of evidence-based BCTs proposed to be effective in altering specific determinants of behaviour (Michie, Johnston, Francis, Hardeman & Eccles, 2008).

Numerous reviews have demonstrated the effective use of BCTs to encourage positive changes in health professional behaviour (Davey 2013; Dombrowski et al., 2016). Ivers et al. (2012) reviewed 140 studies exploring the use of audit and feedback to influence aspects of professional practice, such as prescribing. They found small improvements in health professionals' compliance with desirable practice. Furthermore, a recent review of professional behaviour change interventions conducted by Johnson and May (2015) identified interventions that fell into three main categories: persuasive; educational and informational; and action and monitoring. Interventions in each of these categories used BCTs linked to determinants of behaviour. It was found that behaviour change interventions using techniques based on action (for example, audit, feedback and reminders) and education were more effective at changing professional behaviour than those based on persuasion (for example, local consensus). Using BCTs targeted at determinants of behaviour that may be important when encouraging staff to routinely record patient-reported changes in wellness may be an effective way to increase uptake of this new behaviour. The targeted behaviour change techniques utilised, and literature informing these decisions are discussed later in this chapter in the 'Behaviour change session' section under the heading 'Procedure'.

6.2.2 Aims

With regards to identifying an approach to collecting patient wellness ratings during observations that is sustainable in practice, the following research questions were investigated:

(1) What is the feasibility in practice of involving patients in the management of deterioration by inviting healthcare staff to ask patients the Patient Wellness Questionnaire and record their responses during routine observations? Feasibility will be explored in terms of uptake of this change in practice and its impact on staff workload.

(2) Does the use of motivational and action planning behaviour change techniques encourage healthcare staff to ask patients the Patient

Wellness Questionnaire and record their responses during routine observations?

To address the paucity of evidence exploring the extent to which patients can recognise signs of their deteriorating condition, the study aimed to explore the following research questions:

(3) Is there a correlation between the patient wellness ratings, and EWS and individual vital signs recorded during the same observation?
(4) Do patient wellness ratings predict subsequent EWS and individual vital signs recorded during the next observation and an observation approximately 24 hours later?
(5) What factors moderate the relationship between patient wellness ratings and EWS?

6.3 Methods

6.3.1 Ethical approval

Ethical approval for this study was granted by the NHS Health Research Authority Yorkshire and Humber Research Ethics Committee (Reference: 17/YH/0210). All data was handled in a robust and transparent manner, applying confidentiality and security where appropriate and operating to high ethical and quality standards as outlined by the Health Research Authority's framework for Information Governance.

6.3.2 Setting and participants

The study was conducted within a small community hospital in Yorkshire and Humber that houses a Centre for Oncology. The participating wards were four Oncology wards. Cancer accounts for 28% of deaths in the UK (Office for National Statistics, 2015), and cancer patients can experience poor clinical outcomes, such as clinical deterioration in their condition (Sundar et al., 2017). Pragmatic reasons to invite these wards to participate included their use of an electronic observation system, which allowed for the efficient collection of patient wellness ratings during observation with minimal disruption to the usual routine of healthcare staff. Instead of using the traditional paper based charts, the patients' vital sign measurements are input in to an electronic observation application on a smartphone device. There is also a free text box for healthcare

staff to record notes about the patients' condition. The patients' NHS number can then be used to identify their vital sign measurements and notes electronically. At the time of the study, electronic observation had been in use on each participating ward for different lengths of time (approximately one year, 8 months, 5 months and 3 months).

Healthcare assistant and nursing staff who conducted routine patient observations on the sampled wards were eligible to participate, and these could be permanent or temporary members of staff.

6.3.3 Ward context

Three of the participating wards are primarily Oncology wards, and the fourth is primarily a haematology ward that also incorporates a High Dependency Unit. Each of the four wards has 25 beds. Compared to the three Oncology wards, the haematology ward cares for patients who are the most acutely unwell, and administers chemotherapy to the most patients. One of the Oncology wards cares for patients who are mostly in the palliative stages of cancer. The remaining two Oncology wards care for patients who are moderate in terms of the acuity of their illness.

In terms of adoption of the electronic observation system, two of the participating wards were categorised as engaged, and two were categorised as disengaged with the electronic observation system. These categorisations were based on the perceptions of senior staff who implemented the electronic observation system and trained ward staff to use it, and were recorded prior to starting the study. Their perceptions of ward engagement were based on the wards previous level of engagement with the electronic observation system, such as their attitude to the introduction of the electronic observation system, timeliness of observations using the system and use of the free text box to record notes about the patients' condition.

6.3.4 Procedure

An opportunity sampling strategy was used to recruit healthcare assistants and nursing staff. All nurses and healthcare assistants on shift were approached during their lunch break and given written and verbal information about how they would be involved in the study and had the opportunity to ask the researcher any questions. Healthcare assistants and nurses were invited to participate in the

study because they conduct routine observations with patients. Potential participants were given at least 24 hours to consider if they would like to participate in the study, after which they were approached again during their lunch break to give written informed consent. Participating staff on all four wards were given verbal instructions by the researcher regarding how and when to ask the Patient Wellness Questionnaire, and how and where to record patients' responses to the questions in the electronic observation application. Two of the four participating wards (one engaged and one disengaged ward) were also randomly assigned to the experimental group. Healthcare assistants and nurses working on these wards participated in a 15 minute behaviour change session led by the researcher prior to starting the study. The session used evidence-based behaviour change techniques to encourage healthcare assistants and nurses to ask patients the Patient Wellness Questionnaire during every routine observation, and record their responses (Please see 'behaviour change session' section below for further details).

For the four week study period, as part of routine care, participants were invited to ask patients the two-item Patient Wellness Questionnaire during each routine observation. They then recorded patients' responses by entering their two numerical wellness ratings in to the electronic observation application along with the patients' vital sign measurements. Environmental cues were used on all four participating wards to prompt nurses and healthcare assistants to ask patients the Patient Wellness Questionnaire during observation. Here, the questionnaire was printed, laminated and displayed on the trolley that is moved from patient to patient to measure their vital signs during observation. Although this was part of routine care, the ward sisters assessed the capacity of patients to ensure that they were well enough to participate in the study. Where patients did not want to participate or were not well enough, the following options were available for participants to input in to the electronic observation application: 1) the patient refused to answer, 2) unable to ask Patient Wellness Questionnaire because the patients' medical condition makes it difficult for them to answer. For time efficiency, participants were told they could just input the words 'refused' or 'unable' in to the application to represent the above options. A senior staff member who implemented and trained ward staff on the electronic observation system visited all four wards once a week during the study period to verbally

encourage participating nurses and healthcare assistants to ask patients the Patient Wellness Questionnaire at every observation, and record their responses.

Individual patients did not provide informed consent to participate in the study. Instead, an opt-out approach to patient recruitment was used. A leaflet was given to all patients on admission to the ward by the admitting healthcare assistant or nurse. The leaflet informed patients that the study was taking place, and that they could opt-out of it by telling the nursing staff who informed the researcher. The NHS Health Research Authority Yorkshire and Humber Research Ethics Committee deemed this approach to patient recruitment ethically sound because in current practice patients are asked how they are feeling during routine observation as part usual care (although they are not asked using standardised questions and their responses are not recorded). As such, participating in this study was a low burden to patients because what they experienced was consistent with usual care. An opt out approach to patient recruitment was inclusive in that all patients could be involved, including those who may be too unwell to follow the consent process but were capable of telling nurses and healthcare assistants how they were feeling.

The researcher directly observed participants conducting 20 patient observations (5 observations per ward) to explore whether asking the Patient Wellness Questionnaire as part of routine observation affected healthcare assistant and nurse participants' workload. Directly observing healthcare processes is a rich method for understanding safety and performance improvement (Catchpole et al., 2017), and enabled the researcher to investigate the impact of introducing a new behaviour in to patient observation. An observation framework was designed to guide the researcher in observing the patient observation and recording pertinent information in order to answer the research question (Please see Appendix 10 for observation framework). While observing patient observations, the researcher recorded information about the length of the patient observation, activities occurring as a result of asking the Patient Wellness Questionnaire, and time taken to complete any activities.

6.3.4.1 Patient Wellness Questionnaire

Analysis in Chapter 4 indicated that *Version B* of the Patient Wellness Questionnaire may be the most appropriate version to use to gather patient-reported wellness in future research because it produced the greatest variability in patient wellness ratings. Senior ward staff on the four participating wards were approached and invited to participate in the study described in the current chapter. During this initial meeting, the researcher showed the three Patient Wellness Questionnaire versions to the nursing staff and explained the findings from the pilot study described in Chapter 4, suggesting that *Version B* would be the most appropriate to use (See Table 6.1 for the three Patient Wellness Questionnaire versions). Senior ward staff on the participating wards felt *Version C* of the Patient Wellness Questionnaire was most suitable to use in the current study due to its simplicity and similarity to wording used by staff when talking to patients. The pilot study reported in Chapter 4 demonstrated that *Version C* also produced variability in patient wellness ratings, and most patients felt this version was understandable and appropriate. As such, *Version C* of the Patient Wellness Questionnaire was used in the current study, as opposed to *Version B*. It is worth noting that *Version B* and *C* of the Patient Wellness Questionnaire are identical except for the response option for the first patient wellness question.

Table 6.1 Patient Wellness Questionnaire versions

Version A

How are you feeling?

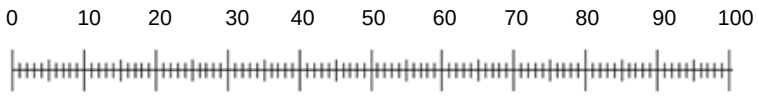
1	2	3	4	5
Very poor	Poor	Fair	Good	Very good

Are you worried about how you are feeling?

Yes	No	Don't know
☐	☐	☐

Version B

How are you feeling?



The worst health you can imagine

The best health you can imagine

How are you feeling compared to the last time we asked you?

1	2	3	4	5
Much worse	Worse	No change	Better	Much better

Version C

How are you feeling?

1	2	3	4	5
Very poor	Poor	Fair	Good	Very good

How are you feeling compared to the last time we asked you?

1	2	3	4	5
Much worse	Worse	No change	Better	Much better

6.3.4.2 Behaviour change session

It may be that some healthcare assistants or nurses are not motivated to adopt a change in practice, and ask patients the Patient Wellness Questionnaire during routine observation. Motivation is one of three essential conditions needed for behaviour to occur (Michie, van Stralen & West, 2011). Michie, Johnston, Francis, Hardeman and Eccles (2008) have linked behaviour change techniques with determinants of behaviour. Behaviour change techniques judged to be effective at changing people's motivation to carry out a behaviour include providing information about the behaviour and outcomes, and identifying and preparing for problems. Drawing upon this evidence, the behaviour change session conducted with participants used these evidence-based behaviour change techniques to increase the motivation of nurses and healthcare assistants to ask patients the Patient Wellness Questionnaire and record their responses. Information about why it may be important to record patients' views on changes in their wellness and how this could improve the management of deterioration was first provided. Participants then proposed potential problems with recording patients' views on changes in their wellness during routine observation, and worked together with the researcher and other participants in the session to identify resolutions to these problems.

Techniques judged to be effective at helping people make actions plans to carry out a behaviour include planning and implementation. Asking patients the Patient Wellness Questionnaire and recording their responses during routine observation is a repeated behaviour performed in a stable context, and as such, these are ideal conditions for this task to become a habit (Gardener, Sheals, Wardle & McGowan, 2014). Forming implementation intentions is an evidence based behaviour change technique (Michie et al., 2013) that has been cited as a method to encourage habit formation (Gardner et al., 2014). Implementation intentions are if-then plans that encourage habit formation (Gollwitzer, 1999). Drawing upon this evidence, in the behaviour change session participants also formed written implementation intentions to ask patients the Patient Wellness Questionnaire and record their responses during routine observations.

6.3.5 Data analysis

A two-way between subjects analysis of variance (ANOVA) was conducted to compare the effects of (1) receiving a behaviour change session; and (2) level of

ward engagement, on the number of patient wellness ratings recorded at observation during the study period (aim 2). Behaviour change session included two levels (an experimental group where staff received a behaviour change session and a control group where they did not). Level of ward engagement also included two levels (wards engaged with the electronic observation system and wards disengaged with the electronic observation system), as defined by senior staff who implemented and trained ward staff on the electronic observation system prior to randomisation.

A multilevel linear model was used to examine the relationship between patient wellness ratings, and EWS and vital sign measurements recorded during the same observation (aim 3), and whether patient wellness ratings predict subsequent EWS or vital sign measurements (aim 4). The moderating effect of patient age, gender and acuity of their illness on the relationship between patient wellness ratings and EWS or vitals sign measurements was also explored in the multi-level models (aim 5). The term “Multilevel random coefficient model” (MRCM), often simplified as ‘multilevel model’ refers to the statistical technique of analysing hierarchically structured data, and “Hierarchical Linear Model” (HLM) is the program used to carry out multilevel modelling. Multilevel analysis allows the phenomena of interest to be explored at different levels of analysis simultaneously (Nezlek, 2001). HLM assesses nested data structures that have relationships within a certain hierarchical level, and can simultaneously analyse relationships between hierarchical levels (Griffin, 1997). Relationships established at an individual level can be explored to determine if they differ between participants, and if person-level factors, such as gender, moderate them. Such analysis allows for the control of repeated measurements taken for individual patients.

Two levels of data were used in the multilevel model. The level 1 data file contained within-participant variables (patient wellness ratings, EWS and individual vital sign measurements that compose the EWS) that were centred around the group mean. The level 1 data file included EWS and vital sign measurements recorded during the same observation as patient wellness ratings, EWS and vital sign measurements recoded during the next observation after that where patient wellness ratings were recorded, and EWS and vital sign measurements recorded during an observation approximately 24 hours

(between 20 to 28 hours) after that where patient wellness ratings were recorded. The time interval between the initial observation and the next observation varied between patients (*M* = 6 hours, 13 minutes; SD = 3 hours, 46 minutes; Min = 17 minutes; Max = 22 hours, 55 minutes). To the researcher's knowledge, there is no previous literature investigating the ability of patients to predict deterioration in their condition to guide the time points chosen in the current study. Therefore, these time points were chosen pragmatically to explore the ability of changes in patient-reported wellness to predict subsequent changes in objective indicators of health (EWS and vital sign measurements).

The level 2 data file contained between-participant variables (age, gender and acuity of illness) that were centred around the grand mean (Louch, O'Hara, Gardner & O'Connor, 2017). In order to measure acuity of patient illness, the average number of patient observations conducted within 24 hours during the patients' hospital stay was used as a proxy measure. The frequency of patient observations increase if abnormal physiology is detected (Petersen, Mackel, Antonsen & Rasmussen, 2014). As such, a greater number of patient observations conducted during a hospital stay indicates that the patient has been more acutely unwell, and experienced more instability in their condition than someone with less patient observations. It is acknowledged that using the average number of observations conducted in 24 hours during a hospital stay as a proxy measure for acuity of illness does not account for differences in the length and number of acute episodes of illness between patients. For instance, two patients may both have an average of 4 observations per 24 hours, yet the length and number of acute episodes of illness they experienced may be different and this information is not captured. Nevertheless, it was felt this was the most pragmatic approach to measuring acuity of illness, given the routinely collected data available.

6.4 Results

6.4.1 Participants

Senior ward staff on the participating wards stated that approximately 90 nurses and healthcare assistants worked across the wards. Of these, a total of 73 nurses and healthcare assistants were invited to participate in the study (81% of all nurses and healthcare assistants working on the wards). Of these, 69 nurses

and healthcare assistants provided informed consent and participated (95% of nurses and healthcare assistants approached). It is likely that the nurses and healthcare assistants who were not approached to participate in the study were working night shifts during the study period. Where potential participants gave a reason for declining participation, 3 said they did not have enough time due to a heavy workload and one was going on annual leave during the study period.

6.4.2 Feasibility of recording patient-reported wellness during routine observation

At least one patient wellness rating was recorded during observation for 103 of the 125 patients cared for on the four participating wards during the study period. ‘Patient refused to answer’ or ‘refused’ was input in to the electronic observation application by nurse and healthcare assistant participants for 2 patients. ‘Unable to ask Patient Wellness Questionnaire because the patients' medical condition makes it difficult for them to answer’ or ‘unable’ was not entered in to the electronic observation application for any of the patients during the study period. Of the total number of observations conducted for all patients during the study period, a patient wellness rating was recorded during 14% of observations with a range of 3% to 55%.

The researcher directly observed participants conducting 20 patient observations (5 observations per ward) to investigate whether asking patient wellness questions as part of routine observation increased their workload. Participants were required to complete activities as a result of asking the Patient Wellness Questionnaire in 3 of the 20 patient observations observed by the researcher. In two of these observations, the patient said they were in pain and asked for pain relief medication. The healthcare assistant or nurse participants proceeded to get these patients pain relief medication, which took approximately 15 minutes as they left the ward to retrieve the medication. In the third observation, the patient said they thought a dressing needed changing. The participant finished the round of patient observations and returned to the patient to change their dressing which took approximately 3 minutes.

6.4.3 Effects of a behaviour change session on participants recording of patient wellness ratings during observation

A two-way between subjects analysis of variance (ANOVA) was conducted to compare the effects of (1) receiving a behaviour change session (experimental

and control); and (2) level of ward engagement (engaged or disengaged), on the number of patient wellness ratings recorded at observation during the study period.

There was a significant main effect of behaviour change session on the number of patient wellness ratings recorded at observation, $F(1, 99) = 5.71$, $p < .05$, $\eta^2p = .54$, with staff in the experimental group recording more patient wellness ratings at observation [$M = 7.64$, $SD = 9.38$] compared to staff in the control group [$M = 4.47$, $SD = 3.7$]. There was also a significant main effect of ward engagement level on the number of patient wellness ratings recorded at observation, $F(1, 99) = 11.41$, $p = .001$, $\eta^2p = .103$, with staff on wards engaged with the electronic observation system recording more patient wellness ratings [$M = 7.6$, $SD = 8.64$] than staff on disengaged wards [$M = 3.94$, $SD = 3.61$].

The main effects were qualified by a significant interaction between the effects of behaviour change session and ward engagement level on number of patient wellness ratings recorded at observation, $F(1, 99) = 10.41$, $p < .05$, $\eta^2p = .095$. Simple main effects analysis showed that staff on engaged wards [$M = 11.57$, $SD = 11.36$] recorded significantly more patient wellness ratings at observation than staff on disengaged wards [$M = 3.33$, $SD = 3.18$] when they received a behaviour change session. There was also a significant difference between the number of patient wellness ratings recorded at observation by staff on engaged wards that did receive the behaviour change session [$M = 11.57$, $SD = 11.36$] and staff on engaged wards that did not receive the behaviour change session [$M = 4.57$, $SD = 3.76$], $F(1, 51) = 10.02$, $p = < .05$, η^2p .164. There was no significant difference between the number of patient wellness ratings recorded at observation by staff on disengaged wards that did receive the behaviour change session [$M = 3.33$, $SD = 3.18$] and staff on disengaged wards that did not receive the behaviour change session [$M = 4.38$, $SD = 3.9$], $F(1, 48) = 1.02$, $p = .318$, $\eta^2p = .021$. The percentage of observations where patient wellness ratings were recorded by nurse and healthcare assistant participants by ward are as follows; engaged ward in the experimental group (16%), engaged ward in the control group (12%), disengaged ward in the experimental group (10%), and disengaged ward in the control group (13%).

The results indicate that receiving a behaviour change session was effective at increasing the number of patient wellness ratings recorded by staff participants on engaged wards only.

6.4.4 Descriptive statistics

Descriptive statistics for all variables are reported in Table 6.2. The normal ranges for vital sign measurements used in the EWS observation chart, issued by Royal College of Physicians (2012) are described. A patients' respiratory rate should fall between 12 and 20 breaths per minute, oxygen saturation should be between 96% and 100%, temperature should range between 36°C and 38°C, systolic blood pressure should fall between 110 mmHg and 220mmHg and heart rate should be between 50 and 90 beats per minute. The mean vital sign measurements for the sample of patients fell within the normal ranges, suggesting that the sample were on average generally well. Although, the lower and/or upper ranges for all vital sign measurements fell outside of the normal range for vital signs, indicating that patients in the sample had abnormal vital sign measures. 28% of 103 patients had an EWS of 3 or above during the study period. An EWS of 3 or above triggers escalation of patient care as instructed by steps in the EWS flow chart (National Clinical Effectiveness Committee, 2013). The percentage of vital sign measurements that fell outside of the normal range during baseline observations for all patients in the sample were as follows; 5% of respiratory rate measurements, 10% of oxygen saturation measurements, 16% of temperature measurements, 23% of systolic blood pressure measurements and 32% of heart rate measurements.

Table 6.2 Descriptive statistics for all variables

	M	*SD*	Min	Max
PWR1	3.35	0.81	1	5
PWR2	2.87	0.74	1	5
Same observation (baseline)				
EWS	1.45	1.61	0	11
RR	16.76	2.26	10	32
O2 Sats	97.21	1.51	90	100
Temp	36.56	0.82	32.60	46.10
BP Systolic	121.21	17.35	65	195
BP Diastolic	70.63	11.03	43	110
HR	84.28	14.18	46	129
Next observation				
EWS	1.45	1.62	0	11
RR	16.82	2.56	9	40
O2 Sats	97.06	1.88	70	100
Temp	36.57	.70	35.0	39.4
BP Systolic	121.68	17.26	58	197
BP Diastolic	70.19	11.93	40	120
HR	83.39	14.03	51	138
Observation 24 hours later				
EWS	1.38	1.46	0	9
RR	16.93	2.74	10	42
O2 Sats	97.19	1.87	70	100
Temp	36.57	0.76	34.8	40.1
BP Systolic	122.99	17.92	84	196
BP Diastolic	70.53	10.91	40	103
HR	84.17	14.65	50	130

Note: M = mean, *SD* = standard deviation, EWS = early warning score, PWR1 = patient wellness rating (question 1), PWR2 = patient wellness rating (question 2), RR = respiratory rate, O2 Sats = oxygen saturation, Temp = temperature, BP systolic = blood pressure systolic, BP Diastolic = blood pressure diastolic, HR = heart rate.

6.4.5 Level 1 models

Level 1 models were examined to investigate the effect of patient wellness rating 1 (Very poor (1), poor (2), fair (3), good (4), very good (5) in response to the question ‘How are you feeling?’) on total EWS, as well as individual vital sign measurements recorded during the same observation, during the next observation and during an observation approximately 24 hours later. For all analyses the estimation of random effects with robust standard errors are reported. The analyses controlled for repeated measurements on patients.

6.4.6 Relationship between patient wellness rating 1, and EWS and vital sign measurements recorded within an observation

The results for the predictor (patient wellness rating 1) modelled independently on EWS and vital sign measures recorded during the same observation are presented in Table 6.3. The findings showed that the EWS and vital sign measurements were significantly different from zero (β_{00}). More importantly, the results also showed no significant associations between patient wellness rating 1 and EWS or vital sign measurements. A marginally significant negative association between patient wellness rating 1 and respiratory rate ($\beta = -0.278$, $p = 0.053$) was found, along with a marginally positive association between patient wellness rating 1 and oxygen saturation ($\beta = 0.178$, $p = 0.068$). These relationships were in the predicted direction but did not reach the usual level of statistical significance.

Table 6.3 Within-person associations between patient wellness rating 1, and EWS and individual vital sign measurements recorded during the same observation

HLM Effect	Symbol	Coeff	SE	Standard coeff	*p*
Intercept: EWS	β_{00}	1.307	0.140	0.656	< .001
Level 1 slope: PWR - EWS	β_{10}	-0.115	0.090	-0.058	0.202
Intercept: RR	β_{00}	16.757	0.205	6.004	< .001
Level 1 slope: PWR - RR	β_{10}	-0.278	0.142	-0.010	0.053
Intercept: O2 Sats	β_{00}	97.091	0.116	52.087	< .001
Level 1 slope: PWR - O2 Sats	β_{10}	0.178	0.096	0.095	0.068
Intercept: Temp	β_{00}	36.550	0.052	36.092	< .001
Level 1 slope: PWR - Temp	β_{10}	-0.030	0.027	-0.030	0.268
Intercept: BP Systolic	β_{00}	123.639	1.458	5.764	< .001
Level 1 slope: PWR – BP Systolic	β_{10}	0.557	0.711	0.026	0.435
Intercept: BP Diastolic	β_{00}	72.426	0.885	5.316	< .001
Level 1 slope: PWR - BP Diastolic	β_{10}	0.635	0.521	0.047	0.226
Intercept: HR	β_{00}	85.004	1.195	4.850	< .001
Level 1 slope: PWR- HR	β_{10}	-0.632	0.668	-0.036	0.346

Note: Level 1 *n* = 103, β = hierarchical multilevel linear modelling symbol, Coeff = unstandardized coefficient, SE = standard error, Standard coeff = standardised coefficient, EWS = early warning score, PWR = patient wellness rating 1, RR = respiratory rate, O2 Sats = oxygen saturation, Temp = temperature, BP systolic = blood pressure systolic, BP Diastolic = blood pressure diastolic, HR = heart rate.

6.4.7 Relationship between patient wellness rating 1, and EWS and vital sign measurements recorded during the next observation

The results for the predictor (patient wellness rating 1) modelled independently on EWS and vital sign measures recorded during the next observation are presented in Table 6.4. Baseline EWS and vital sign measurements recorded during the same observation as patient wellness rating 1 were controlled for (in a second step of the analysis) to explore whether patient wellness rating 1 is associated with a change in EWS and vital sign measurements. In a separate analysis, the findings showed that the EWS and vital sign measurements were significantly different from zero (β00). The results also showed a significant negative association between patient wellness rating 1 and EWS (β = -0.260, *p* = 0.010), which remained significant when controlling for baseline EWS (β = -0.172, *p* = 0.014). A significant negative association between patient wellness

rating 1 and temperature (β = -0.067, *p* = 0.034) was also found, which was reduced to being marginally significant when controlling for baseline temperature (β = -0.061, *p* = 0.079). A marginally significant positive association between patient wellness rating 1 and systolic blood pressure (β = 1.396, *p* = 0.064) was also found, although this became non-significant (*p* > .10) when controlling for baseline measures.

Table 6.4 Within-person associations between patient wellness rating 1, and EWS and individual vital sign measurements recorded during the next observation

HLM Effect	Symbol	Coeff	SE	Standard coeff	*p*
Intercept: EWS	β_{00}	1.380	0.128	0.691	< .001
Level 1 slope: PWR – EWS	β_{10}	-0.260	0.099	-0.130	0.010
Intercept: EWS	β_{00}	1.385	0.130	0.693	< .001
Level 1 slope: PWR	β_{10}	-0.172	0.069	-0.086	0.014
Level 1 slope: Baseline EWS	β_{10}	0.309	0.076	0.155	< .001
Intercept: RR	β_{00}	16.777	0.199	5.308	< .001
Level 1 slope: PWR – RR	β_{10}	-0.151	0.159	-0.048	0.345
Intercept: RR	β_{00}	16.795	0.205	5.314	< .001
Level 1 slope: PWR	β_{10}	-0.034	0.127	-0.012	0.791
Level 1 slope: Baseline RR	β_{10}	0.315	0.088	0.010	< .001
Intercept: O2 Sats	β_{00}	96.966	0.128	41.726	< .001
Level 1 slope: PWR - O2 Sats	β_{10}	0.088	0.094	0.038	0.349
Intercept: O2 Sats	β_{00}	96.967	0.127	41.727	< .001
Level 1 slope: PWR	β_{10}	0.066	0.087	0.028	0.452
Level 1 slope: Baseline O2 Sats	β_{10}	0.154	0.068	0.066	0.025
Intercept: Temp	β_{00}	36.583	0.051	42.525	< .001
Level 1 slope: PWR – Temp	β_{10}	-0.067	0.031	-0.078	0.034
Intercept: Temp	β_{00}	36.583	0.051	42.578	< .001
Level 1 slope: PWR	β_{10}	-0.061	0.034	-0.071	0.079
Level 1 slope: Baseline Temp	β_{10}	0.186	0.053	0.216	< .001
Intercept: BP Systolic	β_{00}	123.608	1.422	5.792	< .001
Level 1 slope: PWR – BP Systolic	β_{10}	1.396	0.744	0.065	0.064
Intercept: BP Systolic	β_{00}	123.665	1.420	5.795	< .001
Level 1 slope: PWR	β_{10}	1.119	0.693	0.052	0.110
Level 1 slope: Baseline BP Systolic	β_{10}	0.299	0.055	0.014	< .001
Intercept: BP Diastolic	β_{00}	71.030	0.945	4.818	< .001
Level 1 slope: PWR - BP Diastolic	β_{10}	0.706	0.639	0.048	0.272
Intercept: BP Diastolic	β_{00}	71.035	0.949	4.819	< .001
Level 1 slope: PWR	β_{10}	0.320	0.576	0.022	0.580
Level 1 slope: Baseline BP Diastolic	β_{10}	0.241	0.061	0.016	< .001
Intercept: HR	β_{00}	84.033	1.129	4.845	< .001
Level 1 slope: PWR- HR	β_{10}	-1.366	0.880	-0.079	0.124
Intercept: HR	β_{00}	84.033	1.130	4.847	< .001
Level 1 slope: PWR	β_{10}	-1.123	0.778	-0.065	0.157
Level 1 slope: Baseline HR	β_{10}	0.368	0.062	0.021	< .001

Note: Level 1 *n* = 103, β = hierarchical multilevel linear modelling symbol, Coeff = unstandardized coefficient, SE = standard error, Standard coeff = standardised coefficient, EWS = early warning score, PWR = patient wellness rating 1, RR = respiratory rate, O2 Sats = oxygen saturation, Temp = temperature, BP systolic = blood pressure systolic, BP Diastolic = blood pressure diastolic, HR = heart rate.

6.4.8 Relationship between patient wellness rating 1, and EWS and vital sign measurements recorded during an observation 24 hours later

The results for the predictor (patient wellness rating 1) modelled independently on EWS and vital sign measures recorded during an observation 24 hours later are presented in Table 6.5. Baseline EWS and vital sign measurements recorded during the same observation as patient wellness rating 1 were controlled for in a second step of the analysis. The findings showed that the EWS and vital sign measurements were significantly different from zero (β00). The results also showed a significant negative association between patient wellness rating 1 and heart rate (β = -1.232, p = 0.040), which was also significant when controlling for baseline heart rate (β = -1.170, p = 0.030).

Table 6.5 Within-person associations between patient wellness rating 1, and EWS and individual vital sign measurements recorded during an observation 24 hours later

HLM Effect	Symbol	Coeff	SE	Standard coeff	*p*
Intercept: EWS	β_{00}	1.244	0.108	0.691	< .001
Level 1 slope: PWR – EWS	β_{10}	-0.055	0.073	-0.031	0.460
Intercept: EWS	β_{00}	1.238	0.108	0.688	< .001
Level 1 slope: PWR	β_{10}	-0.033	0.064	-0.018	0.609
Level 1 slope: Baseline EWS	β_{10}	0.063	0.084	0.035	0.459
Intercept: RR	β_{00}	16.766	0.176	4.952	< .001
Level 1 slope: PWR – RR	β_{10}	-.0.051	0.191	-0.015	0.729
Intercept: RR	β_{00}	16.761	0.176	4.951	< .001
Level 1 slope: PWR	β_{10}	0.040	0.154	0.012	0.797
Level 1 slope: Baseline RR	β_{10}	0.165	0.069	0.049	0.020
Intercept: O2 Sats	β_{00}	96.990	0.151	42.050	< .001
Level 1 slope: PWR - O2 Sats	β_{10}	-0.118	0.108	-0.051	0.275
Intercept: O2 Sats	β_{00}	96.979	0.150	42.045	< .001
Level 1 slope: PWR	β_{10}	-0.896	0.553	-0.388	0.109
Level 1 slope: Baseline O2 Sats	β_{10}	-0.218	0.159	-0.095	0.173
Intercept: Temp	β_{00}	36.549	0.054	39.040	< .001
Level 1 slope: PWR – Temp	β_{10}	-0.021	0.027	-0.022	0.444
Intercept: Temp	β_{00}	36.548	0.054	39.146	< .001
Level 1 slope: PWR	β_{10}	-0.015	0.028	-0.016	0.587
Level 1 slope: Baseline Temp	β_{10}	0.183	0.067	0.196	0.008
Intercept: BP Systolic	β_{00}	124.443	1.706	5.618	< .001
Level 1 slope: PWR – BP Systolic	β_{10}	-1.264	0.879	-0.057	0.154
Intercept: BP Systolic	β_{00}	124.404	1.711	5.616	< .001
Level 1 slope: PWR	β_{10}	-1.277	0.822	-0.058	0.124
Level 1 slope: Baseline BP Systolic	β_{10}	0.118	0.050	0.005	0.020
Intercept: BP Diastolic	β_{00}	71.869	1.017	5.331	< .001
Level 1 slope: PWR - BP Diastolic	β_{10}	0.296	0.533	0.022	0.580
Intercept: BP Diastolic	β_{00}	71.867	1.019	5.331	< .001
Level 1 slope: PWR	β_{10}	0.148	0.530	0.012	0.781
Level 1 slope: Baseline BP Diastolic	β_{10}	0.067	0.055	0.005	0.222
Intercept: HR	β_{00}	84.756	1.271	4.680	< .001
Level 1 slope: PWR- HR	β_{10}	-1.232	0.590	-0.068	0.040
Intercept: HR	β_{00}	84.743	1.268	4.679	< .001
Level 1 slope: PWR	β_{10}	-1.170	0.529	-0.065	0.030
Level 1 slope: Baseline HR	β_{10}	0.173	0.062	0.010	0.007

Note: Level 1 *n* = 103, β = hierarchical multilevel linear modelling symbol, Coeff = unstandardized coefficient, SE = standard error, Standard coeff = standardised coefficient, EWS = early warning score, PWR = patient wellness rating 1, RR = respiratory rate, O2 Sats = oxygen saturation, Temp = temperature, BP systolic = blood pressure systolic, BP Diastolic = blood pressure diastolic, HR = heart rate.

6.4.9 Moderating effects of patient age, gender and acuity of illness

6.4.9.1 Patient age

One marginally significant moderating effect was found for age (β = 0.013, *p* = 0.068) on the positive association between patient wellness rating 1 and EWS recorded during an observation 24 hours later. Given the marginal nature of this moderation effect it was not further explored.

6.4.9.2 Patient gender

There were a number of significant moderating effects for gender. A significant moderating effect was found for gender (β = -0.387, *p* = 0.044) on the negative association between patient wellness rating 1 and EWS recorded during the next observation. However, simple slopes analysis indicated that patient wellness rating 1 and EWS recorded during the next observation were not significantly associated in either males or females (Male, *M*-1*SD*: β = 0.149, SE = 0.590, *p* = .801; female, *M*+1*SD*: β = 0.536, SE = 0.614, *p* = 0.385).

A significant moderating effect for gender was also found for: the positive association between patient wellness rating 1 and oxygen saturation (β = -0.443, *p* = 0.050) recorded during the next observation; and the negative association between patient wellness rating 1 and temperature (β = -0.133, *p* = 0.048) recorded during the next observation. Simple slopes analysis indicated that patient wellness rating 1 and oxygen saturation were marginally significantly related in females but not significantly associated in males (Male, *M*-1*SD*: β = -0.393, SE = 0.273, *p* = .153; female, *M*+1*SD*: β = -0.836, SE = 0.489, *p* = 0.091). However, patient wellness rating 1 was significantly negatively associated with temperature recorded during the next observation in both males and females, with a stronger association in females (*M*+1*SD*: β = -0.345, SE = 0.140, *p* < .05) than males (*M*-1*SD*: β = -0.212, SE = 0.076, *p* < .05).

Lastly, a marginally significant moderating effect was found for gender (β = 0.614, *p* = 0.062) on the negative association between patient wellness rating 1 and respiratory rate recorded during an observation 24 hours later.

6.4.9.3 Acuity of patient illness

A number of significant moderating effects were also found for acuity of patient illness. A significant moderating effect for acuity of patient illness was found for the negative association between patient wellness rating 1 and respiratory rate

(β = -0.121, p < .001) recorded within the same observation. Simple slopes analyses indicated that increasing levels of acuity were associated with increasingly strong negative associations between patient wellness rating 1 and respiratory rate recorded within the same observation. In particular, although patient wellness rating 1 was significantly negatively associated with respiratory rate at all levels of acuity, the degree of association grew from low (M-1SD: β = -0.312, SE = 0.134, p < .05) to moderate (M: β = -0.564, SE = 0.172, p < .001) to high (M+1SD: β = -0.817, SE = 0.223, p < .001) levels of acuity.

There was a significant moderating effect for acuity of patient illness (β = -0.091, p < .001) on the negative association between patient wellness rating 1 and EWS recorded during the next observation. Simple slopes analyses indicated that increasing levels of acuity were associated with increasingly strong negative associations between patient wellness rating 1 and EWS recorded during the next observation. Patient wellness rating 1 was significantly negatively associated with EWS at all levels of acuity, but the degree of association grew from low (M-1SD: β = -0.336, SE = 0.092, p < .001) to moderate (M: β = -0.527, SE = 0.094, p < .001) to high (M+1SD: β = -0.717, SE = 0.097, p < .001) levels of acuity.

A significant moderating effect for acuity of patient illness was also found for; the negative association between patient wellness rating 1 and respiratory rate (β = -0.144, p < .001) recorded during the next observation; the positive association between patient wellness rating 1 and systolic blood pressure (β = -0.593, p < .001) recorded during the next observation; and the positive association between patient wellness rating 1 and diastolic blood pressure (β = -0.475, p = 0.013) recorded during the next observation. However, simple slopes analysis indicated that acuity of illness was not significantly associated with; the negative association between patient wellness rating 1 and respiratory rate recorded during the next observation at low (M-1SD: β = 0.097, SE = 0.124, p = 0.434), moderate (M: β = -0.019, SE = 0.129, p = 0.881) or high (M+1SD: β = -0.136, SE = 0.135, p = 0.315) levels of acuity; or the positive association between patient wellness rating 1 and diastolic blood pressure recorded during the next observation at low (M-1SD: β = 0.606, SE = 0.597, p = 0.313), moderate (M: β = -0.387, SE = 0.749, p = 0.607) or high (M+1SD: β = -1.380, SE = 1.039, p = 0.187) level of acuity. Furthermore, simple slopes analysis revealed that acuity

of illness was marginally significantly associated with the positive association between patient wellness rating 1 and systolic blood pressure recorded during the next observation in low levels of acuity (*M*-1*SD*: β = 1.367, SE = 0.696, *p* = 0.052). However, moderate (*M*: β = 0.127, SE = 0.731, *p* = 0.862) and high (*M*+1*SD*: β = -1.112, SE = 0.882, *p* = 0.21) levels of acuity of illness were not significantly associated with the positive association between patient wellness rating 1 and systolic blood pressure recorded during the next observation.

There was a significant moderating effect for acuity of patient illness (β = -0.072, *p* < .001) on the negative association between patient wellness rating 1 and EWS recorded during an observation 24 hours later. However, simple slopes analysis revealed that acuity of illness was not significantly associated with the negative association between patient wellness rating 1 and EWS recorded during an observation 24 hours later at low (*M*-1*SD*: β = 0.083, SE = 0.051, *p* = 0.107), moderate (*M*: β = 0.025, SE = 0.056, *p* = 0.658) or high (*M*+1*SD*: β = -0.034, SE = 0.060, *p* = 0.579) levels of acuity.

A significant moderating effect for acuity of patient illness was also found for; the negative association between patient wellness rating 1 and respiratory rate (β = -0.245, *p* < .001) recorded during an observation 24 hours later; and the negative association between patient wellness rating 1 and heart rate (β = -0.513, *p* < .001) recorded during an observation 24 hours later. Simple slopes analysis revealed that acuity of illness was not significantly associated with the negative association between patient wellness rating 1 and respiratory rate recorded during an observation 24 hours later in patients with low levels of acuity (*M*-1*SD*: β = -0.203, SE = 0.152, *p* = 0.186). However, the negative association between patient wellness rating 1 and respiratory rate recorded during an observation 24 hours later was significant in moderately and highly acutely unwell patients, with the association growing from moderate (*M*: β = -0.715, SE = 0.223, *p* < .001) to high (*M*+1*SD*: β = -1.227, SE = 0.306, *p* < .001) levels of acuity.

Lastly, a marginally significant moderating effect for acuity of patient illness (β = -0.618, *p* = 0.070) was found for the negative association between patient wellness rating 1 and heart rate recorded during the next observation.

6.4.10 Level 1 models

Level 1 models were then examined to investigate the effect of patient wellness rating 2 (Much better (1), better (2), no change (3), worse (4), much worse (5) in response to the question ‘How are you feeling compared to the last time you were asked?’) on EWS and vital sign measurements recorded during the same observation. For all analyses the estimation of random effects with robust standard errors are reported. The analyses controlled for repeated measurements on patients.

6.4.11 Relationship between patient wellness rating 2, and EWS and vital sign measurements recorded within an observation

The results for the predictor (patient wellness rating 2) modelled independently on EWS and vital sign measures recorded during the same observation are presented in Table 6.6. Baseline EWS and vital sign measurements recorded during the previous observation were controlled for. Baseline patient wellness rating 1 (Very poor (1), poor (2), fair (3), good (4), very good (5) in response to the question ‘How well are you feeling?’) recorded during the previous observation was then also controlled for. The results showed a marginally significant associations between patient wellness rating 2 and EWS recorded during the same observation when controlling for baseline patient wellness rating 1 (β = -0.175, p = 0.066). A significant association between patient wellness rating 2 and systolic blood pressure recorded during the same observation when controlling for baseline patient wellness rating 1 was also found (β = 2.677, p = 0.018).

Table 6.6 Within-person associations between patient wellness rating 2, and EWS and vital sign measurements recorded during the same observation

HLM Effect	Symbol	Coeff	SE	Standard coeff	*p*
Intercept: EWS	β_{00}	1.402	0.178	0.593	< .001
Level 1 slope: PWR2 – EWS	β_{10}	0.129	0.161	0.055	0.429
Level 1 slope: Baseline EWS	β_{10}	0.346	0.052	0.147	< .001
Intercept: EWS	β_{00}	1.403	0.178	0.594	< .001
Level 1 slope: PWR 2	β_{10}	0.115	0.107	0.049	0.286
Level 1 slope: Baseline PWR 1	β_{10}	-0.175	0.093	-0.074	0.066
Level 1 slope: Baseline EWS	β_{10}	0.334	0.054	0.141	< .001
Intercept: RR	β_{00}	16.337	0.256	4.370	< .001
Level 1 slope: PWR2 – RR	β_{10}	-0.104	0.223	-0.028	0.643
Level 1 slope: Baseline RR	β_{10}	0.339	0.065	0.091	< .001
Intercept: RR	β_{00}	16.322	0.254	4.366	< .001
Level 1 slope: PWR 2	β_{10}	0.000	0.205	0.000	0.999
Level 1 slope: Baseline PWR 1	β_{10}	0.206	0.201	0.055	0.312
Level 1 slope: Baseline RR	β_{10}	0.377	0.067	0.101	< .001
Intercept: O2 Sats	β_{00}	97.221	0.177	35.372	< .001
Level 1 slope: PWR2 – O2 Sats	β_{10}	-0.180	0.116	-0.065	0.129
Level 1 slope: Baseline O2 Sats	β_{10}	0.087	0.084	0.032	0.308
Intercept: O2 Sats	β_{00}	97.223	0.176	35.372	< .001
Level 1 slope: PWR 2	β_{10}	-0.189	0.119	-0.069	0.119
Level 1 slope: Baseline PWR 1	β_{10}	-0.086	0.117	-0.031	0.467
Level 1 slope: Baseline O2 Sats	β_{10}	0.097	0.078	0.035	0.217
Intercept: Temp	β_{00}	36.562	0.075	13.302	< .001
Level 1 slope: PWR2 – Temp	β_{10}	0.052	0.096	0.051	0.591
Level 1 slope: Baseline Temp	β_{10}	0.275	0.039	0.271	< .001
Intercept: Temp	β_{00}	36.562	0.075	35.978	< .001
Level 1 slope: PWR 2	β_{10}	0.039	0.113	0.038	0.730
Level 1 slope: Baseline PWR 1	β_{10}	-0.042	0.058	-0.041	0.474
Level 1 slope: Baseline Temp	β_{10}	0.284	0.038	0.279	< .001
Intercept: BP Systolic	β_{00}	121.205	2.141	4.802	< .001
Level 1 slope: PWR2 – BP Systolic	β_{10}	0.886	0.913	0.035	0.337
Level 1 slope: Baseline BP Systolic	β_{10}	0.263	0.124	0.010	0.039
Intercept: BP Systolic	β_{00}	121.199	2.141	4.802	< .001
Level 1 slope: PWR 2	β_{10}	1.188	0.974	0.047	0.229
Level 1 slope: Baseline PWR 1	β_{10}	2.677	1.095	0.106	0.018
Level 1 slope: Baseline BP Systolic	β_{10}	0.258	0.125	0.010	0.045
Intercept: BP Diastolic	β_{00}	70.732	1.227	4.057	< .001
Level 1 slope: PWR2 – BP Diastolic	β_{10}	0.021	0.634	0.001	0.973
Level 1 slope: Baseline BP Diastolic	β_{10}	0.150	0.141	0.009	0.293
Intercept: BP Diastolic	β_{00}	70.757	1.225	4.058	< .001
Level 1 slope: PWR 2	β_{10}	-0.145	0.754	-0.008	0.849
Level 1 slope: Baseline PWR 1	β_{10}	0.959	0.983	0.056	0.335
Level 1 slope: Baseline BP Diastolic	β_{10}	0.157	0.140	0.009	0.267
Intercept: HR	β_{00}	83.883	1.685	4.091	< .001
Level 1 slope: PWR2 – HR	β_{10}	-0.145	0.992	-0.007	0.885
Level 1 slope: Baseline HR	β_{10}	0.268	0.095	0.013	0.007
Intercept: HR	β_{00}	83.886	1.685	4.091	< .001
Level 1 slope: PWR 2	β_{10}	-0.534	1.030	-0.026	0.607
Level 1 slope: Baseline PWR 1	β_{10}	-0.320	0.940	-0.016	0.735
Level 1 slope: Baseline HR	β_{10}	0.246	0.095	0.012	0.013

Note: Level 1 *n* = 103, β = hierarchical multilevel linear modelling symbol, Coeff = unstandardized coefficient, SE = standard error, Standard coeff = standardised coefficient, EWS = early warning score, PWR1 = patient wellness rating 1, PWR2 = patient wellness rating 2, RR = respiratory rate, O2 Sats = oxygen saturation, Temp = temperature, BP systolic = blood pressure systolic, BP Diastolic = blood pressure diastolic, HR = heart rate.

6.5 Discussion

In the current study, healthcare assistants and nursing staff were invited to record patient-reported changes in wellness using *version C* of the Patient Wellness Questionnaire during routine observation. The study sought to explore a) the implementation and feasibility of routine recording of patient-reported wellness in practice, and b) whether patient-reported changes in wellness were associated with objective, clinical measures of patient health, such as the EWS. Addressing this second questions allows us to begin to understand patients' ability to recognise deterioration in their condition, and therefore the likely clinical effectiveness of recording patient-reported wellness. The discussion below focuses firstly on the feasibility and implementation of routinely recording patient-reported wellness during observation. Preliminary findings regarding the clinical effectiveness of routinely recording patient-reported wellness are then discussed.

6.5.1 Feasibility and implementation of routinely recording patient-reported wellness during observation in practice

The feasibility and implementation of engaging patients in the management of deterioration in hospital by routinely recording their views on changes in their wellness during observation are discussed under four key headings: the ability to recruit staff to participate in the study; the appropriateness of recording patient-reported wellness for patients, uptake of routine recording of patient-reported wellness by staff and its impact on staff workload; and the use of targeted BCTs to encourage and support staff to adopt this new practice.

6.5.1.1 Recruiting healthcare assistants and nursing staff to the study

There was a high recruitment rate of healthcare assistants and nurses to the current study, where 95% of healthcare assistants and nurses approached to participate in the study were successfully recruited and consented. The high recruitment rate may be accounted for by the high level of support and engagement for the study from senior ward staff. The local collaborator for the study was a senior member of staff who implemented and trained ward staff on the sampled wards in the use of the electronic observation system. Her job role involved the day-to-day management of the electronic observation system and

as such she had a vested interest in improving the efficacy of the system. The local collaborator was an experienced nurse and had longstanding working relationships with all senior and junior ward sisters working on the sampled wards. This gave her greater power to encourage their engagement with the study compared to the researcher who had no previous working relationship with the ward staff.

6.5.1.2 Appropriateness of routinely recording patient-reported wellness for patients

Appropriateness of routinely recording patient-reported wellness is explored in terms of data collected about patients' willingness to answer the Patient Wellness Questionnaire at observation, and their capability to do so. At least one patient wellness ratings was recorded during observation for 103 of the 125 patients cared for on the participating wards during the study period. This suggests that healthcare assistant and nurse participants felt it was appropriate to ask the majority of patients about their wellness using the Patient Wellness Questionnaire and record their responses. During the consent process, healthcare assistant and nurse participants were given written and verbal instruction by the researcher that they should use their clinical judgement to determine if it was appropriate to record patient-reported wellness for a patient. They could input the words 'refused' or 'unable' in to the electronic observation application to indicate that the patient refused to answer or that they were unable to ask the patient about their wellness because their condition made it difficult for them to answer.

'Refused' was input in to the electronic observation application for two patients during the study period. This suggests that only 3% of patients were not willing to answer the Patient Wellness Questionnaire during observation on some occasions. After refusing to answer questions about their wellness during an observation, both patients were willing to answer the questions during an observation at a later time point (indicated by the presence of patient wellness ratings input in to the electronic observation application at a later observation). Unfortunately, it is unknown why the patients refused to answer the Patient Wellness Questionnaire. 'Unable' was not input in to the electronic observation application for any patients during the study period.

The initial findings suggest that routinely recording patient-reported wellness is appropriate for the majority of patients as only a small number of patients refused to answer questions about their wellness, and no patients were identified as incapable of answering the patient wellness questions. However, it must be considered that where patients refused to answer or were unable to answer because of their medical condition, healthcare assistant and nurse participants may not have input this information in to the electronic observation application. The researcher questioned whether all patients cared for on the sampled wards during the study period would have the capability to answer the Patient Wellness Questionnaire during every observation, particularly as one ward cared for mostly palliative patients. In line with this, it should be considered that the true rates of patient refusal to answer the Patient Wellness Questionnaire may also not have been documented.

6.5.1.3 Uptake of the new practice and impact on staff workload

Of the total number of observations conducted for all patients during the study period, a patient wellness rating was recorded during 14% of observations with a range of 3% to 55%. Therefore, patient wellness ratings were not recorded at a large number of observations during the study period. As previously discussed, a proportion of the observations without patient wellness ratings may be accounted for by undocumented patient refusals to answer the Patient Wellness Questionnaire, or them being incapable of answering due to their medical condition. Furthermore, it may have been that patients were asleep during some observations and as such were not asked the Patient Wellness Questionnaire.

Effective communication with patients is vital for a positive nurse-patient relationship and for the delivery of high quality care (McCabe, 2004; Roohangiz, Aghabarari, Shiri, Karimi & Samami, 2016), yet the literature suggests that nurses can be ineffective at communicating with patients (Gilmartin, & Wright 2008; Jangland, Gunningberg, & Carlsson, 2009). Routinizing conversations that elicit communication about patient wellness may be beneficial as it encourages open dialogue between ward staff and patients. Indeed, the pilot study reported in Chapters 4 and 5 found that routinely asking patients about changes in their wellness uncovered concerns patients had that related to communication failure with health professionals, for instance requests for pain relief that had not been

acted on by staff. However, it is important to ensure that routinely asking patients about their wellness does not overwhelm resources. The researcher observed 4 healthcare assistant and nurse participants asking patients the Patient Wellness Questionnaire during routine observation to explore how routinely asking patients about their wellness impacted upon staff workload. Participants were required to complete activities as a direct result of asking the Patient Wellness Questionnaire in 3 of the 20 patient observations observed by the researcher. These activities included administering pain relief medication and changing a dressing. The findings suggest that routinely asking patients about their wellness during observation has a small impact on staff workload.

It should be acknowledged that the researcher observed only a small proportion of routine observations and so conclusions about the impact of routinely recording patient-reported wellness on staff workload should be interpreted tentatively. In the future, observing healthcare assistant and nurse participants conducting a larger number of observations where they did or did not ask patients the Patient Wellness Questionnaire may give a greater insight in to the impact of routinely recording patient-reported wellness on staff workload. Also, whether an activity occurred as a result of asking patients about their wellness was interpreted from the researcher's perspective, and it is unknown whether participants would have still carried out these activities if they had not asked patients the Patient Wellness Questionnaire. Nevertheless, preliminary findings suggest that asking patients about their wellness using the Patient Wellness Questionnaire during routine observation does not overwhelm resources.

6.5.1.4 Supporting healthcare assistants and nurses to adopt a new practice

Targeted BCTs judged to be effective at changing people's motivation to carry out a new behaviour were used to encourage healthcare assistant and nurse participants to adopt a change in practice, by asking patients the Patient Wellness Questionnaire and recording their responses during routine observation. The 15 minute behaviour change session was led by the researcher, and given to participants working on wards in the experimental group. The following BCTs were employed in the session: providing information about involving patients in recognising deterioration and the potential benefits for

patient outcomes, identifying and preparing for problems, and forming implementation intentions to routinely record patient-reported wellness during observation.

It was found that receiving a behaviour change session was effective at increasing the number of patient wellness ratings recorded by participants during routine observation, but this was significant only on wards that showed high previous levels of engagement with using the electronic observation system. In the current study, engagement was defined as attitude to the introduction of the electronic observation system, timeliness of observations using the system and use of the free text box to record notes about the patients' condition. This suggests that in order for BCTs to be effective at encouraging health professionals to adopt a new practice, health professionals may first need to have previously engaged with systems related to the new practice, and have a positive attitudes towards these. The researcher identified a small amount of cross-over between participants working on wards in the experimental and control group. Two of the 69 healthcare assistant and nurse participants worked predominantly on a ward in the experimental group, and as such received a behaviour change session aimed at increasing their recording of patient-reported wellness. However, during the study period they occasionally worked on wards in the control group where participants had not received the behaviour changes session. It is worth considering that this cross-over may have had a small effect on the findings.

The findings resonate with broader research that has explored social cognitive theories to understand professional behaviour change (Ajzen, 1991; Johnson & May, 2015). One such social cognitive theory is Ajzen's (1991) theory of planned behaviour which states that individuals' attitudes towards a behaviour are one factor that determines behaviour performance. Consistent with this theory, Bernhardsson, Johansson, Nilsen, Oberg and Larsson (2014) asked 419 primary care physical therapists to complete a validated web-based questionnaire to capture their self-reported attitudes relating to the use of evidence-based practice and guidelines. It was found that positive attitudes towards evidence-based practice and guidelines were associated with more frequent use of guidelines. Taken together with the findings of the current study, it may be necessary to first improve health professionals' attitudes towards a new practice

for BCTs to be effective in motivating staff to adopt the practice. Where attitudes towards a new practice are negative, this may be a barrier to the efficacy of BCTs in altering behaviour.

Other factors associated with the behaviour change session may also have influenced the study findings. The delivery of the behaviour change session to participants on the engaged ward was perceived by the researcher to be consistently more successful when compared to delivery on the disengaged ward. It is noted that the setting for the behaviour change session varied between the two wards in the experimental group, and this may have affected the delivery of the session. On the engaged ward, the behaviour change sessions were always held with participants in a quiet private room on the ward after a huddle, whereas on the disengaged ward, the behaviour change sessions were sometimes held in a private room but were often delivered around the nursing station desk.

The researcher found it difficult at times to hold participants attention when the behaviour change sessions were held around the open nursing station desk, compared to in a private room. Participants were often approached by relatives midway through the session or left the session to attend to a patient ringing their buzzer. Furthermore, when the sessions were held around the nursing station, participants were less likely to write down their implementation intention to record patient-reported wellness. Not all participants had a place to sit around the nursing station, making it impractical to write. Therefore, these participants would not necessarily have benefitted from forming implementation intentions.

It is important to consider intervention fidelity and any deviations from the protocol. Otherwise, it could be concluded that an intervention is ineffective when it may be that the intervention was just not delivered as intended (Hardeman et al., 2008). Lawton et al. (2017) piloted the Patient Reporting and Action for a Safe Environment (PRASE) intervention on UK hospital wards to investigate how patient feedback on the safety of their care can be used to enhance patient safety at a ward level. An assessment of fidelity was conducted to understand how the intervention was received and used by the intervention wards. It was found that improvements in harm free care were largest for wards that showed the greatest

compliance with the intervention. With regards to the current study, consistent improved delivery of the behaviour change session to participants on the engaged ward compared to the disengaged ward may partially account for the finding that the session was effective at increasing recording of patient-reported wellness on the engaged ward only. It may be that participants on the engaged ward received the session as intended allowing for the effects of BCTs to be realised, whereas often the disengaged ward did not.

6.5.2 Initial insights in to the clinical effectiveness of routinely recording patient-reported wellness

Preliminary findings that provide insight in to the clinical effectiveness of routinely recording patient-reported wellness in practice, and shed light on the ability of patients to recognise genuine deterioration in their condition are discussed under four key headings: ability of patient-reported wellness to predict subsequent clinical deterioration; signs and symptoms indicative of clinical deterioration; patient factors implicated in the ability of patients to recognise clinical deterioration; and use of EWS as an outcome measure.

6.5.2.1 Ability of patient-reported wellness predict subsequent clinical deterioration

The findings show that there were no significant associations between patient wellness rating 1 and EWS or vital sign measurements recorded within the same observation. However, significant negative associations were found between patient wellness rating 1, and EWS and temperature recorded during the next observation. Furthermore, a significant negative association was found between patient wellness rating 1 and heart rate recorded during an observation 24 hours later. The direction of the association is consistent with what would be expected in that lower patient wellness ratings (indicating poorer patient-reported wellness) were associated with higher EWS, temperature and heart rate measurements (indicating poorer objective patient health). Only one significant associations was found between patient wellness rating 2 and systolic blood pressure recorded during the same observation when controlling for baseline patient wellness rating 1.

The findings suggest that what patients say about their wellness may not necessarily be reflected in the objective measurements of their health taken at that time. Instead, patients' ratings of their wellness may be a precursor for subsequent improvement or decline in their condition as indicated by objective measurements of their health. This supports evidence in the literature suggesting that patients who voice concerns about changes in how they feel are in the early stages of clinical deterioration (Cioffi, 2000; Grossman & Wheeler, 1997; Minick & Harvey, 2003). In line with this, health professionals interviewed in study 1 within the thesis talked about patients identifying subjective cues to suggest their condition is deteriorating before these appear in objective EWS measurements.

Furthermore, the findings shed light on the type of information patients can give about their wellness that may aid the identification and prediction of clinical deterioration. Patient wellness rating 1 captured patients' ratings of their wellness at the time, and was found to be significantly associated with a number of EWS and vital sign measurements during the next observation and during an observation 24 hours later. Patient wellness rating 2 captured the patients' ratings of a change in their wellness from a previous time point, and had only one significant association with systolic blood pressure. It may be that it is more useful to routinely collect patient wellness rating 1 from patients compared to patient wellness rating 2.

6.5.2.2 Signs and symptoms indicative of clinical deterioration

Interestingly, patients' ratings of their wellness were significantly associated with measurements of vital signs that can be experienced as bodily sensations, such as temperature and heart rate, rather than vital signs that may less clearly experienced as bodily sensations, such as oxygen saturation. This empirical evidence contributes towards our limited understanding of how patients recognise clinical deterioration in their condition. Related literature exploring how health professionals recognise clinical deterioration in hospital proposes that health professionals consider what patients say about how they are feeling to determine their level of concern for the patient (Cioffi, 2000; Grossman & Wheeler, 1997; Minick & Harvey, 2003). For instance, Cioffi (200) found that where a patient says they are 'just not right' or 'feel different', nurses perceive this to be a subtle change associated with clinical deterioration. However, these

studies have not delved in to the factors that underpin a patient feeling ‘just not right’ or feeling different.

Other research has identified that the presence or absence of symptoms was an important indicator of change in clinical condition for patients who experienced acute illness within the context of a long-term health problem (Rainey, Ehrich, Mackintosh & Sandall, 2013). The current study advances our understanding of factors that underpin non-specific feelings patients have about their condition, suggesting that patients may recognise subjective bodily sensations, such as a racing heart to inform their views about their wellness. Although, there is a possibility that being unwell in hospital can cause patients to feel anxious and this could affect certain vital signs that the patient may experience as bodily sensations, such as heart rate. Where patients may attribute a racing heart to a decline in their wellness, this may in fact be explained by feelings of anxiety. Nevertheless, the findings also sheds light on which patient-reported symptoms may be predictive of subsequent deterioration in a patients’ condition as indicated by worsening EWS and vital sign measurements.

6.5.2.3 Patient factors implicated in the ability of patients to recognise clinical deterioration

The current study explored person-specific factors that moderated the association between patient-reported wellness and objective EWS and vital sign measurements. These person-specific factors were patient age, gender and acuity of their illness.

A stronger negative association between patients’ ratings of their wellness and their temperature recorded during the next observation was found in female patients compared to male patients. This finding suggests that females may be better able to predict deterioration in their condition, as indicated by abnormal temperature measurements, than males.

Interesting significant findings were identified when considering acuity of patient illness as a moderating factor. A stronger negative association between patients’ ratings of their wellness and respiratory rate recorded during the same observation, and during an observation 24 hours later was found for highly

acutely unwell patients compared to low and moderately unwell patients. This finding suggests that highly acutely unwell patients may be better able to predict deterioration in their condition, as indicated by abnormal respiratory rate measurements compared to patients who have low or moderate levels of acuity. Furthermore, a stronger negative association between patients' ratings of their wellness and EWS recorded during the next observation was found for highly acutely unwell patients compared to low and moderately unwell patients. Again, this finding suggests that highly acutely unwell patients may be better able to predict deterioration in their condition, as indicated by elevated EWS compared to patients who have low or moderate levels of acuity.

It should be considered that there is greater frequency of, and variability in EWS recorded in more acutely unwell patients, compared to less acutely unwell patients. It may be that a greater number of patient wellness ratings and EWS data points recorded for more acutely unwell patients allows more opportunities for a strong association to be found compared to less acutely unwell patients. Nevertheless, taken together these findings indicate that patient-reported wellness may be more predictive of subsequent deterioration in patients whose conditions are more unstable, and as such, have a greater chance of deteriorating compared to patients who are more stable. Therefore, it may be appropriate to routinely record patient-reported wellness for highly acutely unwell patients only in order to aid health professionals in the timely recognition and response to clinical deterioration.

6.5.2.4 Use of EWS as a proxy measure for clinical deterioration

In the current study, EWS and the vital sign measurements that comprise it were used as a proxy measure for clinical deterioration. It should be noted that there are some potential limitations with using EWS as a proxy measure, and other proxy measures could have been used. A recent systematic review of 232 articles exploring the strengths and weaknesses of EWS systems identified that they are limited by their intermittent and user-dependent nature (Downey, Tahir, Randell, Brown & Jayne, 2017). Numerous studies have identified that EWS systems are prone to infrequent monitoring (Christensen et al., 2011b; Hands et al., 2013; Jonsson et al., 2011; Neary et al., 2015b; Odell, 2015; Smith, 2011; Stevenson et al., 2014; Thorpe, 2015; Watson et al., 2014; Le Jeune et al., 2013).

For instance, Simmes et al. (2012) conducted a retrospective study of surgical patients before and after the implementation of an EWS system and found EWS recordings were frequently incomplete. User error can also occur when recording vital signs and calculating the EWS (Cherry and Jones, 2015; Smith and Oakey, 2006), and calculation errors were found to be 11 times more likely to result in under-scoring rather than over-scoring meaning deteriorating patients may not be recognised (Austen et al., 2012).

The researcher accounted for the potential issue of calculation errors in the current study by checking 10% of the EWS calculations for accuracy (60 of the 598 EWS calculations recorded during the study period). All of the EWS calculations checked by the researcher were accurately recorded by healthcare assistant and nursing staff. Furthermore, the potential issue of infrequent monitoring was offset by the monitoring of frequency and timeliness of observations in the electronic observation system. Healthcare assistants and nursing staff on the sampled wards were aware that the clinical contact who implemented and trained staff in the use of the electronic observation system monitored the frequency and timeliness of their observations. As a result, observations on the sampled wards were mostly frequent and timely, and where observations were missed or late, healthcare assistants and nurses were required to note down a reason in the electronic observation system.

In terms of the efficacy of EWS as a measurement of patients' clinical condition, evidence supports the use of the National EWS that is used in UK hospitals. Goldhill, McNarry, Mandersloot and McGinley (2005) analysed the vital sign measurements and EWS obtained from 1047 patients assessed by an intensive care outreach service in a UK hospital. They found that an increasing EWS was associated with more intervention ($p < 0.0001$) and higher hospital mortality ($p < 0.0001$). Furthermore, researchers tested the ability of national EWS to discriminate patients at risk of cardiac arrest, unplanned admission to Intensive Care Unit, or death within 24 hours of a national EWS recording. They found that compared to 33 other EWS currently in use, the national EWS (used in hospitals that participated in the research in this thesis) has a greater ability to discriminate patients at risk of cardiac arrest, unplanned admission to Intensive Care Unit, or death (Smith, Prytherch, Meredith, Schmidt & Featherstone, 2013).

It is acknowledged that other proxy measures of deterioration could have been used in the current study. Extended hospital stays which fall outside of the average range could have been used as a proxy measure for patient deterioration. However, length of hospital stay can be influenced by a number of non-clinical factors, such as the availability of community services (Brasel, Lim, Nirula & Weigelt, 2007). Cardiac arrest rates have been commonly used as an outcome measure in studies exploring approaches to improve recognition and response to clinical deterioration (Frost et al., 2015; Green et al., 2018), and could have been used as an outcome measure in the current study. Cardiac arrest call audit data was used to identify wards that may benefit from an intervention to improve early recognition of deterioration in the pilot study described in Chapters 4 and 5. However, cardiac arrest was not used as an outcome in the current study because it is a relatively rare event. The cardiac arrest call audit data used in the pilot study demonstrates this, where the mean number of cardiac arrests between 2014 and 2015 on the sampled wards was 15.

Furthermore, mortality rates could have been used as a proxy measure for preventable patient deterioration. However, it is noted that some deaths in hospital are unpreventable, and evidence suggests mortality rates are a poor predictor of preventable complications (Hayward & Hofer, 2001). As previously discussed, the researcher was able to offset potential limitations of using EWS as a proxy measure for deterioration, which would not have been possible if length of hospital stay or mortality rates were used. Moreover, pragmatic reasons favoured the use of EWS as a proxy measure for deterioration. Health professionals interviewed in study 1 proposed the routine recording of patient-reported wellness during observation as a potentially feasible approach to involving patients. EWS routinely recorded during observation provided an objective measure of patient health that could be compared to patient-reported wellness recorded at the same time point.

6.5.3 Strengths and limitations

There are various strengths to consider when critically appraising this study. In the pilot study reported in Chapters 4 and 5, patients gave their informed consent to participate in the study where they were asked the Patient Wellness

Questionnaire after each observation by the researcher over a number of days. Requiring patients to give informed consent meant that patients included in the study were those who were mostly well, and excluded those who were too unwell to complete the consent process (for instance, read information sheets and write their consent), but may have been well enough to answer questions about how they were feeling. After all, healthcare assistants and nurses ask patients how they are feeling as part of usual care, although not routinely.

In the current study, the participating wards agreed to embed the routine recording of patient-reported wellness in to usual care. Unlike in the pilot study where informed consent was required, embedding routine recording of patient-reported wellness in to usual care allowed for the inclusion of all patients in the study for whom clinical staff felt it was appropriate. Participating in the study was low burden for patients as what they experienced was consistent with usual care. Embedding the practice in to usual care also allowed the researcher to collect data from more unwell patients to explore the relationship between patient-reported wellness and objective EWS in patients whose health declined. To begin to understand whether routinely recording patient-reported wellness can aid health professionals in recognising deterioration, it was vital to include patients in the study whose condition had deteriorated.

There were a number of challenges and limitations to conducting this research. One of the main limitations of the study was that patient wellness ratings were not recorded at a large number of observations during the study period. A patient wellness rating was recorded during only 14% of observations with a range of 3% to 55%. It will be important to gain a greater understanding of why healthcare assistants and nurses did not record patient wellness ratings during the majority of observations. It may be that recording this information during every observation is too frequent. Further research is needed to explore whether there is a more appropriate frequency at which to record patient wellness ratings during observation.

Furthermore, a key challenge of the study related to the method used to prompt healthcare assistant and nurse participants to ask patients the Patient Wellness Questionnaire. Initially, the researcher’s local collaborator (the senior nurse in

charge of the electronic observation system) agreed to programme the two patient wellness questions in to the electronic observation application. The questions would appear along with the vital sign prompts within the electronic observation application on the handheld device used by staff to conduct observations, and funding was available from the researcher's supervisor team to pay the programmers for their time.

Prompting staff to ask patients about their wellness by having the questions appear in the application would have been the most ideal method because it is consistent with the usual way that staff record patient information during routine observation. Unfortunately, the owners of the electronic observation system denied the programming of the patient wellness questions in to the electronic observation application. Subsequently, the researcher discussed with the local collaborator the most appropriate alternative method of prompting staff to ask patients the patient wellness questions during observation. Hanging laminated paper prompts with the patient wellness questions and response options off the observation trolley was thought to be the most appropriate alternative. It may be that more patient wellness ratings would have been recorded during observation if the questions were programmed in to the application because staff would be less likely to miss the prompt.

In terms of the multilevel modelling analysis used within this study, running multiple comparisons may have implications for the findings. Running multiple comparisons in multilevel modelling can increase the risk of a type 1 error (concluding that a significant difference exists when it does not). This is referred to as the family wise error rate (Armstrong, 2014). The Bonferroni correction could have been used in the analysis to adjust probability (*p*) values associated with each individual comparison to ensure the probability value is maintained at 0.05 across all comparisons, reducing the chance of type 1 error (Amstrong, 2014; Dunn, 1961).

6.5.4 Recommendations and conclusions

This study has highlighted a number of considerations and recommendations that may support future involvement of patients in the management of clinical

deterioration in hospital by routinely recording patient-reported wellness during observation:

- Engagement and support from senior ward staff for routine recording of patient-reported wellness during observation is important to encourage frontline staff to adopt the change in practice.
- It may be necessary to support healthcare assistant and nursing staff to begin routinely recording patient-reported wellness in practice. The use of BCTs targeted at increasing motivation to adopt the change in practice, and encourage the practice to become habitual may be appropriate to support staff who have a positive attitude towards conducting routine observations. Where there is a lack of engagement with routine observations, other approaches to encourage and support staff to routinely record patient-reported wellness during observation may be required.
- It may be more useful to routinely collect patient wellness rating 1 (Very poor (1), poor (2), fair (3), good (4), very good (5) in response to the question ‘How are you feeling?’) from patients compared to patient wellness rating 2 (Much better (1), better (2), no change (3), worse (4), much worse (5) in response to the question ‘How are you feeling compared to the last time you were asked?’). Patient wellness rating 1 was significantly associated with a number of EWS and vital sign measurements captured during the next observation and during an observation 24 hours later.
- It may be more appropriate to routinely record patient-reported wellness for highly acutely unwell patients compared to low and moderately acutely unwell patients. The strongest significant associations between patient-reported wellness, and EWS and vital sign measurements were in highly acutely unwell patents compared to low and moderately acutely unwell patients.

The evidence suggests that routinely recording patient-reported wellness may be one feasible strategy that could aid health professionals in the early recognition of clinical deterioration in practice.

Chapter 7

General discussion: Thesis summary, reflections, critique and directions for future research.

7.1 Chapter summary

This final chapter reiterates the thesis aims and provides a brief description of the research studies conducted to address the aims. The key findings of each study are then outlined with regards to the research questions posed in this thesis. Reflections and limitations of the thesis are then discussed, and directions for future research are proposed. Lastly, practical implications of the applied research that has been conducted and described throughout the thesis are outlined.

7.2 Thesis aims and overview

Fifteen years ago, the release of reports such as 'To Err is Human' (Kohn, Corrigan, & Donaldson, 1999) and 'An Organisation with a Memory' (Department of Health, 2000) highlighted concerning inadequacies in the quality and safety of healthcare, and arguably launched the modern patient-safety movement (Wachter, 2010). Focused research efforts have resulted in notable improvements in discrete areas of healthcare quality and safety (Pham, Girard & Pronovost, 2013; Treadwell, Lucas & Tsou, 2013; Walker, Reshamwalla & Wilson, 2012). For instance, hospital acquired infections have been significantly reduced through enhanced hand hygiene and robust screening for drug resistent organisams (Huskins et al., 2011; Salgado et al., 2013). However, levels of harm from medical error have remained stubbornly unchanged (Landrigan et al., 2010; Vincent et al., 2008). Considering that patients themselves (and in some cases their relatives) are at the centre of patient safety, involving patients and relatives in efforts to improve the quality and safety of care is essential. There is scope for

patients and relatives to have a role in ensuring their care is safe at most stages of their care (Johnson, 2015; Longtin et al., 2010; Vincent & Coulter, 2002). Nevertheless, involving patients in their care can pose a number of challenges. As previously discussed, it can be difficult to strike a balance between informing patients about patient safety issues they could be involved in without being made to feel fearful. Furthermore, the important contribution patients can make must be recognised without making them feel responsible and accountable (Lawton & Armitage, 2012).

With regards to management of deteriorating patients in hospital, measures are in place to improve early recognition of, and appropriate response to clinical deterioration (for example, the use of Early Warning Score systems and the establishment of Critical Care Outreach Teams) (NICE 2007). Despite these measures, some patients who are deteriorating continue to go unrecognised and appropriate, timely action is not always taken (Hodgetts et al, 2002; McGloin et al, 1999; McQuillan et al, 1998). Anecdotal evidence suggests that patients and their relatives may be aware that a patients' clinical condition is deteriorating. They may recognise the subtle, subjective cues of deterioration before these are detected by health professionals through observation and monitoring (Greenhouse, Kuzminsky, Martin & Merryman, 2006; O'Dell, Gerber, Gager, 2010). Strategies to involve patients and relatives in the escalation of patient care have proceeded on the basis of high profile, anecdotal evidence, as opposed to peer reviewed, empirical evidence. Furthermore, it is unclear whether it is clinically effective to involve patients and relatives in the management of deterioration by inviting them to escalate patient care (Albutt, O'Hara, Conner & Lawton, 2016).

Clearly patients, and in some instances their relatives have the greatest personal knowledge about the patient. It is intuitive to think that patients and relatives could contribute towards improving the early recognition of, and response to clinical deterioration. However, in a complex and resource limited healthcare industry, it is difficult to engage patients and relatives in the management of clinical deterioration in a way that is feasible and acceptable. A measured, evidence-based approach was required to determine the optimal method of engaging patients and relatives in the management of the deteriorating patient, to allow the expertise of patients, relatives and providers to be utilised. It was

important to actively involve patients, relatives and health professionals in the development of the patient and relative engagement strategy. Therefore, this thesis aimed to address the following research questions:

1. *How have patients and relatives previously been involved in monitoring, detecting and escalating clinical deterioration in hospital?*
2. *From a health professional perspective, can patients and relatives aid health professionals in the detection and escalation of deteriorating patients, and how might they be involved?*
3. *Are there feasible and acceptable approaches to using the Patient Wellness Questionnaire to routinely collect patients', relatives' and healthcare assistants' views on changes in patient wellness in practice?*
4. *Does routinely recording patient-reported wellness provide novel information to suggest the patient is deteriorating?*

To address the novel research questions posed within this thesis, a systematic review described in Chapter 2 was first undertaken to explore how patients and relatives have previously been involved in escalating clinical deterioration in hospital. Study 1 (Chapter 3) examined the views and experiences of health professionals regarding the potential for involving patients and relatives in recognising clinical deterioration to aid early detection of deteriorating patients. The health professionals interviewed generated a potentially appropriate method to engage patients and relatives in the management of deterioration. Based on the information gathered in study 1, studies 2 and 3 (Chapters 4 and 5) sought to develop intervention components and test the feasibility and acceptability of an intervention to promote patient and relative involvement in recognising clinical deterioration in practice. In study 2, focus groups with healthcare staff and patient representatives were used to develop a two-item questionnaire to prompt patients and relatives for their views on changes in the patients' wellness while in hospital. Study 3 tested the feasibility and acceptability of using the questionnaire to routinely collect patient and relative-reported changes in patient wellness. Study 4 (Chapter 6) investigated the potential clinical effectiveness of recording patient-reported changes in wellness during routine observation. To investigate this, the associations between patient-reported wellness, and EWS and individual vital sign measurements were explored.

7.3 Summary of key findings

7.3.1 How have patients and relatives previously been involved in monitoring, detecting and escalating clinical deterioration in hospital?

High profile cases of unrecognised deterioration resulting in the unexpected death of paediatric patients, despite relatives raising the alarm, have led a number of hospitals to implement patient and relative led escalation services. These allow the opportunity for patients and relatives to bypass healthcare staff on the ward and activate the Critical Care Outreach Team (CCOT) when they suspect the patient is deteriorating. At the inception of this thesis there was limited understanding of how patients and their relatives recognise and escalate clinical deterioration, or how the expertise of patients and their relatives may be best utilised to contribute towards improving the management of clinical deterioration in hospital. No previous systematic review had explored studies on the implementation and effectiveness of patient and relative led escalation services. As such, a systematic review was conducted as part of the thesis to (1) identify and describe systems involving patients and relatives in the process of escalating in-hospital clinical deterioration; (2) describe how these systems have been implemented; and (3) investigate the effectiveness of these systems at preventing in-hospital clinical deterioration. Key reflections on the findings of the review are discussed.

The first key reflection refers to the research designs and methods used within the reviewed studies. The majority of studies used non-clinical outcome measures to explore the feasibility and acceptability of patient and relative led escalation, and its impact on healthcare staff and their available resources. It is entirely appropriate to ensure the intervention is acceptable to users and does not have negative unintended consequences. However, the reviewed studies proposed patient and relative led escalation as an intervention to reduce preventable deterioration, but the clinical effectiveness of the service was not investigated. Studies that did employ clinical outcome measures were poorly designed in that the effects of patient and relative led escalation on clinical outcome measures were not isolated from the effects of clinician led escalation. Therefore, reported changes in clinical outcomes could not be attributed to patient and relative led escalation only.

The second key reflection from the systematic review relates to the appropriateness of the use of patient and relative led escalation services by patients and relatives. Communication failure between healthcare staff, patients and relatives was cited as a reason for patient and relative led escalation in all studies. The types of communication failure reported were unrelated to communication about concerns over a patient's deteriorating clinical condition and often related to poor patient and family experience such as, dismissive interaction between staff and family. Uncovering and addressing such communication issues is important. However, it could be argued that activating a CCOT comprised of health professionals with critical care skills may not be the most appropriate or cost-effective method to resolve concerns that are non-life threatening.

The third key reflection from the systematic review considers the paucity of evidence exploring the detection of clinical deterioration by patients and relatives within the reviewed studies. Yet, it is noted that appropriate patient and relative led escalation depends wholly on the ability of patients and relatives to effectively detect patient deterioration. The extent to which patients and relatives can effectively detect patient deterioration warrants further investigation, and subsequent studies conducted within this thesis aimed to address this evidence gap. The thesis also sought to generate empirical evidence to inform our understanding of effective approaches to engaging patients and relatives to reduce preventable deterioration in hospital.

7.3.2 From a health professional perspective, can patients and relatives aid health professionals in the detection and escalation of deteriorating patients, and how might they be involved?

Previous approaches to involving patients and relatives in the management of deterioration explored in the systematic review did not have a strong evidence base. This thesis endeavoured to develop an evidence base to begin to understand whether it is feasible and acceptable to involve patients and relatives in the management of deterioration from the perspectives of health professionals, and how this involvement might occur in practice. Inviting stakeholders to participate in the design of a complex intervention ensures that

it is appropriate and consistent with the culture of the organisation it will be used within.

Health professionals interviewed in study 1 were open to discussing the contribution patients and relatives could make to improve the management of deterioration, and generated alternative approaches to patient and relative led escalation that may better utilise the expertise of patients and relatives. The study findings suggested that health professionals viewed patients as having greater potential to contribute towards the management of deterioration compared to relatives in a non-paediatric setting where relatives may be absent for long stretches of time. First, potentially feasible and acceptable ways to involve patients and relatives in practice centred on patient involvement; routinely prompting patients for their views on changes in wellness during observations. Second, barriers to patient involvement related to simple issues of practicality, for instance, patients must be conscious in order to have a role in the management of deterioration, whereas barriers to relative involvement centred on more complex, abstract issues. These included the difficulties in creating partnerships with relatives, and suggested a more limited role for them in recognising deterioration. For relatives to become more involved in recognising deterioration in adult patients, it may first be important to work to improve partnerships between health professionals and relatives.

As previously outlined, potentially feasible and acceptable methods of involving patients in recognising deterioration were suggested. Enabling patients to become more involved in the management of deterioration, by recording their views on wellness during routine observation was suggested by health professionals interviewed in study 1. Routinizing conversations about changes in patient wellness may encourage more dialogue between the nursing staff taking observations and patients. It may aid the recognition of clinical deterioration, but may also serve to uncover and resolve non-life threatening concerns such as miscommunication between health professionals, and patients and relatives. Subsequent studies within the thesis explored the implementation, feasibility and acceptably in practice of this potentially appropriate method of involving patients in the management of deterioration.

7.3.3 Are there feasible and acceptable approaches to using the Patient Wellness Questionnaire to routinely collect patients', relatives' and healthcare assistants' views on changes in patient wellness in practice?

When exploring the feasibility and acceptability of routinely recording patient-reported wellness, an approach suggested by health professionals in study 1, it was important to consider how best to prompt patients for this information. During study 2, focus group discussions with healthcare assistants (who predominantly conduct clinical observations) and patient representatives were held and three versions of a short questionnaire to capture patients' views on their health and wellness were developed. The questionnaire versions were adapted for use with relatives and healthcare assistants conducting observations. Two approaches to using the Patient Wellness Questionnaire to collect this information from patients, relatives and healthcare assistants were trialled in study 3. Firstly, these groups were invited to routinely record their views on the patients' health and wellness themselves during routine observation and at visiting hours. As data collection progressed, it became clear that inviting patients, relatives and healthcare assistants to record answers to the Patient Wellness Questionnaire was not a feasible method to routinely collect this information. This was reflected in the low percentage of patient wellness ratings recorded using the method.

Subsequently, a new method of data collection was explored whereby the researcher attended day time observations for each patient participant, and recorded theirs and the healthcare assistants' patient wellness ratings. The researcher also attended visiting hours to capture relatives' patient wellness ratings. Although the latter method is not sustainable in practice, it allowed sufficient data to be collected from patients to ensure the analysis could be performed to explore variability in their ratings. In terms of patients' ratings of their wellness, these varied in response to all three versions of the questionnaire. Finding that patient-reported wellness does vary in response to the Patient Wellness Questionnaire was important because it suggested that patients can subjectively perceive changes in their wellness overtime. Furthermore, qualitative content analysis of patient participants' feedback revealed the majority of patients felt comfortable answering the Patient Wellness Questionnaire and understood what the questions were asking them. The

majority of patient participants also felt that it was acceptable to be asked patient wellness questions as frequently as every observation. There was a lack of data collected on healthcare assistants' and relatives' ratings of patient wellness using both the trailed approaches to data collection, and as such, descriptive statistics could not be calculated to explore variability in their ratings. This finding suggested that relatives may not be able to routinely contribute information to support the routine monitoring of patient health.

The findings of study 3 suggested that routinely recording patient-reported wellness is acceptable to patients, and finding variability in patients' wellness ratings indicated that it has the potential to aid health professionals in the management of clinical deterioration. Furthermore, the findings support the possibility that routinizing conversations about changes in patient wellness may encourage more open dialogue between ward staff and patients. Indeed, routinely asking patients about changes in their wellness uncovered concerns patients had that related to communication failure with health professionals, such as requests for pain relief that had not been acted on by staff. Further exploration of feasible and sustainable approaches to routinely recording patient-reported wellness in practice were required, and the clinical effectiveness of recording this information warranted investigation.

7.3.4 Does routinely recording patient-reported wellness provide novel information to suggest the patient is deteriorating?

Study 3 piloted approaches to routinely collecting patient wellness ratings using the Patient Wellness Questionnaire on in-patient wards. Where the researcher attended observation to record patients' ratings, this was acceptable to most patients. However, there was limited uptake where patients and relatives were invited to complete the questionnaire themselves, and staff were invited to record patients' wellness ratings during observation. It may be necessary to encourage and support staff to adopt this change in practice. Study 4 sought to explore the use of targeted behaviour change techniques (BCTs) to encourage healthcare assistant and nurse participants to ask patients the Patient Wellness Questionnaire and record their responses during routine observation. The study also investigated whether patient-reported changes in wellness were associated with objective, clinical measures of patient health, such as the EWS. This developed our understanding of patients' ability to recognise deterioration in their

condition, and therefore the likely clinical effectiveness of routinely recording patient-reported wellness.

The four participating wards in study 4 used an electronic observation system to conduct patient observations. In terms of adoption of the system, two of the participating wards were categorised as engaged, and two were categorised as disengaged with the electronic observation system. These categorisations were based on the perceptions of senior staff who implemented the electronic observation system and trained ward staff to use it. Wards in the experimental group consisted of one engaged and one disengaged ward. Healthcare assistants and nurses working on these wards received a 15 minute behaviour change session led by the researcher which utilised information provision, problem solving and implementation intentions to encourage staff to routinely record patient-reported wellness during observation. Receiving a behaviour change session was found to be effective at increasing the number of patient wellness ratings recorded by participants during routine observation, but this was significant only on wards that showed high previous levels of engagement with using the electronic observation system. This finding indicated that is it may be necessary to alter health professionals' attitudes towards a new practice to ensure these are positive, before BCTs can be effective in motivating staff to adopt the practice.

With regards to the clinical effectiveness of routinely recording patient-reported wellness, preliminary findings revealed that patients' views on their wellness may not be associated with the objective measurements of their health taken at that time. Instead, patients' ratings of their wellness may be a precursor for subsequent improvement or deterioration in their condition as indicated by objective measurements of their health. For example, the results showed a significant negative association between patient wellness rating 1 and EWS ($\beta = -0.260$, $p = 0.010$), and patient wellness rating 1 and temperature ($\beta = -0.067$, $p = 0.034$) recorded during the next observation. Furthermore, a significant negative association between patient wellness rating 1 and heart rate ($\beta = -1.232$, $p = 0.040$) recorded during an observation 24 hours later was also found.

The findings also shed light on which types of patients it may be most useful to routinely record patient-reported wellness for. Stronger significant associations

between patient-reported wellness and objective EWS suggested that highly acutely unwell patients may be better able to predict deterioration in their condition, as indicated by poor EWS compared to low or moderately acutely unwell patients. The evidence generated within this study and the others conducted in the thesis suggested that routinely recording patient-reported wellness may be one feasible strategy that could aid health professionals in the early recognition of clinical deterioration in practice.

7.4 Development of Patient Wellness Questionnaire

The Patient Wellness Questionnaire used in study 4 was developed and tested in the previous studies within the thesis. The following provides a brief overview of the decision making process surrounding the development of the Patient Wellness Questionnaire used in the final study, Question and response options that were potentially appropriate for use within the Patient Wellness Questionnaire were first identified when interviewing health professionals in study 1 and within the self-rated health literature. These question and response options (outlined in tables 4.1 and 4.2) were presented to patient representatives and healthcare assistants in focus groups during study 2. Here, these groups discussed the acceptability and ease of understanding of the question and response options from the perspectives of hospitalised patients. Based on focus group discussion, three versions of the Patient Wellness Questionnaire were developed (Please see table 4.3 for questionnaire versions). The questionnaire versions were piloted on in-patient wards to further explore which version may be most suitable to use in a larger scale study. Thirty patients participated in the pilot study and responded to the Patient Wellness Questionnaire during every observation where possible. The analysis explored which questionnaire produced the greatest variation in patient responses. Finding that patients' answers about their wellness varied in response to the Patient Wellness Questionnaire versions indicated that patients were subjectively perceiving changes in their wellness overtime. The analysis revealed that *Version B* of the Patient Wellness Questionnaire produced the greatest variability in patient wellness ratings, and as such may be the most appropriate version of the questionnaire to use to gather patient-reported wellness in the final study within the thesis.

Senior ward staff on the wards participating in the final study were approached by the researcher and invited to participate. The researcher showed the three Patient Wellness Questionnaire versions to the nursing staff and explained the findings from the pilot study described in Chapter 4, suggesting that *Version B* would be the most appropriate to use. However, senior ward staff on the participating wards felt *Version C* of the Patient Wellness Questionnaire was most suitable to use in the final study due to its similarity to wording used by staff when talking to patients. *Version C* was found to produce variability in patient wellness ratings, and most patients felt this version was understandable and appropriate. As such, *Version C* of the Patient Wellness Questionnaire was used in the final study, as opposed to *Version B*. It should be considered that *Version B* and *C* of the Patient Wellness Questionnaire are identical except for the response option for the first patient wellness question.

7.5 Thesis reflections

7.5.1 Integrating approaches to reduce preventable deterioration

The management of clinical deterioration is a highly complex practice requiring effective collaboration between health professionals within multidisciplinary teams, but also between health professionals, patients and relatives. A combination of multiple systems and approaches are needed to achieve improvement. Research within this thesis has explored the role patients and relatives can have to contribute towards improved management of deterioration. The evidence within the thesis suggested that patients' views on their wellness may be an indication of subsequent deterioration in their condition, and as such, patient-reported wellness may be used to aid health professionals in the early recognition of deterioration. Other researchers have pursued alternative approaches to aid early detection and escalation of clinical deterioration, such as continuous monitoring technologies and combining data to predict deterioration. It will be important for different approaches to become integrated to enable the greatest improvements in the management of patient deterioration to be realised. The following provides an overview of research findings within the different approaches to reduce preventable deterioration, and outlines where the research within the thesis sits in the context of wider research efforts.

7.5.1.1 Electronic observation systems and continuous vital sign monitoring

It has been argued that patients can experience clinical deterioration that may go undetected if it occurs in the time between routine observations which commonly occur every 4 to 6 hours (Brown, Terrence, Vasquez, Bates & Zimlichman, 2014). Modern technologies have been developed to allow for electronic observation systems that can continuously monitor patients' vital signs in a minimally intrusive way. These technologies include devices that sit under the mattress and continuously detect pulse, respiration and movement (Brown et al., 2014), to wearable devices that record physiological signs (Seoane et al., 2013). Researchers have explored the use of continuous vital sign monitoring systems to aid detection of clinical deterioration in low to medium risk patients on general hospital wards (Ben-Ari, Zimlichman, Adi & Sorkine, 2010; Brown, Terrence, Vasquez, Bates & Zimlichman, 2014; Zimlichman et al., 2012).

Brown et al. (2014) investigated the effects of continuous heart rate and respiratory rate monitoring on a medical-surgical ward on unplanned transfers to, and length of stay on the Intensive Care Unit and length of stay on the medical-surgical ward. Continuous monitoring was implemented on the experimental ward and explored pre and post-implementation, and in comparison to a control ward where continuous monitoring was not in use. There was no significant change in rate of Intensive Care Unit admission before and after implementation of continuous monitoring, or in comparison to the control ward. However, continuous monitoring was associated with a significant decrease in total length of stay on the medical-surgical ward and Intensive Care Unit for transferred patients. An important issue to consider with continuous monitoring is the sensitivity and specificity of the systems and subsequent alert frequency. Zimlichman et al. (2012) explored the use of continuous heart rate and respiratory rate monitoring, and found that this produced a low alert frequency, suggesting that health professionals may not experience alarm fatigue from continuous monitoring alerts. The findings of these two studies support the ability of continuous monitoring systems to accurately predict clinical deterioration.

7.5.1.2 Combining data types to identify deteriorating patients

The use of big data and analytics has been proposed as another approach that could improve management of clinical deterioration. Evidence has explored the combination of several types of data to identify patients with early signs of clinical deterioration. These types of data include vital sign measurements and clinical laboratory results. It has been suggested that the use of algorithms that combine several variables, rather than the use of single parameter with simple cut offs may be more effective to enhance the detection of clinical deterioration (Bates & Zimlichman, 2014).

Mohammed et al. (2013) investigated the use of blood test results in combination with EWS data to predict the risk of in-hospital mortality. Certain routine blood test results (albumin, sodium, white cell count and urea) and EWS taken within 24 hours of admission were found to be significant predictors of death (Mohammed et al., 2013). Furthermore, Keil, Hutchinson and Leary (2014) investigated the use of a track and trigger system based on common laboratory results (referred to as Laboratory Early Warning Score; LEWS). They found that 77% of patients who had a cardiac arrest during the study period had blood test results within the previous 24 hours that triggered the LEWS. The findings suggest that track and trigger systems based on laboratory test results could compliment EWS systems in identifying patients at risk of deterioration. Kipnis et al. (2016) researched the use of multiple data streams that are available in modern electronic medical records to develop algorithms to identify patients at risk of deterioration. These data streams included individual physiologic data points (laboratory tests and vital signs), neurological status checks obtained from nursing flowsheets, end of life care directives (for instance, physician orders regarding patient resuscitation preferences), and health care utilization services indicators (for instance, length of hospital stay and transfers to Intensive Care). The combined score was better able to predict transfer to Intensive Care Unit and patient death compared to EWS alone (Kipnis et al., 2016).

7.5.1.3 Integration of numerous approaches

Researchers have begun to study how different approaches to improve the management of clinical deterioration can become integrated, and whether

integrating these approaches is indeed more clinically effective. Bai et al. (2015) explored the integration of continuous monitoring systems with the use of clinical laboratory test results to identify whether their combined use enhances the prediction of deteriorating patients. They found that integrating monitoring alarms with laboratory test resulted in better prediction of cardiac arrest compared to the use of monitoring alarms alone. A study conducted by Schmidt et al. (2014) in two UK hospitals has also investigated the integration of multiple approaches to detect patient deterioration. They harnessed the use of electronic health records, mobile technology and analytic approaches to identify patients who may be deteriorating. The findings indicated a strong relationship between the increasing use of the integrated approach and reduced mortality for patients in 56 diagnosis groups used within the National Health Service (Schmidt et al., 2014).

7.5.1.4 Routinely recording patient-reported wellness in the context of other approaches

To put the research conducted within this thesis in the context of wider research efforts, routinely recorded patient-reported wellness could be considered as another data stream to be used alongside others, such as EWS and laboratory tests to aid identification of deterioration. The introduction of pioneering technologies and complex algorithms based on multiple data streams of course have the potential to provide breakthroughs in the effective management of clinical deterioration. Ultimately, continuous monitoring technologies, and the combined use of data streams aim to bring health professionals to the deteriorating patient's bedside at the right time to enable complete assessments to be conducted, and appropriate interventions to be carried out (Zimlichman et al., 2012). It could be argued that there remains no substitute for the use of clinical judgement based on knowledge of the patients' condition that is informed to some extent by what the patient says about how they feel. As well as having the potential to contribute towards algorithms to detect deterioration, routinely recording patient-reported wellness appeared to encourage health professionals to openly communicate with their patients which may be just as important for early recognition and response to deterioration.

7.5.2 Engaging healthcare assistants and nursing staff in research to embed recording of patient-reported wellness in to practice

Studies within the thesis highlighted the importance of engagement and support from senior ward staff to enable successful study implementation. In study 4, 95% of healthcare assistants and nurses approached to participate in the study were successfully recruited and consented. This recruitment rate is in contrast to that of the pilot study (study 3) discussed in Chapters 4 and 5 where only 42% of healthcare assistants approached to participate in the study agreed to take part. Yet, the involvement of healthcare assistants and nurses in studies 3 and 4 were similar. In study, 3 they were invited to rate patients' wellness from their own perspective using the Patient Wellness Questionnaire after routine observations and in study 4 they were invited to ask patients the Patient Wellness Questionnaire and record patients' ratings of their own wellness at routine observations.

In study 4, discussed in Chapter 6, the researcher had strong and consistent support throughout study set up and data collection from a senior member of nursing staff who implemented and trained ward staff on the sampled wards in the use of the electronic observation system. This clinical contact had longstanding working relationships with all senior and junior ward sisters working on the sampled wards, and encouraged their engagement with the study. She visited all four sampled wards once a week during the study period to verbally encourage nurses and healthcare assistants to participate in the study, and liaised with the ward sisters who also encouraged staff to participate through verbal communication and emails.

This level of engagement and support from senior ward staff was not present during the pilot study (study 3) discussed in Chapters 4 and 5. The ward sister on participating wards gave verbal agreement to the researcher that the study could take place on their ward, but there was little to no top-down support for the study to encourage healthcare assistants to participate. It may be that the recruitment rates of healthcare assistant and nursing staff in studies 3 and 4 are impacted by the level of senior support for the study on the ward. The importance of engagement and support from senior ward staff when implementing applied health services interventions is well documented (Birkin, Lee & Weiner, 2012;

Henderson, Burmeister, Schoonbeek, Ossenberg & Gneilding, 2014). Future research may seek to explore factors that facilitate senior support for applied heath research. The studies within this thesis indicated that to gain the support of senior ward staff, it may be necessary for them to perceive the intervention to be useful, and to have a vested interest in improving the outcomes that the intervention aims to improve.

7.5.3 How routinely recording patient-reported wellness may impact upon quality of care

The literature has highlighted that nurses can recognise patient deterioration through 'gut feelings' and that nurses identify this as intuition. Furthermore, along with abnormal vital sign measurements, nurse 'worry' can be a calling criteria to activate the CCOT in some hospitals (Douw, Waal, van Zanten, van der Hoeven & Schoonhoven, 2015). Douw et al. (2015) proposed that one indicator underlying nurse 'worry' for a patient is the patient stating they do not feel well. A such, it may be that healthcare assistants and nursing staff who conduct observations could use routinely recorded patient-wellness ratings to develop their 'gut feeling' about a patients' wellness. Healthcare staff have proposed that patients who voice concerns about changes in how they feel are often in the early stages of clinical deterioration, and that this may precede the appearance of abnormal vital signs (Cioffi, 2000; Grossman & Wheeler, 1997; Minick & Harvey, 2003). Routinely recorded patient-reported wellness may prompt staff to be vigilant to the possibility that a patient may be deteriorating despite the presence of normal vital sign measurements.

Routinely recording patient-reported wellness aimed to contribute towards improving early recognition of clinical deterioration, and may also impact upon the timely escalation of care for deteriorating patients. Escalation of patient care involves recognition of a change in patient status indicative of clinical deterioration by nursing staff, who communicate this to junior medical staff. Junior doctors review the patient and escalate care to senior medical staff for advice or to implement effective management (Johnston et al., 2015). Previous studies have found that communication failures can contribute to information breakdown along the escalation pathway resulting in poor outcomes for deteriorating patients (Johnston, Arora, King, Stroman & Darzi, 2014;

Mackintosh & Sandall, 2010). Johnston et al. (2014) conducted interviews with 41 nursing and medical staff working across 3 UK hospitals to explore influences on escalation of care on surgical wards. Barriers to escalation included failure to communicate concerns about a deteriorating patient to a senior colleague. Findings revealed that fear of a negative response was identified as a main reason why nurses may not communicate their concerns about a patient to a senior staff member, even when abnormal vital sign measurements are detected (Johnston et al., 2014). Routinely recorded patient-reported wellness may provide nurses with another piece of information to suggest the patient may be deteriorating and increase their confidence to escalate patient care earlier.

In terms of the impact of routinely recording patient-reported wellness on general quality of care, routinizing conversations that elicit communication about patient wellness may be beneficial as it encourages open dialogue between ward staff and patients. Health professionals interviewed in study 1 acknowledged the importance of speaking to patients but felt there was often not enough time to engage in patient-centred aspects of care, such as maintaining regular communication with patients. Incorporating conversations with patients about how they are feeling in to routine care may contribute towards addressing the perceived lack of day-to-day discussion between health professionals and patients. Study 3 supported the possibility that having regular conversations with patients about how they are feeling may unveil other concerns the patient has that do not relate to suspected clinical deterioration, but have consequences for patient safety and experience and require a response.

7.5.4 Role of relatives

The research conducted within this thesis suggested that it may be difficult to involve relatives in the recognition of patient deterioration in hospital, and that there may be a more limited role for relatives compared to patients. When asked to generate approaches to involve patients and relatives in the management of clinical deterioration, health professionals focussed on ways to involve patients. Nevertheless, studies within the thesis explored the feasibility and acceptability of the suggested approach with both patients and relatives. Health professionals in study 1 proposed the routine recording of patient-reported wellness during observation as a potentially useful approach to patient involvement. In study 2,

a questionnaire to prompt patients for their views on changes in wellness was developed and adapted for use with relatives. Study 3 piloted the feasibility and acceptability of routinely recording patients' views on their wellness during observation and relatives' views on the patients' wellness during visiting hours. The initial findings showed that it was difficult to recruit relatives to a study where the nature of it required them to visit the patient regularly in hospital. Where relatives were recruited to the study, there was substantial missing data on their views on the patients' wellness. This indicated that most relatives do not visit the patient regularly while they are in hospital to enable them to contribute towards routine monitoring of the patients' health in practice. However, only a small number of relatives were approached to participate in the study and a larger-scale study may have produced different findings.

It should be considered that findings within this thesis do not support the involvement of relatives in the management of deterioration because it was not appropriate to involve relatives using an approach that was proposed to be suitable for use with patients. Interviews conducted with health professionals in study 1 provided initial insight in to some of the general barriers to relative involvement that may need to be addressed before they can have a greater role in the management of deterioration. As well as conducting research to address these barriers, it may be important to separately consider how patients and relatives can be involved to reduce preventable deterioration and the extent to which this varies in different contexts. The research within this thesis showed that approaches to involvement that may be potentially appropriate and clinically effective for patients, may not be for relatives. Suggestions for future research to further investigate the role of relatives in the management of clinical deterioration are outlined in section 7.5.3.

7.6 Limitations and directions for future research

An in-depth discussion of the limitations of the research conducted within the thesis has been outlined throughout the chapters, along with clear direction for future research to further our understanding of the involvement of patients and relatives in reducing preventable deterioration. The following outlines some

general, overarching considerations regarding the limitations of the research and future directions.

7.6.1 Further exploration of the clinical effectiveness of routinely recorded patient-reported wellness

Study 4 within the thesis provided initial findings regarding the association between patient-reported wellness and EWS, an objective measure of patient health. These findings have allowed us to begin to understand the extent to which patients can recognise deterioration in their condition, and therefore the likely clinical effectiveness of routinely recording patient-reported wellness. Future research may seek to expand our understanding of the clinical effectiveness of routinely recording patient-reported wellness by using larger samples of patients with different diagnoses as study 4 included Oncology patients only. As previously discussed, routinely recorded patient-reported wellness has the potential to be a data stream that can be combined with EWS and laboratory tests to aid identification of deterioration. Future research ought to explore the inclusion of routinely recorded patient-reported wellness in predictive algorithms used to identify deteriorating patients. It may be that the predictive ability of these algorithms is enhanced when patient-reported wellness is also considered.

A more general consideration that may be explored in future research is the sensitivity and specificity of recording patient-reported wellness using the Patient Wellness Questionnaire. What is the rate of false positives produced by the Patient Wellness Questionnaire? To answer this question, a prospective study design could be used to investigate the relationship between patient-reported wellness and the subsequent incidence of poor health outcomes indicative of clinical deterioration, such as cardiac arrest, transfer to higher level care or death. This will allow for a greater understanding of the extent to which poor patient-reported wellness is followed by subsequent clinical deterioration in the patients' condition.

7.6.2 Frequency of routinely recording patient-reported wellness

The frequency of routine observation varies between patients and increases if abnormal vital sign measurements are detected (Petersen, Mackel, Antonsen & Rasmussen, 2014). Evidence generated within the thesis explored the

acceptability of recording patient-reported wellness during every observation (where possible) from a patient perspective. Preliminary findings revealed that 88% of patient participants who gave feedback about taking part in the pilot study reported in Chapters 4 and 5 felt that it was acceptable to be asked the Patient Wellness Questionnaire as frequently as every observation. Subsequently, in study 4 reported in Chapter 6, healthcare assistants and nurses were invited to record patient wellness ratings during every observation (where possible) for patients who they felt it was appropriate. One of the main limitations of the study was that patient wellness ratings were not recorded in a large number of observations during the study period. Over the four participating wards, a patient wellness rating was recorded during only 14% of observations with a range of 3% to 55%.

Study 4 did not investigate why patient wellness ratings were recorded in only a small percentage of observations during the study period. The researcher proposed a number of explanations that may account for this finding, such as non-documentation of patients' refusals to answer the questions or where they were unable to due to their medical condition. However, it would have been interesting to conduct interviews with some of the participating healthcare assistants and nurses to gain an understanding of why patient wellness ratings were recorded during so few observations. There is no previous literature in this area to inform our understanding and this is the first study to explore routinely recording patient-reported wellness. Further research is needed to identify the appropriate frequency at which to record patient-reported wellness during routine observation in terms of acceptability to health professionals and patients, and clinical effectiveness to aid health professionals in detecting clinical deterioration.

7.6.3 Involving relatives in the management of clinical deterioration

Health professionals interviewed in study 1 discussed barriers to involving relatives in the management of clinical deterioration in hospital. Barriers to relative involvement related to complex, abstract issues, such as the difficulties in creating partnerships between health professionals and relatives. Participants stated that health professionals can lack respect for relatives. Future research may seek to understand why there can be a lack of respect and mistrust between health professionals and relatives, as this could have a bearing on the perceived

utility of relatives in recognising deterioration. It may be that health professionals do not always have the time, resources or skill to achieve a continuous shared understanding with relatives about the patients' condition and treatment plan. This may result in misunderstanding and frustration for relatives that can erode respect between health professionals and relatives.

Understanding why negative relationships form between health professionals and relatives is useful, but it will also be important for researchers to identify factors that support positive partnerships between them. Belanger, Bourbonnais, Bernier and Benoit (2017) conducted a literature review that may contribute towards our understanding of how to create positive partnerships between health professionals and relatives, and supports the idea that skill is required on the part of the health professional. Sixty-seven articles were reviewed to understand the thoughts, feeling and behaviours of nurses and caregivers that may result in positive or negative communication patterns. The authors concluded that relatives can be components of a positive partnership with nurses when they believe they are well informed, they feel safe and feel their contributions are recognised by nurses who have addressed their needs. The review highlighted that nurses require skills to interact with relatives in a way that ensures they can build a positive partnership. Training nurses to communicate effectively with relatives was proposed, and may support the development of positive partnerships between nurses and relatives (Belanger, Bourbonnais, Bernier & Benoit, 2017). It may be necessary to enhance positive partnerships between health professionals and relatives to create an environment where relatives can become more involved in aiding health professionals to recognise clinical deterioration.

It is warranted to further explore the role of relatives in contributing towards improved management of clinical deterioration. However, it must not be assumed that all patients have relatives that are willing and able to be involved, and it should also be acknowledged that some patients in hospital do not have any relatives or visitors. Future research investigating how relatives could be involved in aiding the detection and escalation of deterioration must be careful not to introduce inequalities in care. It will be important to consider how to support the

delivery of high quality, safe care for patients who do not have relatives or visitors, as well as those who do.

7.7 Practical implications

The applied health research conducted within this thesis has a number of practical implications for healthcare providers, patients and their relatives. Although the implications of this research have been thoroughly discussed throughout chapters within the thesis, a summary of the key implications are listed below.

- Previous approaches to involving patients and relatives in the management of deterioration in practice were based on provider intuition and anecdotal evidence. High quality, rigorous empirical evidence is required to understand how the expertise of patients and their relatives may be best utilised to contribute towards improving the management of clinical deterioration in hospital.
- Key stakeholders, such as health professionals and patients should be involved when developing an intervention to promote patient involvement in clinical deterioration to ensure it is embedded within the culture of the organisation within which is will ultimately be used.
- Frontline healthcare assistants and nurses need support to begin to engage patients in the management of deterioration by routinely recording patient-reported wellness during observation. Targeted BCTs are effective to encourage staff with positive attitudes towards patient observations to adopt this new practice.
- It may be more useful to routinely collect patient wellness rating 1 (a rating of their current condition) from patients compared to patient wellness rating 2 (a rating of relative change in their condition).
- It may be more appropriate to routinely record patient-reported wellness for highly acutely unwell patients compared to low or moderately acutely unwell patients.
- It is difficult to involve relatives in routine monitoring of patients in hospital as many relatives do not visit the patient in hospital on a regular basis.

- Improved partnerships between health professionals and relatives may be required for relatives to have a greater role in the management of clinical deterioration.

7.8 Concluding comments

In-hospital clinical deterioration that is not promptly responded to can result in a number of severe consequences for patients. Such serious adverse events may be prevented by recognising and responding to early signs of clinical deterioration. To aid health professionals in recognising and responding to clinical deterioration, Early Warning Score systems and Critical Care Outreach teams have been introduced in numerous countries including the UK, USA and Australia. Despite these measures, some patients who are deteriorating continue to go unrecognised and appropriate, timely action is not always taken.

As the model of care has shifted from a paternalistic approach to one in which patients are empowered to be active partners in their healthcare, the potential for patients and their relatives to support staff in the management of clinical deterioration has been considered. Previous approaches to involving patients and their relatives in their healthcare to reduce preventable deterioration have proceeded on the basis of anecdotal evidence and provider intuition, and little was known about the clinical effectiveness of involving patients and relatives in this patient safety problem.

The research conducted as part of this thesis has aimed to generate high quality, robust evidence to explore whether it is feasible, acceptable and clinically effective to involve patients and their relatives in the management of clinical deterioration in hospital. The systematic review revealed a number of gaps within the previous literature, some of which were addressed in subsequent research studies. Study 1 explored the potential for involving patients and relatives in the management of in-hospital clinical deterioration, and studies 2, 3 and 4 report the development and evaluation of a novel health services intervention to promote patient and relative involvement in recognising clinical deterioration in hospital.

Research exploring the involvement of patients and relatives in the management of deterioration is in its infancy. However, it is hoped that findings within the thesis

can be used to guide clinicians and researchers interested in the role that patients and relatives can have to improve the timely recognition of, and response to clinical deterioration. Some of the challenges of involving patients and relatives in this patient safety problem are also highlighted. The findings generated through this thesis suggest that routinely recording patient-reported wellness during observation is one feasible, acceptable and potentially clinically effective approach that could contribute towards improving the management of clinically deteriorating patients.

References

Adelstein, B., Piza, M. A., Nayyar, V., Mudaliar, Y., Klineberg, P. L., & Rubin, G. (2011). Rapid response systems: A prospective study of response times. *Journal of Critical Care 26*(6), 653.e11-653.e18.

Agency for Healthcare Research and Quality. (2007). National healthcare quality report. Retrieved October 8, 2017, from https://archive.ahrq.gov/qual/qrdr07.htm

Alam, N., Hobbelink E. L., van Tienhoven, A. J., van de Ven, P. M., Jansma, E. P., & Nanayakkara, P. W. (2014). The impact of the use of early warning score (EWS) on patient outcomes: a systematic review. *Resuscitation, 85*(5), 587–594.

Albutt, A. K., O'Hara, J. K., Conner, M. T., Fletcher, S. J., & Lawton, R. J. (2016). Is there a role for patients and their relatives in escalating clinical deterioration in hospital? *Health Expectations*. doi: 10.1111/hex.12496

Amaral, A. C. K., McDonald, A., Coburn, N. G., Xiong, W., Shojania, K. G., & Fowler, R. (2015). Expanding the scope of Critical Care Rapid Response Teams: A feasibility approach to identify adverse events. A prospective observational chart. *BMJ Quality & Safety, 24*(12), 764-768.

Appleby, J., Raleigh, V., Frosini, F., Bevan, G., Gao, H., & Lyscom, T. (2011). *Variations in healthcare: The good, the bad and the inexplicable*. London, UK: The Kings Fund.

Armstrong, R. A. (2014). When to use the Bonferroni correction. *Ophthalmic & Physiological Optics. The Journal of the College of Optometrists, 34*, 502-508.

Auerbach, A. D., Landefeld, C. S., & Shojania, K. G. T. (2007). The tension between needing to improve care and knowing how to do it. *New England Journal of Medicine, 357*, 608-613.

Austen, C., Patterson, C., Poots, A., Green, S., Weldring, T., & Bell, D. (2012). Using a local early warning scoring system as a model for the introduction of a national system. *Acute Medicine, 11*(2), 66–73.

Azjen, I. (1991). The theory of planned behaviour. *Organisational Behaviour and Human Decision Processes, 50*, 2, 179-211.

Ball, D. R., & Frerk, C. (2015). A new view of safety: Safety 2. *British Journal of Anaesthesia, 115*(5), 645-647.

Bai, Y., Do, D. H., Harris, P. R. E., Schindler, D., Boyle, N. G., Drew, B. J., Hu, X. (2014). Integrating monitor alarms with laboratory test results to enhance patient deterioration prediction. *Journal of Biomedical Informatics, 53*, 81-92.

Bates, D. W., & Zimlichman, E. (2014). Finding patients before they crash: The next major opportunity to improve patient safety. *BMJ Quality and Safety, 0*, 1-3.

Beaumont, K., Luettel, D. & Thomson, R. (2008) Deterioration in hospital patients: early signs and appropriate actions. *Nursing Standard, 23*(1), 43–48.

Belanger, L., Bourbonnais, A., Bernier, R., & Benoit, M. (2016). Communication between nurses and family caregivers of hospitalised older persons: a literature review. *Journal of Clinical Nursing, 26*, 609-619.

Benn, J., Koutantji, M., Wallace, L., Spurgeon, P., Rejman, M., Healey, A., & Vincent, C. (2009). Feedback from incident reporting: Information and action to improve patient safety. *BMJ Quality and Safety, 18*, 11-21.

Benyamini, Y. (2003). Gender differences in the self-rated health-mortality association: is it poor self-rated health that predicts mortality or excellent self-rated health that predicts survival? *Gerontologist, 43*(3), 396-405.

Benyamini, Y. (2011). Why does self-rated health predict mortality? An update on current knowledge and a research agenda for psychologists. *Psychology & Health, 26*(11), 1407-1413.

Ben-Ari, J., Zimlichman, E., Adi, N., & Sorkine, P. (2010). Contactless respiratory and heart rate monitoring: Validation of an innovative tool. *Journal of Medical Engineering and Technology, 34*, 393-398.

Berger, Z., Flickinger, T. E., Pfoh, E., Martinez, K. A., & Dy, S. M. (2014). Promoting engagement by patients and families to reduce adverse events in acute care settings: A systematic review. *BMJ Quality and Safety, 23*, 548-555.

Bernhardsson, S., Johansson, K., Nilsen, P., Oberg, B., & Larsson, M. E. H. (2014). Determinants of guideline use in primary care physical therapy: A cross-sectional survey of attitudes, knowledge and behaviour. *Physical Therapy, 94*, 3, 343-354.

Berwick, D. M. (2013). *A promise to learn – a commitment to act: Improving the safety of patients in England*. London, UK: Stationery Office.

Birkin, S. A., Lee, S. Y. D., & Weiner, B. (2012) Uncovering middle managers' role in healthcare innovation. *Implementation Science 7*, 28.

Bogert, S., Carmen, F., & Rutledge, D. N. (2010). Experience with family activation of rapid response teams. *Medsurg Nursing: Official Journal of the Academy of Medical-Surgical Nurses, 19*(4), 215-223.

Bokhari, S. W., Munir, T., Memon. S., Byrne, J. L., Russell, N. H., & Beed, M. (2010). Impact of critical care reconfiguration and track-and-trigger outreach team intervention on out-comes of haematology patients requiring intensive care admission. *Annals of Haematology, 89*, 505–512.

Boniatti, M. M., Azzolini, N., Viana, M. V., Riberio, B. S. P., Coelho, R. S., Castilho, R. K., ... Filho, M. R. (2014). Delayed medical emergency team calls and associated outcomes. *Critical Care Medicine, 42*(1), 26-30.

Bowen, G. A. (2008). Naturalistic inquiry and the saturation concept: a research note. *Qualitative research, 8*(1), 137-152.

Boyatzis, R. E. (1998). *Transforming qualitative information: Thematic analysis and code development*. Thousand Oaks, CA: Sage.

Brady, P. W., Zix, J., Brilli, R., Wheeler, D. S., Griffith, K., Giaccone, M. J., … Tegtmeyer, K. (2014). Developing and evaluating the success of a family activated medical emergency team: A quality improvement report. *BMJ Quality and Safety, 0*, 1-9.

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology, 3*(2), 77-101.

Brasel, K. J., Lim, H. J., Nirula, R., & Weigelt, J. A. (2007). Length of stay: An appropriate quality measure? *Archives of Surgery, 142*(5), 461-466.

Brennan, T. A., Leape, L. L., Laird, N. M., Hebert, L., Localio, R., Lawthers, A. G., … Hiatt, H. H. (1991). Incidence of adverse events and negligence in hospitalized patients — Results of the Harvard medical practice study I. *The New England Journal of Medicine, 324*, 370-376.

Brown, H., Terrence, J., Vasquez, P., Bates, D. W., Zimlichman, E. (2014). Continuous monitoring in an inpatient Medical-Surgical Unit: A controlled clinical trial. *The American Journal of Medicine, 127*, 226-232.

Cardona-Morrella, M., Prgomet, M., Lake, R., Nicholson, M., Harrison, R., Long, J., … Hillman, K. (2015). Vital signs monitoring and nurse–patient interaction: A qualitative observational study of hospital practice. *International Journal of Nursing Studies, 56*, 9-16.

Caron-Flinterman, J. F., Broerse, J. E., & Bunders, J. F. (2005). The experiential knowledge of patients: a new resource for biomedical research? *Social Science & Medicine, 60*, 2575-2584.

Carr, S. M., Lhussier, M., Foster, N., Geddes, L., Deane, K., Pennington, E., … Hildreth, A. (2011). An evidence synthesis of qualitative and quantitative research on component intervention techniques, effectiveness, cost-effectiveness, equity and acceptability of different versions of health-related lifestyle advisor role in improving health. *Health Technology Assessment, 15*(9), 1-229.

Catchpole, K., Neyens, D. M., Abernathy, J., Allison, D., Joseph, A., & Reeves, S. T. (2017). Framework for direct observation of performance and safety in healthcare. *BMJ Quality and Safety, 26*, 1015-1021.

Chan, P. S., Jain, R., Nallmothu, B. K., Berg, R. A., & Sasson, C. (2010). Rapid response teams: A systematic review and meta-analysis. *Archives of Internal Medicine, 170*(1), 18-26.

Chen, J. G., Kemper, A. R., Odetola, F., Cheifetz, I. M., & Turner, D. A. (2012). Prevalence, characteristics, and opinions of pediatric rapid response teams in the United States. *Hospital Paediatrics, 2*(3), 133-140.

Cherry, P.G., & Jones, C.P., 2015. Attitudes of nursing staff towards a modified early warning system. *British Journal of Nursing, 24* (16), 812–818.

Christensen, D., Jensen, N.M., Maaloe, R., Rudolph, S.S., Belhage, B., & Perrild, H. (2011). Low compliance with a validated system for emergency department triage. *Danish Medical Bulletin, 58* (6), A4294.

Chua, W. L., Macket, E. K. C., & Liaw, S. Y. (2013) Front line nurses' experiences with deteriorating ward patients: a qualitative study. *International Nursing Review, 60*, 501–509.

Churpek, M. M., Yuen, T. C., & Edelson, D. P. (2013). Risk stratification of hospitalised patients on the wards. *Chest, 143*(6), 1758-1765.

Cioffi, J. (2000). Recognition of patients who require emergency assistance: a descriptive study. *Heart & Lung 29*(4), 262-268.

Clifton, D. A., Clifton, L., Sandu, D. M., Smith, G. B., Tarassenko, L., Vollam, S. A., & Watkinson, P. J. (2015). 'Errors' and omissions in paper-based early warning scores: The association with changes in vital signs- a database analysis. *BMJ Open, 5*(7). doi: 10.1136/bmjopen-2014-007376

Coleman, E. A., Smith, J. D, Frank, J. C., Min, S. J., Parry, C., & Kramer, A. M. (2004). Preparing patients and caregivers to participate in care delivered

across settings: The Care Transitions Intervention. *Journal of American Geriatrics Society, 52*(11), 1817-1825.

Conner-Spady, B. L., Marshall, D. A., Bohm, E., Dunbar, M. J., Loucks, L., Khundairy, A., A., & Noseworthy, T. W. (2015). Reliability and validity of the EQ-5D-5L compared to the EQ-5D-3L in patients with osteoarthritis referred for hip and knee replacement. *Quality of Life Research, 24*(7), 1775-1784.

Coulter, A., & Ellins, J. (2006). Patient-focused interventions: A review of the evidence. Retrieved January 27, 2015, from www.health.org.uk/QQUIP

Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I., & Petticrew, M. (2008). Developing and evaluating complex interventions: the new Medical Research Council guidance. *British Medical Journal, 337*, 979-983.

Davey, P., Brown, E., Charani, E., Fenelon, L., Gould, I. M., Holmes, A., … Wilcox, M. (2013). Interventions to improve antibiotic prescribing practices for hospital inpatients. *Cochrane Database Systematic Reviews*, 4, doi: 10.1002/14651858.CD003543.pub3.

Davidoff, F., Dixon-Woods, M., Leviton, L., & Michie, S. (2015) Demystifying theory and its use in implementation. *BMJ Quality & Safety, 0*, 1-11.

Davis, R. E., Sevdalis, N., & Vincent, C. A. (2011). Patient involvement in patient safety: How willing are patients to participate? *BMJ Quality & Safety, 20*, 108-114.

Davis, R. E., Sevdalis, N., Jacklin, R., & Vincent, C. A. (2007). Patient involvement in patient safety: What factors influence patient participation and engagement? *Health Expectations, 10*(3), 259-267.

De Meester, K., Bogaert, P. V., Clarke, S. P., & Bossaert, L. (2012). In-hospital mortality after serious adverse events on medical and surgical nursing units: A mixed methods study. *Journal of Clinical Nursing, 22*, 2308–2317.

De Meester, K., Das, T., Hellemans, K., Verbrugghe, W., Jorens, P. G., Verpooten, G. A. & Van Bogaert, P. (2013). Impact of a standardized nurse observation protocol including MEWS after Intensive Care Unit discharge. *Resuscitation, 84*, 184–188.

Dean, B. S., Decker, M. J., Hupp, D., Urbach, A. H., Lewis, E., & Benes-Stickle, J. (2008). Condition HELP: A pediatric rapid response team triggered by patients and parents. *Journal for Healthcare Quality, 30*(3), 28-31.

Department of Health (2015).The NHS Constitution for England. Retrieved 11th October, 2017, from https://www.gov.uk/government/publications/thenhs-constitution-for-england/the-nhs-constitution-for-england

Department of Health. (2000*). An organisation with a memory*. London, UK: The Stationary Office.

Dixon-Woods, M., Agarwal, S., Jones, D., Young, B., & Sutton, A. (2005). Synthesising qualitative and quantitative evidence: A review of possible methods. *Journal of Health Services Research and Policy, 10*(1), 45-53.

Dixon-Woods, M., Leslie, M., Tarrant, C., & Bion, J. (2013). Explaining Matching Michigan: An ethnographic study of a patient safety program. *Implementation Science, 8*(1), 70.

Dobbins, M., Robeson, P., Jetha, N. J., & DesMeules, M. (2008). A methodology for searching the grey literature for effectiveness syntheses related to public health: A report from Canada. *Health Informatics, 17*, 9-12.

Dombrowski, S. U., Campbell, P., Frost, H., Pollock, A., McLellan, J., MacGillivray, S., ... Williams, B. (2016). Interventions for sustained healthcare professional behaviour change: A protocol for an overview of reviews. *Systematic reviews, 5*(1), 137, doi:10.1186/s13643-016-0355-9.

Douw, G., Huisman-de Waal, G., van Zanten, A. R. H., van der Hoeven, J. G., & Schoonhoven, L. (2016). Nurses' 'worry' as predictor of deteriorating surgical ward patients: A prospective cohort study of the Dutch-Early-Nurse-Worry-Indicator-Score. *International Journal of Nursing Studies, 59*, 134, 140.

Downey, C. L., Tahir, W., Randell, R., Brown, J. M., & Jayne, D. G. (2017). Strengths and limitations of early warning scores: A systematic review and narrative synthesis. *International Journal of Nursing Studies, 76*, 106-119.

Dunn, O. J. (1961) Multiple comparison among means*. Journal of the American Statistical Association, 56*, 52-64.

Entwistle, V. A., Mello, M. M., & Troyen, A. (2005). Advising patients about patient safety: Current initiatives risk shifting responsibility. *Joint Commission Journal on Quality and Patient Safety, 31*(9), 483-494.

Faulkner, A., & Thomas, P. (2002). User-led research and evidence-based medicine. *The British Journal of Psychiatry, 180*, 1-3.

Francis, R. (2013). *Report of the Mid Staffordshire NHS Foundation Trust public inquiry.* London, UK: Stationery Office.

Frankenberg, E., & Jones, N. R. (2004). Self-rated health and mortality: does the relationship extend to a low income setting? *Journal of Health and Social Behaviour, 45*(4), 441-452

Franklin, C. & Mathew, J. (1994). Developing strategies to prevent in-hospital cardiac arrest: Analysing responses of physicians and nurses in the hours before the event. *Critical Care Medicine, 22*(2), 244-247.

Frost, S. A., Chapman, A., Aneman, A., Chen, J., Parr, M. J., Hillman, K. (2015). Hospital outcomes associated with introduction of a two-tiered response to the deteriorating patient. *Critical care and resuscitation, 17*(2), 77-82.

Fudge, N., Wolfe, C. D., & McKevitt, C. (2008). Assessing the promise of user involvement in health service development: ethnographic study. *British Medical Journal, 336*, 313-317.

Gardner, B., Sheals, K., Wardle, J., & McGowan, L. (2014). Putting habit into practice, and practice into habit: A process evaluation and exploration of the acceptability of a habit-based dietary behaviour change intervention. *International Journal of Behavioural Nutrition and Physical Activity, 11*, 135.

Gerdik, C., Vallish, R. O., Miles, K., Godwin, S. A., Wludyka, P. S., & Panni, M. K. (2010). Successful implementation of a family and patient activated rapid response team in an adult level 1 trauma centre. *Resuscitation, 81*(12), 1676-1681.

Giles, S. J., Lawton, R. J., Din, I., & McEachan, R. R. C. (2013). Developing a patient measure of safety (PMOS). *Quality and Safety in Health Care, 22*(7), 554-567.

Gill, F. J., Leslie, G. D., & Marshall, A. P. (2016). The impact of implementation of family-initiated escalation of care for the deteriorating patient in hospital: A systematic review. *Worldwide Views on Evidence-based Nursing, 13*(4), 303-313.

Gilmartin, J., & Wright, K. (2008). Day surgery: Patients' felt abandoned during the preoperative wait. *Journal of Clinical Nursing, 17*(18), 2418-2425.

Giustini, D. (2012). Finding the hard to finds: searching for grey literature [slides]. Retrieved February 23rd, 2015, from

http://www.slideshare.net/giustinid/finding-the-hard-to-finds-searching-for-grey-gray-literature-2010

Goldhill, D. R., McNarry, A. F., Mandersloot, G., McGinley, A. (2005). A physiologically-based early warning score for ward patients: The association between score and outcome. *Anaesthesia, 60*(6), 547-553.

Gollwitzer, P. M. (1999). Implementation intentions: Strong effects of simple plans. *American Psychologist, 54*, 493–503.

Gravel, K., Legare, F., & Graham, I. (2006). Barriers and facilitators to implementing shared decision-making in clinical practice: a systematic review of health professionals' perceptions. *Implementation Science, 1*(1), 16.

Green, M., Lander, H., Snyder, A., Hudson, P., Churpek, M., Edelson, D. (2018). Comparison of the Between the Flags calling criteria to the MEWS, NEWS and the electronic Cardiac Arrest Risk Triage (eCART) score for the identification of deteriorating ward patients. *Resuscitation, 123*, 86-91.

Greenhouse, P. K., Kuzminsky, B., Martin, S. C., & Merryman, T. (2006). Calling a Condition H(elp)- One facility gives patients and families the ability to summon a rapid response team. *American Journal of Nursing, 106*(11), 63-66.

Griffin, M. A. (1997). Interaction between individuals and situations: Using HLM procedures to estimate reciprocal relationships. *Journal of Management, 23*(6), 759-773.

Grossman, S. C., & Wheeler, K. (1997). Predicting patients' deterioration and recovery. Clinical Nursing Research, 6(1), 45-58.

Guinane, J., Hutchinson, A. M., Bucknall, T. K. (2018). Patient perceptions of deterioration and patient and family activated escalation systems: A qualitative study. *Journal of Clinical Nursing*, doi: 10.1111/jocn.14202

Gusi, N., Olivares, P. R., & Rajendram, R. (2010). The EQ-5D health-related quality of life questionnaire. In V. R. Preedy & R. R. Watson (Ed.), *Handbook of disease burdens and quality of life measures* (pp. 87-99). New York, NY: Springer.

Hammerstrøm, K., Wade, A., & Jørgensen, A. M. K. (2010). Searching for studies: A guide to information retrieval for Campbell Systematic Reviews. Campbell Systems. Reviews. Retrieved February 23rd, 2015, from,

http://www.google.co.uk/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CCIQFjAA&url=http%3A%2F%2Fwww.campbellcollaboration.org%2Flib%2Fdownload%2F969%2F&ei=U0_rVLb3Lc2y7Qbb3YCABw&usg=AFQjCNFaMpfmnGfsTaQufaG_E4SJs3BmJw&sig2=FjWZiFXlKjKMjc-5wDRZxw

Hands, C., Reid, E., Meredith, P., Smith, G. B., Prytherch, D. R., Schmidt, P. E. & Featherstone, P. I. (2013). Patterns in the recording of vital signs and early warning scores: Compliance with a clinical escalation protocol. *BMJ Quality and Safety, 22*(9), 719-726.

Hardeman, W., Michie, S., Fanshawe, T., Prevost, T. A., Mcloughlin, K., & Kinmouth, A. L. (2008). Fidelity of delivery of a physical activity intervention: Predictors and consequences. *Psychology and Health, 23*(1), 11-24.

Hayes, N. (2000). *Doing psychological research*. Buckingham, UK: Open University Press.

Hayward, R. A., & Hofer, T. P. (2001). Estimating hospital deaths due to medical errors: Preventability is in the eye of the reviewer. *JAMA*, *286*, 415-420.

Henderson, A., Burmeister, L., Schoonbeek, S., Ossenberg, C & Gneilding, J. (2014). Impact of engaging middle management in practice interventions on staff support and learning culture: A quasi-experimental design. *Journal of Nursing Management, 22*, 995-1004.

Hodgetts, T. J., Kenward, G., Vlackonikolis, I., Payne, S., Castle, N., Crouch R., … Shaikh L. (2002) Incidence, location and reasons for avoidable in-hospital cardiac arrest in a district general hospital. *Resuscitation, 54*(2): 115–123.

Hogan, H., Healey, F., Neale, G., Thomson, R., Vincent, C., & Black, N. (2012). Preventable deaths due to problems in care in English acute hospitals: A retrospective case record review study. *BMJ Quality & Safety, 21*, 737-745.

Hogan, J. (2006). Why don’t nurses monitor the respiratory rates of patients. *British Journal of Nursing, 15*, 489-492.

Hong-Mei Wang, D., L., Patrick, T., C., Edwards, A., M., Skalicky, H., Z., & Wen-Wen, G. (2012). Validation of the EQ-5D in a general population sample in urban China. *Quality of Life Research, 21*(1), 155-160.

Hueckel, R. M., Mericle, J. M., Frush, K., Martin, P. L., & Champagne, M. T. (2012). Implementation of Condition Help family teaching and evaluation of family understanding. *Journal of Nursing Care Quality, 27*(2), 176-181.

Huis, A., van Achterberg, T., de Bruin, M., Grol, R., Schoonhoven, L., Hulscher, M. (2012). A systematic review of hand hygiene improvement strategies: A behavioural approach. *Implement Science, 7*, 92.

Huskins, C. W., Huckabee, C. M., O'Grady, N. P., Murray, P., Kopetskie, H., Zimmer, L., … Goldmann, D. W. (2011). Intervention to reduce transmission of resistent bacteria in intensive care. *The New England Journal of Medicine, 364*, 1407-1418.

Idler, E. L., & Benyamini, Y. (1997). Self-rated health and mortality: a review of twenty-seven community studies. *Journal of Health and Social Behaviour, 38*(1), 21-37.

Ivers, N., Jamtyedt, G., Flottorp, S., Young, J. M., Odgaard-Jensen, J., French, S. D., …Oxman, A. D. Audit and feedback: Effects on professional practice and healthcare outcomes. *Cochrane Database Systematic Reviews*, doi: 10.1002/14651858.CD000259.pub3.

Institute of Medicine. (2001). *Crossing the quality chasm*. Washington, DC: National Academy Press.

James, J., Butler-Williams, C., Hunt, J., & Cox H. (2010). Vital signs for vital people: an exploratory study into the role of the healthcare assistant in recognising, recording and responding to the acutely ill patient in the general ward setting. *Journal of Nursing Management, 18*, 548– 555.

Jangland, E., Gunningberg, L., & Carlsson, M. (2009). Patients' and relatives' complaints about encounters and communication in health care: Evidence for quality improvement. *Patient Education and Counselling, 75*(2), 199-204.

Jha, V., Buckley, H., Gabe, R., Kanaan, M., Lawton, R., Melville, C., … Wright, J. (2015). Patients as teachers: A randomised controlled trial on the use of personal stories of harm to raise awareness of patient safety for doctors in training. *BMJ Quality and Safety, 24*(1), 21-30.

Johnson, M. J., & May, C. R. (2015). Promoting professional behaviour change in healthcare: What interventions work, and why? A theory-led overview of systematic reviews. *BMJ Open*, doi: 10.1136/bmjopen-2015-008592.

Johnston, M. J., Arora, S., King, D., Bouras, G., Almoudaris, A. M., Davis, R., & Darzi, A. (2015). A systematic review to identify the factors that affect failure to rescue and escalation of care in surgery. *Surgery, 157*(4), 752-763.

Johnston, M. J., Arora, S., King, D., Stroman, L., & Darzi, A. (2014). Escalation of care and failure to rescue: A multi-center, multi-professional qualitative study. *Surgery, 155*(6), 989-994.

Jones, D. A., DeVita, M. A., & Bellomo, D. (2011). Rapid-response teams. *The New England Journal of Medicine, 365*, 139-146.

Jones, D., Mitchell, I., Hillman, K., & Story, D. (2013). Defining clinical deterioration. *Resuscitation, 84*(8), 1029-1034.

Jonsson, T., Jonsdottir, H., Moller, A. D., Baldursdottir, L. (2011). Nursing documentation prior to emergency admissions to the intensive care unit. *Nursing in Critical Care, 16*(4), 164-169.

Jorm, C. M., Dunbar, N., Sudano, L., & Travaglia, J. F. (2009). Should patient safety be more patient centred? *Quality and Safety Policy, 33*(3), 390-399.

Kaplan, L. J., Maerz, L. L., Schuster, K., Lui, F., Johnson, D., Roesler D, … Davis, K. A. (2006). Uncovering system errors using a rapid response team: cross-coverage caught in the crossfire. *The Journal of Trauma, 67*(1), 173-178.

Karademas, E.C., Kynigopoulou, E., Aghathangelou, E., & Anestis, D. (2011). The relation of illness representations to the ‘end-stage’ appraisal of outcomes through health status, and the moderating role of optimism. *Psychology and Health, 2*6, 567–583.

Karademas, E.C., Zarogiannos, A., & Karamvakalis, N. (2010). Cardiac patient–spouse dissimilarities in illness perception: Associations with patient self-rated health and coping strategies. *Psychology and Health, 25*, 451–463.

Keil, M., Hutchinson, S., & Leary, T. (2014). Laboratory early warning score versus clinical early warning score as a predictor of imminent cardiac arrest. *Critical Care, 18*(1), 81.

Keogh, B. (2013). Review into the quality of care and treatment provided by 14 hospital trusts in England: overview report. Retrieved 8th October, 2017, from http://www.nhs.uk/NHSEngland/bruce-keogh review/Documents/outcomes/keogh-review-final-report.pdf

Kipnis, P., Turk, B. J., Wulf, D. A., LaGuardia, J. C., Liu, V., Churpek, M. M., … Escobar, G. J. (2016). Development and validation of an electronic medical record-based alert score for detection of inpatient deterioration outside the ICU. *Journal of Biomedical Informatics, 64*, 10-19.

Kohn, L. T., Corrigan, J. M., & Donaldson, M. S. (1999). *To err is human: Building a safer health system*. Washington, DC: The National Academies Press.

Kondracki, N. L., Wellman, N. S., & Amundson, D. R. (2002). Content analysis: review of methods and their applications in nutrition education. *Journal of Nutrition Education and Behaviour, 34*(4), 224–230.

Kristensen, M., Iversen, A. K. S., Gerds, T. A., Østervig, R., Linnet, J. D., Barfod, C., … Iversen, K. (2017). Routine blood tests are associated with short term mortality and can improve emergency department triage: A cohort study of >12,000 patients. *Scandinavia Journal of Trauma, Resuscitation and Emergency Medicine, 25*(115), doi: https://doi.org/10.1186/s13049-017-0458-x

Kyriacos, U., Jelsma, J., & Jordan, S. (2011). Monitoring vital signs using early warning scoring systems: a review of the literature. *Journal of Nursing Management, 19*(3), 311-330.

Lamont, T., & Waring, J. (2015). Safety lessons: shifting paradigms and new directions for patient safety research. *Journal of Health Services Research Policy, 20*(1), 1-8.

Landrigan, C. P., Parry, G. J., Bones, C. B., Hackbarth, A. D., Goldmann, D. A., & Sharek, P. J. (2010). Temporal trends in rates of patient harm resulting from medical care. *New England Journal of Medicine, 363*(22), 2124-2134.

Lawton, R. J., O'Hara, J. K., Sheard, L., Armitage, G., Cocks, K., Buckley, H., … Wright, J. (2016). Can patient involvement improve patient safety? A cluster randomised control trial of he Patient Reporting and Action for a Safe Environment (PRASE) intervention. *BMJ Quality and Safety, 0*, 1-10.

Lawton, R., & Armitage, G. (2012). The role of the patient in clinical safety. Retrieved on June 30, 2015 from, http://www.health.org.uk/sites/default/files/TheRoleOfThePatientInClinicalSafety.pdf

Lee, A., Bishop, G., Hillman, K. M., & Daffurn, K. (1995). The medical emergency team. *Anaesthesia and Intensive Care, 23*(2), 183-186.

Leuvan, C. H. V., & Mitchell, I.(2008). Missed opportunities? An observational study of vital sign measurements. *Critical Care Resuscitation , 10*, 111–115.

Louch, G., O'Hara, J., Gardner, P., & O'Connor, D. (2017). A daily diary approach to the examination of chronic stress, daily hassles and safety perceptions in hospital nursing. *International Journal of Behavioural Medicine, 24*, 6, 946-956.

Ludikhuize, J., Smorenburg, S. M., De Rooij, S. E., De Jonge, E. (2012). Identification of deteriorating patients on general wards; measurement of vital parameters and potential effectiveness of the Modified Early Warning Score. *Journal of Critical Care, 27*, 7–13.

Lyons, M. (2007). Should patients have a role in patient safety? A safety engineering view. *Quality and Safety in Health Care, 16*(2), 140-142.

Mackintosh, N., Davis, R. E., Easter, A., Rayment-Jones, H., Sevdalis, N., Wilson, S., … Sandall, J. (2017). Interventions to increase patient and family involvement in escalation of care for acute illness in community health and hospital settings. *Cochrane Database of Systematic Reviews, 10*, doi: 10.1002/14651858.CD012829.

Mackintosh, N., Rainey, H., & Sandall, J. (2010). Managing Complications in Maternity And Acute Medicine Confidential Interim Report to King's Health Partners, PSSQ.

Mackintosh, N., & Sandall, J. (2010). Overcoming gendered and professional hierarchies in order to facilitate escalation of care in emergency situations: the role of standardised communication protocols. *Social Science and Medicine, 71*, 1683-1686.

Mahood, Q., Van Eerd, D., & Irvin, E. (2014). Searching for grey literature for systematic reviews. *Research Synthesis Methods, 5*(3), 221-234.

Makary, M. A., & Daniel, M. (2016). Medical error-the third leading cause of death in the US. *British Medical Journal*., doi: 10.1136/bmj.i2139

Malhotra, A., Maughan, D., Ansell, J., Lehman., R., Henderson, A., Gray, M., Stephenson, T., & Bailey, S. (2015). Choosing wisely in the UK: The Academy of Medical Royal Colleges' initiative to reduce the harm of too much medicine. *British Medical Journal, 350*. doi: https://doi.org/10.1136/bmj.h2308

Marshall, M., Pronovost, P., & Dixon-Woods, M. (2013). Promotion of improvement as a science. *The Lancet, 381*(9864), 419-421.

McCabe, C. (2004). Nurse-patient communication: An exploration of patients' experiences. *Journal of Clinical Nursing, 13*, 41-49.

McCaskey, M. S. (2007). Paediatric assessment: The little differences. In Camp-Sorrel, D., & Hawkins, R. A. (Eds.), *Clinical manual for the oncology advanced practice nurse* (pp. 21-24). Pittsburgh, PA: Oncology Nursing Society.

McCawley, B. A., Gannotta, R. J., Champagne, M. T., & Wood, K. A. (2013). Calling a 'Condition H'. *Nursing Management, 44*(12), 30-35.

McDonald, K. M. (2013). Considering Context in Quality Improvement Interventions and Implementation: Concepts, Frameworks, and Application. *Academic Paediatrics, 13*, S45-S53.

McEachan, R. R., Lawton, R. J., O'Hara, J. K., Armitage, G., Giles, S., Parveen, S., … Wright, J. (2014). Yorkshire Quality and Safety Research Group. Developing a reliable and valid patient measure of safety in hospitals (PMOS): A validation study. *BMJ Quality and Safety, 23*(7), 565-573.

McGloin, H., Adam, S. K., & Singer. M (1999). Unexpected deaths and referrals to intensive care of patients on general wards. Are some cases potentially avoidable? *Journal of the Royal College of Physicians of London, 33*(3), 255-259.

McQuillan, P., Pilkington, S., Allan, A. Taylor, B., Short, A., Morgan, G., … Smith, G. (1998). Confidential inquiry into quality of care before admission to intensive care. *British Medical Journal, 316*(7159), 1853-1858.

Michie, S., Richardson, M., Johnston, M., Abraham., C., Francis, J., Hardeman., W., …Wood., C. E. (2013). The behaviour change technique taxonomy (v1) of 93 hierarchically clustered techniques: Building an international consensus for the reporting of behaviour change interventions. *Annals of Behavioural Medicine, 46*(1), 81-95.

Michie, S., van Stralen, M. M., & West, R. (2011). The behaviour change wheel: A new method for characterising and designing behaviour change interventions. *Implementation Science, 6*, 42.

Michie, S., Johnston, M., Francis, J., Hardeman, W., & Eccles, M. (2008). From theory to intervention: Mapping theoretically derived behavioural determinants to behaviour change techniques. *Applied Psychology: An international Review, 57*(4), 660-680.

Minnick, P., & Harvey, S. (2003). The early recognition of patient problems among medical-surgical nurses. *Medsurg Nursing: Official Journal of the Academy of Medical-Surgical Nurses, 12*(5), 291-297.

Mockford, C., Fritz, Z., George, R., Court, R., Grove, A., Clarke, B., Field, R., Perkins, G. D. (2015). Do not attempt cardiopulmonary resuscitation (DNACPR) orders: a systematic review of the barriers and facilitators of decision-making and implementation. *Resuscitation, 88*, 99–113.

Mohammed, A. M., Rudge, G., Watson, D., Wood, G., Smith, G. B., Prytherch, D. R., … Stevens, A. (2013). Index blood tests and National Early Warning Scores within 24 hours of emergency admission can predict the risk of in-hospital mortality: A model development and validation study. *PLoS ONE, 8*(5), doi: e64340. https://doi.org/10.1371/journal.pone.0064340

Mok, W, Q., Wang, W., & Liaw, S. Y. (2015). Vital signs monitoring to detect patient deterioration: An integrative literature review. *International Journal of Nursing Practice, 21*(2), 91-98.

Mossey, J. M., & Shapiro, E. (1982). Self-rated health: A predictor of mortality among the elderly. *American Journal of Public Health, 72*(8), 800-808.

National Clinical Effectiveness Committee. (2013). National Early Warning Score- National clinical guideline no. 1. Retrieved 20th December, 2017, from http://health.gov.ie/wp-content/uploads/2015/01/NEWSFull-ReportAugust2014.pdf

National Confidential Enquiry into Patient Outcome and Death. (2005). An acute problem? Retrieved January 21, 2015, from http://www.ncepod.org.uk/2005aap.htm.

National Confidential Enquiry into Patient Outcome and Death. (2012). Time to intervene? Retrieved October 11, 2017, from http://www.ncepod.org.uk/2012report1/downloads/CAP_fullreport.pdf

National Patient Safety Agency. (2007). Recognising and responding appropriately to early signs of deterioration in hospitalised patients. Retrieved January 21, 2015 from, http://www.nrls.npsa.nhs.uk/resources/?entryid45=59834.

National Patient Safety Agency. (2010). About the cleanyourhands campaign. Retrieved July 3, 2015, from http://www.npsa.nhs.uk/cleanyourhands/about-us/

Nezlek, J. B. (2001). Multilevel random coefficient analysis of event-and interval-contingent data in social and personality psychology research. *Personality and Social Psychology Bulletin, 27*(7), 771-785.

NHS Confederation. (2016). Key statistics on the NHS. Retrieved April 20, 2017, form http://www.nhsconfed.org/resources/key-statistics-on-the-nhs

NHS England (2014). Five Year Forward View. Retrieved October 11, 2017, from https://www.england.nhs.uk/ourwork/futurenhs/

NHS England (2015). The NHS atlas of variation in healthcare. Retrieved October 10, 2017, from https://www.networks.nhs.uk/nhs-networks/staffordshire-shropshire-and-black-country-newborn/documents/documents/atlas-of-unwarranted-variation-in-maternity-care-1

NHS England (2016). A shared commitment to quality from the national quality board. Retrieved October 8, 2017, from https://www.england.nhs.uk/wp-content/uploads/2016/12/nqb-shared-commitment-frmwrk.pdf

NHS Right Care. (2016). NHS Atlas of variation in healthcare 2015. Retrieved August 3, 2016, from http://www.rightcare.nhs.uk/atlas/2015_IAb/atlas.html

NICE. (2007). Acutely ill adults in hospital: Recognising and responding to deterioration. Retrieved October 31, 2017, from https://www.nice.org.uk/guidance/cg50/resources/acutely-ill-adults-in-hospital-recognising-and-responding-to-deterioration-pdf-975500772037

NICE. (2011). Improving the detection and response to patient deterioration. Retrieved September 20, 2017, from https://www.nice.org.uk/sharedlearning/improving-the-detection-and-response-to-patient-deterioration

Nwulu, U., Westwood, D., Edwards, D., Kelliher, F., & Coleman, J. J. (2012). Adoption of an electronic observation chart with an integrated early warning scoring system on pilot wards: A descriptive report. *Computers Informatics Nursing, 30*(7), 371-379.

O'Dell, M., Gerber, K., & Gager, M. (2010). Call 4 concern: Patient and relative activated critical care outreach. *British Journal of Nursing, 19*(22), 1390-1395.

O'Dell, M., Victor, C., & Oliver, D. (2009). Nurses' role in detecting deterioration in ward patients: systematic literature review. *Journal of Advanced Nursing, 65*(10), 1992- 2006.

Office for National Statistics. (2015). Deaths registered in England and Wales. Retrieved 20th December, 2017, from https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/bulletins/deathsregistrationsummarytables/2015

Øvretveit, J. (2009). *Does improving quality save money? A review of evidence of which improvements to quality reduce costs to health service providers*. London, UK: The Health Foundation.

Paciotti, B., Roberts, K. E., Tibbetts, K. M., Weirich Paine, C., Keren, R., Barg, F. K., … Bonafide, C. P. (2012). Physician attitudes toward family-activated medical emergency teams for hospitalised children. *The Joint Commission Journal of Quality and Patient Safety, 40*(4), 187-192.

Patel, M. S., Jones, M. A., Jiggins, M., & Williams, S. C. (2011) Does the use of a track and trigger warning system reduce mortality in trauma patients? *Injury, 42*, 1455–1459.

Paterson, R., MacLeod, D. C., Thetford, D., Beattie, A., Graham, C., Lam, S., & Bell, D. (2006). Prediction of in-hospital mortality and length of stay using an early warning scoring system: Clinical audit. *Clinical Medicine, 6*, 281–284.

Patton, M. Q. (1990). *Qualitative evaluation and research methods* (2nd ed.). Thousand Oaks, CA : Sage.

Petersen, J. A., Mackel, R., Antonsen, K., & Rasmussen, L. S. (2014). Serious adverse events in a hospital using Early Warning Scores- What went wrong? *Resuscitation, 85*, 1699-1703.

Pham, J. C., Girard, T. & Pronovost, P. J. (2013). What to do with healthcare incident reporting systems. *Journal of Public Health Research, 2*(3). doi: 10.4081/jphr.2013.e27

Pittet, D., Panesar, S. S., Wilson, K., Longtin, Y., Morris, T., Allan, V., … Donaldson, L. (2011). Involving the patient to ask about hospital hand hygiene: a National Patient Safety Agency feasibility study. *Journal of Hospital Infection, 77*(4), 299-303.

Popay, J., Roberts, H., Sowden, A., Petticrew, M., Aria, L., Rodgers, M., & Britten, N. (2006). Guidance on the Conduct of Narrative Synthesis in Systematic Reviews: A Produce from the ESRC Methods Programme. Version 1.

Portela, M. C., Pronovost, P. J., Woodcock, T., Carter, P., & Dixon-Woods, M. (2015). How to study improvement interventions: A brief overview of

possible study types. *BMJ Quality and Safety*. doi: 10.1136/bmjqs-2014-003620

Pronovost, P. J., Miller, M. R., & Wachter, R. M. (2006). Tracking progress in patient safety : An elusive target. *JAMA, 296*(6), 696-699.

Provenzano, A., Rohan, S., Trevejo, E., Burdick, E., Lipsitz, S., & Kachalia, A. (2015). Evaluating inpatient mortality: A new electrnoic review process that gathers information from front-line providers. *BMJ Quality and Safety, 24*, 31–37.

Rainey, H., Ehrich, K., Mackintosh, N., & Sandall, J. (2013). The role of patients and their relatives in ‘speaking up’ about their own safety-a qualitative study of acute illness. *Health Expectations, 18*, 392–405.

Rainey, H., Ehrich, K., Mackintosh, N., & Sandall, J. (2013). The role of patients and their relatives in 'speaking up' about their own safety- a qualitative study of acute illness. *Health Expectations*. 10.1111/hex.12044

Rakowski, W., Mor., V., & Hiris, J. (1991). The association of self-rated health with two-year mortality in a sample of well elderly. *Journal of Aging and Health, 3*, 527-545.

Ray, E. M., Smith, R., Massie, S., Erickson, J., Hanson, C., Harris, B., & Willis, T. S. (2009). Family alert: Implementing direct family activation of a pediatric rapid response team. *Joint Commission Journal on Quality and Patient Safety, 35*(11), 575-580.

Raymond, J., Kyzer, B., Copper, T., Stephens, K., Oldendick R., Coker, D., … Barker, J. (2009). South Carolina patient safety legislation: the impact of the Lewis Blackman Hospital Patient Safety Act on a large teaching hospital. *Journal of the South Carolina Medical Association, 105*(1), 12-15.

Roohangiz, N., Aghabarari, M., Shiri, M., Karimi, M., & Samami, E. (2016). Communication barriers perceived by nurses and patients. *Global Journal of Health Science, 8*(6), 65-74.

Rose, L. & Clarke, S.P. (2010) Vital signs. *The American Journal of Nursing, 110* (5), 11.

Royal College of Physicians (2012). Observation chart for the National Early Warning Score. Retrieved 19th December, 2017, from file:///C:/Users/abigailalbutt/Downloads/NEWS%20-%20observation%20chart%20with%20explanatory%20text%20(1).pdf

Salgado, C. D., Sepkowitz, K. A., John, J. F., Cantey, J. R., Attaway, H. H., Freeman, K. D., … Schmidt, M. G. (2013). Copper surfaces reduce the rate of healthcare-acquired infections in the intensive care unit. *Infection Control and Hospital Epidemiology, 34*(5), 479-486.

Schmidt, P.E., Meredith, P., Prytherch, D.R., Watson, D., Watson, V., Killen, R.M., … Smith, G.B. (2014). Impact of introducing an electronic physiological surveillance system on hospital mortality. *BMJ Quality and Safety, 0*, 1-11.

Schoenfeld, D. E., Malmrose, L. C., Blazer, D. G., Gold, D. T., & Seeman, T. E. (1994) Self-rated health and mortality in the high-functioning elderly: A closer look at healthy individuals: MacArthur Field Study of Successful Aging. Journal of Gerontology: *Medical Sciences 49*(3), M109-115.

Scott, J., Dawson, P., & Jones, D. (2012). Do older patients' perceptions of safety highlight barriers that could make their care safer during organisational care transfers? *BMJ Quality & Safety, 21*, 112-117.

See, M. T., Chan, W. C., Huggan, P. J., Tay, Y. K., & Liaw, S. Y. (2014). Effectiveness of a patient education intervention in enhancing the self-efficacy of hospitalised patients to recognise and report acute deteriorating conditions. *Patient Education and Counselling, 97*(1), 122-127.

Seoane, F., Ferreira, J., Alvarez, L., Buendia, R., Ayllon, D., Llerena, C., Gil-Pita, R. (2013). Sensorized garments and textrode-enabled measurement instrumentation for ambulatory assessment of the autonomic nervous system response in the ATREC project. Sensors (Basel). *Sensors, 13*, 8997-9015.

Seon-Ha, K., Min-Woo, J., Jong-Won, L., Hyeon-Jeong, L., & Jong, K., K. (2015). Validity and reliability of EQ-5D-3L for breast cancer patients in Korea. *Health and Quality of Life Outcomes, 13*. doi: 10.1186/s12955-015-0399-x.

Shearer, B., Marshall, S., Buist, M. D., Finnigan, M., Kitto, S., Hore, T., … Ramsay, W. (2012). What stops hospital clinical staff from following protocols? An analysis of the incidence and factors behind the failure of bedside clinical staff to activate the rapid response system in a multi-campus Australian metropolitan healthcare service. *BMJ Quality and Safety, 21*(7), 569-575.

Shojania, K.G., & Grimshaw, J. M. (2005). Evidence-based quality improvement: The state of the science. *Health Affairs, 24*(1), 138-150.

Siemonsma, P. C., Schroder, C. D., Dekker, J. H. M., & Lettinga, A. T. (2008). The benefits of theory for clinical practice: Cognitive treatment for chronic low back pain patients as an illustrative example. *Disability and Rehabilitation, 30*(17), 1309-1317.

Simmes, F.M., Schoonhoven, L., Mintjes, J., Fikkers, B.G., & van der Hoeven, J.G. (2012). Incidence of cardiac arrests and unexpected deaths in surgical patients before and after implementation of a rapid response system. *Annals of Intensive Care, 2*(1), 20.

Sirriyeh, R., Lawton, R., Gardner, P., & Armitage, G. (2012). Reviewing studies with diverse designs. The development and evaluation of a new tool. *Journal of Evaluation in Clinical Practice, 18*(4), 746-752.

Smith, A.F., & Oakey, R.J. (2006). Incidence and significance of errors in a patient ‘track and trigger' system during an epidemic of Legionnaires' disease: retrospective casenote analysis. *Anaesthesia 61*(3), 222–228.

Smith, G. B., Prytherch, D. R., Meredith, P., Schmidt, P. E., & Featherstone, P. I. (2013). The ability of the National Early Warning Score (NEWS) to discriminate patients at risk of early cardiac arrest, unanticipated intensive care unit admission, and death. *Resuscitation, 84*(4), 465-470.

Snilstveit, B., Oliver, S., & Vojtkova, M. (2012). Narrative approaches to systematic review and synthesis of evidence for international development policy and practice. *Journal of Development Effectiveness, 4*(3), 409-429.

Soar, J., & Subbe, C. P. (2012). Identifying the patient at risk of deterioration, intensive care unit admission or cardiac arrest: Stop predicting, start preventing. *Critical Care Medicine 40*(7), 2243-2244.

Stacy, K. M. (2011). Progressive care units: Different but the same. *Critical Care Nursing, 31*(3), 77-83.

Stelfox, H. T., Bagshaw, S. M., & Gao, S. (2014). Characteristics and outcomes for hospitalized patients with recurrent clinical deterioration and repeat medical emergency team activation. *Critical Care Medicine, 42*(7), 1601-1609.

Stevenson, J.E., Israelsson, J., Nilsson, G.C., Petersson, G.I., & Bath, P.A. (2014). Recording signs of deterioration in acute patients: the documentation of vital signs within electronic health records in patients who suffered in-hospital cardiac arrest. *Health Informatics Journal, 22*(1), 21-33.

Sundar, R., Custodio, A., Petruckevich, A., Chenard-Poirier, M., Ameratunga, Collins, D., … Lopez, J. (2017). Clinical outcomes of patients with advanced biliary tract cancer in dedicated phase I unit. Clinical Oncology, In Press, doi: https://doi.org/10.1016/j.clon.2017.11.011

The Health Foundation. (2011). *Improvement science*. London, UK: The Health Foundation.

The Health Foundation. (2013). *Involving patients in improving safety*. London, UK: The Health Foundation.

Thomas, K., Force, M. V., Rasmussen, D., Dobb, D., & Whildin, S. (2007). Rapid response team: Challenges, solutions, benefits. *Critical Care Nurse, 27*(1), 20-27.

Tirkkonen, J., Yla-Mattila, J., Olkkola, K. T., Huhtala, H., Tenhunen, J., & Hoppu, S. (2013). Factors associated with delayed activation of medical emergency team and excess mortality: An Utstein-style analysis. *Resuscitation, 84*(2), 173-178.

Titler, M.G., Kleiber, C., Steelman, V. J., Rakel, B. A., Budreau, G., Everett., L. Q., … Goode, C. J., (2001). The Iowa model of evidence-based practice to promote quality care. *Critical Care Nursing Clinics of North America, 13*(4), 497-509.

Treadwell, J.R., Lucas, S., & Tsou, A.,Y. (2013). Surgical checklists: A systematic review of impacts and implementation. *BMJ Quality and Safety.* doi: 10.1136/bmjqs-2012-001797

Trier, H., Valderas, J. M., Wensing, M., Martin, H. M., Egebart, J. (2015). Involving patients in patient safety programmes: A scoping review and consensus procedure by the LINNEAUS collaboration on patient safety in primary care. *The European Journal of General Practice 21*(1), 56-61.

Trinkle, R. M., & Flabouris, A. (2011). Documenting Raid Response System afferent limb failure and associated patient outcomes. *Resuscitation, 82*(7), 810-814.

Vincent, C., Aylin, P., Franklin, B. D., Holmes, A., Iskander, S., Jacklin, A., & Moorthy, K. (2008). Is health care getting safer? *BMJ, 337*, 1205-1207.

Wachter, R. M. (2010). Patient safety at ten: unmistakable progress, troubling gaps. *Health Affairs, 29*(1), 165-173.

Walker, I. A., Reshamwalla, S., Wilson, I. H. (2012). Surgical safety checklists: Do they improve outcomes? *British Journal of Anaesthesia, 109*(1), 47-54.

Wheatley, I. (2006). The nursing practice of taking level 1 patient observations. *Intensive and Critical Care Nursing, 22*, 115–121.

World Health Organisation. (2006). Quality of care: A process for making strategic choices in health systems. Retrieved October 8, 2017, from, http://www.who.int/management/quality/assurance/QualityCare_B.Def.pdf

Wu, S., Wang, R., Zhao, Y., Ma, X., Wu, M., Yan, X., & He, J. (2013). The relationship between self-rated health and objective health status: A population-based study. *BMC Public Health, 13*(320). doi: 10.1186/1471-2458-13-320

Zimlichman, E., Szyper-Kravitz, M., Shinar, Z., Klap, T., Leykovich, S., Unterman, A., … Shoenfeld, Y. (2012). Early recognition of acutely deteriorating patients in non-intensive care units: Assessment of an innovative monitoring technology. *Journal of Hospital Medicine, 7*(8), 628-633.

Appendices

Chapter 2

Chapter 3

Chapter 4

Chapter 6

Appendix 1 PRISMA Checklist (Preferred Reporting Items for Systematic Reviews and Meta-analyses) modified for narrative analysis

Section/ topic	Checklist item	Reported on page #
TITLE	Identify the report as narrative review.	12
ABSTRACT	Structured abstract including background, objectives, data sources, study eligibility criteria, study appraisal and synthesis method, results, conclusions and implications of key findings.	NA
INTRODUCTION		
Rationale	Describe rationale for review in the context of what is already known.	12-13
Objectives	Provide explicit statement of questions being addressed, referring to participants, interventions, comparisons, outcomes and study design.	13-14
METHODS		
Research questions	Indicate primary research focus.	13-14

Eligibility criteria	Specific study characteristics and report characteristics used as criteria for eligibility with rationale.	15
Information sources	Describe all information sources – databases, with search terms.	14-15
Study selection	State process for selecting studies – screening for eligibility.	15
Data collection process	Describe data extraction from reports and process of confirming data in tables.	15-16
Data items	List all variables for which data is sought with assumptions and simplifications.	15-16
Risk of bias	Describe methods to assess risk of bias of individual studies and how used in synthesis.	15
Summary measures	State summary measures in narrative format.	15-16
Synthesis of results	Describe method of handling data and combining results of studies.	15-16
RESULTS		
Study selection	Number of studies screened, assessed for eligibility and included in the review with reasons for exclusions in a diagram	17-18
Study characteristics	For each study, present characteristics for which data were extracted and rated.	18-20
Synthesis and rating	Present results – narrative.	20-24
DISCUSSION	Summary of evidence, limitations, and conclusions and implications for future research.	24-28
FUNDING	Describe sources of funding.	NA

Note: Reproduced from Moher, D., Liberati, A., Tetzlaff, J., Altman, D. G., PRiSMA Group. (2009). Preferred reporting items for systematic reviews and meta-analyses: the PRiSMA statement. *Ann Intern Med, 151,* 264 –269.

Appendix 2 Academic literature database search strategy

Database: Ovid MEDLINE(R) < 1990 to 2015 >

Search strategy:

1	Patient* activat* (708)
2	Relative activat* (260)
3	Family activat* (209)
4	1 or 2 or 3 (1176)
5	Rapid response team* (568)
6	Medical emergency team* (337)
7	Critical care outreach team* (27)
8	Condition help (9)
9	5 or 6 or 7 or 8 (850)
10	4 and 9 (10)

Database: PsycINFO < 1990 to 2015 >

Search strategy:

1	Patient* activat* (293)
2	Relative activat* (98)
3	Family activat* (9)
4	1 or 2 or 3 (400)
5	Rapid response team* (23)
6	Medical emergency team* (24)
7	Critical care outreach team* (3)
8	Condition help (2)
9	5 or 6 or 7 or 8 (49)
10	4 and 9 (0)

Database: CINAHL < 1990 TO 2015 >

Search strategy:

1 Patient* activat* (1,935)

2 Relative activat* (168)

3 Family activat* (126)

4 1 or 2 or 3 (2,198)

5 Rapid response team* (385)

6 Medical emergency team* (250)

7 Critical care outreach team* (32)

8 Condition help (243)

9 5 or 6 or 7 or 8 (879)

10 4 and 9 (2,699)

Database: Cochrane Library < 1990 to 2015 >

Search strategy:

1 Patient* activat* (68)

2 Relative activat* (19)

3 Family activat* (2)

4 1 or 2 or 3 (88)

5 Patient* deteriorat* (124)

6 4 and 5 (1,076)

Appendix 3 Grey literature database search strategy

Search engine: Google < 01/01/1990 to 23/02/2015>

Search strategy:

1 family rapid response team (6,480,000)

2 relative rapid response team (3,130,000)

3 patient rapid response team (18,700,000)

4 family medical emergency team (58,200,000)

5 relative medical emergency team (2,120,000)

6 patient medical emergency team (16,700,000)

7 family critical care outreach team (3,210,000)

8 relative critical care outreach team (533,000)

9 patient critical care outreach team (21,900,000)

10 family condition help (710,000,000)

11 relative condition help (388,000,000)

12 patient condition help (287,000,000)

Search engine: Google Scholar < 01/01/1990 to 23/02/2015>

Search strategy:

1 family rapid response team (572,000)

2 relative rapid response team (712,000)

3 patient rapid response team (355,000)

4 family medical emergency team (596,000)

5 relative medical emergency team (337,000)

6 patient medical emergency team (969,000)

7 family critical care outreach team (90,300)

8 relative critical care outreach team (50,600)

9 patient critical care outreach team (54,200)

10 family condition help (3,210,000)

relative condition help (4,460,000)

patient condition help (3,030,000)

Appendix 4 Characteristics of included academic studies

Lead author/ year	Paediatric or adult sample	Setting	Design	Primary objective	Type of patient/ relative activated RRT	Main finding(s) relating to patient and relative led escalation
Bogert (2010)	Information not given	500 bed community hospital Pilot ward- medical pulmonary unit	Descriptive design	Information not given	Activation of condition H team which has distinct staff from the RRT who triage care and determine whether RRT required	8 condition H activations in 13 weeks. All activations met at least one of the policy criteria. No activations required RRT intervention. Patients and relatives felt more empowered. Most activations dealt with communication issues between patients, families and staff. Some calls considered problematic and demanding by staff.
Brady (2014)	Paediatric patients	577 bed academic, freestanding secondary care children's hospital	Descriptive design, quantitative evaluation	To compare the rate of PICU transfer for relative versus clinician-activated RRT. To compare relatives and clinicians reasons for activating RRT	Direct activation of the same RRT who respond to clinicians activations	83 relative activated RRT in 6 years (average of 1.2 MET activations per month). Relative activations represented 2.9% of all RRT activations. Significant increase in relative activated RRT over study period. 24% of 40 relative activated RRTs resulted in transfer to PICU compared to 60% of 1,156 clinician activated RRTs. Clinical deterioration more commonly the reason for clinician than relative activated RRTs. Relatives identified lack of response from clinicians and dismissive interaction between family and clinicians as reasons for activations. 37 family calls identified clinical deterioration.

Lead author/ year	Paediatric or adult sample	Setting	Design	Primary objective	Type of patient/ relative activated RRT	Main finding(s) relating to patient and relative activated RRT
Gerdik (2010)	Adult patients	696 bed adult level 1 trauma centre Pilot wards- five medicine-surgery units and one oncology unit	Descriptive design, cross-sectional survey	Information not given	Direct activation of the same RRT who respond to clinicians activations	25 patient or relative activated RRTs in 2 years (48% of calls initiated by relatives, 52% by patient) Patient/ relative activated calls were appropriate (no overload of false positives). Reasons for call included 'something is just not right', worried, shortness of breath and increased pain. Found significant increase in transfer to higher level care, a non-sig decrease in non-ICU AEs found and a significant decrease in mortality. Survey showed patients and families very satisfied with patient/ family activated RRT.
Greenhouse (2006)	Information not given	520 bed tertiary care hospital	Descriptive design, semi-structured interviews	Information not given	Activation of condition H team which has distinct staff from the RRT who triage care and determine whether RRT required	21 condition H activations in 9 months. Majority of calls met at least one of the two criteria. Most calls related to communication issues between patients and clinicians. Five of the calls were related to needing more effective pain management. Four were made by mistake. One was made due to chest pains.

Lead author/ year	Paediatric or adult sample	Setting	Design	Primary objective	Type of patient/ relative activated RRT	Main finding(s) relating to patient and relative activated RRT
Hueckel (2012)	Paediatric patients	186 bed children's hospital Pilot wards- Paediatric Bone Marrow Transplant Unit and Intermediate Care Unit.	Descriptive design, quantitative evaluation	To increase nursing and family awareness about the condition H service using formalised scripted teaching at the time of admissions.	Activation of condition H team which has distinct staff from the RRT who triage care and determine whether RRT required	47 RRT activations during the 12 week pilot and 2 of these were relative initiated condition H calls. No significant difference in compliance with nurse education about condition H between the 2 pilot units. PBMTU- monthly checks showed 64% to 90% (80% mean) of 38 eligible families received condition H teaching. 88% of 32 eligible families completed the family understanding survey. All but one family indicated that they had heard about condition H and could give a reason for calling. Intermediate care unit- 107 of 159 admitted families received condition H teaching (from 53% to 85% of families each week). 81% of families participated in the survey. 98% of families had heard about condition H, 74% could describe a reason for calling condition H and 76% knew how to activate a condition H.
McCawley (2013)	Information not given	86-bed community hospital Pilot wards- general surgery, medicine oncology, orthopaedics and progressive care	Descriptive design	To revise the Condition H education program for staff, patients and families. To observe staff members approach to teaching condition H protocols, patient and family knowledge about condition H and patient outcomes after improved condition H knowledge and usage.	Activation of condition H team which has distinct staff from the RRT who triage care and determine whether RRT required	91.7% of families received condition H education at pre-intervention which significantly increased to 97% post-intervention. At post-intervention 481 family surveys were completed. Family understanding of when and how to call condition H was 80% overall. There was a non-significant increase from 3 to 5 in number of condition H calls made from 3 months pre-intervention to 3 months post-intervention.

Lead author/ year	Paediatric or adult sample	Healthcare Setting	Design	Primary objective	Type of patient/ relative activated RRT	Main finding(s) relating to patient and relative activated RRT
O'Dell (2010)	147 adult patients transferred to general hospital wards from the ICU (phase 1) and adult patients on two surgical wards who had been admitted from any ward (phase 2).	800 bed district general NHS hospital	Descriptive design	To introduce and evaluate a system that allowed patients and relatives to directly access RRT team through a process of self-referral.	Activation of Call 4 Concern team (UK name for condition H team) which has distinct staff from the RRT who triage care and determine whether RRT required	Phase 1: 12 C4C activations in 6 months. Majority calls made by relatives. 2 cases where relative called C4C and patient was critically ill. In the other 10 cases, less critical intervention was needed. Patient feedback questionnaires showed majority (n =25) felt they had enough information about C4C (83%) and felt reassured this service was available (90%) Context assessment index showed that CCO and surgical ward staff felt the C4C project was being implemented in an environment receptive to change and conductive for person centred practice. Phase 2: 27 C4C activations in 3 months. 85.7% of ICU staff had heard about C4C and 18.4% had been involved in explaining it to patients. Just over half of surgical ward staff had heard about C4C.
Ray (2009)	Paediatric patients	140-bed children's hospital	Descriptive design, cross-sectional survey	Information not given	Direct activation of the same RRT who respond to clinicians activations	Since family activated was introduced, mean number of RRT calls significantly increased from 16 to 24 calls per 1,000 discharges. In 5% of all calls family concern was noted as reason for activation. 2 relative activated RRTs in a year. Median number of calendar days between cardiac arrests increased from 34 to 104 days since initial implementation of RRT. Did not have sufficient data to evaluate impact of family activation on cardiac arrests.

Appendix 5 Characteristics of included grey literature websites

Lead author, year and/or website title	Location	Audience	Host	Resource provided	Evaluation
Applying patient and family centred concepts to rapid response teams	USA	Healthcare staff	Public-private partnership	Guidelines for healthcare staff for patient and family activation of RRT within the context of partnership and collaboration with patients and families.	No evaluation
Bartoo (2009)	USA	Patients, relatives and healthcare staff	Healthcare organisation	Information about the implementation of family initiated RRT at the hospital, justification for its implementation, how patients were educated about it, healthcare staff concerns about it and how the system has been used since its implementation.	Found that only one of the 6 RRT calls made by family during the pilot study were non-emergent.
Critical care outreach team: Patient and family access	USA	Patients and relatives	Healthcare organisation	Power point presentation detailing the history of RRT at the hospital, outcomes after implementing RRT, plans for implementing patient and family activated RRT including education, implementation and ongoing evaluation, results of pilot study and changes made based on pilot findings.	No patient and family requests made for the activation of RRT during the pilot study

Lead author, year and/or website title	Location	Audience	Host	Resource provided	Evaluation
Condition H brochure	USA	Patients and relatives	Healthcare organisation	A brochure for patients and their relatives detailing the Josie King story which prompted the development and implementation of condition H in hospitals, information about what condition H is, along with when and how to initiate a condition H.	No evaluation
Family activated rapid response	USA	Patients and relatives	Healthcare organisation	Information in a leaflet about what the RRT is, when and how to call the RRT.	No evaluation
Family activation: The next generation of rapid response	USA	Healthcare staff	Private company	Information on the background as to why patient and family activated RRT has been developed and guidance on how to deal with resistance from staff members and successfully implement a patient and family activated RRT	No evaluation
Flow chart for Rapid Response Team Initiated by the Patient or Family Member/Visitor	USA	Healthcare staff	Healthcare organisation	Flow chart showing the different sequence of events that occur when a patient or family member activates the RRT. Information appears targeted towards informing nurses of what actions to take.	No evaluation
Information for patients and their carers	UK	Patients and relatives	NHS healthcare organisation	Leaflet providing information including what a RRT is, who is in the RRT, what the service provides, how and when to call the RRT	No evaluation

Lead author, year and/or website title	Location	Audience	Host	Resource provided	Evaluation
Implementation action planning document	USA	Healthcare staff	Healthcare organisation	Condition H implementation action planning tool- document instructs healthcare staff to list 3 actions their team will commit to in order to promote or advance implementation of the Condition H program at their facility within the next week, month and 3 months.	No evaluation.
Landro (2009)	USA	Patients, relatives and healthcare staff	Private newspaper company	Research findings from the implementation of a patient and relative activated RRT in children's hospital. Patients and relatives could directly call the RRT using the same system at hospital staff	After a year, found "family concern" was behind 20% of the calls — more than half the patients in those calls had to be transferred to an intensive-care unit. Mean number of RRT calls has increased significantly, to 24 calls per 1,000 discharges from 16. Only about two calls per year have been placed by family members, "and all of those have required transfer to the ICU, so no one is calling to complain about something that isn't legitimate," says Willis (medical director of the hospital's pediatric intensive-care unit and co-director of North Carolina Children's Centre for Clinical Excellence). Most families still prefer to have a professional call on their behalf, so family concern continues to be cited by staff as a reason for 6% of all their own calls to the rapid-response team.

Lead author, year and/or website title	Location	Audience	Host	Resource provided	Evaluation
LaVelle (2011)	USA	Healthcare staff	Non-profit medical organisation	Information and considerations to guide healthcare organisations in designing a patient and relative activated RRT to be implemented in their hospital and research investigating hospitals regarding their implementation of a patient and relative activated RRT.	Only 12.5% of the hospitals assessed for this article incorporated patient and family activation into their initial rapid response systems; 58% delayed patient or family activation three or four years until their basic RRT program was up and running well. In 90% of the hospitals, the staff-initiated RRT also responds to patient or family activated calls; 67% of hospitals did not utilize a physician as part of the RRT. Several hospitals had smaller or different teams ready to respond to patient or family activated calls. This adds a triage step to determine whether additional resources are needed. Direct activation of the RRT by the patient or family was allowed in 73% of the hospitals surveyed. 17% of hospitals chose an indirect approach where patients and families may initiate the request for assistance, but activation of RRT was limited to staff members

Lead author, year and/or website title	Location	Audience	Host	Resource provided	Evaluation
Muhlenberg Community Hospital- rapid response team	USA	Patients and relatives	Healthcare organisation	Information regarding the purpose of RRT, why to activate it, when to activate it and why not to wait for a nurse before activating it if deterioration is suspected.	No evaluation
New rapid response teams stress family involvement	USA	Healthcare staff	Private newspaper company	Information about Josie King's case- an example of when a patient deterioration went unrecognised which prompted the implementation of patient and relative activated RRT along with guidance and considerations to help healthcare organisations implement a patient and family activated RRT.	No evaluation
Rabin (2013)	USA	Patients and relatives	Private newspaper company	Information about staying safe in hospital including a description of condition H. Calling a condition H in hospital is compared to calling 911 at home.	No evaluation

Lead author, year and/or website title	Location	Audience	Host	Resource provided	Evaluation
Rapid response teams	USA	Patients and relatives	Non-profit organisation	Information on how RRT operate and the benefits of having rapid response systems. Research findings from a survey investigating whether hospitals implemented a rapid response team, how often rapid response teams were getting called, were patients and families able to activate rapid response teams and are they activating it, how the hospital educates both staff and patients and families about rapid response teams, what the benefits the hospital has seen from implementing these teams and what challenges they faced during the implementation.	Results of survey: All 34 had implemented rapid response methods. Mean number of activations of rapid response teams in 2009 was 114.7 21 Hospitals allowed patients and families to active rapid response teams. A variety of methods were used to educate patients and families including: posters, brochures, welcome packets and patient handbooks. Hospitals reported many benefits of rapid response teams. The most common were: Fewer codes (52.9%) Increased Employee satisfaction (23.5%) Learning opportunities for staff (20.6%) Fewer Transfers to the ICU (14%) The greatest challenge to implementing rapid response teams was staff acceptance

Lead author, year and/or website title	Location	Audience	Host	Resource provided	Evaluation
Rapid response team family brochure	USA	Patients and relatives	Healthcare organisation	Brochure to inform patients and their relatives of what the RRT is, when to call it and how to call it.	No evaluation
REACH: Patient and family activated escalation of care	Australia	Healthcare staff	Healthcare organisation	Power point presentation detailing research findings, specifically the results of a patient and family activated escalation intervention	Number of patient and family activated RRT in the hospitals. Orange Health Service- 20 months, 5 calls Calvary Mater Newcastle- 13 months, 0 calls Dubbo Base Hospital- 11 months, 1 call Bathurst Base Hospital- 8 months, 0 calls The Children's Hospital Westmead- 8 months, 11 calls Balmain Hospital- 8 months, 0 calls Hornsby Hospital- 4 months, 0 calls Royal North Shore Hospital- 4 months, 2 calls
Stollery's rapid response team gives power to parents	Canada	Patients, relatives and healthcare staff	Healthcare organisation	Information about why the hospital has implemented a family activated RRT, an example of a family activated RRT which identified deterioration and resulted in transfer to higher level care.	The RRT was activated about 70 times since the family activated RRT service was introduced (no indication of timeframe given).

Lead author, year and/or website title	Location	Audience	Host	Resource provided	Evaluation
Valley children's healthcare- rapid response team	USA	Patients and relatives	Healthcare organisation	Information about the patient and family activated rapid response service at this hospital including how RRTs operate, how patients and families can activate them and benefits of having RRTs on patient outcomes.	No evaluation
What patients and relatives need to know- rapid response teams	USA	Patients and relatives	Healthcare organisation	Information about when and how patients or their relatives should activate the RRT	No evaluation

Appendix 6 Interview schedule

1. Introduce self as 1st year PhD student. Explain this project is one of the study's to be included in PhD thesis. Ask have you read the information sheet? We are conducting a study looking at healthcare professional's perceptions of patient and relative involvement in detecting and escalating clinical patient deterioration. We are hoping to interview a range of healthcare staff groups on medical and surgical wards on this topic and there are no right or wrong answers.

2. Say the interview will be audio recorded but will be kept confidential and anonymous using pseudonyms.

3. Explain how data will may be presented at conferences and used in publications or my thesis

4. Do you have any other questions before we start?

5. Obtain consent

Questions

6. Background information
    a. What was your speciality?
    b. How long were you working in your speciality for?
    c. What trust did you work with?
    d. What unit/ward did you work on?

7. Which types of patients do you think are most at risk of clinical deterioration? For instance deterioration that results in AKI or cardiac arrest

8. Which wards do you think these at risk patients are likely to be on?

9. What signs do you think nurses might use to identify a patient who is deteriorating?

10. Do you think patients and/or their relatives know when the patient is deteriorating?

11. If yes, how do you think patients and relatives might express this feeling?

12. Do you think patients and relatives can provide useful information to help healthcare staff to identify and respond to patient deterioration?

13. What kind of information do you think they could provide to help healthcare staff identify deterioration?
14. In the context of a busy ward how do you think patients and relatives might be involved in the process of detecting and escalating patient deterioration?

Appendix 7 Patient representative focus group topic guide

Introduction: Outline purposes of study. Explain that we are interested in finding out their personal views; there are no ‘right’ or ‘wrong’ answers to any of the questions. Reiterate voluntary nature and safeguarding of confidentiality. Offer opportunity to raise further questions/concerns. Take informed consent.

[Participants will be asked to imagine a scenario. They will be asked to imagine that they are a patient in hospital. They have been in hospital for a few days now and will be discharged soon. While in hospital, they have been asked to complete a measure to get their perspective on changes in their health, condition or wellness. We want the measure to capture patient perspectives on changes in their health and the significance they attach to these changes].

Question options

1. How in general would you rate your health?
2. How are you feeling?
3. How well are you feeling?
4. How worried are you about your health?
5. How concerned are you about your health?

When presenting participants with each question, ask them to consider the following:

What do you think the question is asking you? What does this question mean to you?

Which question(s) do you think would be the most appropriate to use to get the patients perspective on changes in their health, condition and wellness?

Could the wording of the question be changed to improve its clarity, and if so, how?

[While asking participants to still imagine the scenario, explain to them that they will be asked to complete the measure after each time they have their observations taken if it is convenient for them eg. they’re awake etc. Explain

that we now need to give the selected question a timeframe for patients to compare changes in their health over time].

Timeframe of questions

How in general would you rate your health compared to your last rating?

How in general would you rate your health compared to the last time you rated your health?

How are you feeling compared to the last time you answered this question?

Response options

Five point Likert scales:

Very poor - Poor - Fair - Good - Very good

Much worse - Worse - No change - Better - Much better

Appendix 8 Healthcare assistant focus group topic guide

Introduction: Outline purposes of study. Explain that we are interested in finding out their personal views; there are no ‘right’ or ‘wrong’ answers to any of the questions. Reiterate voluntary nature and safeguarding of confidentiality. Offer opportunity to raise further questions/concerns. Take informed consent.

Question options

1. How in general would you rate your health?
2. How are you feeling?
3. How well are you feeling?
4. How worried are you about your health?
5. How concerned are you about your health?

When presenting participants with each question, ask them to consider the following:

What do you think the question is asking you? What does this question mean to you?

Which question(s) do you think would be the most appropriate to use to get the patients perspective on changes in their health, condition and wellness?

Could the wording of the question be changed to improve its clarity, and if so, how?

Timeframe of questions

How in general would you rate your health compared to your last rating?

How in general would you rate your health compared to the last time you rated your health?

How are you feeling compared to the last time you answered this question?

Response options

Five point Likert scales:

Very poor - Poor - Fair - Good - Very good

Much worse - Worse - No change - Better - Much better

Appendix 9 Patient participant study feedback questions

PATIENT WELLNESS QUESTIONNAIRE FEEDBACK

We'd like to get your opinion on the questions you were asked about your health during this study. You will read some statements that describe the questions. Please indicate your agreement or disagreement with the following statements by circling your response on the scale. Please leave any comments about your decision in the 'further comments' box below.

How are you feeling?

1	**2**	**3**	**4**	**5**
Very poor	Poor	Fair	Good	Very good

I understood what this question was asking me

1	**2**	**3**	**4**	**5**
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

Further comments eg. What you thought this question was asking you about

I was comfortable with answering this question

1	2	3	4	5
Strongly Disagree	Disagree	Neither agree or Disagree	Agree	Strongly Agree

Further comments

How are you feeling compared to the last time I asked you?

1	2	3	4	5
Much better	Better	No change	Worse	Much worse

I understood what this question was asking me

1	2	3	4	5
Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree

Further comments eg. What you thought this question was asking you about

I was comfortable with answering this question

1	**2**	**3**	**4**	**5**
Strongly Disagree	Disagree	Neither agree or Disagree	Agree	Strongly Agree

Further comments

STUDY FEEDBACK

In the next section we'd like to ask you some more general questions about how you found taking part in the study. Please write your responses in the text boxes.

1. **How did you feel about how often you were asked the questions?**

2. **Did you ever feel like you didn't want to answer the questions when you were asked? Please tick one box.**

Yes **No**

3. **If you answered yes, why did you not feel like answering the questionnaire?**

4. **Will the answers you give to these questions about how you are feeling help staff to recognise if you are getting more unwell in hospital?**

5. **During your stay in hospital, did you notice any changes in your health or wellness?**

☐ **Yes** ☐ **No** ☐ **Don't know**

6. **If you answered yes, what changes in your health or wellness did you notice?**

7. Were you concerned about these changes?

☐ Yes ☐ No ☐ Don't know

8. If you answered yes, why were you concerned?

9. Who did you tell about these changes in your health or wellness and how did they respond?

Appendix 10 Observation framework

Healthcare assistant PIN: _____

Ward: _____

Activity as a result of asking Patient Wellness Questionnaire:

Activity category: _____

Time taken to complete activity: _____