What are patients’ perceptions of their safety within an acute hospital setting? A study to inform the development of a measurement questionnaire

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Awarding institution: King's College London

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What are patients’ perceptions of their safety within an acute hospital setting?
   A study to inform the development of a measurement questionnaire

A thesis submitted in partial fulfilment of the requirements of the degree of
   Doctorate of Healthcare

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   King’s College London
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Abstract

Background

Approaches to safety improvements have been driven by empirical studies focusing on healthcare staff development. Traditionally, tools used to measure safety have focused on understanding safety climate and safety culture from the healthcare professional perspective. However, few studies have concentrated on patients’ experiences and their perceptions of safety and there are few validated tools to measure patient perceptions of safe/unsafe care. Consequently, little is known about how patients decide if they are safe, and how their experiences and voices can influence and drive safety improvements.

Aim

The overall aim of the study was to explore what patients understood by being safe, and how they experienced safety within an acute hospital setting. The findings were then used to inform the development of the King’s Patient Safety Measure (KPSM).

Setting of study

The study was carried out within a large acute teaching hospital in London with a diverse socio-demographic and ethnic population.

Methods

A sequential mixed methods design was used, where the results of each objective informed the next objective of the study. There were four objectives, the first of which involved a scoping review of the literature and feedback from patient representatives within the acute trust, to inform the layout and questions to be examined in the pilot questionnaire. The second objective was to
development and pilot test the questionnaire using cognitive interviewing. The third objective involved conducting a cross-sectional study to establish the validity and reliability of the tool in a questionnaire to 158 patients within general medical wards. Survey analysis involved descriptive statistics, factor analysis. Objective four explored the relationships between patient demographics (ethnic background, age, gender, social deprivation, family support), mode of admission and patient perceptions of safety, using ANOVA.

**Findings**

This study demonstrated that a validated tool can be developed with patients to measure how safe they feel during their acute hospital stay. Key items that patients identified in making them feel unsafe included poor communication with health professionals, especially with communication about medications, poor infection control practice and staffing levels. Items that patients identified in making them feel safe included staff showing compassionate care, clear communication and adequate staffing levels. Exploratory factor analysis was used to establish the factor loading for each of the thirteen items of the questionnaire. Factor loadings for all items were between 0.52 and 0.86, demonstrating that all the items made an important contribution to a single factor. The Cronbach alpha score for the thirteen-item score was 0.914 illustrating internal consistency of the overall scale, therefore suggesting all thirteen items should be kept. The Pearson correlation score of .648 with question 12, “How safe you felt during your hospital stay demonstrated strong construct validity, illustrating the thirteen-item scale was a reliable measure of aspects of safety that were important to patients.

There were no statistically significant differences in the perceptions of feeling safe between ethnic background and mode of admission, age, sex and whether they have family support during their hospital stay. Thus, the measure was found to be appropriate and universally applicable for all patients.
Recommendations

- Healthcare policy makers need to acknowledge that patients experience and describe their world of safety differently from healthcare professionals, and consequently the framework in which to engage them needs to shift to enable their voices to be heard.

- Further testing of the KPSM should be undertaken as the tool has the potential to be used as an early warning trigger tool and for the findings to be used as learning for health care staff.

Conclusion

Assessment of patients’ perceptions and experiences of safety remains a challenge. In this study patients reported the King’s Patient Safety Measure was easy to complete and captured items that were important in making them feel safe. The involvement of patients in the development of the King’s Patient Safety Measure demonstrated the important contribution patients can make to the safety agenda and in doing so, provides a patient feedback method which ensures their voices can be heard.
Acknowledgements

Firstly, and most importantly, I must thank the Florence Nightingale Foundation and Anne O'Brien, Director of Clinical Governance at NHS Professionals (my sponsor) for the opportunity to carry out this research by awarding me the Research Scholarship.

I would like to thank my supervisors Professor Jane Sandall, Sir George Alberti, Dr David Foster and the Faculty statistician Trevor Murrells for their excellent support with my academic work. Without their generous time, invaluable guidance, commitment and encouragement I could not have completed this study.

Sincere thanks go to Dr Ed Glucksman who kindly agreed to support my study and gave insightful thoughts during challenging times.

Special thanks go also to the clinical administrators whose support and enthusiasm enabled patients to participate in the study.

I am deeply grateful to all those patients who agreed to participate in the study and for sharing their experiences of their care. The feedback they have provided has given insight into what matters to patients when it comes to feeling safe in hospital.

And finally, I must thank my husband Brian and my son James for their continued patience and support with my Doctorate in Healthcare.
**List of abbreviations**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>A&amp;E</td>
<td>Accident and Emergency</td>
</tr>
<tr>
<td>AHRQ</td>
<td>Agency for Healthcare Research and Quality</td>
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<tr>
<td>ANOVA</td>
<td>Analysis of Variance</td>
</tr>
<tr>
<td>CAHPS</td>
<td>Consumer Assessment of Healthcare Providers and Systems</td>
</tr>
<tr>
<td>CI</td>
<td>Confidence intervals</td>
</tr>
<tr>
<td>CQC</td>
<td>Care Quality Commission</td>
</tr>
<tr>
<td>CQUIN</td>
<td>Commissioning for Quality and Innovation</td>
</tr>
<tr>
<td>DH</td>
<td>Department of Health</td>
</tr>
<tr>
<td>HCAHPS</td>
<td>Hospital Consumer Assessment of Healthcare Providers and Systems</td>
</tr>
<tr>
<td>HSMR</td>
<td>Hospital Standardised Mortality Ratio</td>
</tr>
<tr>
<td>HSOPSC</td>
<td>Hospital Survey of Patient Safety Culture</td>
</tr>
<tr>
<td>ICPS</td>
<td>International Classification for patient Safety</td>
</tr>
<tr>
<td>KPSM</td>
<td>King’s Patient Safety Measure</td>
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<tr>
<td>MANOVA</td>
<td>Multivariate analysis of variance</td>
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<tr>
<td>Abbreviation</td>
<td>Description</td>
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<tr>
<td>NHS</td>
<td>National Health Service</td>
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<td>NPSA</td>
<td>National Patient Safety Agency</td>
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<td>PPE</td>
<td>Picker Patient Experience Questionnaire</td>
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<tr>
<td>PMOS</td>
<td>Patient Measure of Safety</td>
</tr>
<tr>
<td>PRASE</td>
<td>Patient Reporting and Action for a Safe Environment</td>
</tr>
<tr>
<td>PREOS-PC</td>
<td>Patient Reported Experiences and Outcomes of Safety in primary Care</td>
</tr>
<tr>
<td>PWASQS</td>
<td>Patient Willingness to Speak to Ask Questions Survey</td>
</tr>
<tr>
<td>SHMI</td>
<td>Summary Hospital-level Mortality Index</td>
</tr>
<tr>
<td>UK</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
<tr>
<td>YCFF</td>
<td>Yorkshire Contributory Factors Framework</td>
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Chapter 1 Background

1.1 Contextual background

Patient safety has become a high priority in healthcare in the United Kingdom as a result of increasing numbers of errors experienced by patients (Department of Health, 2000; NHS Scotland, 2010). Indeed, NHS England (2018) aspires to become one of the safest healthcare systems in the world. On a global scale, a review of patient safety research carried out for the World Health Organization’s World Alliance for Patients Safety Programme (Jha et al, 2010) of hospitalised patients suffering harm from adverse incidents indicated the prevalence was between 3 and 16 percent. The cost of adverse events to the NHS is significant, but for patients the experience and trauma caused cannot be easily quantified (Vincent & Coulter, 2002; Rathert et al, 2011a). This illustrates the need for robust safety improvement programmes to reduce harm to patients.

Interest in this area arose from the researcher’s role as a Divisional Head of Nursing within a large teaching hospital in London. The role provided both professional and operational leadership to 600 nursing staff across two specialty areas. The researcher also had lead responsibility for clinical governance, including patient safety. Examples of monitoring safety involved establishing where things had gone wrong. This included reviewing adverse events, for example, by using root cause analysis tools (Vincent, 2010). These tools ask a series of questions to ascertain where the primary cause of an error has occurred. Experience of using such tools shows that staff are interviewed about the event, clinical practices scrutinised, and recommendations made. The only involvement made by patients is to inform them that an adverse event has occurred and what action has been taken to prevent such an event occurring again.

This approach was also adopted for serious incidents, where there was no requirement to seek patient or relatives’ views about their experiences and
perceptions of what happened. Reviews of adverse events, serious incidents and root cause analysis forms included presentation at the various Trust safety forums. Patients’ experiences of such events were not discussed in these forums. If reference was made to patient feedback it was in the context of the patients’ experience rather than asking the question: did the patients feel safe?

Traditionally, safety improvements focused on reviewing organisational governance structures, along with training and development of staff, with little input and feedback from patients (Vincent, 2010). Patients' views and perceptions of what makes them feel safe should influence the safety improvement agenda (Vincent & Coulter, 2002; Entwistle et al, 2010). In not doing so a real opportunity is lost to inform the safety agenda. Patients can provide a unique insight into how safety can be improved (WHO, 2009; Doyle et al, 2013). It is this gap in understanding safety from the patients’ perspective that has informed the author’s thinking and development of this study.

Safety is multidimensional (Vincent, 2010) in that it is fundamentally seen as a component of quality care (Kohn, 2000; Vincent, 2010). Kohn (2000) argues that quality has two primary dimensions: safe care, which is practice that is consistent with current knowledge and customs, and external environmental factors which drive quality improvement. These are regulatory/legislative and economic activities. In relation to safe care Kohn (2000) argues this refers to freedom from accidental harm. The empirical evidence illustrates the variability in how safety is understood and measured (Kohn et al, 2000; Vincent & Coulter, 2002). Research studies on patient safety measurement have customarily focused on measuring safety culture and safety climate, examining safety from an organisational and healthcare professional perspective, with very few studies measuring safety from the patients’ perspective (Vincent & Coulter, 2002; Vincent, 2010; Entwistle et al, 2010). This study aimed to explore what patients understood by being safe, and how they experienced safety within an acute hospital setting. The findings were used to inform the development of the
King's Patient Safety Measure (KPSM). Four objectives were set to answer the research question. These were:

1. A scoping review of the literature and feedback was sought from patient representatives within the acute trust, to inform the layout and questions to be examined in the pilot questionnaire.

2. Develop and pilot the questionnaire using cognitive interviewing.

3. Establish the validity and reliability of the tool in a questionnaire to 158 patients in general medical settings.

4. Explore relationships between patient demographics (ethnic background, age, gender, social deprivation, family support), mode of admission and patient perceptions of safety.

1.2 The emerging concept of safety as a component of care

Establishing the origins of and influences on patient safety are important in seeking understanding about the concept of safety and its role in the improvement and measurement of patient care (Vincent, 2010; Emanuel et al, 2015). Certainly, the concept of patient safety was not a prominent feature in healthcare during the early twentieth century. Healthcare professionals were seen as well-trained, conscientious staff who did not make mistakes (Vincent, 2002; Emmanuel et al, 2015). The focus was on the failing of patients' biological systems rather than errors made by healthcare professional (Emmanuel et al, 2015). There was very little evidence within the nursing and medical literature during this time regarding safety. The concept of patient safety was not even considered by governments as a pressing issue (Vincent, 2002; Emmanuel et al, 2015). The turning point came when there were widespread variations in the quality of care across geographical areas, especially within the United States (Vincent, 2002). The need to examine
variation essentially came from the spiralling healthcare costs, rather than from a desire to improve the quality of care patients received (Vincent, 2002). Within the UK the Department of Health (DH) published the report An Organisation with a Memory (2000) to address safety issues. The report reviewed the scale and nature of serious incidents in the NHS, to examine its capacity to learn from them and to recommend measures to reduce the number of repeated cases. The report found that the NHS had no systematic way of identifying and learning from errors. Furthermore, there were no methods to deal with things when they went wrong. The report recommended the introduction of clinical governance systems to tackle the problems. In 2001 the National Patient Safety Agency (NPSA) was launched and its purpose was to operate a mandatory reporting system for incidents and near-misses.

Within the UK the significant change in focus on patient safety came with the Bristol Royal Infirmary Inquiry. The inquiry was carried out because of the high death rates of young babies undergoing heart surgery (Bristol Royal Infirmary, 2001). The investigation was ground-breaking as it showed that the actions of individual staff were influenced and constrained by the wider organisation and environment, thus acknowledging the context in which safety failures occurred (Bristol Royal Infirmary, 2001). The inquiry made a number of recommendations. These included involving patients and the public in decisions about their treatment and care, including more openness about clinical performance, thus allowing patients to access information about hospitals. Consequently, key organisational drivers for the improvement of safety were introduced. In 2008 Lord Darzi published High Quality of Care for All NHS Next Stage Review Final Report (Department of Health, 2008a). The report involved a year-long process with patients, NHS staff and key stakeholders, and recommended a move away from centrally set targets to more personalised care, managed at the local level. Lord Darzi emphasised the need for increased quality of care, patient choice and accountability to the public. The Healthcare Commission was set up to monitor compliance with safety and quality standards in the acute care setting. This included national
commissioning initiatives such as Commissioning for Quality and Innovation (CQUIN), which linked service improvements with payment for acute organisations (Department of Health, 2008b). These changes would help to strengthen the focus on safety from an organisational and healthcare perspective.

A second pivotal point for the NHS occurred when the findings from the report into the failings at Mid-Staffordshire Hospital were announced (HM Government, 2013a). It is significant to note that the investigation was initiated following concerns raised by patients and relatives about the standards of care and high mortality rates, and not from healthcare professionals (HM Government, 2013a). This illustrated patients and relatives were able to recognise poor and unsafe practices and therefore had a vital role to play in safety improvement (Vincent & Coulter, 2002; Agoritsas et al, 2005; Entwistle et al, 2010; Doyle et al, 2013).

The findings of the report, known as the Mid-Staffordshire NHS Foundation Trust Public Inquiry, chaired by Robert Francis QC (HM Government, 2013a) stated the board was ultimately responsible for the failings in care. There was a culture of pursuing cost-cutting initiatives to achieve foundation status and consequently the board did not listen to the complaints of patients and staff. Furthermore, there were systemic failures across the NHS to address the concerns raised by patients and their families. This included GPs and MPs who failed to take any action. The government was seen as being too remote and not putting patients first and this was compounded by the role of the regulator. The Healthcare Commission failed to bring the problems of the hospital to national attention (HM Government, 2013a).

The report made 290 recommendations. Fundamentally, there needed to be a move towards developing a culture whereby patients were put first. This changed the political and public landscape across healthcare, and the quality and safety of services that patients received. The government commissioned subsequent high-profile reports on safety. These were the Review into quality
of care and treatment provided by 14 hospital trusts in England led by Sir Bruce Keogh (HM Government, 2013b), A promise to learn – a commitment to act: Improving the safety of patients in England (HM Government, 2013c), and Hard Truths: The journey to putting patients first, Volume 1 of the Government’s response to the Mid-Staffordshire NHS Foundation Trust Public Enquiry (HM Government, 2014) following the investigation into Mid-Staffordshire Hospital.

Sir Bruce Keogh’s review focused on the quality of care and treatment provided by 14 hospital trusts across England (HM Government, 2013b). These hospitals were selected for review because they had been outliers for the last two consecutive years on either the Summary Hospital-Level Mortality Index (SHMI) or the Hospital Standardised Mortality Ratio (HSMR). The review found these organisations had limited understanding about how important it was to listen to both patients and staff, including how to engage them to improve services and set ambitions for improvement. These included providing patients and the public with access to accurate, insightful and easy-to-understand data about the quality of services. Furthermore, patients, carers and members of the public would be increasingly treated as equal partners in the design and assessment of their local NHS, including feeling confident that their feedback is listened to and has an impact on their own care and the care of others.

The Francis Report (HM Government, 2013a) shaped how national initiatives on safety improvement now include a component to include feedback from patients on their experiences (NHS England, 2014a; NHS England, 2014b; Picker Institute, 2015). Consequently, the Care Quality Commission (CQC) introduced new standards of care to promote high quality and safety for patients.
1.3 Patient safety: progress to date

Safety is often viewed as the absence of accidents and incidents, or as few things as possible go wrong. If mistakes happen it is down to technical, human and organisational causes (Hollnagel et al 2015). This view of safety is known as Safety 1. Safety 2 is a new approach that defines safety as the ability to make things go right and not merely the absence of failures or adverse outcomes (Braithwaite et al 2015 p. 419). Health care is delivered within a complex adaptive system where staff adapt to situations to create safety. This adaptation to situations to make systems safe is called resilience engineering (Hollnagel 2014, Mannion & Braithwaite 2019).

1.3.1 Safety 1

This is a “find and fix” model, which aims to ensure the number of adverse events is as low as possible (Braithwaite et al 2015). Therefore, safety is defined by its opposite, that is, by the lack of safety (accidents, incidents and risks). The focus is on events where safety is absent, rather than where safety is present. This reactive approach assumes safety is achieved by finding and then eliminating the cause of adverse events, for example by using a root cause analysis tool (Hollnagel 2014).

1.3.2 Limitations of Safety 1

Braithwaite et al (2015) argue that whilst there have been improvements in safety using the Safety 1 approach, these have been confined to niche areas such as central line infection bundles and checklists in theatres. This is because they have been in areas where problems have been easy to understand and working practices are clear and controllable, with little external influence. However, healthcare operates in complex settings, is unpredictable and there is a high degree of dependence on what happens externally.
(Braithwaite et al 2015, Hollnagel 2014, Mannion & Braithwaite 2019). This includes the increasing requirements to meet regulation regimes. Consequently, there are increased attempts at standardisation with more policies and regulations, along with multiple guidelines and accreditation schemes. The burden of these falls to frontline staff, who are required to meet them, whilst facing very busy working environments. This is because policy makers, regulators and managers are remote from the clinical setting and base their efforts on what they imagine everyday clinical work to be. Work as imagined is always different from work that is done (Hollnagel et al 2014).

1.3.3 Safety 2

The focus is on how frontline staff facilitate and manage their work flexibly and safely, that is work that is done, rather than work that is imagined. The principle of Safety 2 is that all performance regardless of whether it goes well or fails, operates from the same source. These are the same behaviours and practices of staff (Braithwaite et al 2015). The focus is to understand how and why things go well, acknowledging that safety is better examined by this approach, rather than focusing on why things fail. Safety 2 examines how people adjust what they do to match the situation, based on availability of resources such as time and manpower.

1.3.4 Resilience and safety management

It is excepted that variability in performance is the reason why things succeed, as well as the reason why things go wrong. Therefore, safety is seen as the ability to succeed under varying conditions by improving resilience. Hollnagel (2014) argues that Safety 2 and improving the resilience of staff offers a proactive approach to safety management. He describes resilience as resilience engineering which consists of four components. These are; learning
from what has happened; responding – knowing what to do and being capable of doing it; monitoring what to look for and anticipating – finding out and knowing what to expect. Therefore, resilience engineering needs to include both Safety 1 and Safety 2 approaches (Hollnagel 2014, Mannion & Braithwaite 2019). Mannion and Braithwaite (2019) suggest that incident reporting systems capture essential information that can inform improvement of care but have not yet been fully utilised within health care.

1.3.5 Relevance of resilience and safety management to study

The objective of this study was to explore what patients understood by being safe, and how they experienced safety within an acute hospital setting. The findings would then be used to inform the development of the Kings Patient Safety Measure (KPSM). This focused on both a Safety 1 and Safety 2 approach. Patients would be asked to rate situations based on how safe/unsafe they felt (Safety 1). But they would also be asked to provide examples of situations in which they felt safe (Safety 2). The results could then be used to monitor and learn, and enable staff to respond and anticipate potential problems, thus building resilience within healthcare teams, based on patient feedback.

1.4 Summary

In summary, whilst the emerging concept of patient safety has been driven by a reduction in variation in care to control costs (Doyle et al, 2013; HM Government 2013c), the role of patients and their families in identifying poor care has moved to the forefront of patient safety improvement and indeed has the potential to build resilience in healthcare teams.

1.5 Defining safety in order to measure it
It was important to define what patient safety was to ensure accurate measurement of the concept (Greenhalgh, 2010). Vincent (2010) argued defining patient safety was dependent on how the concept of safety is interpreted. Some definitions describe safety as a whole-systems approach within an organisation to review where things have gone wrong (Vincent, 2010; Emmanuel et al, 2015). For example, the Canadian Patient Safety Dictionary (Davies et al, 2003 p.12) refers to the need to focus on unsafe acts within the healthcare system to improve safety outcomes:

“The reduction and mitigation of unsafe acts within the healthcare system, as well as through the use of best practices shown to lead to optimal patient outcomes”.

Other definitions expand on the whole-systems approach to include the use of scientific approaches to achieve safety improvements and use specific terminology such as adverse events as a point of focus for improvement. This is illustrated by Emmanuel et al’s (2015 p6) definition:

“Patient safety is a discipline in the healthcare sector that applies safety science methods toward the goal of achieving a trustworthy system of healthcare delivery. Patient safety is also an attribute of health care systems; it minimises the incidence and impact of, and maximises recovery from, adverse events.”

Kohn et al’s (2000) definition of patient safety can be easily understood and acknowledges the goal of safety is to prevent harm to patients, and harm is what patients care about the most (Kohn et al, 2000; Vincent, 2010). The definition “freedom from accidental injury” (Kohn et al, 2000 p.58) illustrates the importance of seeking patients’ views and experiences from a quality perspective in determining if they feel safe which is the focus of this study. This illustrates the importance of articulating what safety actually is (Runciman et al, 2009; World Health Organization, 2009; Emanuel et al, 2015).
These definitions of patient safety demonstrate the concept is multifactorial. However, the use of terminology such as ‘trustworthy systems’ may have a different meaning for patients, compared to healthcare professionals (Vincent, 2010). What is more, exploring safety from such perspectives may not capture what safety means to patients.

A number of national websites with responsibility for healthcare, and those representing patients, were reviewed to ascertain their definitions of safety (Care Quality Commission, 2014a; NHS England, 2014b; Patients Association 2014; Picker Institute Europe 2015). None of these websites provided a definition, although reference was made to the monitoring and improvement in quality and patient safety. Consequently, there continues to be significant challenges to implementing patient safety policies and practices, due to the inconsistent definitions of safety. For example, the Sign up to Safety Campaign (NHS England, 2014a) launched by the then Secretary of State for Health Jeremy Hunt. This national programme aimed to halve avoidable harm in the NHS over the following three years, including saving 6,000 lives. The campaign provided no definition of safety but did make five safety pledges. These were; putting patients first; continually learning by acting on feedback from patients and lessons learnt from incident reporting and investigation; having an open and transparent culture to tackle patient safety issues and supporting staff to come forward in raising their concerns; collaborating with other organisations and teams, including sharing learning to create a national approach to safety; and being supportive and kind to staff, helping them bring joy and pride to their work.

1.6. WHO conceptual framework International Classification for Patient Safety

The World Health Organisation (2013) believe patients have a legal right to safety. The changing role of patients was acknowledged as moving from being purely recipients of care to active, empowered and informed co-producers of
health. Therefore, any approach to redesigning healthcare systems at all levels to make it safer, needed to involve patients (World Health Organisation 2009). In 2004, the World Health Organisation launched the World Health Alliance for Patient Safety (World Health Organization, 2009) to define key safety concepts into agreed classifications, with the aim of providing a comprehensive understanding of patient safety. The framework, known as the International Classification for Patient Safety, provided consistent use of key concepts, definitions and preferred terms to enable better understanding of patient safety data to be shared across disciplines, organisations and countries (Runciman et al, 2009; World Health Organization, 2009). Table 1.1 below shows the top ten high-level classes, known as the International Classification for Patient Safety (ICPS). The framework allowed for the continuous learning and improvement cycle emphasising identification of risk, prevention, detection, reduction of risk, incident recovery and system resilience. It has therefore been chosen as the conceptual framework for this study. Application of the framework within the study is discussed in chapter 2.

**Table 1-1 WHO Classification**

<table>
<thead>
<tr>
<th>Classification</th>
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<tbody>
<tr>
<td>1 Incident</td>
</tr>
<tr>
<td>2 Patient outcomes</td>
</tr>
<tr>
<td>3 Patient characteristics</td>
</tr>
<tr>
<td>4 Incident characteristics</td>
</tr>
<tr>
<td>5 Contributing factors/hazards</td>
</tr>
<tr>
<td>6 Organisational outcomes</td>
</tr>
<tr>
<td>7 Detection</td>
</tr>
<tr>
<td>8 Mitigating factors</td>
</tr>
<tr>
<td>9 Ameliorating actions</td>
</tr>
</tbody>
</table>
The WHO conceptual framework for patient safety provides a definition of patient safety and has therefore been chosen as the definition for this study:

“Patient safety is the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum. An acceptable minimum refers to the collective notions of given current knowledge, resources available and the context in which care was delivered weighed against the risk of non-treatment or other treatment.

1.7 Measuring patient safety

Early studies on measuring safety have focused on applying tools to measure the safety culture or climate within organisations, providing insights into areas for improvement (Hutchinson et al, 2006; NHS Scotland, 2010; Health Foundation, 2011). Safety culture relates to how safety is viewed and delivered within an organisation (Health Foundation, 2011). Safety climate is part of the safety culture and refers to staff attitudes about patient safety within an organisation (Health Foundation, 2011). Empirical studies (Hutchinson et al, 2006) reporting on the development and validation of safety climate and culture measurement tools are biased towards healthcare professionals’ views and perceptions of safety, as they are reliant on only these groups completing the tool (Greenhalgh, 2010; Giles et al, 2013) without capturing the views of patients.

As a consequence, these measurement tools have not been validated to measure the views and experiences of patients (Greenhalgh, 2010) and have therefore not formed part of the scoping review presented in chapter 2. Measurement of patient safety from the patients’ perspective was a relatively new concept within the patient safety field (Wolosin et al, 2006; Davis et al, 2008). Indeed, only two studies involving the development of one measurement
tool of patients’ perceptions of their safety were published in the UK (Giles et al, 2013 McEachan et al 2014) during the time of this review. Consequently, little is known about how patients decide if they are safe, and how their views and experiences can influence and drive safety improvements. The empirical evidence suggests that patients are reluctant to raise concerns for fear of reprisals (Schwappach, 2008, World Health Organization, 2009). However, patients experience their pathways of care and are in a unique position to observe and provide insight into what safety is from their perspectives (Vincent & Coulter, 2002; World Health Organization, 2009). It is therefore important to explore further the way in which patients’ experience, and perceive safety (Vincent & Coulter, 2002). This knowledge will enable safety improvement programmes to be informed by the patients’ perspectives. This study is based on the premise that patients have a role to play in influencing the way safety improvements are developed and delivered in the NHS. Therefore, the aims of this study are to examine what patients’ perceptions of their safety are within an acute hospital setting, which can inform the development of a measurement questionnaire.
Chapter 2 Review of patient experiences and perceptions of safety

2.1 Introduction

The previous chapter illustrated the need for further research in safety from the patients’ perspective and examined the concepts of safety and the importance of defining safety to enable measurement of the concept. A definition of safety was provided for this study, along with the rationale. This chapter discusses the scoping review of the literature that was carried out. The framework for the review is discussed, including how the findings have informed the study.

The purpose of this scoping review was two-fold: to establish what research studies had been conducted on patients’ experiences and perceptions of safety, and to examine further the use of questionnaires in healthcare which measured patients’ perceptions of safety. This approach would help to establish gaps in the literature and inform the design of this study. Evidence was drawn from the literature on patient safety to inform the early development the King’s Patient Safety Measure (KPSM). The scoping review formed part of objective 1 of the study, which was to complete a scoping review of the literature and obtain feedback from patient representatives within the acute trust, to inform the layout and questions to be examined in the pilot questionnaire. This is discussed in detail in chapter 3. Arksey and O’Malley’s (2005) methodological framework for scoping reviews was used as this allowed the author to explore the evidence available relating to patients’ perceptions of safety.
2.2 Rationale for scoping review

Arksey & O'Malley’s (2005) scoping framework was chosen because it provided a systematic approach. The framework consists of five stages (Table 2.1) and aims to identify all the relevant literature, regardless of the study design, including how best to present a large body of evidence (Arksey & O'Malley, 2005). The process involves a narrative review of the literature (Arksey & O'Malley 2005). This approach is based on an interpretative narrative approach which focuses in developing a critique based on the relevance, credibility and contribution of the evidence (Davis et al 2009). This enables an open and exploratory nature of the literature when little is known about the subject, in this case patients’ perceptions of safety and allows the evidence to be presented in context to the reader (Arksey & O'Malley 2005). The scoping review does not aim to assess the quality of research and therefore cannot determine research itself is of poor quality (Arksey & O'Malley 2005, Davis et al 2009, Goryakin et al 2010).

Table 2-1 Scoping review framework

<table>
<thead>
<tr>
<th>Stage 1</th>
<th>Identify the research question</th>
</tr>
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<tbody>
<tr>
<td>Stage 2</td>
<td>Identify relevant studies</td>
</tr>
<tr>
<td>Stage 3</td>
<td>Study selection</td>
</tr>
<tr>
<td>Stage 4</td>
<td>Charting the data</td>
</tr>
<tr>
<td>Stage 5</td>
<td>Collecting, summarizing and reporting results</td>
</tr>
</tbody>
</table>
2.3 Stages of scoping review

Stage 1 focuses on the research question in order to guide the approach to the search strategy. For example, the study population, setting and outcomes. Defining key parameters helps to prevent scoping large numbers of unmanageable studies, whilst capturing those that are relevant (Arksey & O’Malley 2005).

Stage 2 involves conducting a comprehensive scoping review of databases to ensure all relevant studies are captured (Arksey & O’Malley, 2005, Davis et al 2009). The research strategy involves searching different sources to ensure a comprehensive scoping review. Arksey & O’Malley (2005) argue that from a practical point of view, decisions need to be made on the time span and language for coverage of the review. Search sources should include databases, reference lists, hand-searching of key journals and relevant organisations and networks.

Stage 3 involves having an inclusion and exclusion criteria based on the research question to ensure key studies are selected that are relevant. For example, the type of studies, study populations and the setting of studies. The approach is similar to search strategies used in systematic reviews (Davis et al 2009).

Stage 4 involves charting key items of information from the studies (Arksey & O'Malley 2005). This involves synthesising and interpreting data by sorting key material themes (Arksey & O'Malley, 2005). Arksey & O'Malley (2005) recommend a common narrative descriptive-analytical framework which includes collecting standard information on each study, such as the aims and methodology used (Table 2.2). This enables a systematic approach to charting the data which is more understandable to readers.
Stage 5 involves developing a narrative account for collating, summarising and presenting the results of the scoping review (Arksey & O’Malley 2005). This helps to make comparisons between studies, identify contradictory evidence and gaps in the literature.

### 2.4 Application of Arksey & O’Malley’s Methodological Scoping Review

### 2.5 Stage 1 Identifying the research question

Objectives were set for the scoping review, based on the research question. These were:

- To search and review studies undertaken regarding patients’ experiences of their care and safety within an acute hospital setting.

- To search and critically review studies undertaken to measure adult patients’ perceptions and experiences of their safety.
2.6 Stage 2 Identifying relevant studies

A systematic search of databases included Ovid Medline, CINHAL, British Nursing Index, Cochrane, PubMed and Web of Science. Additional studies were identified through journal databases, and bibliographies (Table 2.3). A 10-year time frame was set to complete the scoping review due to the time-limited factor of this doctorate. Therefore, this scoping review was conducted between December 2005 and March 2015 to inform the research study. A further hand search was conducted of the reference lists of selected papers, and papers suggested by key contacts were considered.

Table 2-3 Journal databases

<table>
<thead>
<tr>
<th>Journal Database</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ovid Medline</td>
</tr>
<tr>
<td>CINHAL</td>
</tr>
<tr>
<td>British Nursing Index</td>
</tr>
<tr>
<td>Cochrane</td>
</tr>
<tr>
<td>PubMed</td>
</tr>
<tr>
<td>Web of Science</td>
</tr>
</tbody>
</table>

2.7 Search terms

The following search terms (table 2.4) were used to search for studies: patients’ views, thoughts and perceptions of safety; patient experience; patient-centred care; clinical outcomes; safety measures; safety measurement tools; safety culture; safety climate.
Table 2-4 Search terms used in CINAHL

| 1. Patient perceptions of safety |
| 2. Patient experiences of safety |
| 3. Surveys |
| 1+2+3 |
| 2+3 |

2.8 Search of networks and organisations

As well as clinical and academic literature, there were a number of key organisations whose websites were also reviewed. These included the Department of Health, the Patients’ Association, NHS England, the Health Foundation, and the CQC. The purpose was to gain insight into the broader context of patient safety (Entwistle et al, 2010; Rainey et al, 2013), which informed the scoping review. UK national policy and reviews relating to safety improvements were sourced. Only two studies of the development of the same measurement tool (Giles et al, 2013, McEachan et al 2014) have been undertaken in the UK, therefore the search was widened to include international websites. These included Institute of Medicine, the Picker Institute Europe, and the Agency for Healthcare Research and Quality (AHRQ) in the US, and the World Health Organization in Switzerland. Terms frequently referenced in UK national policy literature and investigation reports into patient safety were applied to the search (Health Foundation, 2011; HM Government, 2013a).

2.9 Stage 3 Study selection

The aim of this study was to be able to generalise the findings to the general hospital setting (Bowling, 2009; Greenhalgh, 2010). Therefore, studies that
focused on patients cared for in maternity units, day surgery and psychiatric services were excluded from the scoping review. An inclusion and exclusion criteria (Table 2.5) was used to ensure the search achieved the review’s objectives. The inclusion criteria were not restricted to study design or sample size.

**Table 2-5 Inclusion & exclusion criteria**

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults over the age of 18 years</td>
<td>Adolescents or children under 18 years of age</td>
</tr>
<tr>
<td>Studies published since December 2005</td>
<td>Studies, reviews and articles published before December 2005</td>
</tr>
<tr>
<td>Studies covering the acute health care services</td>
<td>Studies and reviews covering maternity, day case, mental health services</td>
</tr>
<tr>
<td>Studies reporting safety measurement tools focusing primarily on patient feedback</td>
<td>Studies reporting safety measurement tools which focus primarily on healthcare professionals’ feedback</td>
</tr>
<tr>
<td>Studies reporting safety measurement tools focusing on feedback from patients and healthcare professionals</td>
<td>Reports on safety and governance frameworks</td>
</tr>
<tr>
<td>Studies carried out both within and outside the UK</td>
<td>Specific measurement of safety improvement initiative e.g. World Health Organization surgical safety checklist</td>
</tr>
<tr>
<td></td>
<td>Studies examining safety climate and safety culture</td>
</tr>
<tr>
<td></td>
<td>Measurement of specific clinical intervention e.g. medication safety</td>
</tr>
</tbody>
</table>
2.10 Eligibility criteria

The flow diagram (Figure 2) gives numerical value to the process. After the inclusion and exclusion criteria were applied, remaining study abstracts were screened. The scoping review identified 21,790 studies after duplicates were removed; 699 studies remained after application of the inclusion and exclusion criteria. A full text review of these articles identified 46 articles, which were assessed against the eligibility criteria.
Figure 2.2.1 Flow diagram - scoping review

Records identified through database search
(n = 21,807)

Additional records identified through other sources
(n = 12)

Records after duplicates removed
(n = 21,790)

Records screened
(n = 699)

Records excluded
(n = 653)

Full-text articles assessed for eligibility
(n = 46)

Full-text articles excluded,
(n = 24)

Studies included in descriptive overview
(n = 15)

Studies included in critical review
(n = 7)
2.11 Stage 4 Charting the data

At stage 4 a narrative descriptive-analytical framework is recommended by Arksey & O’Malley (2005). This would involve charting key information on each study (Appendix 1 - 4), for example, general and specific information about the study; the study population; type of intervention and outcome measures. Whilst this helped to organise presentation of the studies, the approach did not enable critical appraisal of the quality of survey design in research studies or determine generalisability of findings (Arskey & O’Malley 2005, Davis et al 2009, Goryakin et al 2010).

A search was undertaken of the websites of the Equator (Enhancing the Quality and Transparency of health research) Network and STROBE (strengthening the reporting of observational studies in epidemiology) to find a validated review tool for questionnaire studies. None were found. Therefore, Greenhalgh’s (2010) checklist (Table 2.6) for critiquing papers on questionnaire research was applied at stage 4 and stage 5, and formed the critical appraisal of these studies. The framework includes examining claims made by researchers about how a questionnaire has been designed and developed, including reliability and validity. However, the author found that the framework did not provide examples of these. Rattray & Jones (2007) framework in the essential elements of questionnaire design and development was applied, alongside Greenhalgh’s checklist. The benefits of this approach were that Greenhalgh’s checklist enabled a critique of studies conducting questionnaire research, for example were adequate instructions and explanations included to participants? Rattray & Jones (2007) focused on key elements in the design of a questionnaire, such as item generation, including the application of factor analysis.

Charting of the data was conducted on two levels. Firstly, a descriptive-analytical review of studies which did not involve patient safety measure tools as set out in Arskey & OMalley’s framework at stage 4. This approach would
enable selection of relevant studies which would inform the author's understanding of how patients experienced and perceived safety. Secondly, a critical review of studies which focused on the design and development of patient safety measures, in order to examine the quality of research. It was necessary to carry out a critical appraisal of studies examining patient safety measurement using questionnaires in this way, in order to inform the design and testing of the King’s Patient Safety Measure. For example, questions regarding the design of the questionnaire, tests for face and content validity and whether the instructions on how to complete a tool were clear to study participants (Gerrish & Lacey 2010). These methodological approaches impact on the reliability and validity of a tool and are an important element in the critical appraisal of studies involving the use of questionnaires (Greenhalgh 2010).

**Table 2-6 Greenhalgh checklist**

<table>
<thead>
<tr>
<th>Number</th>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>What did the researchers want to find out, and was a questionnaire the most appropriate research design?</td>
</tr>
<tr>
<td>2</td>
<td>If an “off the peg” questionnaire (i.e. previously published and validated one) was available, did the researchers use it (and if not, why not)?</td>
</tr>
<tr>
<td>3</td>
<td>What claims have the researchers made about validity and reliability of the questionnaire. Are these justified?</td>
</tr>
<tr>
<td>4</td>
<td>Was the questionnaire appropriately structured and presented, and were the items worded appropriately for the sensitivity of the subject area and the health literacy of the respondents?</td>
</tr>
<tr>
<td>5</td>
<td>Were adequate instructions and explanations included?</td>
</tr>
<tr>
<td>6</td>
<td>Was the questionnaire adequate piloted, and was the definitive version amended in the light of the pilot results?</td>
</tr>
<tr>
<td>7</td>
<td>Was the sample of the potential participants appropriately</td>
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<tr>
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<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>8</td>
<td>How was the questionnaire distributed (e.g. by post, email, telephone) and administered (self-completion, researcher-assisted completion), and were these approaches appropriate?</td>
</tr>
<tr>
<td>9</td>
<td>Were the needs of particular subgroups taken into account in the design and administration of the questionnaire? For example, what was done to capture the perspective of illiterate respondents or those speaking a different language from the researcher?</td>
</tr>
<tr>
<td>10</td>
<td>What was the response rate, and why? If the response rate was low (less than 70 percent), have the researchers shown that no systematic differences existed between responders and non-responders?</td>
</tr>
<tr>
<td>11</td>
<td>What sort of analysis was carried out on the questionnaire data and was this appropriate? Is there any evidence of “data dredging” – that is, analyses that were not hypothesis driven?</td>
</tr>
<tr>
<td>12</td>
<td>What were the results? Were they definitive (statistically significant), and were important negative and non-significant results reported?</td>
</tr>
<tr>
<td>13</td>
<td>Have qualitative data (e.g. free text responses) been adequately interpreted (e.g. using an explicit theoretical framework). Have quotes been used judiciously to illustrate more general findings rather than to add drama?</td>
</tr>
<tr>
<td>14</td>
<td>What do the results mean and have the researchers drawn an appropriate link between the data and their conclusion?</td>
</tr>
</tbody>
</table>

### 2.12 Essential elements of questionnaire design and development

Rattrary & Jones (2007) argue that the design and development of a questionnaire should follow a systematic and structured approach and recommend tests for validity and reliability. This will ensure that the questionnaire gives consistent and reliable results across time (Greenhalgh,
There are three essential stages; stage 1; item generation and scale construction; stage 2 piloting questionnaire – item analysis; stage 3 factor analysis (Table 2.7).

2.13 Stage 1 Item generation and scale construction

In stage 1 item generation involves accessing a number of sources including consulting with experts, proposed respondents and a review of the literature. The research question should be referred to frequently during this stage to ensure the items are relevant. During this stage subscales are developed. Validity of a questionnaire in the early stages of design involves testing the face and content validity and can occur at both stage 1, when seeking feedback from experts and proposed respondents and at stage 2, during piloting testing. Validity refers to whether the questionnaire measures what it is supposed to measure (Gerrish & Lacey 2007). Face validity is a subjective measure and relates to a subjective assessment of the layout and relevance of the questionnaire (Bowling 2009, De Vaus 2014). Content validity is determined by asking an expert panel or respondents (during the pilot stage) whether the questionnaire has captured key items that represent the area being examined (Gerrish & Lacey 2007, De Vaus 2014). During this stage consideration should be given to the use of free text questions. Rattray & Jones (2007) argue that free text responses provide valuable insight the early development of items. A range of response scales are available to use. The most common is the Likert scale. This provides ordinal data and measures the level of agreement (Gerrish & Lacey 2007, De Vaus 2014).

2.14 Stage 2 Piloting questionnaire: item generation

In Stage 2 the questionnaire is piloted. This will help to identify items that are not relevant, which can be discarded and is achieved by testing the reliability of the tool. Reliability refers to how well a questionnaire measures what it claims to measure (Gerrish & Lacey 2007, Walker & Almond 2010). There are several...
measures which determine reliability in a tool. Firstly, Cronbach’s alpha is a measure of internal consistency, i.e. a measure of how well each scale item measures the same concept (Aday & Cornelius, 2006). It can be applied in two ways. Firstly, how well items relate to each other and secondly, reporting for the whole questionnaire (Gerrish & Lacey 2010). A questionnaire is judged to have good internal consistency when Cronbach’s alpha is 0.70 or above. This suggests that 70 percent is of an acceptable level, with 30 percent due to random error (Bowling & Ebrahim, 2005). Test re-test reliability is a measure of the repeatability of a tool, when administered over a number of occasions (Gerrish & Lacey 2010). Statistical tests that can demonstrate this are Cohen’s kappa co-efficient and Pearson’s correlation. A correlation above 0.8 indicates good test-retest reliability (Gerrish & Lacey 2010).

2.15 Stage 3 Factor analysis

The first stage of factor analysis involves the production of a correlation matrix that identifies the level of association between each item. This is followed by the extraction of groups of items based on their level of inter-correlation into a smaller number of categories, known as factors. The final stage is the process of rotation, which maximises the separation of the factors. The aim is to determine whether or not each factor has a coherent set of items that combine to make conceptual sense. Factor analysis is conceptually similar to thematic analysis in qualitative research, in that the emerging factors resemble common themes. The difference is that factor analysis is based on numerical scores, rather than words (Walker & Almond 2010). There are two types of analysis, principle component analysis, which is used in the early stages of the development of a questionnaire and confirmatory factor analysis, which is used in the later stages of a questionnaires development to confirm that the items included in an existing scale fit together.

Factor analysis is used to establish the constructs or domains within the developing measure (Bowling & Ebrahim, 2005, Gerrish & Lacey 2010, Walker & Almond 2010). Essentially, is the tool measuring the underlying concept that
it claims to measure (Bowling 2009). Factor analysis groups items together according to their level of inter-correlation (Walker & Almond 2010). Construct validity relates to convergent validity and discriminant validity. Convergent validity is demonstrated when a questionnaire correlates with a related measure and does not correlate with a different measure (discriminant validity) (Gerrish & Lacey 2010).

Table 2-7 Essential elements of questionnaire design & development (Rattray & Jones, 2007)

<table>
<thead>
<tr>
<th>Stage 1 Item generation and scale construction</th>
</tr>
</thead>
<tbody>
<tr>
<td>What will the questionnaire measure?</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>What types of scale can be used?</td>
</tr>
<tr>
<td>How do I generate items for my questionnaire?</td>
</tr>
<tr>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Stage 2 Piloting questionnaire: item analysis</td>
</tr>
<tr>
<td>Piloting the questionnaire: item analysis</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
| Items deemed theoretically important:  
| Is your measure affected by social desirability?  
| Reliability  
| Internal consistency  
| Test retest  
| Inter-observer  
| Validity  
| Face or content  
| Concurrent or discriminant  
| Predictive  
| Stage 3 Factor Analysis  
| Further development:  
| Exploratory factor analysis  
| Principal components analysis (PCA):  
| Explores the inter-relationship of variables  
| Provides a basis for the removal of redundant or unnecessary items  
| PCA is used to identify the underlying domains or factors within a measure  
| Prior to analysis, must propose an underlying theoretical structure  
| Ensure that the data set is appropriate  
| Must follow a predefined and systematic analytic sequence  
| Further development:  
| Confirmatory factor analysis  
| Allows the further testing of the construct validity of the measure  

2.16 Scoping review of studies referring to patient safety

Seven studies that examined patient experience surveys and made a reference to safety were included (appendix 1) along with four studies exploring patients’
experiences with adverse events (appendix 2) and four examining patients’ characteristics on their experience of safety (appendix 3). Table 2.8 presents the studies included in the review.
### Table 2-8 Studies selected for review

<table>
<thead>
<tr>
<th>Author</th>
<th>Patient experience survey</th>
<th>Patient experience with adverse events</th>
<th>Patient characteristics</th>
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</thead>
<tbody>
<tr>
<td>Agoritsas et al (2005)</td>
<td></td>
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<td></td>
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<tr>
<td>Anhang et al (2014)</td>
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<td>x</td>
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<tr>
<td>Davies et al (2008)</td>
<td>x</td>
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<tr>
<td>DeCourcy et al (2012)</td>
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<td>Doyle et al (2013)</td>
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<td>Entwistle et al (2010)</td>
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<td>Evans et al (2006)</td>
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<td>Iedema et al (2012)</td>
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<td>Jeffs et al (2012)</td>
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<td>Jenkinson et al (2002)</td>
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<td>Jha et al (2008)</td>
<td>x</td>
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<td>Long et al (2008)</td>
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<td>Schoen et al (2005)</td>
<td>x</td>
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<tr>
<td>Rainey et al (2013)</td>
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<td>x</td>
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<tr>
<td>Rathert et al (2011a)</td>
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</table>
2.17 Scoping review of patient measurement tools

Seven studies examining questionnaires (table 2.9) were included in the review using Greenhalgh’s (2010) checklist for questionnaire research and Rattray & Jones framework (2007). Three studies were conducted in the United States (Sorra et al 2012, Rathert et al 2011b, Wolosin et al 2006), one study was completed in Switzerland (Schwappach et al 2008), one was conducted in Finland (Sahlstrom et al 2004), and two in the United Kingdom which involved the development of one patient safety measurement tool (Giles et al 2012, McEachan et al 2014). Appendix 2 provides details of these seven clinical studies, outlining the author details and country of publication; setting; the purpose of the study; design; sample size; and data analysis. The outcomes are presented along with details of limitations within each study.

Table 2-9 Patient perceptions of safety measure studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Study involved design and development of a new tool</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wolosin et al 2005</td>
<td>United States</td>
<td></td>
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<tr>
<td>Schwappach 2008</td>
<td>Switzerland</td>
<td>x</td>
</tr>
<tr>
<td>Rathert et al 2011b</td>
<td>United States</td>
<td>x</td>
</tr>
<tr>
<td>Sorra et al 2012</td>
<td>United States</td>
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<td>Giles et al 2013</td>
<td>United Kingdom</td>
<td>x</td>
</tr>
<tr>
<td>McEachan et al 2014</td>
<td>United Kingdom</td>
<td>x</td>
</tr>
<tr>
<td>Sahlstrom et al 2014</td>
<td>Finland</td>
<td>x</td>
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</tbody>
</table>
2.18 Stage 5 Collating, summarising and reporting results

A narrative account, summarising and presenting the results of the scoping review is presented.

2.19 Patients’ experiences with national surveys

The patient experience studies are categorised into four areas, based on their topic of focus. Firstly, studies examining the implementation and impact of national surveys, studies exploring patients and family’s ability to speak up about safety concerns, studies investigating the impact of patients recommending a hospital and findings from small-scale studies.

Three studies examined the implementation and impact of national surveys (Schoen et al, 2005; Jha et al, 2008, DeCourcy et al, 2012). Schoen et al’s (2005) study was conducted across six countries: Australia, Canada, Germany, New Zealand and the UK. The aim of the study was to provide a patient and cross-national perspective throughout these countries, to examine country systems performance with a focus on safety, co-ordination of care, access and chronic disease management. Adults aged 18 and over who had experienced a hospital admission, excluding admission for normal pregnancy, were randomly selected to participate. In total 750 adults in Australia, Canada and New Zealand, and 1,500 in the UK, were asked to complete a questionnaire. The questionnaire was designed by researchers at the Commonwealth Fund and Harris Interactive, with advice from experts in each country. No reference was made to the input from patients, suggesting the tool was biased towards healthcare professionals and researchers.

Overall, the findings illustrated similar deficiencies in care in a number of areas. These included poor communication and failures to co-ordinate care, especially during interactions with medical staff. New Zealand and the UK scored the
lowest levels of patient engagement. Participants across all countries reported poor communication during discharge, with a particular concern regarding medications. Patients who experienced complex care reported failures in the co-ordination of care in the community, especially when they saw multiple doctors. The study found that in all countries the likelihood of co-ordination failures increased significantly with the number of doctors that patients saw. In all the countries patients reported high rates of medical and medication errors and said they were not informed about the mistakes. Diagnostic and laboratory tests were also reported as errors, with patients reporting they had received the incorrect results or delays in receiving abnormal results. Schoen et al’s (2005) study demonstrated that none of the countries ranked higher or lower across all the dimensions of care examined. The study provides opportunities to learn from feedback provided by patients to improve care, thus illustrating the valuable contribution patients can make (Vincent 2002).

Jha et al (2008) study focused on the performance of hospitals within the US, in particular the HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems) survey relating to performance on quality of care. The HCAPS was developed by the Agency for Healthcare Research and Quality and asks patients twenty-seven questions about their experiences of hospital care. The study (Jha et al 2008) examined whether key characteristics of hospitals that were believed to improve patient experience (e.g. high ratio of nurses to patients) were associated with better experiences for patients and whether there was a link with performance on indicators of the quality of clinical care. The study suggested that moderately high levels of satisfaction with care (67.4 per cent) were correlated with the measures of patients’ experiences. This was in comparison with hospitals in the bottom quartile of the ratio of nurses to patients. Jha et al (2008) suggested that high nurse staffing levels may be associated with better experiences for patients. However, the authors acknowledge the need for further research to investigation the causality and strength of relationship between nurse-staffing levels and patients’ experiences. Furthermore, hospitals in the top quartile of HCAPS ratings performed better
than those in the bottom quartile for care that patients received for myocardial infarction performed better than those in the bottom quartile. Consequently, Jha et al (2008) argued that such evidence could provide hospitals with an area to focus on in terms of improving the patients’ experience. The researchers acknowledged whilst they examined patient experience at over 2,400 hospitals, over forty-percent of hospitals in the US did not provide HCAHPS data, therefore leading to positive response bias. The quality of care in the non-responding hospitals was slightly lower than the responding hospitals.

DeCourcy et al’s (2012) study focused on the English NHS national inpatient survey programme. The aim of the study was to investigate how the data had been used and to summarise what had been learnt about patients’ evaluation of care. A systematic review was carried out between 2002 and 2009; 41 papers were included in the review. These were annual surveys (9), evidence-based articles and reports (13), multiple survey comparison reports (9), ethnicity, age and patient experience (3) and sociological studies (7). In a number of papers, patients with poorer health and those from minority ethnic backgrounds were more negative about the care they had received. In contrast, those patients that reported their own health as good or very good were more likely to report a more positive experience. In some studies, elective patients and patients admitted to specialist trusts, trusts outside of London, older people and men were more likely to respond positively. DeCourcy et al (2012) argued that socio-demographic variables needed to be considered when interpreting results.

The results of the sociological studies showed that there was a relationship between staff satisfaction results in staff surveys and patient satisfaction in the national patient survey. In particular, patients’ perceptions of adequate staffing levels and the amount of dignity and respect they were treated with correlated with the staff’s feelings of work pressure and staffing levels. In London, this was a particular feature. There was a very strong relationship between the use of temporary staff, indicating high levels of vacancy and low levels of patient
satisfaction. Staff who reported greater levels of satisfaction with their jobs and lower levels of intention to leave their current job were corroborated with improved patient evaluation of care.

DeCourcy et al (2012) argued that whilst recent papers had applied more advanced analytical techniques, the data presented was mostly descriptive. Many of the papers did not perform original analyses and used reported outcomes from official annual survey reports to monitor feedback from patients. DeCourcy et al (2012) found that many papers used the question “Overall, how would you rate the care you received?” to gauge the importance patients’ placed on different aspects of their care. Improvements were only found in areas where there had been government-led campaigns and incentives. DeCourcy et al (2012) found that in some studies patients were asked to report in detail on their experiences. This offered data that was much more useful and could be used to development a summary score, when combined with all the questions in one survey to create a dependent variable that better represented the topics. Certainly, the emerging picture of the inpatient survey demonstrated that the tool in itself was not a quality improvement tool. It can monitor trends and provide comparative data but is not enough to improve patients’ experiences. The authors recommended further research on how surveys can be used to make improvements on care.

Davies et al (2008) and Entwistle et al (2010) studies examined issues about speaking up for patients and their families. Davies et al (2008) explored surgical patients’ willingness to question healthcare staff on issues related to the quality and safety of their healthcare. The study was conducted in an inner-city teaching hospital in London. Whilst this is a small-scale study with a sample size of eighty patients, it does provide insight into how difficult it is for patients to speak up. This was a cross-sectional study using the Patient Willingness to Speak to Ask Questions Survey (PWASQS). Davies et al (2008) study demonstrated that patients were more willing to ask doctors and nurses factual as opposed to challenging questions. The study also found that men,
who were less educated or unemployed, were less willing to challenge healthcare professionals regarding their care. The authors (Davies et al 2008) argue that patient involvement strategies should consider patient characteristics to promote patient involvement. Therefore, the study raises valuable points in how to engage with vulnerable groups. The authors do acknowledge that replication and assessment of the generalisability of the findings needs to be examined to determine the extent the patients’ condition, demographic characteristics and healthcare staffs’ attitudes, beliefs and behaviours could affect patient’s willingness to speak up.

Entwistle et al (2010) study focused on patients and family members experiences of speaking up about safety concerns during their treatment. The study involved interviewing 71 participants and conducting 21 group discussions. Participants who had had a recent experience of care and raised concerns were recruited to the study. These included adults aged over sixty-five (n=24) recruited from general practices; parents of children recently hospitalised with asthma (n=20); women treated with surgery were recruited from a breast clinic (n=20); patients recruited from NHS lists for planned surgery (n=23); adults well enough to give consent, having experienced a mental illness (n=19) and people who had reported a concern or complained (n=23). Entwistle et al (2010) found that 35 participants in the interviews had identified a total of 128 safety concerns in the course of their treatment. These included; deterioration in their condition that healthcare professionals had not noticed or taken seriously; missed diagnoses and delays in referral and treatment; errors in prescribing; dispensing and administering medicines; errors in technical testing and treatment procedures; omissions or mistakes in communication; shortfalls in hospital accommodation and cleanliness; exposure or threats to other patients and deficiency in inpatient nursing.

Participants viewed speaking up about their safety concerns as difficult and required careful consideration, and a lot of energy. Participants stated the main reason for not speaking up was strongly influenced by how healthcare
professionals behaved and related to them. The study also found that participants’ ability to speak up was influenced by how they assessed the gravity of the threat of harm; the relative importance of their concern given other patients' needs and staff workload and priorities, their confidence about their grounds for concern.

Participants gave various reasons for speaking up (or not) when they became concerned about their safety. These were identified into four main themes, which were:

- Judgements about whether and to what extent situations were problematic

Participants described emotional/physical problems and formed judgements about how likely, how imminent and how grave the problem was, along with how serious the shortfall in standards of care were; assessment of the relative importance of their concern in relation to other patients and staff workload

- Judgements about personal ability to assess problems

Participants wanted to be sure of their ground before speaking up. Participants were more confident about their ability to judge whether and to what extent something was problematic if they were familiar with their condition and treatment

- Judgements about roles and responsibilities

Participants expected health professionals and health services to take responsibility for safety, but also recognised their own role in promoting safety. However, participants described willingness to contribute without challenging staff in ways that would not be interpreted as disrespectful.
• Judgements about the likely consequences of speaking up

Participants anticipations of staff responses dominated their discussions about the likely consequences of speaking up. Anticipating or receiving a positive response was clearly described as influencing the ability to speak up. Patients feared that speaking up would lead to them being seen as a difficult patients and staff being less willing to care for them.

Some participants reported positive and reassuring responses, while others reported negative responses, which exacerbated their anxieties. Entwistle et al (2010) study illustrates how difficult it is for patients to speak up for fear of the consequences. Entwistle et al (2010) acknowledged that there was no attempt to validate patients’ assessments of threats to their safety, nor to ascertain the frequency with which safety incidents occurred, or whether patients spoke up and how healthcare professionals responded. Therefore, the findings were based purely on what patients said. Certainly, without validation the findings were open to question (Greenhalgh 2010). However, the study did capture patient perceptions and therefore reflected what mattered to them.

Jenkinson et al’s (2002) study aimed to determine what aspects of healthcare provision were most likely to influence the satisfaction with care and willingness to recommend a hospital to others. The study also aimed to explore the extent to which satisfaction was a meaningful indicator of patient experience. A postal survey was conducted, and patients were selected if they had recently experienced an in-patient stay. Patients were asked to complete the Picker Institute Survey on specific aspects of their care and to evaluate their overall experience. Patients aged over 18, who had attended one of five hospitals in Scotland, were selected; 2,049. questionnaires were returned (65 percent response rate). Jenkinson et al's (2002) study found 90 percent of respondents were satisfied with their experience. Age and overall self-assessed health were only weakly associated with satisfaction. The major determinants of satisfaction were physical comfort, emotional support and respect for patient preferences.
However, 55 percent of patients who rated their care as ‘excellent’ indicated problems on 10 percent of the issues mentioned in the Picker questionnaire. As a result, Jenkinson et al (2002) argued that patient satisfaction scores presented a limited and optimistic picture. They suggested that detailed questions about specific aspects of patients’ experiences were more likely to be useful in monitoring their performance of hospital departments, thus illustrating a different approach to using survey results to improve patient care.

One small-scale study (Long et al, 2008) was also included in the scoping review. Long et al’s (2008) study explored barriers and enablers in safety and quality as identified by patients. The study was conducted in an Australian hospital with the aim of developing recommendations for patient input into quality. Discovery interviews were conducted with 30 patients aged 18 and over who had experienced an adverse event. Long et al (2008) found that a lack of information provision was identified as a key component of driving failure both for patients and healthcare professionals in preventing an adverse event. While the study illustrated the significant role that communication played in preventing harm for patients, it was very small-scale. Furthermore, a hospital-wide patient group who were not part of the original 30 patients were asked to validate the themes from the discovery interviews, along with clinicians and quality managers. The patient wide group would not have experienced the care described in the discovery interviews and the validation by healthcare professionals would have introduced researcher bias (Greenhalgh 2010). Consequently, conclusions cannot be drawn from the findings.

In summary, the scoping review of patient experience surveys illustrated similar themes of safety that patients stated affected their safety. Communication, failures to co-ordinate care, interactions with medical staff and nurse staffing levels were aspects of safety that patients identified. The empirical evidence suggested that patient experience surveys had made limited impact on improvements in care, unless supported by a government initiative such as infection control. Overall ratings on care were also found to be of limited value,
as patients were likely to score their overall care experience as good, but then
give a lower score to aspects of their care (Jenkinson et al, 2002.

2.20 Patients’ experiences with adverse events

Four studies dealt with patients’ experiences with adverse events. Agoritsas et
al’s (2005) study aimed to estimate the frequency of undesirable events
reported by recently discharged patients and to identify correlations of
undesirable events. The study was conducted in a hospital in Switzerland and
data were obtained from the 2001 Picker Patient Opinion survey with a total
sample size of 1,518 patients and 1,433 responses (response rate 94.4
percent). Patients were asked about the frequency of undesirable events that
may have occurred in hospital. The study also examined the association
between the occurrence of the incidents and the global rating of the hospital
stay; analysis as unfavourable (good, fair or poor) versus favourable (excellent
or very good). The authors stated that two items from the Picker survey,
respect and dignity and the global rating were analysed in the study. The main
variable in the analysis were patient reports of undesirable events. Data
analysis involved analysing the proportion of patients who rated their care
unfavourably, based on the occurrence of each adverse event. The authors
then used unadjusted odds ratios of the rating of care unfavourably for each
adverse event to inform development of a multiple regression model, to identify
events that were independently associated with unfavourable assessments.
Multiple regression was used to establish a causal relationship between more
than one independent variable (undesirable events) and one dependent
variable (Walker & 2010). Odds ratios were used to determine the test of
significance (Walker & Almond 2010).

The proportion of patients who rated their care unfavourably increased with the
number of interpersonal and process-related problems, but less so with medical
problems. Furthermore, the odds of an unfavourable rating increased with each
additional interpersonal problem. Of 1,433 respondents, 725 (response rate
50.6 percent) reported at least one event. The most frequent events were phlebitis (11 percent); unavailable medical record (9.5 percent); failure to respect confidentiality (8.4 percent) and hospital acquired infection (8.2 percent). Multivariant analysis demonstrated that a number of events were associated with unfavourable assessment. These were; feeling rejected by the healthcare team; reporting that healthcare staff neglected important information; not getting enough painkillers; needless repetition of a test and being handled roughly. Adjustment for patient characteristics and the hospital department did not change these results. The frequency of undesirable events was similar for both men and women but was associated with increased length of stay. Patients with a depressed mood were strongly associated with interpersonal problems.

The authors conclude that the undesirable events relating to interpersonal problems were most strongly associated with unfavourable ratings of care overall, in contrast to medical problems with showed a weak association. Agoritsas et al (2005) recommend that summarising the patients’ experience over the hospital stay, allows the patient to report on the general delivery of care. This is because patients’ overall global assessment and rating of care is based on the whole experience of their care pathway. Agoritsas et al (2005) suggest that 3 types of questions are useful for quality improvement. These are; ratings, reports of usual patterns of care and reports of discrete events. However, no reference is given to how this can be achieved. Generalisability of the findings is questionable because patients in Switzerland have a longer length of stay. The study also failed to independently verify whether reported events had occurred.

Evans et al’s (2006) study aimed to seek public opinion on the rate and severity of adverse events experienced in hospitals, using a lay definition and the public's perception of safety in hospitals. The authors did not state what this definition was, therefore questioning what they actually measured. The study was conducted in Adelaide, Australia. Adults aged 18 and over living in the city
were selected for the study. Data collection involved household-based interviews. A total of 2,945 interviews were conducted, with a response rate of 78.4 percent; 67 percent of respondents over the age of 40 reported having at least one member of their household hospitalised in the past five years. Descriptive analysis was used to determine the adverse event rate and severity of the adverse event, with categorical variables recorded as counts. Univariate analysis was used to determine those participants most likely to have experienced an adverse event, using binomial generalised liner model. Univariate analysis is used to compare the mean scores of the two groups to determine the impact of one independent variable on the dependent variable (Pellant 2013) and therefore was an appropriate statistical test to conduct. Multivariate analysis was then conducted to determine the best joint predictors of safety (Pellant 2013). The authors state that the conventional p value of $p < 0.05$ represent the statistical significance level. Multivariate analysis is used to compare a number of different dependent variables, in this case joint predictors of safety.

Respondents stated that seven percent of those hospital admissions were associated with an adverse event; 59.7 percent rated the adverse event as really serious; and 48.5 percent stated that prolonged hospital stays resulted from an adverse event. Predictors of perceived lack of safety for respondents demonstrated the more severe the adverse event, the more perception of the lack of safety. Participants who were less than 60 years old or were an indigenous Australian were more likely to have experienced an adverse event. Multivariate analysis indicated that the best joint indicators for perceptions of lack of safety in hospitals were being female, residing in a metropolitan area. Evans et al’s (2006) study found that perception of safety in hospital was largely affected by the experience of an adverse event. The authors concluded that the experience of adverse events negatively impacted on public confidence in hospitals.
Doyle et al’s (2013) study explored evidence of links between patient experience, clinical safety and effectiveness. A systematic review of 55 studies was conducted across primary and secondary care. Studies were included if they measured associations between patients’ reporting of their experience and patient safety and clinical effectiveness. To broaden the search terms and provide a framework for analysis the authors combined elements from patient experience frameworks used by the Institute of Medicine, Picker Institute and NICE. Two dimensions were identified. These were; relational aspects and functional aspects. Relational aspects related to the interpersonal aspects of care and the functional aspects related to basic expectations about how care was delivered.

First, the review demonstrated that there was a consistent positive association between patient experience, patient safety and clinical effectiveness across a wide range of disease areas, settings, outcome measures and study designs. Second, the review demonstrated positive association between patient experience and self-rated and objectively measured health outcomes, which included adherence to recommended medication and treatments, preventative care such as the use of screening services and immunisations, the use of healthcare resources such as hospitalisation and the length of stay and the number of primary care visits.

However, studies that explored associations between patient experience and technical quality, the evidence was mixed. Overall, there was less evidence on safety compared to effectiveness and the authors recommend further research is required in this area. The authors argued that patient experience is a central pillar of quality in healthcare, alongside clinical effectiveness and patient safety. Doyle et al (2013) concluded that their study illustrates that patient experience, patient safety and clinical effectiveness are linked and therefore should be looked at as a group to improve quality in healthcare.
Anhang et al’s (2014) study explored further the link between patient experience, patient safety and clinical effectiveness. The authors conducted a systematic review of the literature to explore the association between patient experience measures and other indicators of healthcare quality. The indicators were; patient behaviour; clinical processes; clinical outcomes; efficiency; and safety. The study focused on articles that reported results from the Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys, the most widely used source of patient experience measures in the US. The CAHPS programme is a public-private initiative standardising surveys of patient experience (World Health Organization 2009). In total 34 articles were identified.

Patient behaviour involved examination between the patient-physician relationship. Better patient reported experiences, especially trust in physicians and belief that physicians had a comprehensive knowledge of the patient were associated with patients’ adherence to medical advice. In terms of clinical processes, hospitals with the highest HCAHPS scores performed significantly better for some diseases. Examples given included acute myocardial infarction, congestive heart failure and pneumonia and surgery, compared to hospitals with the lowest HCAHPS scores. Furthermore, patients’ overall ratings of their hospitals were positively associated with the hospital’s performance measures for these diseases. Within the United Kingdom 19 different conditions showed a similar pattern. In relation to efficiency the evidence found that patients’ overall ratings of hospitals’ care and discharge planning were independently associated with lower 30-day readmission rates for acute myocardial infarction, heart failure and pneumonia. In terms of safety, reports of positive patient experiences were associated with lower prevalence of inpatient complications, especially with pressure ulcers, post-operative respiratory failure, pulmonary embolism and deep vein thrombosis. In one study a significant relationship between patients reports of hospital staff responsiveness and decreased likelihood of central line-associated blood stream infections was found. Hospitals where patients
reported a more positive experience tended to have staff with more positive perceptions of safety.

Anhang et al’s (2014) study corroborated the findings in Doyle et al’s study (2013). A positive association between patient experience and patient adherence was identified, as well as clinical outcomes. Furthermore, Anhang et al’s (2014) study demonstrated there was a positive association between patient experience and best practice clinical processes, better hospital safety culture and lower unnecessary utilisation, such as visits to accident and emergency departments. However, the authors found no positive association between patient experience and clinical processes or outcomes. They argued this was not surprising, as clinical process measures have not been shown to be consistently and positively related to each other. Anhang et al (2014) argued that well developed and standardised patient experience measures complement measures of technical care quality by providing information about aspects of the care pathway, which patients are best placed to comment on as they are the only ones who experience the pathway. Moreover, to ensure patient experience data is actionable for healthcare organisations and meaningful to patients, surveys should inquire about specific care experiences. The example Anhang give is whether doctors and nurses listened carefully, rather than focusing on the overall satisfaction of the experience, which they argued is highly subjective. Furthermore, focusing on the infrastructure and processes of certain aspects of care may result in broader improvements, as common characteristics of the system can influence a broad range of outcomes. In conclusion Anhang et al (2014) suggest that quality improvement aimed at enhancing patient experience may improve clinical quality and reduce cost.

In summary, the empirical evidence on patients’ experience with adverse events demonstrates that patients can recognise and report their experience with adverse events. The studies illustrated how patient experience, clinical effectiveness and patient safety were linked, and therefore should be examined together. Furthermore, the empirical evidence suggested that well developed
and standardised patient experience measures complemented by measures of safety would enable a stronger focus on specific aspects of care for improvement. However, the empirical evidence on the use and interpretation of the global rating scale was mixed. Agoritsas et al (2005) argued that overall global assessment and rating of care is based on the whole experience of the patient care pathway, and therefore suggested that allows the patient to report on the general delivery of care. In contrast Anhang et al (2014) argued that for patient experience surveys be meaningful they needed to ask specific questions about care, thus enabling organisations to target key areas for improvement.

2.21 Patient characteristics and patient safety

Four studies looked at how patient characteristics – their knowledge and insight, as well as that of their families – can influence their perception of safety. Rathert et al’s (2011a) study explored patients’ perceptions of safety. Their research question asked; “What can consumers tell us about patient safety in the hospital?” The setting of the study was conducted in large Mid-western city area, in the US. Adult patients aged 18 years and over who had had a recent hospital admission were recruited: telephone interviews were conducted with 39 participants. Although this was a small-scale study it does provide insight into issues about safety, which are important to patients and the findings are corroborated by similar studies in this field (Doyle et al 2013; Anhang et al 2014). Rathert et al (2011a) identified three themes: communication, staffing issues and medication administration. Participants associated process problems, for example delays, or lack of information with safety rather than quality problems. Participants also acknowledged the important role that family caregivers played as advocates. Rathert et al (2011a) concluded that patients were acutely aware of care processes that pose a risk to their safety. Indeed, feedback from patients may help to identify areas where there are higher risks of preventable adverse events.
Idemea et al’s (2012) study explored what patients and their families knew about problems and failures in healthcare. Semi-structured interviews were conducted with 39 patients and 80 family members in their homes. The aim of the study was to map patients’ experiences of healthcare incidents and incident disclosure communication. Idemea et al’s (2012) study demonstrated that patients and relatives had considerable knowledge about health service risks and problems. They also had insight into where care could be improved. Patients and family members stated the challenges they faced when trying to negotiate their knowledge and insights with health service staff. Idemea et al (2012) concluded that patients and family members would benefit from a structured process to enable them to engage in helpful conversations with healthcare professionals.

Jeffs et al (2012) study explored patients’ and family members’ perspectives on how safety threats were detected and managed during the transition of care from the acute hospital setting to complex continuing care, and what strategies would improve patients’ care. Semi-structured interviews were conducted with 15 patients who were transferred to a complex continuing care/rehabilitation setting, and seven family members. Jeffs et al (2012) study identified three key main themes in participants’ perceptions: lack of information, a feeling of getting funnelled through too soon, and difficulty adjusting to the shift from total care to almost self-care. Some participants described not being informed about their transfer, or that the transfer happened too early. Participants identified the need to have a co-ordinated approach to care transition that engages patients and families. Jeffs et al (2012) suggested these findings provided key areas that impact on safety from patients and their families, and ways to improve care, and they argue that patients and families should play a more active role in their care planning and self-care management.

Rainey et al (2013) explored the experiences and views of patients and their relatives to determine the potential for involvement in promoting their safety. This was a small-scale study involving 13 patients with chronic disease and
seven relatives from two medical wards in two UK hospitals. Participants were interviewed with a focus on patients who were discharged home. The study identified that the ability to speak up about concerns was influenced by the ability of participants to recognise changes in their clinical condition, the ability to self-monitor their care, and confidence and trust in healthcare professionals. Patients described the importance of their long-term relationship with a trusted healthcare professional and particularly being recognised as an individual. Relatives also valued such relationships. The culture of an organisation was an important factor in influencing patients and relatives speaking up. An example given was that staff appeared too busy to talk. This reduced opportunities to engage with staff and raise concerns.

Although Rainey et al’s (2013) study was small scale the findings are corroborated by the studies conducted by Jeffs et al (2012), Rathert et al (2011a) and Idemea et al (2012) which demonstrate the role of family members acting as advocates for patients, in particular patients with complex care plans transitioning across systems of healthcare, and those living with chronic disease.

2.22 Summary of scoping review

These studies highlight the need to focus on vulnerable groups of patients and illustrate how patient experience surveys can contribute to improving care for these patients.

Firstly, patient surveys are used in a number of countries as part of national performance programmes and public disclosure of performance indicators (World Health Organization, 2009 p.118). Within the UK the National Patient Survey is completed on a yearly basis with feedback given to organisations and the results published on trust and national websites (Picker Institute, 2015). While there is reference to improvements in care with the use of such surveys as the NHS Friends and Family Test (NHS England 2014b) and national patient
survey of the NHS, there is little or no interaction with patient safety programmes (World Health Organization, 2014). Patient experience surveys have demonstrated improvements in patient care when there has been a national drive on improvement. Indeed, a number of these studies illustrate the limitations of using patient experience surveys to improve patient experience and care, in particular interpretation of the global rating score.

Furthermore, they have recommended the need to use patient experience surveys to focus and inform key areas for improvement. Patients’ experiences with adverse events studies illustrated that patients were able to recognise unsafe care and report it. The studies exploring patient characteristics and patient safety demonstrated how families and carers acted as advocates for patients.

All the studies make a link between patient experience, patient safety and clinical effectiveness. More recent studies (Agoritsas et al, 2004; Evans et al, 2006; Doyle et al, 2013; Anhang et al, 2014) have identified similar themes which impact on safety: communication, the number of doctors that patients see, and the impact of staffing levels. These studies have demonstrated how patients and family members can recognise an adverse event and make recommendations for improving care.

2.23 A review of patient safety measurement tool studies

In total seven papers were reviewed. One paper (Sorra et al, 2012) examined the relationship between a healthcare professional measurement tool of safety and a patient experience survey. The remaining six papers focused on the application of patient safety measurement tools completed by patients (Wolosin et al, 2006; Schwappach, 2008; Rathert et al, 2011b; Giles et al, 2013; McEachan et al 2014; Sahlstrom et al, 2014) (Appendix 4).
2.24 What did the researchers want to find out?

The starting point for interpreting any study is to ask what researchers want to find out, and how have they used the literature to formulate the research question and study design (Lacey & Gerrish, 2010). Therefore, in the case of developing questionnaires, how has the literature been interpreted by the authors to inform the design of their questionnaire (Rattray & Jones, 2007). Two studies (Wolosin et al 2006, Sorra et al 2012) used previously published questionnaires to achieve their study aims. The remaining five studies developed new questionnaires to examine patients’ perceptions and experiences of their safety, arguing there were no validated tools to achieve their study aims (Schwappach, 2008; Rathert et al, 2011; Giles et al, 2013; McEachan et al 2014; Sahlstrom et al, 2014).

2.25 Aims of studies using published questionnaires

Sorra et al’s (2012) objective was to examine the relationship between two Agency for Healthcare Research and Quality (AHRQ) questionnaires of hospital patient safety and quality which are widely used across the US (Sorra et al, 2012). These were the Consumer Assessment of Healthcare Providers and Systems patient experience questionnaire (CAHPS), and a staff survey measuring safety culture called Hospital Survey on Patient Safety Culture (Hospital SOPS). Sorra et al (2012) refer to previous research within healthcare and other industries to illustrate a strong association between staff satisfaction and patient satisfaction. The rationale for the study was that many hospitals administer safety culture measurement tools to staff and patient safety experience surveys to their patients. Therefore, it was important to examine whether there was a relationship between the two tools to help hospitals make sense of these measures and to invest time in them. Sorra et al (2012) hypothesized that the measurement tools were positively related. They examined the relational aspects between staff perceptions of their safety culture and patients’ satisfaction with their care.
The study carried out by Wolosin et al (2006) examined how four different variables influenced patients’ perceptions of their safety. These were: what patients’ perceptions of their personal safety was; how the characteristics of patients and hospitals influence their perceived safety; how did perceived safety relate to other patient satisfaction issues; and how could hospitals maximize patients’ perceptions of their safety? In order to answer these research questions, the authors obtained data from a patient experience tool called Press Ganey’s inpatient survey. The findings from the study could then be used to inform safety development strategies based on what influenced patients’ experiences of their safety (Wolosin et al, 2006). Wolosin et al (2006) provides no further information on the structure of the Press Ganey’s inpatient tool, including piloting and testing the reliability and validity of the tool.

### 2.26 Aims of studies designing implementing new questionnaires

In Giles et al’s (2013) study the authors focused on patients being able to identify safety incidents based on a previously developed safety framework tool called the Yorkshire Contributory Factors Framework (YCFF). A systematic review of patient safety incidents was conducted to inform the development of the framework. The YCFF consisted of a taxonomy of factors contributing to patient safety incidents. These included factors for example, physical environment, communication, leadership and teamwork. Giles et al (2013) argue that while patients provide feedback on their experiences, there is no existing measurement tool, which asks patients to comment on factors contributing to safety incidents. Therefore, the purpose of their study was to explore the extent to which patients were able to provide feedback on contributory factors represented in the tool; to develop indicators of each contributory factor in the form of questionnaire items; to test the face validity of the questionnaire known as the Patient Measure of Safety (PMOS). A further
study was undertaken by McEachan et al (2014) to test the reliability and validity of this tool within an acute hospital setting.

Rathert et al’s (2011b) study took a different perspective on what influences patients’ perceptions of their safety. They examined the relationships between service quality, patient safety perceptions and patient satisfaction. Within the study Rathert et al (2011b) make references to previous research studies suggesting a link between these three concepts leading to patients concluding their safety is at risk. The authors designed their questionnaire around these three variables to test the hypothesis that there is a mediating role for patient safety perceptions.

Schwappach’s (2008) study focused on developing and piloting an inpatient safety survey within two Swiss hospitals. The aim of the tool was to obtain data from patients relating to specific safety events, which could be quickly fed back to staff. The design of the tool was informed by incidents identified within the literature and through discussion with a panel of safety experts. The authors designed a patient safety questionnaire around four domains following a review of the literature: treatment safety, device safety, medication safety and patient participation in promoting safety. Patients were then asked to report their experiences and ratings of care and choose answers that would meet their personal views best. The study published the items in the survey, along with the number of responses for each one. However, design of the items was biased towards the healthcare professional’s perspective, for example hand washing, with no evidence of patient involvement.

Sahlstrom et al (2014) focused on examining patients’ experiences of patient safety and their participation in promoting safe care during their most recent hospital stay. A new questionnaire was developed based on the Finnish Patient Safety Strategy of conceptual model of factors that influence patient participation in preventing errors and related literature. The resulting Patient Experiences on Patient Safety questionnaire included four domains; treatment
safety; device safety; medication safety and patient participation in promoting safety.

2.27 Methods

Each of the studies used a cross-sectional approach with data being collected at a single point in time (Greenhalgh, 2010). Results of the studies therefore must be interpreted with caution, as they cannot illustrate causality (Greenhalgh, 2010). In Sorra et al’s study (2012) data from the staff survey, Hospital SOPS, was obtained in 2008, while the patient experience survey, CAHPS, was collected in 2007. The environment in which patients were being cared for would have been delivered by a different set of staff compared with those who completed the staff survey; suggesting results should be interpreted with caution (Bowling & Ebrahim, 2005; Sorra et al, 2012). However, using a cross-sectional approach does allow for the standardised measurement of an attribute such as safety and is therefore an appropriate research design for this study (Bowling & Ebrahim, 2005; Aday & Cornelius, 2006).

2.28 Questionnaire design

Rattray & Jones (2007) framework for essential elements of questionnaire design and development refers to the use of statistical tests to determine the reliability and validity of a tool and the item development. Therefore, these tests are examined in this section. Statistical tests used to inform the outcome of findings from questionnaire studies are presented under stage 5, collating, summarising

In Sorra et al’s study (2012) both tools were developed and validated by the AHRQ, confirming they would provide consistent results. The CAHPS tool was developed by AHRQ in partnership with the centres for Medicare and Medicaid Services and was accepted for national implementation in 2006. The tool supports reporting on hospital performance by generating data that can be
compared across hospitals and provides a uniform set of core patient survey measures to support quality improvement. The tool was designed to assess hospital inpatient quality of care from the patient’s perspective and includes 18 items that measure 7 areas regarding the quality of care and service patients receive in hospital. Most items use a 4-point frequency scale (never, sometimes, usually and always). The tool also has 2 single item measures - hospital rating and willingness to recommend. For hospital rating, patients are asked to rate their hospital on a scale of 0 to 10, with 0 being the lowest rating and 10 the highest score.

The Hospital SOPS tool is used to assess hospital staff perceptions about patient safety issues such as medical error and event reporting (Sorra et al, 2012). The tool was pilot tested, revised and then released by AHRQ in 2004. It was designed to assess hospital staff perceptions about patient safety issues, medical error and event reporting. The survey includes 42 items that measure 12 patient safety culture composites. Each of these is calculated as a percent positive score. The items use 5-point Likert responses scale of agreement (strongly disagree to strongly agree) or frequency (never to always). The survey also includes 2 single item measures that ask staff to give their work area/unit a patient safety grade and to estimate the number of events they have reported in the past 12 months.

Giles et al (2013) study was conducted in two phases to assist in the development of their safety measurement tool. In phase 1 patients were asked to identify contributory factors from the YCFF. Unstructured interviews (n=18) used a narrative approach where patients were asked to describe their most recent hospital experience, with an emphasis on patient safety. The authors highlighted that during the pilot interviews the term ‘patient safety’ was not familiar to patients and discouraged patients from participating in the interview. This is supported by Schwappach (2008), who argues that patients are reluctant to raise concerns about their safety for fear of reprisals. As a consequence, the term patient safety was removed from subsequent interviews and patients were
encouraged to describe their experiences relating to safety e.g. delays in waiting for medication (Giles et al, 2013). This illustrates the need to consider carefully the wording used within a questionnaire to ensure the sensitivity of the subject area and the health literacy of the respondents (Greenhalgh, 2010). This was further supported during discussions with a patient panel. The panel were asked to comment and select the contributory factors from the YCFF that patients would definitely not be able to identify/comment on. These included safety culture, policies and procedures. The draft tool was then revised by the research team and the patient panel to strengthen content validity.

There is potential for researcher bias in this study (Greenhalgh, 2010) as the views of researchers could have influenced the patient safety domains which may not been viewed as significant from a patients’ perspective. This was illustrated by new themes which patients identified. These were dignity and respect (Giles et al, 2013). In phase 2 a ‘think aloud’ approach was used with staff and patients. Think aloud is a technique that allows the examination of an individual’s thinking processes and decisions that are being considered at the point in time. Participants are asked to think aloud while completing the questionnaire (Gerrish & Lacey, 2010). The approach is useful for pre-testing questionnaires and to improve clarity and to compare data collected by other methods (Gerrish & Lacey, 2010). The involvement of the patient group to advise on the development of the measurement tool within Giles et al’s study (2013) illustrates the valuable contribution a patient can make and helps to strengthen the tool’s readability (Greenhalgh 2010). The Patient Measure of Safety (PMOS) was developed as a result of the study, consisting 42 items using a 5-point Likert scale from 1 (strongly disagree) to 5 (strongly agree).

In McEachan et al (2014) study the aim was to test the PMOS for reliability and validity. The study included AHRQ staff survey on safety culture being completed by staff on participating wards. The aim was to assess convergent validity of the PMOS, by confirming if there was a correlation between the two tools. McEachan et al (2014) argue that the AHRQ staff survey on safety
culture had been validated in previous studies and therefore was a justifiable measure to use. Factor structure, internal reliability, test re-test, discriminant validity and convergent validity were assessed.

McEachan et al (2014) state that a principle component analysis was performed on correlation matrices with pair-wise deletion using PASW statistics. Pair-wise deletion only removes the specific missing values from the analysis (Pallant 2013). McEachan et al (2014) state that principle component analysis was used in the development of the PMOS. Orthogonal varimax rotation was applied to explore the internal structure of the questionnaire. The purpose of rotation was to present the data in a way that was easy to understand, by identifying patterns for the 13-item scale. The more strongly items were correlated the closer the relationship was between them, thus the need to keep them in the tool (Devellis 2012). Kaiser’s criterion was then used to extract the number of factors to retain because it has been shown to be fairly accurate when sample sizes are above 250 and average communalities are greater than 0.60. Factor loadings above 0.40 were retained. The internal reliability of the retained factors was determined by the Cronbach alpha, with scores of 0.8 and above interpreted as good, 0.7 as acceptable and 0.6 as questionable. McEachan et al (2014) then went on to apply Pearson’s correlations. Pearson’s correlation is a measure of the strength the linear relationship between two variables (Walker & Almond 2010). In this case, to assess test-retest of the questionnaire across participants and explore convergent validity of the PMOS with the AHRQ at ward level. Correlations of 0.1 were interpreted as a small effect, 0.3 as medium and 0.5 as large. Discriminant validity was determined by MANOVA (multivariate analysis of variance) with the ward as the independent factor and the PMOS scales as the dependant factors. MANOVA compares the means of two or more groups to determine if there were differences between the two questionnaires and therefore was an appropriate statistical test to apply. Missing data were excluded. The PMOS consisted of 42 items, using a 5 – point Likert scale from 1 strongly agree, to 5 strongly disagree. Respondents were also able to select a not applicable option. The tool assessed patients’
perceptions of factors across a number of domains. This included communication, the physical environment, the scheduling of care and management of staff and staffing levels. Although McEachan et al (2014) presented and explained the stages of questionnaire development, they did not publish their tool.

Schwappach (2008) conducted three phases in the development of his tool. The first phase involved a review of the literature to inform the content and design of the questionnaire. This was followed by discussions with 8 national experts before the questionnaire was tested with two focus groups of patients. A core question asking patients about their involvement with an adverse event was also included. The item list was informed by the study conducted by Agoristas et al (2005) but adapted by removing items that relating to interpersonal relationships. This was because Swiss hospitals conducted patient satisfaction surveys capturing communication. Also, the list of medical lists and system problems were adjusted, with new items listed, such as medication errors and failure to wash hands. Schwappach (2008) states these changes were made based on a number of criteria and recommendations from experts.

In phase 2 the revised survey was pilot tested with randomly selected patients across to hospitals (Schwappach, 2008). The think aloud approach was also used by Schwappach (2008). Again, the purpose was to test the content and face validity of the tool. In phase 3 patients who had returned the survey and reported an experience of an adverse event were interviewed over the phone by trained researchers, thus ensuring consistency in interviewing technique. The purpose of the interviews was to explore in more detail patients’ experiences of an undesirable event.

Rathert et al's (2011b) tool item development was based on taking items from nationally recognized tools which had been consistently used. Seven items were taken from the Picker Patient Experience Questionnaire to measure
service quality. Rathert et al (2011b) argue that the questionnaire had been used in many studies to measure service quality, and therefore was a reliable tool. Three items were developed to measure patient satisfaction and were taken from patient satisfaction surveys. Rathert et al (2011b) confirm these particular items were chosen as they were used to assess the overall quality of care and general patient satisfaction. The items were also used regularly by the participating hospitals and were highly correlated with patients’ willingness to recommend the hospital to family and friends. The patient safety items were based on the Picker Patient Experience Questionnaire. Patient focus groups were asked to comment on topics that they had observed and believed were indicators of safe care such as checking a patient’s identification prior to administering drugs. Patients were then asked to review the items in the questionnaire for readability and face validity.

In terms of the measure for patient satisfaction the 3 items were used to assess the overall quality of care and satisfaction. These were core items developed by research consultants and used regularly by the participating hospitals. The items were highly correlated with patients’ willingness to recommend the hospital to family and friends. The items asked patients to rate their satisfaction with aspects of their care, for example “Please rate your satisfaction with the trust and confidence that you felt. Participants were asked to rate these items using a 5-point scale, where 1 was poor and 5 was excellent. Rathert et al (2011b) justified using this subscale because the Cronbach alpha estimate for internal consistency was acceptable for all 3 items. (.90 -.94).

The instrument used to assess service quality included 7 items from the Picker Patient Experience Questionnaire. Rathert et al (2011b) argue that the tool has been used in many studies to measure service quality. A subgroup of items referred to as the PPE – 7 was validated in previous study by Jenkinson, et al (2002) as an overall measure of patient centred care and therefore was used for their study. Participants were asked to respond to a 3-point Likert scale frequency where 1 was yes always, 2 was yes sometimes, 3 was no. Rathert et
al (2011b) stated that the measure had demonstrated reliability because it had a Cronbach alpha range between .79 - .83.

The patient safety items were developed for the study. Rather et al (2011b) state these items were designed to be consistent with the PPE questionnaire items. Inpatient focus groups informed the development of the items. A small group of patients then reviewed the items for readability, content and face validity. A 3-point frequency scale was developed where 1 was yes, 2 always and 3 was no. Items within the scale showed a Cronbach alpha score between .89 - .93. However, the study does not present the items, making it difficult to determine what patients were actually asked to rate and there is no reference to using factor analysis in the development of the tool.

Sahlstrom et al’s (2014) questionnaire was based on the Finnish Patient Safety Strategy conceptual model relating to factors that influence patients’ participation in preventing errors. 33 studies were identified and used to assure the content validity of the 27-item questionnaire. Each item included a statement, along with a 5-point Likert scale to determine the participant’s level of agreement, with 1 totally agree, 2 disagree, 3 somewhat agree, 4 totally agree and 5 did not relate to my period of care. An additional 4 closed questions were also included. Patients were asked if they had experienced any errors. If they answered yes, they were asked three more questions. These were; did they report the error; did staff tell them about the errors and did staff apologise for the errors. The content validity was evaluated by a team of national safety experts. The questionnaire was also presented to five patients who were asked to assess face validity. Sahlstrom et al (2014) stated the Cronbach score was between .88 for the total scale; for the subscales – treatment safety .77; device safety .88; medication safety .86 and participation in patient safety promotion .88. The authors identified the databases they searched and confirmed that 33 articles were used to assure the content validity of their questionnaire. However, there is no reference to the selection criteria of the articles, making it difficult to ascertain what the focus was for patient safety.
Patient input into the development of the tool was at a late stage as patients were only asked to comment on the readability of the tool as opposed to its content. This could have led to researcher bias in the areas of safety within the tool (Greenhalgh, 2010).

Wolosin et al (2006) state their survey was based on a conceptual model that took ratings from typical experiences that patients might actually encounter during a hospital stay. Examples given include; admission; meals; tests; treatments and discharge. Details of the statistical test used to determine reliability and validity were stated. Cronbach alpha score for each scale ranged between .84 - .95 and for the entire instrument was .98. demonstrating strong internal reliability of the tool. Construct validity was determined by factor analysis and convergent validity, along with discriminant validity. 9 factors were identified which were similar to the subsections of the questionnaire. Convergent validity was demonstrated by calculating the average corrected item-scale correlations for each subsection; these ranged between 0.62 – 0.86. For discriminant validity the item non-scale correlations ranged between 0.40 - 0.59. 29 survey items were rated using a 5-point Likert scale from 1 very poor to 5 very good. Wolosin et al (2006) provide no further details regarding the pilot testing of the tool, including assessment of the face and content validity. The questionnaire is not published in the study, so it is not clear what each of the items were.

2.29 Summary of questionnaire design

In each of the studies (Wolosin et al, 2005; Schwappach, 2008; Rathert et al, 2011b; Sorra et al, 2012; Giles et al, 2013; McEachan et al 2014; Sahlstrom et al, 2014), the authors used questionnaires to examine safety from different perspectives, illustrating the multi-dimensional aspect of safety. The rationale for the choice of questionnaire or development of a new tool was explained. However, only two studies published their questionnaires in their studies (Schwappach 2008, Sahlstrom et al 2014). Therefore, it was not possible to
determine whether; the questionnaires were appropriately structured and presented; the items were appropriately worded for sensitivity of the subject area. None of the studies discussed how the tools were developed in response to the health literacy of respondents.

In each of the studies (Wolosin et al, 2005; Schwappach, 2008; Rathert et al, 2011b; Sorra et al, 2012; Giles et al, 2013; McEachan et al 2014; Sahlstrom et al, 2014) the authors have used the literature to inform their research questions and the design and focus of their questionnaires. Schwappach (2008) and Sahlstrom et al (2014) have taken a more traditional approach in safety measurement by focusing on asking patients to comment on experiences of safety indicators taken from the healthcare professional perspective such as treatment errors, medication errors, and whether they had experienced undesirable events (Emanuel et al, 2015). This has the potential for researcher bias (Greenhalgh, 2010) as patients could be encouraged to report on safety indicators, which they may not rate as important as healthcare professionals. This was illustrated in the study carried out by Giles et al (2013) where patients identified dignity and respect, which was not based within the YCFF. Wolosin et al (2006), Rathert et al (2011b), Sorra et al (2012), Giles et al (2013) and McEachan et al (2014) have taken a more contemporary view (Emanuel et al, 2015). Patient safety is seen as a dynamic concept related to and influenced by a number of variables, in particular communication as a relational aspect of safety between patients and healthcare professionals and how patients experience it. However, Schwappach (2008) decided to remove items from his questionnaire relating to interpersonal relationships and communication, citing other surveys capture this. It is questionable whether removal of items relating to communication was sensible and indeed whether the study could be replicated in the United Kingdom. Other studies have used interpersonal relationships as a main focus for examining patients’ perceptions of safety. For example, Rathert et al’s study (2011b) examined the relationship between patients’ perceptions of safety, satisfaction and service quality. Sorra et al’s (2012) study examined the relational aspects, but differently and demonstrated
that patients’ experiences of their care and staff’s perceptions of the safety culture within the area are positively linked.

Several of the studies used a Likert scale to measure the concept under investigation such as patient satisfaction (De Vaus 2014). Likert scales provide ordinal data and are a quick and easy way to obtain the level of agreement or disagreement from respondents within a questionnaire (Gerrish & Lacey 2010).

The authors in the studies using new questionnaires have explained how item generation was developed during pilot testing. However, each has used different approaches, and this raises questions about the reliability and validity of the tools. Firstly, patient involvement was used at various stages to assess face and content validity. Giles et al (2013) and Schwappach (2008) used the think aloud technique with patient focus groups at the early stages of development of their tools, along with input from experts in the field of safety. However, patient involvement in Sahlstrom et al (2014) study was at a later stage. Content validity of their tool was evaluated by four national experts and then presented to five patients to assess face validity. This has the potential to introduce researcher bias into the content of the tool. Wolosin et al (2005) and Rathert et al (2011b) have made no reference to pilot testing their tools, thus making it difficult to establish how assessment of face and content validity was tested. Only one study (McEachan et al 2014) used Pearson’s correlation to assess test-retest reliability of the PMOS.

Of the five studies that designed and developed their questionnaires (Schwappach, 2008; Rathert et al, 2011b; Giles et al, 2013; McEachan et al 2014; Sahlstrom et al, 2014) only two studies referenced how factor analysis was applied. These were Wolosin et al (2006) and McEachan et al (2014). Therefore, it was not possible to establish how construct validity was determined in the other studies, that is; how well did the items in the questionnaires represent the underlying concept of safety (Gerrish & Lacey 2010).
Cronbach’s alpha was measured in four studies (Wolosin et al, 2006; Rathert et al, 2011b; Sahlstrom et al, 2014). In two studies (Wolosin et al, 2006, Sahlstrom et al, 2014) the internal consistency was measured for each subscale and then the entire instrument. This illustrated how well each item and the overall questionnaire measured patient safety. Two studies (Rathert et al 2011b; McEachan et al 2014) state their Cronbach alpha scores for each scale, but not the overall score for the instrument, thereby demonstrating internal consistency only for the subscales (items) and not the overall tool (DeVaus 2014)

### 2.30 Sampling frame and response rate

There is variability and rationale in the sampling frame and responses rates stated in the studies. In Sorra et al (21013) study 73 hospitals that submitted data in 2008 for the hospital SOPS survey and data submitted for CAHPS for 2007. The sample sizes between the two measures was not equal and data was collected over two different time periods. No rational was given for the sample size of 73 hospitals.

Giles et al (2013) study involved the very early design and item development of the PMOS, therefore the sample sizes given for the unstructured and structured interviews was consistent at this stage early questionnaire design (Gerrish & Lacey 2010). The authors state that patients were approached to participate during their hospital stay. This had the potential for positive response bias because patients may have been reluctant to raise concerns about their safety for fear of reprisals (Vincent 2000). Details of the selection criteria for patients and staff were not given. In McEachan et al study (2014) the authors conducted two cross sectional studies, one with patients and one with staff within a large acute trust in the North of England. Data was collected from 10 wards. The authors confirm that a minimum sample size of 250 patients was based on recommendations to conduct factor analysis. Although no such stated
sample size was required for staff, the authors aimed to achieve a minimum size of 50%.

In Wolosin et al (2006) study the safety ratings from over 600,000 patients were analysed from hospitals within the United States that applied the Press Ganey Inpatient survey. No further information is given to the rationale for this sampling frame. In Rathert et al’s study (2011b) the characteristics of the three hospitals was not stated. Hospital 1 also had a higher response rate compared to the other two hospitals, therefore potentially introducing response bias (Gerrish & Lacey 2010). There was no reference within the study to explain this. Patients were included if they were aged 18 years and over and had experienced a medical or surgical visit within 90 days. In phase 1 of Schwappach (2008) study a small number of national experts (n=8) and patients were involved in testing the face and content validity of the tool. In phase 2 125 patients out of a sample size of 400 were randomly selected to pilot test the tool in 2 Swiss hospitals. No rationale was given for the sample size. In phase 3 patients were selected if they had returned the survey and reported experience of an incident. Sahlstrom et al (2014) included patients who had being admitted to day surgery or as inpatients and were aged 18 years and over. 368 questionnaires were distributed, with 175 returns. The authors confirmed that the sample size of 175 was calculated to conduct statistical analysis at a power of 80%.

Walker & Almond (2010) suggest minimum sample sizes to achieve a two-tailed significance level set at $p< 0.05$ when using such statistical analysis. Sahlstrom et al (20174) referred to calculating a power calculation at 80 percent. Walker & Almond (2010) and Greenhalgh (2010) argue researchers should clearly state the criteria to predict the minimum sample size requirement to carry out their data analysis. This should include the significance level and direction of the hypothesis. In Rathert et al’s study (2011b) the significance level is not stated but the statistical analysis of each hypothesis is illustrated through the application of the multiple regression model. Sample sizes in some of the studies were small. In Sorra et al’s (2012) study the number of hospitals in the
study was small n = 73. Giles et al (2013) study was conducted in one hospital with a total of 33 patients, thus making it difficult to establish conclusions from the study (Greenhalgh, 2010). In McEachan et al (2014) acknowledged that the response rate from staff was 48%, which was much lower than from patients.

2.31 Instructions given to participants

Only one study explained the instructions given to participants. Rathert et al study (2011b) states that survey packs were mailed to patients. This included a questionnaire, a cover letter and a pre-paid envelope. Non-responders were mailed a reminder letter and a second packet after three weeks and again at six weeks. This approach is likely to have increased the response rate (Gerrish & Lacey, 2010; Greenhalgh, 2010). However, in Wolosin et al’s study (2006) 495 hospitals volunteered to participate in the study, suggesting there was selection bias (Gerrish & Lacey, 2010). These hospitals may already have had a good safety record, which may have positively affected the results of the safety questionnaires being examined in the study (Vincent, 2010).

2.32 What were the results and were they statistically significant?

Studies should confirm what their actual results are and whether they are statistically significant and clinically significant and outline strengths and limitations (Greenhalgh, 2010). The authors in these studies (Wolosin et al, 2006; Schwappach, 2008; Rathert et al, 2011; Sorra et al, 2012; Giles et al, 2013; Sahlstrom, 2014) have each confirmed their results and discussed the statistical significance of their results and drawn conclusions from them. Several of the studies have used statistical analysis such as correlation and multiple regression models.

This is illustrated in Sorra et al’s (2012) study where a statistically significant link is made between the two questionnaires. Sorra et al (2012) conducted bivariate
correlations to illustrate the relationship between variables, in this case the SOPS and CAHPS composite score and the hospital rating and willingness to recommend the hospital. All correlation coefficients produce a number between -1 representing no association, +1 represents a perfect correlation between the two variables, a positive correlation means that as scores on one variable increase, the scores on the other variable also increase. A negative correlation coefficient means that as scores on one variable increase, scores on the other decrease (Walker & Almond, 2010). Multiple regressions were also undertaken to determine if there was a relationship between the independent variable, in this case the hospital SOPS and the CAHPS, as the dependant variables for controlling bed size and ownership. The standardised regression coefficient (Beta) is presented in the study to illustrate regression. This is the weighting given to each independent variable by the regression equation. R gives the strength of the relationship on the scale of 0 to 1. P indicates the statistical significance of the association. The bivariate correlation values for p < 0.05 in Sorra et al’s (2012) study illustrate the statistical significance of the relationship between variables. This was the purpose of their study and therefore an appropriate statistical analysis to use (Greenhalgh, 2010). Sorra et al (2012) present their findings to illustrate the statistical significance of the relationship between the two questionnaires. In summary, the study demonstrated correlations between staff ratings of patient safety culture and patient ratings of care. For example, staff perceptions of patient safety culture were related to patients’ perceptions of their care. Furthermore, where staff have more positive patient safety culture perceptions of care, patients have a more positive experience. The strongest relationship between the various composites was between the hospital SOPS measure of the adequacy of staffing and patients’ perceptions of the responsiveness of staff. Organisational learning and continuous improvement and teamwork within units showed strongest relationships to patients’ experiences with care. The study demonstrated that four patient experience measures showed the strongest relationship to patient safety culture. These were; communication with nurses; communication about
medications; responsiveness of hospital staff and the hospital environment. The study illustrates the global assessment of patient safety culture made by staff is positively related to an overall composite of patients' experiences with hospital care.

Giles et al (2013) used content analysis to code themes in the early development of their items. The PMOS was then further assessed in the study undertaken by McEachan et al (2014) and compared the PMOS tool with the AHRQ safety culture completed by staff. The authors undertook test-retest reliability. The questionnaire was filled in by patients two weeks after the first time of completion. Test-retest is important when a questionnaire is to be used to assess change over time (Gerrish & Lacey 2010). Reliability is determined when a questionnaire can produce the same results on difference occasions, under the same conditions. Reliability scores are reported on a scale of 0 to 1 and interpreted as alpha (Walker & Almond 2010). The authors have stated the statistical test undertaken to assess test-retest and presented their results. The findings showed that items relating to delays did not show acceptable test-retest reliability.

Discriminant validity was determined to assess the extent to which the PMOS discriminated among the 11 wards. The authors used multivariate analysis (MAMOVA) to achieve this. MANOVA determines if the means differences between two or more groups is likely to have occurred by chance (Gerrish & Lacey (2010) and therefore was an appropriate statistical test to carry out. The results showed that three factors significantly discriminated between the hospital units. These were; staff roles and responsibilities; ward type and layout; and equipment. Further tests were undertaken to explore the significant differences between the wards. These showed the following factors; within staff roles and responsibilities factor, the administration ward was shown to be significantly worse, compared to the remaining 11 wards. Convergent validity was assessed by taking the mean PMOS positive index for each ward and correlated with four patient safety outcome measures of AHRQ across 10
wards. McEachan et al (2014) developed the PMOS positive index by summing the number of items that patients responded to by using one of two positive response options. The mean PMOS score for the entire sample was then determined. The results demonstrated that the PMOS positive index correlated highly with the perceptions of safety outcome scale. The authors argued that the more positive PMOS scores among patients, the higher staff rated the ward on perceptions on safety. However, there was no relationship between the PMOS positive index and staff frequency of event reporting, or individual staff event reporting.

Wolosin et al (2006) applied two-way analysis of variance (ANOVA) to compare the mean differences between two or more groups under different two or more conditions (Walker & Almond 2010). In this case, patients’ perceptions of safety (dependant variable) against a number of independent variables (e.g. length of stay). The authors focused on four questions; what was the current status of patients’ perceptions of their personal safety in United States hospitals.; how do characteristics of patients, hospitalisations and hospitals influence perceived safety/; how does perceived safety relate to other patient satisfaction issues? And how can hospitals maximise patients’ perceptions of safety?

Rathert et al (2011b) used multiple regression to test 4 hypotheses across 3 hospitals. These were; service quality was positively related to overall satisfaction; service quality was positively related to patient perceptions of safety; patient safety perceptions were positively related to overall satisfaction; patient safety perceptions would mediate the relationship between service quality and overall satisfaction. The results showed that the first three hypothesis were supported, whilst the fourth hypothesis was partially supported. Indeed, two of the hospitals showed significance in the relationship for hypothesis 4.

Schwappach (2008) applied confidence intervals and odds ratios in phase 2 of his study to help determine the event rate of patients experiencing an adverse
event. 95% (n=125) of patients responded to the survey during the pilot, with n=94 reporting experience of a definitive event and 34 experiencing uncertain events. The authors state the event rate for definitive 0.75 (95% CI 0.54 – 0.97; for uncertain 0.27 (95% CI 0.15 – 0.40); for all events 1.02 (95% CI 0.76 – 1.29.

The frequency of reporting events is presented in the study, for example age, and gender were not significant predictors of reporting definitive events, but of the odds of reporting these events increased with every additional day between the inpatient stay and completion of the survey. In phase 3 patients were interviewed by a trained researcher. No information was provided in the study about how the interviews were analysed, and no definition was given for a definitive event and uncertain event, making it difficult to interpret what the authors were actually discussing.

Sahlstrom et al (2014) determined the mean score of each domain. Criterion of good level of patient safety and participation in promoting safe care at 3.57 on the 4-point Likert scale, for each domain by combining the scores for totally agree and somewhat agree and totally disagree and somewhat disagree. Nonparametric tests were then carried out on the data because it did not meet normal distribution. The authors then applied a logistic regression model to determine the extent to which background variables such as age, gender influenced patients’ assessment of the level of safety (presented as odd ratios and 95% confidence intervals). The results showed that responses varied by age and experience. Patients aged between 66-75 were more critical of treatment and medication safety. Group differences in patients’ ratings of overall patient safety during their most recent period of care is presented, with including the logistic regression results. For example, device safety was reported as the worst aspect of safety, but this varied by both gender and employment. However, a multiple regression table was not presented to illustrate the overall effect of the independent variables on the dependant variables. Results were also presented using mean scores. However, the statistical analysis showed that the data were not normally distributed, therefore
it would have been more appropriate to use the medium score (Walker & Almond 2010).

Multiple regression models were applied to these studies as their study aims were to establish relationships between a number of variables affecting patient safety (Wolosin et al, 2006; Rathert et al, 2011b; Sorra et al, 2012). The analysis is used to establish the causal relationship between more than one independent variable and one dependent variable. Results of multiple regression should have been presented in a table to illustrate the weighting of each variable, the values beta given to the relative importance of each variable in relation to each other, the significance of each variable within the regression model which is illustrated by the p value and the value of r to show the total amount of variation explained by the combination of independent variables in the regression model (Walker & Almond, 2010). In Rathert et al (2011b) do provide tables to illustrate the application of the regression model to each hypothesis. The final hypothesis shows the beta weighting (relative importance) for service quality in hospital 1 to demonstrate why the hypothesis is partially accepted. Wolosin et al’s (2006) study fails to provide a table to illustrate the overall effect of the independent variables, making it difficult to determine their significance (Walker & Almond, 2010).

2.33 Summary of clinical studies examining patient safety measures

When critiquing the studies against Greenhalgh’s (2010) and Rattray & Jones (2007) framework it became apparent that not all studies followed a systematic approach in the design, development and application of their tools. In stage 1; item generation and scale construction, content validity involved healthcare professionals, with examples of late input from patients who were asked to assess the face validity of a tool. The importance of using user groups to assess content and face validity is key to ensuring the tool is sensitive to the
health literacy of the participants (Greenhalgh, 2010). However, not all studies stated how they assessed this. Some studies introduced selection bias as a result (Sorra et al, 2008; Rathert et al, 2011b; Giles et al, 2013), making it difficult to determine the factors contributing to patients’ views and experiences of their safety (Greenhalgh, 2010). Not all studies stated they had undertaken a pilot study of their tool. Tests for reliability included Cronbach alpha score for subscales. Some studies also presented a Cronbach alpha score for the global rating scale, illustrating construct validity of their tool. Only two studies presented their application of factor analysis to test the construct validity of their tools, including the interrelationships between the variables. Many of the measurement tools have been developed and used predominantly in the US, suggesting that they need to be tested in the UK (Greenhalgh, 2010; Health Foundation, 2011; Health Foundation, 2013). Further studies are therefore required where the views and experiences of patients inform the development and validation of safety measurement tools.

In terms of the results, some authors have used ANOVA and MANOVA to determine the difference between three or more independent variables (Walker & Almond 2010), for example the impact of patient characteristics. Multiple regression has then been used in some studies (Agoritsas et al 2005) to determine if there was a cause and effect relationship between risk factors such as increased length of stay and the dependant outcome (experiencing an adverse event. Odd ratios were then used to determine the increased likelihood of experiencing and adverse event, for example the increased number of interactions with doctors.

### 2.34 Latest contributions to the field

A further scoping review of the literature was undertaken from April 2015 to May 2018, following completion of this study, using the same methodology (Arksey & O’Malley 2005; Rattray & Jones 2007; Greenhalgh 2010). The same research terms used in the original scoping review were applied. These were: patients’
experience with adverse events, patient characteristics and patient experience surveys, along with studies examining the development of patient safety measurement tools. No specific studies were identified that solely examined patient characteristics. Patient safety measurement studies were reviewed in the critical appraisal. Table 2.10 presents the studies that were examined. Appendix 5 provides details of each study.

**Table 2-10 Studies selected for review April 2015 onwards**

<table>
<thead>
<tr>
<th>Author</th>
<th>Patient experience survey</th>
<th>Patient experience with adverse events</th>
<th>Patient characteristics</th>
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<tr>
<td>Abrahamson et al 2016</td>
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<td>Ball et al 2018</td>
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<td>Christiansen, et al 2016</td>
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<td>Carter et al 2017</td>
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<td>Dixon et al 2015</td>
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<td>Harrison et al 2015</td>
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<td>Hassen et al 2017</td>
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<td>InHealth Associates 2015</td>
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<td>Kemp et al 2016</td>
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<td>Lovink et al 2015</td>
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<td>Manacorda et al 2016</td>
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<td>Martzolf et al 2016</td>
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2.35 Patient experience surveys

Nine studies (InHealth Associates, 2015; Raleigh et al, 2015; Abrahamson et al 2016; Martsof et al, 2016; Christiansen, et al 2016; Manacorda et al, 2016; Hassen et al, 2017; Carter et al 2017; Balll et al 2018) were identified following completion of this study. Two studies conducted in the US examined patient experience and nurse staffing. First, Martsof et al (2016) examined the association between hospital nurse staffing and the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS), using a patient experience survey. This was a retrospective study using cross-sectional and longitudinal models to estimate the effect of nurse staffing levels and skills mix on several of the HCAHPS measures. Data from 341 hospitals within the US measuring nurse staffing, patient experience and hospital characteristics from 2009 to 2011 were examined. After controlling for unobserved hospital characteristics, the positive influences of increased nurse staffing levels and skills mix were relatively small in size and limited to a few patients’ inpatient experience. These were discharge information and communication about medications. Indeed, the results of scores from the 13-item scale within this study demonstrated that staffing levels impacted on how safe patients felt. Item 10 There were always enough staff to care for me on this ward had a 43% response rate overall. Examples of early coding from the open-ended questions of descriptors of safety illustrated that patients felt safe when staff spent time explaining the treatment plan to them, in a way that patients could understand. Poor communication with staff was reported so frequently, as an early code of feeling unsafe that further coding was undertaken to identity key areas of concern. Poor communication about medication was the main code that emerged, illustrating how important this was to patients.
Carter et al (2017) examined the association between patient experience factors and the likelihood of 30-day readmission. A prospective cohort study was undertaken in two inpatient units at a hospital in Massachusetts. 846 patients admitted between January 2012 and January 2016 who met the eligibility criteria were enrolled (48% response rate). The study found readmitted participants were less likely to have a high school diploma (p=0.02). Multivariant models adjusted for baseline variables demonstrated that participants who reported being very satisfied with their care were less likely to be readmitted (p=0.007). Participants who reported that doctors always listened to them carefully were less likely to be readmitted (p=0.03). The authors concluded that participants who reported high levels of satisfaction and good communication were less likely to be readmitted. Thus, illustrating the impact of communication on patient outcomes.

In Ball et al study (2018) the authors state that variation in post-operative mortality rates has been associated with differences in registered nurse staffing levels (Aiken et al 2014; Aiken 2016). Their observational study (Ball et al 2018) examined if missed nursing care mediated the observed association between nurse staffing levels and mortality. Data from the RN4CAST study (2009-2011) combined routinely collected data on 422,730 surgical patients from 300 general acute hospitals in 9 countries, with survey data from 26,516 registered nurses, to examine association between nurses’ staffing, missed care and 30-day inpatient mortality. Staffing and missed care were derived from the nurse survey. A mediator was defined as a variable that accounted, in whole or in part, for the relationship between independent (staffing level) and dependent variables (30-day inpatient mortality). The results were presented as 4 models to examine the association between nurse staffing and 30-day inpatient mortality.
Model 1 – Each additional patient per nurses is associated with a 7% increase in odd of a patient dying within 30 days of admission (OR 1.068 95% CI 1.031 – 1.1106)

Model 2 – Missed care is significantly associated with 30-day case mix adjusted inpatient mortality. Each 10% increase in missed care is associated with a 16% increase in the odds of a patient dying within 30 days of admission

Model 3 – When the relationship between nurse staffing and education are included, the relationship between staffing and mortality is reduced

Model 4 – Missed care mediates the association between nurse staffing and patient mortality

The authors conclude that when nurses have too many patients to care for and do not have time to complete all the necessary care, missed care increases the odds of poor patient outcomes.

Abrahamson et al’s (2016) study examined the relationship between nurse-reported safety culture and the patient experience. Multivariate mixed-effects regression models were specified using data from hospitals that administered both the HCAHPS and the Agency for Healthcare Research and Quality (AHRQ) staff safety culture measure. Abrahamson et al (2016) found that patients’ overall satisfaction was significantly associated with the percentage of male patients and the education level of patients within the hospital.

Christiansen et al’s (2016) study explored the impact of the NHS in England’s Open and Honest Care Programme on patient safety, patient and staff experience and improvement practices within acute hospital settings. This programme formed a key aspect of the Nursing and Midwifery and Care Staff Strategy launched by the Department of Health in England and Wales in 2012. The purpose of the programme was to drive organisational learning and improvement, through the continuous collection, analysis and sharing of patient safety data, together with staff and patient experience information and service
improvement stories. These included the NHS Safety Thermometer data, Friends and Family test data and information on healthcare-associated infections, along with patient stories and improvement stories describing what trusts had learnt; 18 hospital trusts participated in the study. An electronic survey was administered to 387 staff and 13 semi-structured interviews were conducted with senior nurses and ward managers. Respondents were asked to rate, using a five-point Likert scale, the degree to which they rated data sets were valuable to inform their clinical practice. The most useful information was the metric relating to hospital-acquired associated infections, then patient experience information, staff experience information and patient stories: 86 percent strongly agreed or agreed that access to the information helped the organisation to understand where action could be taken to reduce harm to patients or to improve patient safety. Christiansen et al (2016) found that bringing together the metric data and narrative stories of patient stories into one report was powerful as this enabled nurse managers and nurses to gain a more complete picture of the safety and quality of care. The study demonstrated how the use of patient stories set the context in which safety was experienced by patients and enabled organisations to focus on improvements. The use of open-ended questions within the King’s Patient Safety Measure achieved a similar outcome. The tool enables patients to comment on aspects of care that made them feel both safe and unsafe and to make recommendations for improvement. Furthermore, the tool asks patients to confirm what staff could have done differently to make them feel safe. This allows the opportunity for staff to learn what went wrong for patients and what patients wanted to change.

Hassen et al’s (2017) study aimed to evaluate the surgical ward environment with respect to process driven and structural factors to identify quality markers for safe care. This was a small-scale study involving 15 patients, 16 nurses, and 15 doctors across three hospital sites. Semi-structured interviews were carried out with participants. While this is a small-scale study the findings make for interesting reading as they showed that staff identified a number of different safety indicators to patients, such as staff experience and nurse staffing levels;
in contrast, patients (87 percent, n=13) identified staff attentiveness as their top-rated indicator. Although this study did not examine the differences of perceptions of safety between staff and patients it does illustrate that patients describe their perceptions of safety differently to health care professionals. Coding of the open-ended questions demonstrated that showing compassion and clear communication were the most frequent codes that emerged in making patients feel. However, having sufficient staffing levels was a code that emerged in descriptors of feeling unsafe. This suggests that patients are able to recognise when staffing levels are not adequate in making them feel. However, further research is needed to establish if there is an association between patients reporting concerns regarding staffing levels and whether this leads to direct harm.

The King's Fund/Picker Institute Europe report (Raleigh et al, 2015) on patients' experience surveys demonstrated results of national surveys had little impact on improving patient experience. Indeed, no surveys have made a significant impact at a national or local level, except on infection control. This was because of the national programme to improve infection control practice, especially with reduction in MRSAs. The authors (Raleigh et al, 2015) recommended linking findings from surveys to transformational programmes to ensure a strong focus and commitment. The report published by InHealth Associates (2015) examined the impact of using patient experience data. 14 trusts were contacted to provide information on what information was being gathered and interpreted to improve patient care. Whilst there was a commitment to making a difference for patients it was acknowledged that trusts faced huge challenges in collecting data in order to make sense of it.

The Policy Innovation Research Unit report on Friends and Family test (Manacardo et al 2016) examined the impact of the Friends and Family test in general practice. Semi-structured interviews were conducted with 42 general practices across England. While the study was conducted in general practice the findings provide wider learning for the NHS. The study suggested that the
tool was limited in demonstrating improvements in care. The authors (Manacorda et al, 2016) argued that the question asking patients if they would recommend the practice to family and friends, was of limited value. Earlier studies (Jenkinson et al 2002) suggested that the value of the overall rating of satisfaction in questionnaires is not a reliable measure of satisfaction. Manacorda et al (2016) recommended asking patients’ views on aspects of the clinical service which would act as a diagnostic tool to make staff aware of problems within the service. This recommendation is supported by the findings from Anhang et al’s (2014) study which proposed using measurement tools that asked about the technical aspects of their care, as well as the quality aspects, by linking the two more-detailed feedback on areas for improvement.

2.36 Patients’ experiences of adverse events and patient characteristics

A total of six studies were identified (Harrison et al, 2015; Dixon et al, 2015; Lovink et al, 2015; Kemp et al, 2016; Yan et al, 2017; Walton et al, 2017). Harrison et al (2015) conducted a systematic review of studies of patients’ experiences with adverse events. Thirty-three publications were reviewed and identified similar themes to those within this study, in particular the themes that emerged from the open-ended questions. These were: medication errors, communication and co-ordination of care. Harrison et al (2015) found that patients’ income, education health burden and marital status influenced the likelihood of reporting incidents. Furthermore, Harrison et al (2015) found several studies reported that younger patients, below the age of 60, were more likely to report adverse incidents. However, significant differences by age and sex were not found. The authors argued that further research was required on both the experience of patients involved with adverse events and the influence of patient demographics.

Dixon et al’s (2015) study conducted a survey focused on the perceptions of surgical safety practice with 345 patients following elective surgery. Their
results found that patients undergoing their first surgery and patients with higher incomes were associated with a significant decrease in specific safety perceptions. Qualitative feedback from patients demonstrated the physician-patient relationship was the most important factor that positively influenced patient safety perceptions.

Lovink et al (2015) examined the experiences of safety of adult patients during their haemodialysis treatment. However, the study was very small-scale with a total of 12 patients and therefore no conclusions can be drawn from this study (Greenhalgh, 2010). Kemp et al (2016) examined the relationship between patient experience and adverse events. A telephone survey was completed with 25,098 patients following discharge from 93 hospitals in Canada. They found that inpatient experience ratings were associated with patient safety incidents.

Yan et al (2017) examined the frequency of undesirable events reported by adult patients (N=341) during their hospital stay and the relationship between undesirable events and perceptions of safety and satisfaction with care in China. Patients were interviewed after discharge using a survey instrument. Yan et al (2017) developed their item list based on the research of Agoritsas et al (2005) which was referenced in the scoping review of this study. The authors found that the most frequent event was insufficient explanation about medication side-effects and patients’ perceptions of safety and satisfaction with care were related to their experience of undesirable events. Yan et al (2017) argued that patient incident reporting systems should be developed to improve patient contribution to problem areas in care.

Walton et al (2017) carried out a large-scale study which examined the experiences of patients within hospitals in New South Wales who had suffered an adverse event. Their findings demonstrated that patients whose first language was not English and those who had been admitted through the emergency route, were significant indicators for predicting the occurrence of an
adverse event. The authors concluded that patient experience surveys may not be sufficiently robust to capture the context in which patients experience adverse events. Certainly, this was a limitation of this study as patients who were not able to speak and read English were excluded.

2.37 Patient safety measurement studies

Four studies were carried out in England (Lawton et al, 2015; Ricci-Cabello et al, 2016; Lawton et al, 2017; O'Hara, 2017) during completion of this study, three within the acute hospital setting (O'Hara et al, 2017) and one within the GP practice setting (Ricci-Cabello et al, 2016) (Table 2.11). In Lawton et al (2017) the patient safety measure was used as part of an intervention. Appendix 5 provides a review of these studies.

Table 2-11 Patient perceptions of safety measure studies April 2015 onwards

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Study involved design and development of a new tool</th>
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<tr>
<td>O'Hara 2017</td>
<td>United Kingdom</td>
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<td>Lawton et al 2015</td>
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<td>Lawton et al 2017</td>
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<tr>
<td>Ricci-Cabello et al 2016</td>
<td>United Kingdom</td>
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Lawton et al's (2015) study examined whether the safety information provided by patients was different from that provided by staff, and whether this was related to safety outcomes. Data were collected from 33 hospital wards, across three acute hospitals within the UK. Staff (n=648) completed four outcome
measures of AHRQ hospital survey of patient safety culture (HSOPC). Patients (N= 822) completed the PMOS, along with the Friends and Family test. The authors also collected safety outcome data for harm-free care on each of the wards, otherwise known as the Safety Thermometer. Data was collected over a period of four months. Pearson correlations were undertaken to assess association between harm-free care score, PMOS and 4 patient safety outcomes from HSOPSC. Scatter plots were used to assess if relationships between variables was linear and whether particular wards represented outliers, and Spearman’s rank correlations, to ensure patterns of findings were same if assumptions of linearity were not met. MANOVA was undertaken to compare trusts across the 4 measures and to identify differences in safety scores.

The response rate for patients was 80% and staff 50%. Correlation of different measures of quality of care showed; Friends and family test score correlated with PMOS, but was not significant with safety HSOPC & safety thermometer data; perceptions of patient safety and number of safety events reported significantly correlated with percentage of harm-free care (p<0.00 1); negative correlation, as number of safety events reported by staff increased percentage of harm-free care decreased; frequency of reporting events not associated with harm-free care; no correlation between perceptions of safety, patient safety grade and PMOS score; number of events reported by staff did not show significant negative correlation – the more safety events reported by staff, the lower the PMOS score (r=0.43); high correlations between HSOPSC patient safety grade and perceptions of safety (r=0.91) – demonstrating the two scales were measuring the same concept. The Friends and family test and HSOPSC outcomes measures did not differ significantly.

Lawton et al (2015) found that the Friends and Family test and the PMOS independently predicted safety outcomes. The Friends and Family test was also significantly correlated with the PMOS but was not associated with safety outcomes or staff measures of safety. Furthermore, staff responses to the
patient safety culture survey were not significantly correlated with patient responses to the patient safety measure of safety.

A more recent study by Lawton et al (2017) involved a multicentre cluster randomised controlled trial to evaluate the efficacy of the Patient Reporting and Action for a Safe Environment (PRASE) intervention tool, which included the PMOS questionnaire. Thirty-three wards across five hospitals in the United Kingdom participated. The PRASE intervention tool involved two interventions; PMOS tool; proforma for patients to report both safety concerns and positive experiences. PIRT tool (patient incident reporting tool). The primary outcome measurements were; routinely collected ward level harm free care and patient level feedback on safety, using the Patient safety thermometer and the PMOS. Secondary outcomes were; 3 CQUIN questions measured in NHS Inpatient survey; NHS Friends and Family test question – How likely are you to recommend this ward to family and friends, if they needed similar treatment; staff perceptions of safety culture using 4 outcome questions from HSOPS. Patient feedback was given to each ward as part of multidisciplinary meeting. Change cycles lasting 6 months during 12-month period.

Feedback was considered in multidisciplinary action planning. Lawton et al (2017) found that all wards participated, along with 86 percent of patients. The authors found no significant effect of the intervention on any outcomes at six and 12 months, although greatest improvements were seen on the wards that had the best compliance with the intervention. Lawton et al (2017) argued that adherence to the implementation of action plans was poor and, consequently, safety outcomes may have been too blunt a measure. Lawton et al (2015) went on to say they were unable to demonstrate any overall effect of the intervention on either measure of patient safety.

O’Hara et al’s intervention (2017) study was an exploratory pilot of three mechanisms for collecting data on safety concerns from patients during their hospital stay, rather than using a safety measure tool. These were interviews at
the bedside, a paper-based form or telephone hotline. 178 out of 432 patients were recruited to the programme, with a response rate of 41%. Healthcare professionals and patients coproduced the mechanisms. The mechanisms were trailed using a cluster randomisation at ward level. A cluster sample is taken from different locations to ensure a diverse representation within the target population (Walker & Almond 2010). Nine wards participated, and each mechanism was tested over a 3-month period. Patients were asked to feedback their safety concerns via the mechanism on their ward. Covariance analysis was used to determine the differences between the mechanisms in the number of reports, controlling for age, gender, duration of hospital stay and a combined degree of prior experience score.

Patients who participated in face-to-face interviews at the bedside significantly reported more safety concerns (p<0.01), compared with those using the paper-based form (p<0.01) and patients using the hotline mechanism (p<0.01). There was a significant association between the type of reporting and whether a patient reported one or more safety concerns (p<0.01). Of the patients who reported in the face to face interviews 64% reported one or more safety concern. Indeed, 49% of all patients who reported a safety concern were in the face to face interviews. However, the study found no statistical difference between the number of classified incidents, or physician-rated preventability. The authors suggested that interviewing patients at the bedside was likely to be the most effective means of gathering safety concerns from inpatients. Interestingly, the study did not find an association between the number of patients reported safety concerns and the number of reported incidents. These studies have attempted to examine the relationship between patient perceptions of safety with health outcomes.

Ricci-Cabello et al's (2016) study set out to develop and validate a patient-reported instrument for measuring experiences and outcomes related to patient safety in primary care, known as Patient Reported Experiences and Outcomes of Safety in Primary Care (PREOS-PC). A mixed-methods approach using
quantitative and qualitative research methods was applied. Development of the tool, including item generation, involved a multistage process by an international expert panel and informed by a systematic review of instruments, a meta-synthesis of qualitative studies and four patient focus groups. This was a large-scale study across 45 GP practices in England, capturing 6,736 patients; 1,244 questionnaires were returned (18.5 percent response rate). The authors used confirmatory factor analysis to examine the construct validity of the scales. The six multi-item scales showed high internal consistency (Cronbach’s alpha 0.75-0.96). The outcome of the study was the development of a validated tool to use in GP practices. The questionnaire was specifically designed to be used in primary care as it covered key dimensions of the conceptual framework for primary care. Two further articles have been published in relation to this study. First, Ricci-Cabello et al’s (2017a) study to explore patients’ experiences and perceptions of patient safety in English general practices with the aim of identifying patient-centred recommendations for improving patient safety. A qualitative content analysis was conducted on responses to open-ended questions. The second study (Ricci-Cabello et al, 2017b) aimed to examine patient-reported experiences and outcomes of patient safety in primary care. The findings from these studies showed that patients were more willing to speak up about their experiences, able to identify safety problems they were involved with, mostly with appointments, diagnosis, communication with healthcare professionals and co-ordination of care between providers.

2.38 Summary

The scoping review identified similar themes in relation to what patients identified as impacting on their safety. These included poor communication with staff leading to medication errors and interactions with multiple doctors. A number of studies were small scale (Kemp et al, 2016; Lovink et al, 2016), making it difficult to draw conclusions.
Attempts have been made to examine the relationship between patients’ perceptions of safety and their impact on health outcomes and improvements. It is worth noting how the results from these surveys were used to provide feedback on targeted areas for safety improvement. Lawton et al (2015) and O’Hara et al (2017) used the safety thermometer to measure the impact on harm-free care and the safety culture measure and Friends and Family test with limited impact. The safety thermometer measures key nurse-sensitive indicators of safety such as infection rates, pressure ulcers and falls (NHS England 2014d). The safety culture tool was developed for the use of staff. Consequently, it may not reflect how patients view and experienced safety. Indeed, previous studies (Agoritsas et al, 2005; Wolosin et al, 2006; Schwappach, 2008; Rathert et al, 2011; Sorra et al, 2012; Giles et al, 2013; Sahlstrom, 2014; Yan et al, 2017) demonstrated that patients view threats to their safety differently.

This would suggest that using the safety thermometer and the safety culture measure may not be reliable tools in linking patient feedback to safety. It is clear more work is needed to ascertain whether patient feedback on safety enables a targeted approach to safety improvement and health outcomes for patients. In contrast, Christiansen et al (2016) used patient stories linked to metric data to help target areas for improvement and argued that the narrative data was an effective approach in helping staff to target safety improvement.

A number of studies (Agoritsas et al, 2004; Evans, 2006; Doyle et al, 2013; Anhang et al, 2014) examined the impact of patient safety surveys in making improvements in safety. The use of narratives from patients, either through patient stories or completion of open-ended questions, demonstrated a valuable feedback in helping staff to make targeted improvements in care.

Four studies on patient safety measurement tools have been completed in England since the first scoping review was undertaken in March 2015, (Lawton et al, 2015; Ricci-Cabello et al, 2016; Lawton et al, 2017; O’Hara, 2017).
illustrating the need for further work in this field. Many studies exploring patients’ perceptions of safety either, through the application of a safety measurement tool or satisfaction surveys have been small scale, making it difficult to draw conclusions (Lovink et al (2015); Hassen et al’s (2017). Furthermore, few studies have examined the impact of patient characteristics on patients’ experiences of safety within the acute hospital setting. Harrison et al’s (2015) systematic review demonstrated the need for further research in this area. None of the studies illustrated that patients’ perceptions of safety was measured

The purpose of this synthesis of the two scoping reviews was to understand what mattered to patients in making them feel safe and how the information could be used to inform the development of the King’s Patient Safety Measure questionnaire.

Synthesis of studies within the first scoping review examining patient experience, patients’ experience with adverse events and patient characteristics suggested similar themes that patients stated impacted on how safe they felt. Firstly, patients described safety in the context of their whole pathway, which included earlier admissions. Patients also identified factors there were different to those stated by healthcare staff. For example, the findings in Giles et al’s (2013) study that identified dignity and respect as contributing factors affecting patients’ perceptions of their safety. These new themes suggest that tools developed from staff perceptions of safety may not capture the contributory factors from patients’ perspectives (Giles et al, 2013), and bring into question studies that have attempted to validate the use of such tools (Gerrish & Lacey, 2010; Greenhalgh, 2010). Secondly, there were key trigger points in the patients’ pathways when they were more likely to feel unsafe. These included; poor communication about medication; seeing multiple doctors; increased level of complexity with their care; poor discharge planning and the number of nurses on duty. Communication was a reoccurring theme within these trigger points.
There was also an association between staffs’ perceptions of safety and patient experience.

In each of the studies the literature has informed how the authors examined the concept of safety in different ways from the patients’ perspective, illustrating the multifactorial aspects of patient safety (Vincent et al, 2013). Rathert et al (2011b) used Attribution Theory as their theoretical framework to articulate how the concept of safety would be examined, including the rationale and design of the questionnaire (Rattray & Jones, 2007).

The evidence on patient characteristics was inconclusive. Some studies demonstrated that an increased length of stay and patients who were depressed impacted on their safety. There was also variability with age and socio-economic background. Synthesis of studies within the second scoping review illustrated that what mattered to patients in making them feel safe remained unchanged. Issues with communication and interactions with multiple staff remained a factor. The influence of patient characteristics also remained inconclusive.

Application of Rattray & Jones framework (2007) helped to assess the strengths and limitations of studies that focused on the design and development of questionnaires and demonstrated the need to have a systematic approach to questionnaire development. This ensured that such tools were reliable and valid. In some studies, global rating scores were used. However, the interpretation of global ratings scores was mixed. In the patient experience studies where global rating scores were provided there was no evidence of how patient experience had been improved. The studies which examined the impact of this score demonstrated that it was not a reliable measure of patient experience and recommended that further analysis of specific ratings of care was a more appropriate for approach for targeting safety improvement. This would have implications for the content and design of a questionnaire and how it’s results could be used to improve safety. Both scoping reviews provided
examples of themes that could be used for item development. For example, items on staffing levels and communication concerning medication and discharge planning.

In the contemporary studies in the second scoping review authors examined how the use their questionnaires acted as early warning tools for potential harm (Lawton et al 2015; Ricci-Cabello 2016; Lawton et al 2017) and for improving health outcomes for patients (Ricci-Cabello 2016). These studies demonstrate the opportunity of using questionnaires in a proactive way to improve care for patients

2.39 Influence on this study

The influence of patient characteristics on patients’ perceptions of safety was inconclusive. Therefore, this was explored further within this study. Using a systematic approach to questionnaire design and development was essential in developing a validated and reliable tool. Therefore, Rattray and Jones framework (2007) was used in this study. This included the use of factor analysis to develop items and the use of tests to determine reliability and validity. The scoping reviews identified potential themes which were used to develop items. These included asking questions about communication on medication and discharge planning and helped to inform item development. The involvement of patients at the early stages of questionnaire design was important in ensuring the tool reflected items that were important to patients and that the tool was easy to understand and complete, strengthen the face and content validity. Therefore, the aim in this study has been to involve patients in the early stages of the development of the questionnaire.

A number of studies carried out pilot studies prior to undertaking a cross-sectional study. The methods used in these studies have informed the methods used in this study. Once the King’s Patient Safety Measure has been developed a cross-sectional study will be undertaken to further test the tool in
clinical practice. A number of studies presented the statistical tests applied to their findings. These included ANOVA and MANOVA. A data analysis plan was developed and will be informed by these tests.

Several studies within the second review focused on the use of their questionnaires as early warning tools to prevent harm and to illustrate improvement in health outcomes. This study focuses on developing a tool that has the potential to be used in clinical practice. Therefore, it’s relevance to clinical practice and ease of use will need to be considered when developing the tool and during the pilot and cross-sectional study.

In summary, it is clear further work is required on the use of patient safety measurement tools and how patient characteristics impact on patients’ experiences of safety. The ability to measure safety has not been demonstrated in any of the studies. Developing such a measurement tool may enable organisations to demonstrate whether patients feel safer following re-designing of care pathways, and more importantly, whereby the voices of patients can be heard and acted on within the safety agenda.
Chapter 3 Methodology and research design

3.1 Introduction

The previous chapter illustrated how the findings from the scoping review informed the design of this study. This chapter presents the objectives of the study and how these informed the choice of research design and theoretical framework. The rationale for the sampling and data collection methods are discussed, along with analysis of the data. The process of obtaining research governance and ethical approval are presented, including how feedback from patients and the research governance teams informed and refined the design of the questionnaire and data collection methods. The objectives of the pilot study are presented, as is how the findings informed the design of the questionnaire for the main study.

3.2 Objectives of study

The study had four key objectives in order to answer the research question and to inform the development the King’s Patient Safety Measure.

1. A scoping review of the literature and feedback was sought from patient representatives within the acute trust, to inform the layout and questions to be examined in the pilot questionnaire.

2. Develop and pilot the questionnaire using cognitive interviewing.

3. Establish the validity and reliability of the tool in a questionnaire to 158 patients in general medical settings.

4. Explore relationships between patient demographics (ethnic background, age, gender, social deprivation, family support), mode of admission and patient perceptions of safety.
3.3 Methodology

The methodology describes the research design, data collection tools used and the approach to data analysis. Underpinning the methodology is the philosophical stance which focuses on the differences between the quantitative research paradigm, which is generally associated with the philosophical traditions of positivism and the qualitative research paradigm, most commonly allied to post positivist philosophy (Darlaston-Jones 2007) or Interpretivism. Morgan (2007) describes these paradigms as epistemological stances belief systems that influence how research questions are asked and that worldviews are ways of experiencing and thinking about the world.

Positivism is a philosophy that views reality as universal, objective and quantifiable. The ontological position is that reality is the same for you as it is for me. Through the application of science, we can identify and see that shared reality (Darlaston-Jones 2007). Within this epistemological stance the investigator and subject are independent variables which do not influence each other. However, adopting a belief of a single universal reality fails to recognise the ability of individuals to interpret and make unique sense of their world (Darlaston-Jones 2007).

An alternative view is Interpretivism. This paradigm originated from the writings of Kant who argued that perception relates to human interpretation. The ontological perspective is that reality incorporates the role of context in the construction of identity (Darlaston-Jones 2007). Multiple perspectives provide the researcher with a varied understanding of how an issue appears different to people as a result of their different interpretation of the issues (Darlaston-Jones 2007). Therefore, research conducted within an interpretivist epistemology is likely to involve reliance on the spoken word through conversation, interview, narrative or similar (Darlaston-Jones 2007).
3.4 Mixed Methods

A combination of both these approaches, known as a mixed methods design, provides a more complex understanding of a phenomenon that would otherwise not have been accessible by using one approach alone (Cresswell & Plano Clark 2011). In seeking to answer the research question and objectives of the study it was decided that mixed methods design was the most appropriate.

Within this discussion it is important to consider the difference between multiple method research and mixed methods research in order to offer some clarity and confirmation in the choice of mixed methods. The terms are often confused and mistaken as synonymous. However, there is general agreement that there are differences between the two (Johnson et al 2006). A mixed methods approach uses both qualitative and quantitative data collection methods. Multiple or multi method research involves data collection using two methods from the same paradigm, such as interviews and focus groups (Green & Thorogood 2011). Important aspects of mixed methods research include its consideration from initial philosophical underpinnings, through data collection, analysis and interpretation (Green & Thorogood 2011).

When considering the philosophical stance within mixed methods, authors refer to pragmatism. Morgan (2007) presents pragmatism as an alternative to positivism. Pragmatism is outcome-orientated and interested in determining the meaning of things (Darlaston-Jones 2007). In pragmatism the belief is that theories can be contextualised and generalised by analysing them from transferability to other situations (Darlaston-Jones 2007). There is a focus on communication and shared meaning in order to create practical solutions to social problems. The underlying belief is that qualitative and quantitative approaches can be combined in order to compliment both the advantages and disadvantages of using both approaches (Shannon-Baker 2016). Pragmatism allows the researcher to use a combination of whichever methods are needed to find answers to the research questions. The emphasis is on the research
question using all approaches available to understand the issues (Shannon & Baker 2016). The use of mixed methods enables researchers to use multiple methods, different worldviews and different assumptions gained from different forms of data collection and analysis (Cresswell & Plano Clark 2011). Therefore, within this study a pragmatic approach was used by the researcher initially to consider the research question. This led to the development of the four objectives and the data collection methods such as open-ended and closed questions in the King’s Patient Safety Measure.

3.4 Research Design

A sequential mixed methods design was used, where the results of each objective informed the next objective of the study (Bowling & Ebrahim, 2005, National Institute of Health, 2013), allowing for a more in-depth study of patient safety (Gerrish & Lacey, 2010). This approach was chosen because it has been applied to similar studies where questionnaires were designed and developed (Schwappach, 2008; Rathert et al, 2011b; Giles et al 2013). The mixed methods approach helped to focus the study design in answering the research question by examining patients’ perceptions of their safety within an acute hospital setting and fits well with the development of a measurement questionnaire (Gerrish & Lacey, 2010; National Institute of Health, Office of Behavioural and Social Sciences Research, 2013). The sequential mixed methods design was broken down into the four objectives.

3.5 Conceptual Framework

The WHO International Classification for Patient Safety (2009) was used as the conceptual framework. The framework was chosen for this study as it offered a structure in which to examine the evidence on patient safety and informed the development of the KPSM. The conceptual framework consists of ten high level classes (Table 3.1) which provides a comprehensive understanding of the domain of safety. It aims to illustrate continuous learning and improvement.
through the identification of risk, prevention, detection, reduction of risk, incident recovery and system resilience at a regional, national and international level (World Health Organisation 2009).

**Table 3-1 Definition of classes**

<table>
<thead>
<tr>
<th>No</th>
<th>Class</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Incident type</td>
<td>Clinical procedure or process</td>
</tr>
<tr>
<td>2</td>
<td>Patient Outcomes</td>
<td>Impact upon patient which are wholly or attribute to an incident</td>
</tr>
<tr>
<td>3</td>
<td>Patient characteristics</td>
<td>Patient demographics, the original reason for seeking care and primary diagnosis</td>
</tr>
<tr>
<td>4</td>
<td>Incident characteristics</td>
<td>Circumstances surrounding the incident surrounding the patient's journey, through the healthcare system, who was involved and who reported</td>
</tr>
<tr>
<td>5</td>
<td>Contributing factors/hazards</td>
<td>Actions of influences which are thought to have played a part in the origin or development of an incident, or to increase the risk of an incident e.g. behaviours, performance, communication, systems failures</td>
</tr>
<tr>
<td>6</td>
<td>Organisational outcomes</td>
<td>Impact upon an organization e.g. increased use of resources, media attention, legal action, rather than clinical ramifications</td>
</tr>
<tr>
<td>7</td>
<td>Detection</td>
<td>Actions taken to reduce risk (secondary prevention)</td>
</tr>
<tr>
<td>8</td>
<td>Mitigating factors</td>
<td>Actions taken to reduce risk (secondary prevention)</td>
</tr>
<tr>
<td>9</td>
<td>Ameliorating actions</td>
<td>Actions taken in the rescue phase of an incident (tertiary prevention)</td>
</tr>
<tr>
<td>10</td>
<td>Actions to be taken to reduce risks</td>
<td>Steps taken to prevent reoccurrence of the same or similar patient safety incidents and</td>
</tr>
</tbody>
</table>
The scoping review identified that the concept of safety was multi-dimensional. All the studies that used patient measurement tools provided valuable insight into the development and use of measurement tools within clinical settings. The way in which they examined safety differed and illustrated once again how the concept of safety needed to be defined at the start of this study. Table 3.2 illustrates how the framework was applied during the scoping review and design of the KPSM, for example, incident and patient characteristics. Within the scoping review, studies included examining whether patients' characteristics impacted on how they experienced safety. In terms of item generation for the KPSM, key themes of safety that mattered to patients were identified through this process. These included communication with healthcare professionals and staffing levels.

Table 3-2 Application of WHO Conceptual Framework for the International Classification of Patient Safety

<table>
<thead>
<tr>
<th>No</th>
<th>Class</th>
<th>Definition</th>
<th>Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Incident type</td>
<td>Clinical procedure or process</td>
<td>Service delivery e.g. delays with diagnostic tests</td>
</tr>
</tbody>
</table>
| 2  | Patient Outcomes     | Impact upon patient which are wholly or attribute to an incident          | Scoping review – studies examining patient experience with adverse events; patient experience surveys; studies on patient experience referencing patient incidents  
KPSM – analyzing results of feedback from patients |
<table>
<thead>
<tr>
<th>No</th>
<th>Class</th>
<th>Definition</th>
<th>Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Patient characteristics</td>
<td>Patient demographics, the original reason for seeking care and primary diagnosis</td>
<td>Scoping review – references made to impact of patient characteristics on results (KPSM – testing hypothesis)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Incident characteristics</td>
<td>Circumstances surrounding the incident surrounding the patient’s journey, through the healthcare system, who was involved and who reported</td>
<td>Scoping review - studies which referenced impact of whole patient journey, in the way patients described their experience (KPSM – pilot study highlighted patients described their perceptions, through the whole pathway of care)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Contributing factors/hazards</td>
<td>Actions of influences which are thought to have played a part in the origin or development of an incident, or to increase the risk of an incident e.g. behaviours, performance, communication, systems failures</td>
<td>Scoping review – identified themes which impacted on how safe patients felt. These informed item development of the KPSM (Themes – communication; discharge planning; infection control practice; staffing levels)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Organisational outcomes</td>
<td>Impact upon an organization e.g. increased use of resources, media attention, legal action, rather than clinical ramifications</td>
<td>Scoping review – demonstrated that use of national surveys e.g. Friends &amp; Family test &amp; National Inpatient survey had made limited impact on improving care. Studies using measurement tools had such very little evidence of reduction in reductions, although studies examining patient</td>
</tr>
</tbody>
</table>
experience with adverse events did demonstrate how improved communication with patients on medications, improved compliance and health outcomes.

| Detection | Actions taken to reduce risk (secondary prevention) | Scoping review – few studies had demonstrated how they had taken actions to reduce risks. The focus was on identifying issues. |
| Mitigating factors | Actions taken to reduce risk (secondary prevention) | Scoping review – few studies had demonstrated how they had taken actions to reduce risks. The focus was on identifying issues. |
| Ameliorating actions | Actions taken in the rescue phase of an incident (tertiary prevention) | Scoping review – few studies had demonstrated how they had taken actions to reduce risks. The focus was on identifying issues. |
| Actions to be taken to reduce risks | Steps taken to prevent reoccurrence of the same or similar patient safety incidents and improving systems resilience | Scoping review – few studies had demonstrated how they had taken actions to reduce risks. The focus was on identifying issues. |

### 3.6 Framework for questionnaire design

Rattray & Jones (2007) framework for questionnaire design and development (Table 2.9) was applied to the study to ensure a systematic approach, including the reliability and validity of the tool. Table 3-3 illustrates how the framework was applied to this study.
Table 3-3 Development of patient safety questionnaire using Rattray & Jones (2007) framework for questionnaire design

<table>
<thead>
<tr>
<th>Phase</th>
<th>Stage of questionnaire design</th>
<th>Action</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Purpose</td>
<td>Rationale for questionnaire was to measure patients’ perceptions of their safety.</td>
<td>No evidence from the literature that a questionnaire had been designed entirely with patients and for only patients to complete</td>
</tr>
<tr>
<td></td>
<td>Research question</td>
<td>What are patients’ perceptions of their safety within an acute hospital setting?</td>
<td>To understand what safety means to patients</td>
</tr>
<tr>
<td></td>
<td>Scale and response format</td>
<td>Likert scale used for some questions</td>
<td>Helped to reduce time to complete questionnaire, thereby reducing burden on patients. Likert scales measure attitudes and opinions</td>
</tr>
<tr>
<td></td>
<td>Generation of items</td>
<td>Items generated from literature review and feedback from patients</td>
<td>Identified items that were deemed to be important to patients</td>
</tr>
<tr>
<td>2</td>
<td>Validity</td>
<td>Face validity</td>
<td>To test presentation and layout of a</td>
</tr>
<tr>
<td>Cross-sectional study</td>
<td>Content validity</td>
<td>questionnaire was acceptable to patients</td>
<td></td>
</tr>
<tr>
<td>-----------------------</td>
<td>------------------</td>
<td>------------------------------------------</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>To test whether the items within the tool captured the constructs being measured that were important to patients</td>
<td></td>
</tr>
<tr>
<td>Amendments based on item analysis or related techniques</td>
<td>Cognitive interviews</td>
<td>To reduce recall bias and response burden</td>
<td></td>
</tr>
<tr>
<td>Cross-sectional study</td>
<td>Exploratory factor analysis</td>
<td>Correlation polychromic matrix</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Factor extractions – Eigenvalues</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Factor rotation</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Construct validity</td>
<td></td>
</tr>
<tr>
<td>Reliability</td>
<td>Cronbach alpha reliability</td>
<td>Determines how well the items in questionnaire measure safety</td>
<td></td>
</tr>
<tr>
<td>Confirmation of an independent measure</td>
<td></td>
<td>Informs final design and content of questionnaire</td>
<td></td>
</tr>
<tr>
<td>Revision of measure</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
3.7 Research governance and ethical approval

Full ethics approval and R&D approval were obtained from the NHS Research Ethics Committee on 13 April 2016 (REC 15/EM0434) and the study site on 19 April 2016 (appendices 9 - 15).

3.8 Ethical considerations

The ethics committee stated that patients were not to be overburdened when completing the questionnaire. Therefore, the tool had to be short. During the pilot study the researcher asked participants how easy it was to complete the questionnaire. Overall, their responses were that it was easy to understand and complete, taking no longer than fifteen minutes to complete. This timeframe was therefore stated in the consent letter for the main study (appendix 10). It was acknowledged that the researcher was a senior nurse working in the organisation at the time of the study. Therefore, the consent letter for both the (appendix 9) and for the main study (appendix 10) advised participants that if they had any concerns or questions about the study, they could contact the researcher, the researcher’s supervisor, or the local Patient Advisory Liaison service. The reasons for the study and why participants had been approached was explained in the consent letter. The letter also stated how the information participants provided would be used to improve patient care.

3.9 Voluntary participation

The original plan for this study was to send patients the questionnaire forty hours following their discharge. This approach was chosen because it had been used in similar studies, where the researchers aimed to reduce positive response bias from patients who may have felt vulnerable about raising concerns regarding their safety whilst in hospital. However, research governance approval was not given for this approach. This was because the researcher for this study was not directly involved with the care of these patients
and therefore was not permitted direct access to the patients records to select patients. Therefore, clinical administrators on the wards selected patients. Once patients were identified the researcher met with the patients and consented them. It is acknowledged that through this approach patients may have felt reluctant to decline because the researcher was a senior nurse within the organisation. To address this all patients were informed that they could exercise the right of voluntary participation by opting out, by not completing, not responding or not returning the study questionnaire. Patients were able to withdraw from the study at any time, without giving a reason. They were guaranteed that their subsequent care would not be affected. Some patients did ask questions about how the information they gave would be used and whether it would remain confidential.

3.10 Confidentiality

Patients were assured that any information they provided would be treated in the strictest confidence and not be used for any purpose except for this study. Questionnaires were answered anonymously, and each participate had a unique identification code to ease data management and analysis. Patients were informed that their completed questionnaire would be kept in a locked cabinet within the hospital and would only been seen by the researcher and their supervisor. Once the questionnaires had been analysed, they would be destroyed.

3.11 Setting of study

The study was carried out within a large acute teaching hospital in London. The participating wards consisted of five medical wards, totalling 111 beds, during a three-week period. The speciality of the wards consisted of two acute medical admission wards and three general medical wards. The general medical wards each had a sub-specialty: diabetic foot, cystic fibrosis unit and respiratory medicine.
3.12 Objective 1 Scoping review of literature and feedback from patient representatives

Scoping review of literature and feedback from patient representatives within the acute trust, to inform layout and questions to be examined in the pilot questionnaire

No questionnaires were identified which had been solely developed with patients to measure safety from their perspective. In order to answer the research, question a new questionnaire needed to be developed. The purpose of objective 1 was to conduct a critical review of the literature, which informed the content and design of the patient safety questionnaire. The starting point in the development of a questionnaire is to ask what it will measure (Aday & Cornelius, 2006; Rattray & Jones, 2007; Greenhalgh, 2010). The scoping review of the literature identified numerous questionnaires completed by healthcare professionals with a focus on safety culture and climate (Rathert et al, 2011b; Giles et al, 2013).

Within this study the research question asks: What are patients’ perceptions of their safety within an acute hospital setting? Therefore, the items within the questionnaire were drawn from knowledge gained from the empirical evidence examining safety from the patients’ perspective, for example, questions focusing on experiences of services and how satisfied patients were (Rathert et al, 2011b; Sorra et al, 2012). The National Inpatient Survey (Care Quality Commission, 2014a) was referred to in the item choice of the questionnaire within this study to strengthen the validity of items. This approach was informed by Rathert et al’s study (2011b), which sought evidence from previous studies on the validity of items within the Picker Patient Experience Questionnaire to strengthen their tool. This helped to determine the items used in their measurement tool. This approach to item choice within the King’s Patient Safety Measure enabled patients to respond to questions about what was important to them and therefore relevant to answering the research question.
(Rattray & Jones, 2007). In the first version of the questionnaire (version 1.2, appendix 9) the final item, question 12, asked participants to rate how safe they felt while in hospital. This question was added to give an indicator of safety. The National Inpatient Survey (Care Quality Commission, 2014a) ask patients to rate their experience of their care. Therefore, it was not unreasonable to ask participants to rate how safe they feel in the hospital.

Table 3.4 shows the questions from the CQC Inpatient Questionnaire (2014b), which informed choice of the items in the questionnaire within this study.

### Table 3-4 CQC in-patient questionnaire items which informed doctoral questionnaire

<table>
<thead>
<tr>
<th>CQC Inpatient questionnaire</th>
<th>Doctoral questionnaire</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was your most recent hospital stay planned in advance or an emergency?</td>
<td>Was your recent hospital admission planned or an emergency?</td>
</tr>
<tr>
<td>From the time you arrived at the hospital, did you feel that you had to wait a long time to get to a bed on a ward?</td>
<td>I was allocated a bed straight away</td>
</tr>
<tr>
<td>Did you have confidence and trust in the doctors treating you?</td>
<td>I had confidence in the staff treating me</td>
</tr>
<tr>
<td>Did you have confidence and trust in the nurses treating you?</td>
<td></td>
</tr>
<tr>
<td>Sometimes in a hospital, a member of staff will say one thing, and another will say something different.</td>
<td>Staff were consistent in what they said to me</td>
</tr>
<tr>
<td>Did this happen to you?</td>
<td></td>
</tr>
<tr>
<td>-------------------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td><strong>CQC Inpatient questionnaire</strong></td>
<td><strong>Doctoral questionnaire</strong></td>
</tr>
<tr>
<td>There was no specific question asking about consent</td>
<td>My consent was obtained before a test or an investigation</td>
</tr>
<tr>
<td>In your opinion, were there enough nurses on duty to care for you in hospital?</td>
<td>There were always enough staff to care for me</td>
</tr>
<tr>
<td>Did a member of staff explain the purpose of the medicines you were to take home in a way you could understand?</td>
<td>I was given enough information about my medication in a way I could understand</td>
</tr>
<tr>
<td>Were you told how to take your medication in a way you could understand? Were you given written or printed information about your medications?</td>
<td>I was given enough information about my medication in a way I could understand</td>
</tr>
<tr>
<td>Do you think the hospital staff did everything to help control your pain?</td>
<td>My pain was well controlled</td>
</tr>
<tr>
<td>Did you feel you were involved in decisions your discharge from hospital? Were you given enough</td>
<td>My discharge was well planned</td>
</tr>
<tr>
<td>notice about when you were going to be discharged?</td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>On the day you left hospital was your discharge delayed for any reason?</td>
<td></td>
</tr>
<tr>
<td>What was the main reason for the delay?</td>
<td></td>
</tr>
<tr>
<td>How long was the delay?</td>
<td></td>
</tr>
</tbody>
</table>

### 3.13 Face and content validity

The questionnaire was presented at a directorate research governance meeting where there were patient representatives. This allowed them to assess face and content validity of the tool. Face validity is concerned with the presentation and layout of a questionnaire, while content validity is concerned with whether the items within the tool capture the construct being measured (Gerrish & Lacey, 2010). While these are subjective measures of validity, they are helpful in the early development of a questionnaire (Gerrish & Lacey, 2010). The patients commented on how easy it was to understand each item and the sequencing of questions. Some of the questions and their numbering were changed as a result of this feedback.

### 3.14 Likert Scale

A Likert scale was used in question 3 for 13 items for two reasons. Firstly, to enable participants to complete the overall questionnaire quickly. This was an issue raised by both the research governance committee, and the Trust’s Research and Governance office. Both groups stated it was important to ensure patients were not overburdened when completing the questionnaire. Secondly, Likert scales are designed to measure attitudes or opinions and
therefore appropriate for use in this tool (Aday & Cornelius, 2006; Rattray & Jones, 2007; DeVillis, 2012).

### 3.15 Open-ended questions

In the early stages of a questionnaire’s development open-ended questionnaires can also be used to further develop the tool by illustrating poorly constructed items or new items to be included in future tools (Rattray & Jones, 2007). The questionnaire therefore contains open-ended questions to allow participants to respond in more detail about what affects their safety (Gerrish & Lacey, 2010).

### 3.16 Pilot questionnaire

Appendix 17 shows version 1.2 (date:26.02.16) that was developed during objective 1 of the study.

### 3.17 Objective 2 Pilot Study

Objective 2 aimed to pilot test the questionnaire prior to commencing the main study. The questionnaire was piloted on a small number of participants.

The aim of the pilot study was to test the face and content validity of the pre-designed questionnaire, in preparation for its application in the cross-sectional study in phase 3. The objectives of the pilot were:

1. Assessing the feasibility of applying the questionnaire to patients.
2. Identifying potential sources of response errors in the questionnaire.
3. Modifying the questionnaire as necessary.
3.18 Methods

In objective 2 patient representatives of the patient population were selected and consented. These patients were asked to independently complete the questionnaire. The author then carried out face-to-face cognitive interviews with patients to assess their understanding of the questions, layout of the questionnaire and how easy the tool was to complete (Willis, 2005) to test the content and face validity of the questionnaire (Gerrish & Lacey, 2010). Face validity refers to a subjective assessment of the presentation and relevance of the questionnaire, for example: do the questions appear to be relevant, reasonable, unambiguous and clear (Bowling, 2010). Content validity considers the extent to which the content of the questionnaire appears logical in a balanced way, including capturing the full scope of the topic it is intended to measure (Bowling, 2009).

3.19 Sampling strategy

A purposeful sampling technique was used as it enabled achievement of the study’s aims (Bowling, 2009; Green & Thorogood. 2011; Punch 2012). The study was carried out in a large acute teaching hospital that had a diverse ethnic patient population. Purposeful sampling means that participants are selected purposefully in order to include a pre-determined range of characteristics (Green & Thorogood, 2011). The objective therefore was to capture patients from diverse backgrounds who have had an inpatient stay within an acute hospital setting. Patients were provided with a patient information sheet and consent form and given an opportunity to ask questions (appendix 9) prior to consenting to participant.

Inclusion criteria

- Patients who had an acute hospital admission within the elective and emergency medical pathway.
• Aged 18 years and over
• Due to be discharged within forty-eight hours.

Exclusion criteria
• Patients with an acute episode of psychiatric illness or cognitive impairment, who may have difficulty in consenting and participating in the study.
• Patients who have attended obstetrics and maternity units as the pathways of care are different and specific to this patient population, compared to adults going through the elective and emergency pathways
• Patients who do not speak English as they may have difficulty in consenting to and participating.
• Patients who have attended an outpatient setting such as day surgery, as the focus of this research project is the inpatient group.

3.20 Sample size

Ten participants were selected from the participating wards. The number reflects sample size in similar studies where interviews have been used to explore patients’ perceptions of safety (Taylor, 2008; Rathert et al, 2011b), and allows for equal representation of participants from two specialties (Bowling, 2009; Green & Thorogood, 2011; Punch, 2012).

3.21 Data collection

The author of this study was not directly involved in patient care and therefore was not permitted to access patients’ notes, because of the need to maintain patient confidentiality. Clinical administrators on the participating wards were approached to identify patients. These staff provided administrative support to the clinical teams. The author met with the clinical administrators to outline the objectives of the study and the selection criteria for identifying patients.
3.22 Cognitive interviews

The author returned to carry out the cognitive interviews. Willis (2009) recommends small-scale informal cognitive interviews, which help to illustrate how the questionnaire might be improved. Interviews were conducted on the wards and lasted approximately 30 minutes. The author took notes of comments regarding problems identified during testing. Participants were asked to comment on; whether the instructions were clear; the overall design; layout; how easy it was to read the questionnaire, and the time it took to complete. Verbal probing (Willis, 2005; Willis, 2009) was also used to ask further questions about the design of the tool.

3.23 Question Appraisal System

Potential sources of error in the questionnaire were identified for each question using the checklist from the Question Appraisal System (QAS) used by Willis and Lessler (1999). The QAS was originally developed to test interviewer-administered questionnaires (Willis, 2005). These items included:

- Instruction (problems with any introductions, instruction or explanations from the respondents’ point of view)
- Clarity (problems related to communicating the intent or meaning of the question to the respondent)
- Assumptions (problems with assumptions made or underlying logic)
- Knowledge/memory (respondents are likely to not know or have trouble remembering information)
- Sensitivity/bias (whether questions are sensitive in their nature or likely to produce social acceptable bias)
- Response categories (problems related to the adequacy of the range of responses to be recorded)
- Others (ordering, questionnaire length).
3.24 Results and Analysis

Table 3.5 summarises the characteristics of participants. Table 3.6 illustrates the general comments made by participants, and how these informed the design of the questionnaire for the main study.

**Table 3-5 Patient characteristics**

<table>
<thead>
<tr>
<th>ID</th>
<th>Gender</th>
<th>Age</th>
<th>Ethnic background</th>
<th>Admission route</th>
<th>Length of stay (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Female</td>
<td>44</td>
<td>Black, African</td>
<td>Emergency</td>
<td>3</td>
</tr>
<tr>
<td>2</td>
<td>Female</td>
<td>56</td>
<td>White, English</td>
<td>Emergency</td>
<td>8</td>
</tr>
<tr>
<td>3</td>
<td>Male</td>
<td>40</td>
<td>Polish</td>
<td>Emergency</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>Male</td>
<td>51</td>
<td>White, English</td>
<td>Emergency</td>
<td>2</td>
</tr>
<tr>
<td>5</td>
<td>Female</td>
<td>66</td>
<td>White, Irish</td>
<td>Planned</td>
<td>2</td>
</tr>
<tr>
<td>6</td>
<td>Female</td>
<td>83</td>
<td>White, English</td>
<td>Emergency</td>
<td>5</td>
</tr>
<tr>
<td>7</td>
<td>Female</td>
<td>47</td>
<td>Mixed race, British</td>
<td>Emergency</td>
<td>5</td>
</tr>
<tr>
<td>8</td>
<td>Male</td>
<td>28</td>
<td>White, English</td>
<td>Emergency</td>
<td>5</td>
</tr>
<tr>
<td>9</td>
<td>Male</td>
<td>45</td>
<td>White, English</td>
<td>Emergency</td>
<td>9</td>
</tr>
<tr>
<td>10</td>
<td>Male</td>
<td>46</td>
<td>Black, African</td>
<td>Emergency</td>
<td>4</td>
</tr>
</tbody>
</table>
**Table 3-6 General comments about questionnaire**

<table>
<thead>
<tr>
<th>Participant</th>
<th>Comments</th>
</tr>
</thead>
</table>
| 1           | Very easy to use  
Straightforward to complete  
Boxes make it easy to complete the questionnaire  
Good font size. Can see what you are reading  
Took five minutes to complete  
These are good questions. They are all important to patients  
There are no other questions that could be asked  
Chose not to attend A&E at local hospital, as hospital had poor reputation. Chose hospital as the care is so good  
Fantastic study. Questionnaire should be used in all hospitals |
| 2           | Took 20 minutes to complete  
Easy to understand  
Does not think any other questions should be asked. These are the right questions |
| 3           | Really easy to understand and is clear  
Took 15 minutes to complete  
This is the best hospital  
Emergency department is very good here  
None of the questions needs to be rephrased.  
These are the right questions to ask patients |
| 4           | Very easy to complete  
Took 15 minutes to complete  
Liked the layout, easy to understand and follow |
<table>
<thead>
<tr>
<th>Participant</th>
<th>Comments</th>
</tr>
</thead>
</table>
| 5          | Took 25 minutes to complete  
All the questions are relevant  
Easy to understand  
Very simple layout  
Should ask questions about how can you improve things |
| 6          | 10 minutes to complete  
Layout easy to understand  
I liked the questions, they were very good |
| 7          | 10 minutes to complete  
Good font size  
Easy and straightforward to follow  
It’s to the point  
You should any another box to ask “Any further comments about your stay?” |
| 8          | 10 minutes to complete  
All the questions are relevant  
It’s not too long  
Easy to understand |
| 9          | Easy to complete  
5 minutes  
Layout is good, lots of spacing  
Not too long |
| 10         | I had help to complete the questionnaire the form as I have difficulty staying awake because of my condition  
10 minutes to complete |
3.25 Findings

The general comments from participants demonstrated that the questionnaire was easy to understand, contained aspects of safety that were important to them and was quick to complete. This was important to establish. When seeking ethical and research governance approval the author was asked to keep the questionnaire short so as not to burden patients. Participants liked the layout and how the questionnaire flowed. These comments illustrated the questionnaire had good face validity. Participants were asked if the questions captured what was important to their safety. All participants stated the questionnaire did achieve this, demonstrating the tool had good content validity. In terms of overall comments, all participants said they answered questions based on their whole patient pathway, rather than one specific area, with some also referring back to previous hospital admissions. The instructions for the questionnaire were changed to ask participants to answer questions based on their most recent stay in hospital.

3.26 Revised questionnaire

Some questions were re-phrased; these are captured in below. For example: Question 6: Was there any aspect of your care that you felt unsafe about in hospital? Nine participants ticked NO. However, when interviewed two participants gave examples of incidents, therefore this question was kept in the questionnaire.

Question 14: My pain was well controlled. One participant said they did not experience any pain and therefore did not answer the question, so this question
was changed to: Did you experience any pain during this admission?” Yes/no, if yes was your pain well controlled?

3.27 Amendments to Likert scale

The Likert scale in the pilot questionnaire had a rating scale between 1 least important, to 10 most important.

Hospital Experience
YOUR HOSPITAL EXPERIENCE

Q3. Please rate each of the following items by inserting a number between 1 and 10 in each box in order of importance in making you feel safe.

1 10
LEAST MOST IMPORTANT
IMPORTANT

3.28 Thirteen item- scale

Participants were asked to rate each of the thirteen items based on the care they experienced in making them feel safe using a ten-point Likert scale, ranging from 1 least important to 10 most important.

1. I was allocated a bed straight away
2. Staff listened carefully to what I had to say
3. Staff explained things in a way I could understand
4. I had confidence in the staff treating me
5. Staff were consistent in what they said to me
6. I could have a member of my family or close friend for support when I wanted them
7. Staff were aware of my past medical history
8. My permission was obtained before a test or an investigation
9. Tests were carried out when staff said they would be
10. There were always enough staff to care for me on this ward
11. Staff were familiar with equipment
12. Staff were familiar with procedures
13. I was given information about medication in a way I could understand

Following feedback from participants the scale was amended to make it easier to interpret and score. Firstly, the scale was reduced to a defined 6 responses. This would help to reduce response bias, by reducing the number of scores that participants would have to consider. Secondly, a middle neutral score was omitted, to encourage participants to give a response (Bowling & Ebrahim 2005).

3.29 Overall rating of patient safety
YOUR HOSPITAL EXPERIENCE

Q3. Please rate each of the following items by inserting a number between 1 and 6 in each box based on the care you experienced in making you feel safe.

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Strongly</td>
<td>Moderately</td>
<td>Mildly</td>
<td>Mildly</td>
<td>Moderately</td>
<td>Strongly</td>
</tr>
<tr>
<td>Disagree</td>
<td>Disagree</td>
<td>Disagree</td>
<td>Agree</td>
<td>Agree</td>
<td>Agree</td>
<td></td>
</tr>
</tbody>
</table>

3.30 Overall rating of hospital safety from the patients’ perspective
The final item of the questionnaire asked participants to rate how safe they felt during their current hospital stay using a six-point Likert scale ranging from 1 least safe to 6 very safe.

Q12. OVERALL RATING OF HOSPITAL
Please can you say how safe you felt during your stay at the hospital?

Using a number from 1 to 6 where 1 is the LEAST felt safe you felt, to 6 is where you felt VERY safe all the time.

1 ☐ Least safe
2 ☐ Moderately unsafe
3 ☐ Mildly unsafe
4 ☐ Mildly safe
5 ☐ Moderately safe
6 ☐ Very safe

3.31 Final version of questionnaire

Appendix 19 shows the final version that was used to achieve objective 3 of the study, which was to establish the validity and reliability of the tool in a questionnaire to 158 patients in general medical settings.

3.32 Objective 3 Cross-sectional study

3.33 Introduction

The aim of objective 3 was to carry out a cross-sectional design. This approach was chosen because it has been used in several studies involving surveying patients on safety (Schwappach, 2008; Rathert et al, 2011b; Giles et al, 2013). The approach involves selecting a representative sample from the target population at a given point in time to survey or interview, although there are
limitations to cross-sectional studies (Bowling & Ebrahim, 2005; Greenhalgh, 2010). First, selection bias may occur if participants are not representative of the target population (Bowling & Ebrahim, 2005). Second, if participants are asked to recall an event the information, they report may not be the way the event happened, leading to recall bias. Finally, results from cross-sectional studies must be interpreted with caution, as they cannot illustrate causality (Greenhalgh, 2010). While there are limitations cross-sectional studies can measure the prevalence of the outcome of interest, in this case patients' perception of safety (Bowling & Ebrahim, 2005; Gerrish & Lacey, 2010). The approach also allows for a standardised measurement of patient safety through the application of the questionnaire at given points in time (Bowling & Ebrahim, 2005).

3.34 Sampling strategy

Inclusion criteria

- Patients who had an acute hospital admission within the elective and emergency medical pathway.
- Aged 18 years and over
- Due to be discharged within 48 hours

Exclusion criteria

- Patients with an acute episode of psychiatric illness or cognitive impairment, who may have difficulty in consenting and participating.

Patients were provided with a patient information sheet and consent form and given an opportunity to ask questions (appendix 11) prior to consenting to participant.

3.35 Sample size

The purpose of this study was to explore what patients' perceptions of their safety were. This was a descriptive survey, where the aim was to generalise
the findings from the sample population to the target population (Bowling & Ebrahim, 2005; Walker & Almond, 2010). It was important to ensure a sample of sufficient size to carry out factor analysis. There is no single recommendation for exploratory factor analysis sample size. For example, Kline (1994) suggests 100 or more, Comfrey & Lee (1992) recommend at least 300 and Nunnally (1978) recommends a ratio of participants per variable of at least ten. The King’s Patient Safety Measure consisted of only 13 items, therefore a sample of 150 (based on 10 participants per items and allowing for some attrition) was planned. A sample size of 150 would be sufficient to test for a medium sized effect (difference in total factor scores) between two (n=128) to three groups (n=156) at the 5% level of significance with power 80% (Cohen 1992). Somewhere between a medium and large effect could be tested when there are four or more groups.

3.36 Data collection

The author was not directly involved in patients’ care and therefore was not permitted to access patients’ notes, because of the need to maintain patient confidentiality. Clinical administrators on the participating wards were approached to identify patients. These staff provided administrative support to the clinical teams. The author met with the clinical administrators to outline the objectives of the study, and the selection criteria for identifying patients. The researcher consented and handed out questionnaires to participants.

3.37 Dataset creation

The researcher completed manual data entry and rechecked the entry three times for accuracy. Data were entered directly into an SPSS file.
3.38 Dealing with missing data

Missing data occurred for a number of study variables. Reasons included non-completion of some of the items, including age, gender, ethnic and social-economic background. Results of missing data are presented in the results chapter. Factor means scores derived from the 13 items scale were calculated for all people with one or more non-missing values (151 out of 158 responded to eight or more of the scales items, one person responded to five items, and six did not respond to any item). For the statistical modelling a missing category was added to Gender, Index of Multiple Deprivation and Ethnicity to minimise the number of cases lost from the analysis.

3.39 Data analysis

Data analysis was undertaken using both MPLUS v4.2 and IBM SPSS v. 23. On the advice of the Faculty statistician MPLUS Exploratory Factor Analysis for ordinal/categorical data was used because all the observed scale items were measured on a six-point Likert scale. Since this method was being used rather than conventional factor analysis the assumption of multivariate normality was no longer a requirement.

After consultation with the Faculty statistician, a data analysis plan was produced that was informed by the checklist of in De Vaus (2014). This consisted of three steps.

Step 1: Creation of scale to measure patient perceptions of safety to include descriptive statistics (frequencies, percentages) for each item on the scale, exploratory factor analysis, summary of final items identified by the factor analysis and Cronbach’s alpha to measure internal consistency.

Exploratory factor analysis (EFA) (table 3.7) was used to reduce the 13 patients’ perceptions safety ordinal items (6-point scale: strongly disagree to strongly
agree) into a smaller number of more general factors (unobservable latent variables). This approach was chosen because it identified the minimum number of common factors required to reproduce initial correlations.

To establish the factor loadings promax oblique rotation was carried out. Oblique rotation was used to enable maximum separation of the factors (Walker & Almond 2010). Factor loadings are standardised on a scale of 0 – 1. Factor loadings ranging between 0.4 – 0.9 make an important contribution to the factor and should be kept in a scale (Walker & Almond 2010).

Once the factor structure was established scores were calculated by summing the values for each factor item. These factor scores were then used to ascertain whether patients’ perceptions of their safety differed according to their ethnic background, mode of admission, age, sex and whether they had family support during their hospital stay using a generalised linear model (analysis of covariance).

**Table 3-7 Exploratory factor analysis**

<table>
<thead>
<tr>
<th>Step</th>
<th>Purpose</th>
<th>Approach</th>
<th>Statistical Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Pre-analysis checks</td>
<td>Assess suitability of data set for EFA</td>
<td>Establish sample size thresholds from the literature</td>
<td>Polychoric correlations for ordinal variables calculated using MPlus</td>
</tr>
<tr>
<td></td>
<td>Confirm sufficient sample size</td>
<td>Correlation polychoric matrix</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Identification of emerging themes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Factor Extraction</td>
<td>Determine smallest number of factors that represent</td>
<td>Eigenvalues from EFA</td>
<td>Factors with eigenvalues of ≥1 retained for further</td>
</tr>
<tr>
<td></td>
<td>interrelationships amongst the set of variables</td>
<td>investigation</td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>----------------------------------</td>
<td>-------------</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>Scree plot of eigenvalues (to identify where the slope changes)</td>
<td>Plotting of eigenvalues of each factor to determine which factors to retain</td>
<td></td>
</tr>
<tr>
<td>3. Factor Rotation</td>
<td>Factors rotated to assist with interpretation</td>
<td>EFA</td>
<td>Varimax (orthogonal) or Promax (oblique) rotation (both are provided in MPlus)</td>
</tr>
<tr>
<td>4. Theoretical assessment of the emerging factors</td>
<td>Do the emerging factors make theoretical sense?</td>
<td>To what degree do the factors support underlying theory and/or what might be expected based on other empirical research or direct experience?</td>
<td></td>
</tr>
<tr>
<td>5. Internal consistency of each factor</td>
<td></td>
<td>Cronbach’s alpha</td>
<td></td>
</tr>
</tbody>
</table>

A polychoric correlation matrix was used to identify any emerging patterns amongst the 13 items (correlations between pairs of ordinal variables).

All correlation coefficients produce a score between \(-1\) to \(+1\), where \(0\) represents no association and \(+1\) shows perfection correlation. Walker & Almond (2010) give a guide to interpreting correlation coefficients in the social sciences, where \(0 \to 0.1\) is little or no association; \(0.2 \to 0.3\) is a weak
association; 0.3 – 0.4 moderate association; 0.5 – 0.6 fairly strong association; 0.7 – 0.8 a strong association and 0.8 – 1.0 very strong association.

Eigenvalues were completed and a scree plot produced to help to determine the number of factors in conjunction with a theoretical assessment. Factors with an eigenvalue > 1 were retained for further consideration (Walker & Almond 2010). The internal consistency of each set of items that load onto a particular factor was determined using Cronbach’s alpha. An alpha of ≥ 0.7 is evidence of internal consistency (Tavakol & Dennick 2011).

Pearson’s correlation was applied to determine the strength of relationship between the thirteen items and question 12. (Overall rating of hospital. Please can you say how safe you felt during your stay at the hospital?). The purpose was to determine if question 12 was a valid item to measure patients’ overall rating of how safe they felt. Interpretation of scores within the social sciences ranges from 0.6 – 1 strong correlation; 0.3 – 0.59 moderate to fairly strong correlation; 0.15 – 0.3 weak relationship (Walker & Almond 2010).

Step 2: Describe data – summary statistics for demographics and organisational variables.

Descriptive and correlational approaches were used to describe the data. These were measures of central tendency (mean, median, mode), variation (standard deviation, interquartile range, minimum and maximum values) and frequency distributions (for data measured on a nominal and ordinal scales).

Pairs of variables was correlated using bivariate methods (e.g. Pearson Chi-square, Pearson and polychoric correlation coefficient).

Step 3: Test relationships between demographic factors and organisational factors and patient perceptions of safety.
3.40 General linear model

A general linear model, also known as analysis of covariance or multiple regression with categorical and/or continuous variables, consists of a single dependent variable (factor scores) and a set of independent variables (categorical, ordinal, continuous). The independent variables are used to explain variation in, and to predict, the dependent variable. The F-statistic was used to test whether each independent variable (i.e. gender, Index of multiple deprivation, ethnic background, mode of admission, age and length of stay), in the presence of the other independent variables, explains variability in the dependent variable. The null hypothesis of no difference/association was rejected if the type I error rate (α) was lower than 0.05. The assumption that the model residuals (difference between the observed and predicted values) were normally distributed was assessed using a histogram of the standardised residuals and a Quantile-Quantile (Q-Q) probability plot. A bootstrap analysis with 1,000 bootstrap samples was conducted because there was some evidence of the distribution of the residuals departing from normality.

3.41 Ethical principles

The data was analysed appropriately, as described above. The methodological approach was clearly stated and data quality issues/potential limitations identified in the thesis. True replication will not be possible with this data because it was collected from a sample at a specific time. Public access to the data file will not be possible as ethical approval has not been given.

3.42 Objective 4 Hypothesis

Explore relationships between patient demographics (ethnic background, age, gender, social deprivation, family support), mode of admission and patient perceptions of safety. During the general linear modelling computation, the F statistic was calculated for each variable/group effect. The F statistic is
calculated by dividing the between group variance by the variance within the groups (Pallant, 2010). A statistically significant F statistic (p<0.05) rejects the null hypothesis that the group means are equal.

The scoping review identified studies that examined the role that families played in acting as advocates for patients (Rathert et al 2011a, leedema et al 2012, Jeffs et al 2012, Rainey et al 2013). However, there was limited evidence on the impact of patients’ characteristics. Sahlstrom et al (2014) study demonstrated that older patients (66-75 years) were more critical of their care. Within this study it was important to examine further whether patients’ characteristics influenced patients’ perceptions of their care. If this was indeed the case this would help hospitals to tailor their safety programmes to the requirements of the patient group. Therefore, the following hypothesis formed part of this study.

There are differences between patients’ perceptions of their safety based on their ethnic background, mode of admission, gender, length of stay in hospital, their socioeconomic background, and whether they have family support during their hospital stay.

3.43 Summary

This chapter has illustrated how the aims and objectives have informed the design of the study. The findings from the pilot study informed the final design and layout of the questionnaire to be used in the cross-sectional study. The data analysis plan provided a systematic approach in the development of a reliable and valid questionnaire – the King’s Patient Safety Measure (KPSM). The next chapter will deal with the development and testing of this questionnaire.
Chapter 4 Results

4.1 Introduction

This chapter presents the statistical analysis of the survey data. Descriptive statistics include the socio-demographic characteristics of the participants, their mode of admission, age, gender, ethnic background and length of stay. This is followed by participants’ responses to the 13 item-scale and a final question, asking participants to rate how safe they felt during their hospital stay. The results of the exploratory factor analysis are then presented to show the development of the King’s Patient Safety Measure. The results of the general linear model, to ascertain which factors/variables explain variability in the King’s Patient Safety Measure, are presented and, finally, the responses to the open-ended questions, are described.

4.2 Demographic and socio-economic characteristics

The socio-demographic characteristics (age, gender, ethnic group, length of stay, mode of admission and an Index of Multiple Deprivation (IMD) (Department of Communities & Local Government 2015) of the study participants are presented below (table 4.1). The mean age of the study participants was 55.7 years (range 18 to 97 years, SD = 20.78, missing data n=4 2.5 per cent), 47.5 percent (75) of participants were male and 50.0 percent (79) were female (missing data n=4 2.5 per cent). A total of 90.5 percent (143) of participants were admitted through the emergency pathway, while 9.5 percent (15) were planned.

The English Indices of Deprivation (Department for Communities and Local Government, 2015) is a measure of relative deprivation and not affluence. The indices are based on 37 separate indicators of deprivation, thus providing an overall measure of multiple deprivation experienced by people living in an area. The measure is limited as it does not demonstrate that every person living in a
deprived area will be deprived. Likewise, there will be some deprived people living in the least deprived areas. Application of this tool was recommended by the Faculty of Nursing statistician because it has been used in previous studies. It is based on postcode, is easy to use and offers a reliable response to measuring deprivation, rather than assessment of individual patients’ social factors (Department for Communities and Local Government, 2015). According to the Index of Multiple Deprivation (IMD) score based on postcode, more participants lived in the two most deprived IMD quintiles (58 percent, 91) than the two least deprived quintiles (10.1 percent, 16) (Table 4.1).

Table 4-1 Index of multiple deprivation (IMD) score

<table>
<thead>
<tr>
<th>IMD Score</th>
<th>No</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Below 8.49 (least deprived)</td>
<td>7</td>
<td>4.4</td>
</tr>
<tr>
<td>8.5 – 13.79</td>
<td>9</td>
<td>5.7</td>
</tr>
<tr>
<td>13.8 – 21.35</td>
<td>19</td>
<td>12</td>
</tr>
<tr>
<td>21.36 – 34.17</td>
<td>50</td>
<td>31.6</td>
</tr>
<tr>
<td>Above 34.18 (most deprived)</td>
<td>41</td>
<td>25.9</td>
</tr>
<tr>
<td>Missing/invalid postcode</td>
<td>32</td>
<td>20.3</td>
</tr>
<tr>
<td>Total</td>
<td>158</td>
<td>100</td>
</tr>
</tbody>
</table>

Based on the ethnic group classification of the Office of National Statistics (Department for Communities and Local Government, 2015) 67.7 percent (107) were categorized as white British, 8.9 percent (14) were categorized as white other and 19.6 percent (31) were categorized as from a BME background. A small number, 3.8 percent (n=6), of participants did not respond to this question.
The mean length of stay for participants was 10.15 days (range minimum of 1 day to a maximum of 110 days, SD 15.44, missing data n=4 2.5 percent).

4.3 Participants’ responses to the 13 items using a Likert scale

Participants were asked to rate each of the 13 items based on the care they experienced in making them feel safe, using a six-point Likert scale, ranging from 1 (strongly disagree) to 6 (strongly agree). Table 4.2 illustrates the responses to the 13-item scale.

Table 4-2 Responses to 13 - item scale questionnaire

<table>
<thead>
<tr>
<th>Item</th>
<th>Statements</th>
<th>1 Stron gly disag ree</th>
<th>2 Moderately disag ree</th>
<th>3 Mildly disag ree</th>
<th>4 Mildly agree</th>
<th>5 Moderately agree</th>
<th>6 Strongly agree</th>
<th>Not answ ered</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>I was allocate d a bed straight away</td>
<td>20 (12.7%)</td>
<td>7 (4.4%)</td>
<td>19 (12.0%)</td>
<td>24 (15.2%)</td>
<td>23 (14.6%)</td>
<td>56 (35.6%)</td>
<td>9 (5.7%)</td>
<td>158 (100%)</td>
</tr>
<tr>
<td>2</td>
<td>Staff listened carefully to what I had to stay</td>
<td>3 (1.9%)</td>
<td>8 (5.1%)</td>
<td>10 (6.3%)</td>
<td>17 (10.8%)</td>
<td>38 (24.1%)</td>
<td>74 (46.8%)</td>
<td>8 (5.1%)</td>
<td>158 (100%)</td>
</tr>
<tr>
<td>3</td>
<td>Staff explained things in a way I could</td>
<td>1 (0.6%)</td>
<td>4 (2.5%)</td>
<td>7 (4.4%)</td>
<td>17 (10.8%)</td>
<td>35 (22.2%)</td>
<td>88 (55.7%)</td>
<td>6 (3.8%)</td>
<td>158 (100%)</td>
</tr>
<tr>
<td></td>
<td>Understand</td>
<td>3</td>
<td>3</td>
<td>5</td>
<td>19</td>
<td>25</td>
<td>96</td>
<td>7</td>
<td>158</td>
</tr>
<tr>
<td>---</td>
<td>---------------------------------------------------------------------------</td>
<td>----</td>
<td>----</td>
<td>----</td>
<td>----</td>
<td>----</td>
<td>----</td>
<td>----</td>
<td>------</td>
</tr>
<tr>
<td>4</td>
<td>I had confidence in the staff treating me</td>
<td>1.9%</td>
<td>1.9%</td>
<td>3.2%</td>
<td>12.0%</td>
<td>15.8%</td>
<td>60.8%</td>
<td>4.4%</td>
<td>100%</td>
</tr>
<tr>
<td>5</td>
<td>Staff were consistent in what they said to me</td>
<td>1.3%</td>
<td>3.2%</td>
<td>7%</td>
<td>6.3%</td>
<td>22.2%</td>
<td>55.7%</td>
<td>4.4%</td>
<td>100%</td>
</tr>
<tr>
<td>6</td>
<td>I could have a member of my family or close friend for support when I wanted them</td>
<td>1.3%</td>
<td>0.6%</td>
<td>3.2%</td>
<td>3.8%</td>
<td>15.8%</td>
<td>69.6%</td>
<td>5.7%</td>
<td>100%</td>
</tr>
<tr>
<td>7</td>
<td>Staff were aware of my past medical history</td>
<td>7%</td>
<td>3.8%</td>
<td>3.2%</td>
<td>11.4%</td>
<td>21.5%</td>
<td>48.1%</td>
<td>5.1%</td>
<td>100%</td>
</tr>
<tr>
<td>8</td>
<td>My permission was obtained before a</td>
<td>1.9%</td>
<td>1.9%</td>
<td>3.2%</td>
<td>7.6%</td>
<td>12.7%</td>
<td>68.4%</td>
<td>4.4%</td>
<td>100%</td>
</tr>
<tr>
<td>test or an investigation</td>
<td>9</td>
<td>Tests were carried out when staff said they would be</td>
<td>2</td>
<td>1.3%</td>
<td>5</td>
<td>3.2%</td>
<td>6</td>
<td>3.8%</td>
<td>20</td>
</tr>
<tr>
<td>--------------------------</td>
<td>---</td>
<td>---------------------------------------------------</td>
<td>---</td>
<td>------</td>
<td>---</td>
<td>------</td>
<td>---</td>
<td>------</td>
<td>----</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>There were always enough staff to care for me on this ward</td>
<td>9</td>
<td>5.7%</td>
<td>11</td>
<td>7%</td>
<td>8</td>
<td>5.1%</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td>11</td>
<td>Staff were familiar with equipment</td>
<td>1</td>
<td>0.6%</td>
<td>4</td>
<td>2.5%</td>
<td>3</td>
<td>1.9%</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>Staff were familiar with procedures</td>
<td>1</td>
<td>0.6%</td>
<td>5</td>
<td>3.3%</td>
<td>3</td>
<td>1.9%</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>13</td>
<td>I was given information</td>
<td>2</td>
<td>1.3%</td>
<td>4</td>
<td>2.5%</td>
<td>5</td>
<td>3.2%</td>
<td>17</td>
</tr>
</tbody>
</table>
4.4 Rating their overall safety using a Likert scale

The final item of the questionnaire asked participants to rate how safe they felt during their current hospital stay using a six-point Likert scale ranging from 1 (least safe) to 6 (very safe) (Table 4.3).

**Table 4-3 Responses to final item: overall rating of feeling safe in hospital**

<table>
<thead>
<tr>
<th>Item Statements</th>
<th>1 Least safe</th>
<th>2 Moderately unsafe</th>
<th>3 Mildly unsafe</th>
<th>4 Mildly safe</th>
<th>5 Moderately safe</th>
<th>6 Very safe</th>
<th>Not answered</th>
<th>Tota ls</th>
</tr>
</thead>
<tbody>
<tr>
<td>Please can you say how safe you felt during your hospital</td>
<td>1 0.6%</td>
<td>1 0.6%</td>
<td>7 4.4%</td>
<td>9 5.7%</td>
<td>36 22.8%</td>
<td>98 62%</td>
<td>6 3.8%</td>
<td>158 100%</td>
</tr>
</tbody>
</table>

Using a number from 1 to 6 where 1 is the LEAST safe you felt to 6 is where you felt VERY safe all the time.
4.5 Answering open-ended questions

Participants were asked to respond to a number of open-ended questions to provide examples of specific aspects of their care that made them feel safe or unsafe, including how staff responded. Descriptive content analysis was used to determine codes.

4.6 Exploratory Factor Analysis

The first step involved the calculation of a polychoric correlation matrix (Table 4.4) (ordinal equivalent to a Pearson correlation matrix for interval level data) for the 13 items. The aim was to ascertain the level of association between each item. All items showed association and were therefore suitable for ordinal factor analysis.

**Table 4-4 Polychronic correlation matrix**

<table>
<thead>
<tr>
<th></th>
<th>Q0 1</th>
<th>Q0 2</th>
<th>Q0 3</th>
<th>Q0 4</th>
<th>Q0 5</th>
<th>Q0 6</th>
<th>Q0 7</th>
<th>Q0 8</th>
<th>Q0 9</th>
<th>Q1 0</th>
<th>Q1 1</th>
<th>Q1 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q0 2</td>
<td>0.6</td>
<td>0.6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q0 3</td>
<td>0.3</td>
<td>0.4</td>
<td>0.4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q0 4</td>
<td>0.3</td>
<td>0.6</td>
<td>0.6</td>
<td>0.6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q0 5</td>
<td>0.3</td>
<td>0.4</td>
<td>0.4</td>
<td>0.4</td>
<td>0.5</td>
<td>0.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q0 6</td>
<td>0.3</td>
<td>0.4</td>
<td>0.4</td>
<td>0.4</td>
<td>0.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q0 7</td>
<td>0.3</td>
<td>0.4</td>
<td>0.4</td>
<td>0.4</td>
<td>0.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q0 8</td>
<td>0.3</td>
<td>0.4</td>
<td>0.4</td>
<td>0.4</td>
<td>0.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q0 9</td>
<td>0.3</td>
<td>0.4</td>
<td>0.4</td>
<td>0.4</td>
<td>0.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q1 0</td>
<td>0.3</td>
<td>0.4</td>
<td>0.4</td>
<td>0.4</td>
<td>0.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q1 1</td>
<td>0.3</td>
<td>0.4</td>
<td>0.4</td>
<td>0.4</td>
<td>0.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q1 2</td>
<td>0.3</td>
<td>0.4</td>
<td>0.4</td>
<td>0.4</td>
<td>0.5</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>6</td>
<td>2</td>
<td>6</td>
<td>9</td>
<td>8</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q0 7</td>
<td>0.3</td>
<td>0.5</td>
<td>0.5</td>
<td>0.6</td>
<td>0.6</td>
<td>0.4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q0 8</td>
<td>0.3</td>
<td>0.5</td>
<td>0.5</td>
<td>0.4</td>
<td>0.6</td>
<td>0.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q0 9</td>
<td>0.4</td>
<td>0.6</td>
<td>0.5</td>
<td>0.6</td>
<td>0.6</td>
<td>0.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q1 0</td>
<td>0.3</td>
<td>0.5</td>
<td>0.4</td>
<td>0.6</td>
<td>0.6</td>
<td>0.1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q1 1</td>
<td>0.2</td>
<td>0.5</td>
<td>0.2</td>
<td>0.6</td>
<td>0.4</td>
<td>0.6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q1 2</td>
<td>0.2</td>
<td>0.5</td>
<td>0.2</td>
<td>0.6</td>
<td>0.4</td>
<td>0.4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q1 3</td>
<td>0.4</td>
<td>0.6</td>
<td>0.5</td>
<td>0.5</td>
<td>0.4</td>
<td>0.4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This was followed by exploratory factor analysis of the 13 items undertaken using MPLUS v4.2. The eigenvalue of each factor was calculated to establish the number of factors to retain (appendix 7). The 13 eigenvalues from the exploratory factor analysis have been plotted in figure 4.1. Factors with an eigenvalue of 1 or above were retained for further consideration (Walker & Almond, 2010). The scree plot points towards either a one or two factor solution.
Table 4.5 shows the factor loadings for a single factor solution based on the 13-item scale. All items have factor loadings above 0.4, suggesting each item should be retained.

The two-factor solution consists of Factor 1 where items 1,2,3,4,5,7,8 and 9 group together, with loadings ranging from 0.46 for item 8 to 0.95 for item 2 (see Table 4.5). All items, except item 1 (I was allocated a bed straight away) related to communication with healthcare professionals. Factor 2 consists of items 6,10,11,12, and 13 group together, with scores ranging from 0.41 for item 6 to 1.07 for item 11. Item 6 related to participants having a family member or close friend for support. Item 10 asked if there were always enough staff on the ward, and items 11 and 12 related to staff demonstrating that they were familiar with procedures and the equipment. Item 13 related to communication with healthcare professionals regarding medication.
Table 4-5 Factor loadings for single and two-factor loadings

<table>
<thead>
<tr>
<th></th>
<th>Single factor</th>
<th>Two factors*</th>
</tr>
</thead>
<tbody>
<tr>
<td>F1</td>
<td>F1</td>
<td>F2</td>
</tr>
<tr>
<td>Q01</td>
<td>0.52</td>
<td>0.72</td>
</tr>
<tr>
<td>Q02</td>
<td>0.78</td>
<td>0.95</td>
</tr>
<tr>
<td>Q03</td>
<td>0.82</td>
<td>0.87</td>
</tr>
<tr>
<td>Q04</td>
<td>0.86</td>
<td>0.68</td>
</tr>
<tr>
<td>Q05</td>
<td>0.84</td>
<td>0.66</td>
</tr>
<tr>
<td>Q06</td>
<td>0.65</td>
<td>0.30</td>
</tr>
<tr>
<td>Q07</td>
<td>0.69</td>
<td>0.61</td>
</tr>
<tr>
<td>Q08</td>
<td>0.67</td>
<td>0.46</td>
</tr>
<tr>
<td>Q09</td>
<td>0.75</td>
<td>0.50</td>
</tr>
<tr>
<td>Q10</td>
<td>0.71</td>
<td>0.20</td>
</tr>
<tr>
<td>Q11</td>
<td>0.82</td>
<td></td>
</tr>
<tr>
<td>Q12</td>
<td>0.76</td>
<td></td>
</tr>
<tr>
<td>Q13</td>
<td>0.74</td>
<td>0.37</td>
</tr>
</tbody>
</table>

* PROMAX oblique rotation, correlation between F1, F2 = 0.71
4.7 Number of factors retained

The Cronbach alpha score for the 13 items score was 0.91, demonstrating strong internal consistency of the scale. This suggested that all 13-items should be kept.

A single factor provided a good parsimonious representation of the 13 items and was theoretically sound. The two-factor solution did not convey any major advantages over the single factor solution, the second factor had an eigenvalue close to one and the correlation between factors was high. All items for the single factor had loadings of 0.4 and above. The Cronbach’s alpha for the 13 items was high providing further support for a single factor.

4.8 Distributional assessment of the individual mean scores

Mean scores (summation of all the items divvied by 13) were calculated for each person. The distribution of these scores were examined to determine whether parametric (for normally distributed data) or non-parametric methods should be used for statistical hypothesis testing purposes (variation between groups).

Skewness was -1.49, which indicated clustering of responses to the right-hand side of the mean score distribution (Table 4.6 and Figure 4.2). The kurtosis was 2.79 was close to that expected for normally distributed data (k=3). The mean score was 5.15, the trimmed mean score was 5.24 and the median score was 5.36.

Results of statistical tests for normal distribution are presented Table 4.6 for the 13-item scale.
Table 4-6 Assessment of normality

<table>
<thead>
<tr>
<th>Statistic</th>
<th>Statistic</th>
<th>Std. Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>5.1534</td>
<td>.06909</td>
</tr>
<tr>
<td>95% confidence Interval for Mean</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lower Bound</td>
<td>5.0169</td>
<td></td>
</tr>
<tr>
<td>Upper Bound</td>
<td>5.2899</td>
<td></td>
</tr>
<tr>
<td>5% Trimmed Mean</td>
<td>5.2353</td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>5.3590</td>
<td></td>
</tr>
<tr>
<td>Variance</td>
<td>.726</td>
<td></td>
</tr>
<tr>
<td>Std. Deviation</td>
<td>.85186</td>
<td></td>
</tr>
<tr>
<td>Minimum</td>
<td>1.23</td>
<td></td>
</tr>
<tr>
<td>Maximum</td>
<td>6.00</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>4.77</td>
<td></td>
</tr>
<tr>
<td>Interquartile Range</td>
<td>1.04</td>
<td></td>
</tr>
<tr>
<td>Skewness</td>
<td>-1.494</td>
<td>.197</td>
</tr>
<tr>
<td>Kurtosis</td>
<td>2.788</td>
<td>.391</td>
</tr>
</tbody>
</table>
The histogram in Figure 4.2 shows that the mean score is isolated towards the right of the distribution curve.

A decision was taken to use parametric statistical hypothesis testing approaches whilst accepting there was a degree of skewness in the data. The sample size of 158 was sufficiently large to cope with some departure from normality (Kwak & Kim 2017).

Figure 4.2 Distribution of means score
4.9 Objective 4 Exploring differences in patients’ perceptions of safety

Objective 4 aimed to ascertain whether patients’ perceptions of their safety was dependant on their ethnicity, gender, socioeconomic background, mode of admission, age,

Normality was assessed using skewness and kurtosis and comparing the original mean with the trimmed mean and median. Skewness and kurtosis values provide information on the distribution of the scores, whilst comparisons between the original mean, trimmed mean (removing the top and bottom 5% of values) and median scores indicates to what degree the mean is a reliable measure of the centre of the distribution.

A skewness value of 0 indicates that the distribution is symmetric about the mean and the kurtosis for a normal distribution is 3. Higher values occur when either most of the data is concentrated around the mean or when data is concentrated near the tails of the distribution. length of stay, and whether they have family support during their hospital stay.

4.10 General linear model results

The F statistics computed during the fitting of the general linear model, that tested for association between each factor/variable and mean scale score are shown in Table 4.7. None of the six factors/variables were significantly associated with the mean scale score at the 5% level of significance.
### Table 4-7 General linear model

<table>
<thead>
<tr>
<th>Dependent Variable</th>
<th>Type 111 Sum of Squares</th>
<th>df</th>
<th>Mean Square</th>
<th>F</th>
<th>Sig. (P)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correlated model</td>
<td>10.011</td>
<td>13</td>
<td>.770</td>
<td>1.067</td>
<td>.392</td>
</tr>
<tr>
<td>Intercept</td>
<td>196.733</td>
<td>1</td>
<td>196.733</td>
<td>272.681</td>
<td>.000</td>
</tr>
<tr>
<td>Gender</td>
<td>.605</td>
<td>2</td>
<td>.303</td>
<td>.419</td>
<td>.658</td>
</tr>
<tr>
<td>IMD</td>
<td>2.055</td>
<td>5</td>
<td>.411</td>
<td>.570</td>
<td>.723</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>2.196</td>
<td>3</td>
<td>.732</td>
<td>1.015</td>
<td>.388</td>
</tr>
<tr>
<td>Admission</td>
<td>.915</td>
<td>1</td>
<td>.915</td>
<td>1.269</td>
<td>.262</td>
</tr>
<tr>
<td>Age</td>
<td>.137</td>
<td>1</td>
<td>.137</td>
<td>.189</td>
<td>.664</td>
</tr>
<tr>
<td>LOS</td>
<td>.779</td>
<td>1</td>
<td>.779</td>
<td>1.079</td>
<td>.301</td>
</tr>
<tr>
<td>Error</td>
<td>99.564</td>
<td>138</td>
<td>7.21</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>4146.308</td>
<td>152</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correlated Total</td>
<td>109.575</td>
<td>151</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

There was some departure of the residuals from normality (figures 4.3 and 4.4) but the bootstrap estimates suggest that this non-normality had a limited impact on the overall findings (Appendix 8).
Figure 4.3 standardised residuals

Figure 4.4 Normal Q-Q plot of standardised residuals
4.11 Correlation with patients’ overall rating of how safe they felt

The Pearson correlation between mean safety score and patients’ overall rating of how safe they felt was 0.65. This demonstrates construct validity based on the strength of correlation categorisation proposed by Walker & Almond (2010) where a correlation of 0.6 or higher is deemed as strong.

4.12 Results of open-ended questions

Questionnaires were included in the analysis where participants had responded to one or more of the open-ended questions. A total of 98 questionnaires were included, culminating in 62 percent response rate. Codes were formulated using descriptive content analysis (Schreier, 2012), and the qualitative analysis strategies for analysing open-ended survey questions in ATLAS.ti (University of Surrey, 2017) (Table 4.8) A deductive approach was used whereby the categories within the coding frame were informed by existing research and theory (Schreier, 2012) about patients’ perception of safety.

Table 4-8 Qualitative analysis for open-ended questions

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Reading the texts</td>
</tr>
<tr>
<td>2</td>
<td>Developing a coding scheme</td>
</tr>
<tr>
<td>3</td>
<td>Text searching and auto coding</td>
</tr>
<tr>
<td>4</td>
<td>Coding indexing verses data reduction</td>
</tr>
<tr>
<td>5</td>
<td>Checking summary of codes for consistency and omissions</td>
</tr>
<tr>
<td>6</td>
<td>Looking for similarities or differences</td>
</tr>
</tbody>
</table>
4.13 Early descriptors of feeling safe

Table 4.9 shows early code of feeling safe, ranging from the most frequently occurring to the least.

Table 4-9 Early coding of descriptors of safety

<table>
<thead>
<tr>
<th>Descriptor of safety</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caring, reassuring and kindness of staff</td>
<td>19</td>
</tr>
<tr>
<td>Communication</td>
<td>8</td>
</tr>
<tr>
<td>Specialist teams</td>
<td>4</td>
</tr>
<tr>
<td>Visibility and contact with nurses</td>
<td>4</td>
</tr>
<tr>
<td>Professional behavior of staff</td>
<td>2</td>
</tr>
<tr>
<td>Presence of the matron</td>
<td>1</td>
</tr>
<tr>
<td>Medication</td>
<td>1</td>
</tr>
<tr>
<td>Timeliness of treatment</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>38</td>
</tr>
</tbody>
</table>

Descriptors of caring, reassurance and kindness occurred most frequently when patients described what made them feel safe. Staff communicating with them was the second highest descriptor.
Table 4.10 illustrates text extracts from open-ended questions and how they were coded into the final codes.

**Table 4-10 Early coding of descriptors of safety**

<table>
<thead>
<tr>
<th>Descriptor of safety</th>
<th>Early coding</th>
<th>Final code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staff being friendly - a smile and a chat goes a long way. Nurses and doctors explaining what they were doing and why</td>
<td>Caring, reassuring and kindness of staff</td>
<td>Compassionate care</td>
</tr>
<tr>
<td>The stay here overall has been amazing, and I appreciate everything they have done for me and I couldn't have asked for a better medical and nurse</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Each member of staff co-operated with the other and were concerned about my well being</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The nurses and medical doctors during the week always made sure I knew what was happening and kept me up to date with any procedure I was going to have. I commend the staff and the team because they communicated well. I am very pleased with the support for everything</td>
<td>Communication</td>
<td></td>
</tr>
<tr>
<td>The doctors would tell me kindly the day they expect me to be out of the hospital. They clearly explain to me that my discharge date depends on the tests being done. So then really plan in advance and I am so glad of that. Wouldn't mind giving doctors five stars for that</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Doctors explained things to me what was going to take place

Staff being open about what my treatment was going to be and what was wrong with me. Staff were always clear and listened to what I had to say and suggest solutions and always asked what I thought.

My stay personally hasn’t been too bad, but one of the health carers made things much easier for me by explaining all these doctors’ words, what they mean and actually reassured and showed me that’s what has made me feel a bit more better and safer

I was handled professionally, courteously and with humanity. Extremely happy. (Even the cleaning, kitchen staff)

As a cystic fibrosis patient, I know that we cannot mix because of cross infection so that we have either had Ensuite rooms or a designated toilet made me feel that the staff had our health as a top priority

The multidisciplinary treatment. The combination of the diabetic foot and cardiovascular teams was amazing. To see all disciplines, move first from disagreement but now with agreement, with a sustainable plan

I believe the examples set by diabetic foot has clearly demonstrated the
Advantage of multidisciplinary consultants, resulting in the best possible outcome for sustainable, economic and effective patient recovery

I have been through this before (twice in fact), but the last time, Sept/Oct 2014, is the significant one. I have great confidence in Professor… and all in the diabetic clinic. Other doctors and nurses have filled me with confidence with their confidence and abilities

Amazing care from staff all around. I was seen 5 minutes after arriving and given treatment quickly. Staff made me feel reassured. I was in good hands – always treated with respect and dignity

Timeliness of care

Being checked up on throughout the day, also asked me if I needed anything to ring the buzzer. Just making sure I was alright, also certain people I didn’t want visiting didn’t come into my room

Visibility and contact with nurses

Staffing levels

Being able to summon a nurse at the touch of a button was very good too

Visibility and contact with nurses

Get in and out of bed, using or having help to use toilet or commode with help from the staff and time to time staff checking if I’m ok or I need anything

Visibility and contact with nurses

Constantly being checked on and spoken to in a polite way

Visibility and contact with nurses

Presence of the
The care has been spot on! The young nurses are so aware, so intelligent matron

There was an issue regarding one of the drugs I was being prescribed. Staff responded well – checked out query and consulted with medical team and came to a solution Medication

4.14 Final coding of descriptors of safety

Table 4.11 shows final codes for descriptors of safety, with compassionate care and communication the two most frequently occurring.

Table 4-11 Final coding of descriptors of safety

<table>
<thead>
<tr>
<th>Descriptor of safety</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compassionate care</td>
<td>26</td>
</tr>
<tr>
<td>Communication</td>
<td>8</td>
</tr>
<tr>
<td>Staffing levels</td>
<td>5</td>
</tr>
<tr>
<td>Medication</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>40</td>
</tr>
</tbody>
</table>

The examples of the early coding text illustrated that patients felt safe when staff spent time explaining the treatment plan to them, in a way that patients could understand. Friendliness and kindness of staff was an important feature in patients' experience of feeling safe. Indeed, one patient stated that a smile and a chat go a long way. These codes illustrated that the interaction with staff played a significant factor in making patients feel safe. Patients described and
recognised that the impact of specialist expertise and multidisciplinary team working was a factor in making them feel safe. Staffing levels was also a descriptor of safety. Patients gave examples of constant visibility and regular interaction with staff. Taking time to address concerns regarding a patient’s medication query was also cited as a feature of feeling safe.

4.15 Early codes on perceptions of feeling unsafe

It was interesting to note that the descriptors of safety when carried out poorly were described as features in making patients feel unsafe (Table 4.12). Descriptors of poor communication formed the largest reported descriptor of feeling unsafe. While poor staffing levels and poor attitude of staff were also featured, witnessing challenging behaviour of other patients was not expected.

Table 4-12 Early coding of descriptors of feeling unsafe

<table>
<thead>
<tr>
<th>Descriptor of feeling unsafe</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communication</td>
<td>17</td>
</tr>
<tr>
<td>Witnessing challenging behavior of other patients</td>
<td>5</td>
</tr>
<tr>
<td>Staffing levels</td>
<td>5</td>
</tr>
<tr>
<td>Poor attitude of staff</td>
<td>4</td>
</tr>
<tr>
<td>Poor infection control practice</td>
<td>4</td>
</tr>
<tr>
<td>Feeling isolated and vulnerable</td>
<td>2</td>
</tr>
<tr>
<td>Dirty ward</td>
<td>1</td>
</tr>
<tr>
<td>Temporary staffing</td>
<td>1</td>
</tr>
<tr>
<td>Noisy ward</td>
<td>1</td>
</tr>
<tr>
<td>Delay in treatment</td>
<td>1</td>
</tr>
</tbody>
</table>
4.16 Communication

Descriptions of poor communication occurred most frequently and therefore were coded further to establish the underlying codes. Table 4.13 shows the sub-codes within this major code.

Table 4-13 Feeling unsafe due to poor communication

<table>
<thead>
<tr>
<th>Descriptor of communication</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication</td>
<td>7</td>
</tr>
<tr>
<td>Not listening to me</td>
<td>4</td>
</tr>
<tr>
<td>Discharge planning</td>
<td>2</td>
</tr>
<tr>
<td>Not keeping me up to date</td>
<td>1</td>
</tr>
<tr>
<td>Communication between doctors and nurses</td>
<td>1</td>
</tr>
<tr>
<td>Not aware of my past medical history</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>17</td>
</tr>
</tbody>
</table>

4.17 Extracts of open-ended questions

Table 4.14 shows text extracts from open-ended questions and how they were coded into the final codes.
**Table 4-14 Examples of early coding of text to final coding of descriptors relating to poor communication**

<table>
<thead>
<tr>
<th>Descriptor of feeling unsafe</th>
<th>Early coding</th>
<th>Final code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Some confusion, misunderstanding and poor communication regarding my medication. Resolved only after my asking questions</td>
<td>Not keeping me up to date</td>
<td>Communication</td>
</tr>
<tr>
<td>The A&amp;E doctor had no idea of the importance of anti-rejection drugs for organ recipients. When I arrived on the ward my anti-rejection drugs were not listed (very upsetting and dangerous). Having a curtain pulled around me and a sign saying apron and gloves required. I have no IV, no communication with any patients. This is not mentally safe for me the patient</td>
<td>Medication</td>
<td></td>
</tr>
<tr>
<td>I feel sometimes communication between doctors and nurses is not well. Doctors do other things which they never inform nurses. Yesterday I was to be discharged by a doctor, but nurse didn’t know</td>
<td>Poor communication between doctors and nurses</td>
<td></td>
</tr>
<tr>
<td>Nurse failed to observe my list of allergies and was going to use latex gloves. Nurse came to help me to the toilet on the ward and didn’t know I had a possible fracture of the hip</td>
<td>Not aware of my past medical history</td>
<td></td>
</tr>
<tr>
<td>During the first week while I was in a lot of pain, very weak two-night nurses treated me carelessly. They didn’t believe me when I told them that I</td>
<td>Not listening to me</td>
<td></td>
</tr>
</tbody>
</table>
couldn’t stand or walk or sit in the chair. They tried to force me out of bed. I was never sure when or if I was going home. As my legs are more worse I didn’t know how to cope as I cannot function on my own at home.

<table>
<thead>
<tr>
<th>Descriptor of feeling unsafe</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communication</td>
<td>17</td>
</tr>
<tr>
<td>Poor infection control practice</td>
<td>7</td>
</tr>
<tr>
<td>Staffing levels</td>
<td>6</td>
</tr>
<tr>
<td>Witnessing challenging behavior of other patients</td>
<td>5</td>
</tr>
<tr>
<td>Poor attitude and behavior of staff</td>
<td>4</td>
</tr>
<tr>
<td>Total</td>
<td>39</td>
</tr>
</tbody>
</table>

4.18 Final coding of descriptors of feeling unsafe

Final coding of texts created five main codes, with poor communication by far the largest code (Table 4.15).

Table 4-15 Final coding of descriptors of feeling unsafe

Patients were able to recognise and describe examples of when communication between staff was unclear and how this impacted on their experiences of feeling unsafe. Staff not being aware of patients’ medication or past medical history were particular features. Indeed, one patient stated that staff were not aware that they had a possible hip fracture. The example given regarding not listening to a patient, resulted in that patient experiencing more pain. Patients gave clear
examples of poor infection control practice by clinical staff, thus illustrating patients were able recognise when standards of infection control practice dropped. The impact of poor staffing levels and witnessing the challenging behaviour of other patients on the ward are examined in the section below, including how staff responded to patients raising concerns.

Some descriptors of feeling unsafe were mentioned a few times (Table 4.16) but have been recorded to illustrate they were reported by patients. Such descriptors may be more prevalent in a larger study.

Table 4-16 Other (small) descriptors of feeling unsafe

<table>
<thead>
<tr>
<th>Descriptor of feeling unsafe</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Theft on the ward</td>
<td>2</td>
</tr>
<tr>
<td>Delay in treatment</td>
<td>1</td>
</tr>
<tr>
<td>Noisy ward</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>4</td>
</tr>
</tbody>
</table>

4.19 Staff response to patients’ raising concerns

Patients were given the opportunity to answer open-ended questions, including explaining how staff responded and what staff could have done differently to make them feel safe. Full-text extracts are presented under the five main codes of feeling unsafe (see Tables 4.17 – 4.21), with patients explaining how staff responded to their concerns, or what staff could have done differently to make them feel safe.

Patients were able to articulate clearly examples of when they did not feel safe, including how staff responded, when they informed them. In terms of poor communication (Table 4.17) patients stated they wanted better communication,
including listening more closely to them and providing reassurance. Poor communication regarding medication was cited by two patients. Indeed, poor communication (17) was the highest descriptor cited by patients in making them feel unsafe. Patients were also specific in describing the poor attitude and behaviour of staff. Furthermore, when comparing results of the open-ended questions on poor communication with responses in the 13 item-scale a theme emerges. This was how the impact of communication and interaction with staff was an important factor in making patients feel safe. While 60.8 percent (n=96) of patients strongly agreed with having confidence in staff treating them, the responses dropped when questions were asked about communication and knowledge of staff. 46.8 percent (n=74) of patients stated they strongly agreed with staff listening carefully to what they had to say, whilst 55.7 percent (n=88) of patients strongly agreed with staff being consistent in what they had to say to them, 48.1 percent (n=76) of patients strongly agreed with staff being aware of their past medical history and 54.5 percent (n=86) strongly agreed that information about their medication was given in a way they could understand. Therefore, fewer than half of patients in the sample strongly agreed with aspects of good communication with staff.

### Table 4-17 Poor communication

<table>
<thead>
<tr>
<th>Descriptor</th>
<th>How did staff respond?</th>
<th>What could staff have done differently?</th>
</tr>
</thead>
<tbody>
<tr>
<td>My last stay I had a severe reaction to some medication and was very scared and worried at 03:00am so I phoned my Dad. It took a long time to get a doctor who told me I was tired!! However, I had had a severe reaction to medication.</td>
<td>They called a doctor, but he did not take the time to understand and diagnose my problem, just told me to go to sleep</td>
<td>Some better explanation as to what happened. Someone reassuring me. I was given no explanation until the following day. My Dad had to come into the hospital</td>
</tr>
</tbody>
</table>
CF doctors know about and explained but not the on-call doctor. There seems to be no CF doctor here at night time. Are there any CF doctors here at night time?

Some nurses refused to give me my medication which made my situation worse. They changed my morphine dosage without telling me.

I told the doctor who spoke to the nurses in regard to giving me my medication on time but changed once the doctor was away.

Listened to simple instructions

On one occasion the oxygen was turned up too high. I got a full blast. It freaked me out…

I told the nurse what percentage of oxygen I needed. She didn’t know the liters to administer…

The nurse should read the prescription for oxygen. I reflected on this. The incident happened on another ward, which was a respiratory ward.

Poor infection control practice was the second highest code in the descriptors of feeling unsafe (table 4.18). Indeed, two patients were able to recognise poor infection control practice and described the need for increasing staffing levels and the importance of staff familiarisation with procedures. When comparing results from the 13-item scale 58.9 percent (n=93) patients strongly rated that staff were familiar with equipment, while 58.2 percent (n=92) patients strongly agreed with staff being familiar with procedures. However, 22.2 percent (n=35) of patients moderately agreed that staff were familiar with equipment and 20.9 percent (n=33) of patients moderately agreed that staff were familiar with procedures. It is worth considering whether the responses to these two items
would be higher for the moderately agree response, if the sample size was larger.

**Table 4-18 Poor infection control practice**

<table>
<thead>
<tr>
<th>Descriptor</th>
<th>How did staff respond?</th>
<th>What could staff have done differently?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nurses still refuse to follow barrier techniques with regards to patient care. Not wearing gloves and aprons. Basic care. Even whilst giving IV antibiotics. Some don’t communicate with you. Barely speak. Use of BP cuff and stat monitor, rarely cleaned between patients…</td>
<td>Some nurses don’t seem to care about following hygiene barrier nursing so important…</td>
<td>Employ the correct staff for the specific condition. Give them the skills which make patients feel safe and cared for. Communication in nursing is as important as giving tables. Separate as BP cuff and stat monitor should be in each room. Nurses don’t clean either…</td>
</tr>
<tr>
<td>Infection. Doors left open in isolation room and occasions toilet and shower used by those patients</td>
<td>Staff said no danger as shower room treated</td>
<td>More information concerning type or what precautions to take</td>
</tr>
</tbody>
</table>

Poor staffing levels was the third highest descriptor (6) of feeling unsafe (table 4.19). Two patients described the impact of poor staffing levels, in terms of long waits to have call bells answered and how the use of temporary staff impacted on the quality of care they experienced. Furthermore, only 43 percent (n=68) patients strongly agreed with there always being enough staff to care for them. This illustrated how important adequate staffing levels were to patients in making them feel safe.
Table 4-19 Poor staffing levels

<table>
<thead>
<tr>
<th>Descriptor</th>
<th>How did staff respond?</th>
<th>What could staff have done differently?</th>
</tr>
</thead>
<tbody>
<tr>
<td>A lack of staff to answer call bells. Sometimes could wait up to 30 minutes because shortage of staff. Some agency staff at night and weekends were indifferent and unsympathetic and would refuse to help with care</td>
<td>Confirmed that they are short staffed…</td>
<td>Nothing, because there is just not enough of them to care for a ward full of people</td>
</tr>
<tr>
<td>Bank staff unable to do the job at the level required. I never felt comfortable with any bank staff appointed to me</td>
<td>By trying to appoint consistent care which DID happen a large degree of the time</td>
<td>Better infection control. Partly ignorance, partly couldn’t be bothered.</td>
</tr>
</tbody>
</table>

Witnessing challenging behaviour from other patients and racial abuse of staff and patients was the fourth highest descriptor of feeling unsafe and was cited by three patients (table 4.20). One patient described a situation where another patient threw a table at them and then attacked a nurse. Security was called to the ward. Two patients informed staff. One of these patients wanted to contact the police but said they were discouraged. Another patient wanted to leave the ward as they were concerned the challenging patient would attack them, if the staff fell asleep. The third patient did not answer this question. Witnessing the challenging behaviour of other patients and how this affected these patients and staff was not an item that was asked in the 13 item-scale. Furthermore, the lack of clarity on how staff could have responded demonstrated that managing challenging behaviour was difficult and did make patients feel unsafe.
Table 4-20 Witnessing challenging behaviour from other patients and racial abuse of staff by patients

<table>
<thead>
<tr>
<th>Descriptor</th>
<th>How did staff respond?</th>
<th>What could staff have done differently?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mental health patient had two black nurses with him. The patient was verbally and racially abusive to the nurses and to other patients</td>
<td>I told staff I am going to leave the ward. What if the nurses fell asleep at the same time. The patient could have attacked me…</td>
<td>Very little they could have done…</td>
</tr>
<tr>
<td>I was next to a patient with mental health issues. He threw a table at me and then attacked a nurse. Security came to the ward, left and then the situation happened again</td>
<td></td>
<td>Remove the patient from the ward</td>
</tr>
<tr>
<td>The dedication of the nursing staff on ward like this which is constantly under staffed is outstanding. The other major safety issue is the presence of a very disturbed, very aggressive, very rude patient that nurses on a general medical ward shouldn’t have to deal with. I witnessed a patient call an African nurse in A&amp;E a BABOON</td>
<td>I wanted to contact the police but was told this was being dealt with</td>
<td>No comment</td>
</tr>
</tbody>
</table>
Table 4.21 illustrated responses from patients regarding staff attitudes and perceived poor behaviour.

**Table 4-21 Poor attitude and behaviour of staff**

<table>
<thead>
<tr>
<th>Descriptor</th>
<th>How did staff respond?</th>
<th>What could staff have done differently?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medic attempted to take blood samples 6 times. I asked him to stop and informed him ne was hurting me. He said I needed to expect pain. I explained he was really hurting me and asked him to stop. He said my vein was very bad and I needed an arterial stab for normal bloods. I said no please ask someone else to try. He got very angry and said so you don’t want me to take some blood and stormed out and never asked anyone else to return</td>
<td>Staff nurses and I will be informing his consultant. Just need to get in touch with him and I also told him that I felt he was rude</td>
<td>Be more professional in that exampled one should not behave like that in front of any patient. I understand he was stressed</td>
</tr>
<tr>
<td>Being moved from one ward to another at 3:30am. I was not properly aware. I didn’t know where anything was. Woke up with no wheelchair. Very distressing! I’ve had a stroke.</td>
<td>They took no notice and told me to accept the situation</td>
<td>Wake me up when someone came to take the wheelchair back to the ward</td>
</tr>
</tbody>
</table>
4.20 Summary

The results of the exploratory factor analysis identified a single factor with a Cronbach’s alpha of 0.914. This value was >0.7 which provides evidence of internal consistency and supports the retention of all 13 items. None of the independent variables were associated safety score suggesting the questionnaire can be generalised to the wider adult patient population. The correlation between safety score and how a person rates hospital safety was over 0.6 demonstrating strong construct validity. This also suggests that a person’s single rating of the hospital safety is potentially a useful indicator. Correspondingly, the responses from the open-ended questions corroborated with some of the low scores of the 13 item-scale. This illustrated how the use of open-ended questions provided insight to the reasons for the scores. What is more, combining open-ended questions in a questionnaire alongside a rating scale can provide an organisation with detailed information on what matters to patients in relation to their safety, and ways in which their safety can be improved. In the next chapter the implications for policy, practice and research are discussed.
Chapter 5 Discussion

5.1 Introduction

This chapter discusses the findings from the study and places them in the context of the limited amount of evidence concerning patients’ perceptions and experience of safety and questionnaire design in patient safety. The findings will be interpreted in order to inform the development of the King’s Patient Safety Measure within an acute hospital setting. The strengths and limitations will be considered. Finally, the study’s original contribution to knowledge will be discussed and suggestions for implications for practice and future research.

The aims of this study were to explore what patients understood by being safe, and how they experienced safety within an acute hospital setting. The findings were then used to inform the development of the King’s Patient Safety Measure (KPSM). These aims were set because there had been no questionnaires identified that had been developed solely with patients to measure safety from their perspective. To achieve this the study was broken down into 4 objectives. This approach was chosen because it had been used in similar studies undertaking questionnaire design and provided a systematic approach to the research (Schwappach 2008; Rathert et al 2011b; Giles et al 2013). The results of each objective informed the next objective of the study (Bowling & Ebrahim, 2005, National Institute of Health, 2013), allowing for a more in-depth study of patient safety (Gerrish & Lacey, 2010).

The objectives of the study were;

1. A scoping review of the literature and feedback was sought from patient representatives within the acute trust, to inform the layout and questions to be examined in the pilot questionnaire.

2. Develop and pilot the questionnaire using cognitive interviewing.
3. Establish the validity and reliability of the tool in a questionnaire to 158 patients in general medical settings.

4. Explore relationships between patient demographics (ethnic background, age, gender, social deprivation, family support), mode of admission and patient perceptions of safety.

5.2 Summary of key findings

A sequential mixed methods design was used, where the results of each objective informed the next objective of the study (Bowling & Ebrahim, 2005, National Institute of Health, 2013), allowing for a more in-depth study of patient safety (Gerrish & Lacey, 2010). This approach was chosen because it has been applied to similar studies where questionnaires were designed and developed (Schwappach, 2008; Rathert et al, 2011b; Giles et al 2013). The mixed methods approach helped to focus the study design in answering the research question by examining patients’ perceptions of their safety within an acute hospital setting and fits well with the development of a measurement questionnaire (Gerrish & Lacey, 2010; National Institute of Health, Office of Behavioural and Social Sciences Research, 2013). The sequential mixed methods design was broken down into the four objectives.

This study demonstrated that a validated tool can be developed with patients to measure how safe they feel during their acute hospital stay. Key items that patients identified in making them feel unsafe included poor communication with health professionals, especially with communication about medications, poor infection control practice and staffing levels. Items that patients identified in making them feel safe included staff showing compassionate care, clear communication and adequate staffing levels. Exploratory factor analysis was used to establish the factor loading for each of the thirteen items of the questionnaire. Factor loadings for all items were between 0.52 and 0.86,
demonstrating that all the items made an important contribution to a single factor. The Cronbach alpha score for the thirteen-item score was 0.914 illustrating internal consistency of the overall scale, therefore suggesting all thirteen items should be kept. The Pearson correlation score of .648 with question 12, “How safe you felt during your hospital stay demonstrated strong construct validity, illustrating the thirteen-item scale was a reliable measure of aspects of safety that were important to patients.

There were no statistically significant differences in the perceptions of feeling safe between ethnic background and mode of admission, age, sex and whether they have family support during their hospital stay. Thus, the measure was found to be appropriate and universally applicable for all patients.

5.3 How findings contribute to previous literature

These will be discussed in relation to how each objective was achieved.

5.4 Objective 1 Scoping Review

A scoping review of the literature and feedback was sought from patient representatives within the acute trust, to inform the layout and questions to be examined in the pilot questionnaire.

The purpose of the scoping review was two-fold; to establish what research studies had been conducted on patients’ experiences and perceptions of safety, and to examine further the use of questionnaires in healthcare which measured patients' perceptions of safety. Arksey & O’Malley’s scoping framework was used to collate and organise studies. Four areas of studies were selected for review. These were; patient experience surveys; patient experience with adverse events; the impact of patient characteristics on their experiences if safety and patient measurement studies on safety. Greenhalgh’s checklist
(2010) for survey research and Rattray & Jones framework for survey design (2007) were used to critically appraise studies using surveys.

The scoping review selected studies where patients had identified themes that made them feel unsafe. These were poor communication, failures to coordinate care, particularly during discharge planning and transferring care, and interactions with multiple doctors (Schoen et al, 2005; Jha et al, 2008; DeCourcy et al, 2012), and nurse staffing levels. These corroborated with the themes that emerged from this study (Agoritsas et al, 2005; Wolosin et al, 2006; Schwappach, 2008; Rathert et al, 2011; Sorra et al, 2012; Giles et al, 2013; Sahlstrom, 2014; Dixon et al 2015; Yan et al, 2017) which included poor communication, lack of information about medication, and poor infection control practice.

In the studies focused on patient measurement tools the authors demonstrated how they had used evidence from the literature to inform the design and development of their questionnaires (Wolosin et al 2005, Schwappach 2008, Rathert et a, 2011b Sorra et al 2012, Giles etal 2013, McEachan et al 2014, Sahlstrom et al 2014, Ricci-Cabello et al 2016). These topics helped to inform the development of the 13-item scale within the King’s Patient Safety Measure. To strengthen validity of the item choices, items from the National Inpatient Survey (Care Quality Commission 2014a) were referred to. This approach was influenced by Rathert’s et al study (2011b) which sought evidence from previous studies on the validity of items within the Picker Patient Experience Questionnaire.

Several studie used focus groups and think aloud techniques to seek feedback from patients on the content and layout of their questionnaires (Gerrish & Lacey 201, Giles et al 2013), and these informed techniques used in the development of the KPSM. Early drafts of the questionnaire within this study were presented to patient representatives within the hospital to conduct initial testing of face and content validity. The patients agreed important items to include in
the pilot study. They also stated the questionnaire should be short, so as not to
over burden patients and easy to read. This feedback resulted in the pilot
questionnaire (Version 1.2, appendix 17). The patients also suggested
including an additional question which previous studies did not. In particular,
when asking patients to describe an aspect of their care that made them feel
unsafe, the patient representatives stated that a follow up question should be
included. This was “Did you inform a member of staff that you felt unsafe? and
How did the staff respond?” This provided valuable insight into what staff did
when patients said they felt unsafe. This offers a real opportunity for healthcare
professionals to have insight into what patients perceive as potential harm, and
enables staff to learn and change their practice to protect patients.

Arksey & O’Malley’s (2005) scoping review framework was used because it
provided a methodological approach in which to explore the evidence. Early on
in the scoping review it became clear there were limitations with this process. It
did not enable a critical appraisal on the quality and design of survey’s used in
research studies. The author attempted to address this by searching the
websites of Equator, Network and STROBE. None provided validated tools to
critically appraise studies using surveys or those focusing on design and
development of surveys. It was therefore not possible to determine if the tools
were valid and reliable in these studies (Greenhalgh 2010). To overcome this
the author applied Greenhalgh’s (2010) checklist for critiquing studies using
surveys. However, there were further challenges. Greenhalgh’s checklist
(2010) did not provide sufficient details on a systematic approach to survey
design. The author used Rattray & Jones (2007) framework on survey design
tests that should be used to strengthen validity and reliability of the KPSM. For
example, the use of factor analysis to develop the 13-item scale.

This study contributes to new knowledge by demonstrating during the scoping
review that there was no validated tool to critique studies in survey design. A
new systematic approach has been applied using Greenhalgh’s checklist (2010)
and Rattray & Jones (2007) framework. Feedback from patients at the early stages of design introduced a unique question, asking patient to state if they had informed a member of staff that they felt unsafe and what did the staff do about this?

In summary, objective 1 was achieved as the scoping review and feedback from patients provided insight into the content and layout of the questionnaire, in preparation for the pilot study.

5.5 Conceptual Framework

The scoping review identified that the concept of safety was multi-dimensional, illustrating the need to have a framework through which to examine safety. The WHO Conceptual Framework of International Classification for Patient Safety (2009) was used because it enabled the author to capture the context in which safety was delivered in health care and more importantly, experienced by patients.

5.6 Objective 2 Pilot Study

Develop and pilot the questionnaire using cognitive interviewing.

The aim of the pilot study was to test the face and content validity of the pre-designed questionnaire, in preparation for its application in the cross-sectional study in phase 3. The objectives of the pilot were;

1. Assessing the feasibility of applying the questionnaire to patients.
2. Identifying potential sources of response errors in the questionnaire.
3. Modifying the questionnaire as necessary.

To assess feasibility ten patient representatives of the patient population were selected and consented to participate in the pilot study. Patients were asked to
independently complete the questionnaire. The author then conducted face-to-face cognitive interviews on the wards with patients to assess their understanding of the questions, layout and how easy it was to complete the questionnaire (Willis 2005). Verbal probing (Willis 2005, Willis 2009) was used to ask further questions to confirm what patients were saying. The Question Appraisal System (Willis & Lessler 1999) provided the opportunity to identify potential sources of error within the KPSM. This approach was certainly quick and easy to do, and patients were happy to participate. This was evident from the general comments made by patients about the questionnaire (appendix 6).

Previous studies demonstrated the involvement of patients at this stage in questionnaire design was variable. A number of studies involved patient safety experts and healthcare professionals, along with patients to develop their items (Giles et al 2013, Schwappach 2008). Different methods were used to collect feedback on the early design of measurement tools. The think aloud technique with patient focus groups, along with input from experts in the field of safety was used in a number of studies (Giles et al 2013, Schwappach 2008). A more recent study by Ricci-Cabello et al (2016) used four patient focus groups to inform the development of their tool within GP practice. All these studies involved healthcare professionals, alongside patients in the development of their tools. This had the potential to introduce professional bias in item development. Patient focus groups were considered for this study, however, due to time constraints and the requirement for further ethical approval, this was not possible. This study is unique in that the items were developed solely with patients.

The use of verbal probing (Willis 2005; Willis 2009) and the Question Appraisal system (Willis & Lessler 1999) identified potential sources of error. These included the design of the Likert scale. This was amended following feedback from patients, with the number of scores reduced from 10 to 6. Patients who participated in the pilot stated that the items were important in making them feel safe, for example; staff listened carefully to what I had to say, and staff
explained things in a way I could understand. A key theme that emerged from the pilot was that patients wanted to describe safety within the context of their whole care pathway, which for some patients included experiences of previous admissions. This was not anticipated as it had not been identified in previous studies. This resulted in changes to the final version of the KPSM, where patients were asked to comment on their most recent hospital stay. However, one open-ended question remained, “Please add any further comments that you wish to make about your stay”, allowing patients to include aspects of their whole pathway that were important to them.

In summary, objective 2 of the study was achieved because the pilot study involved patients at the early stages of development of the KPSM, in assessing the feasibility of the questionnaire. Potential sources of error were identified during the cognitive interviews and resulted in changes to the Likert scale and instructions in completing the questionnaire.

### 5.7 Objective 3 Cross-sectional Study

The objective of the cross-sectional study was to establish the validity and reliability of the KPSM questionnaire with a sample of 158 patients in general medical settings.

The cross-sectional approach was chosen because it had been used in similar studies involving surveying of patients (Schwappach 2008, Rathert et al 2011b, Giles et al 2013). It allowed standardised measurement of patient safety through the application of the questionnaire at a given point in time (Bowling & Ebrahim 2005). The data analysis plan provided a systematic process for data analysis, in particular key stages of factor analysis, which ensured testing of the reliability and validity of the KPSM. Step 1 focused on the creation of the scale to measure patient perceptions of safety. Results of the factor analysis illustrated that all 13 items should be retained. Further testing of the 13-item scale within the King’s Patient Safety Measure demonstrated internal
consistency (Cronbach alpha score 0.914), which illustrated this was a reliable and valid measure of patients’ perceptions of safety. In Step 2 of the data analysis plan descriptive data were produced to show how participants responded to the 13-item scale (Table 4.3). Descriptive content analysis (Schrier 2012) was used to examine the responses to the open-ended questions in this study. The themes were then corroborated with the results of the 13-item scale. This provided detailed information on what mattered to patients in making them feel safe, along with suggestions on what staff could have done differently to make them feel safer. This approach corroborates with Christiansen et al (2016) study. Christiansen et al (2016) demonstrated that bringing together metric data and narrative stories of patients into one report was a powerful method enabling healthcare professionals to gain a more complete picture of safety and the quality of care.

Rattray & Jones (2007) recommend the use of open-ended questions in early survey design to inform item development and the application of factor analysis in the final stage of questionnaire development to determine which items should be retained. Application of factor analysis in questionnaire development was not evident in a number of studies (Schwappach 2008, Rathert et al 2011b, Sahlstrom et al 2014), raising questions about the validity of these tools. In contrast, several studies demonstrated how they had used factor analysis to develop their measurement tools (McEachan et al 2014, Ricci-Cabello et al 2016). This study contributes to survey design research by demonstrating a systematic approach, using exploratory factor analysis does ensure the development of a reliable and valid tool.

The responses to the 13-item scale and codes that emerged from the open-ended questions demonstrated that patients described safety differently to healthcare professionals. Firstly, they described their experience of safety across their whole care pathway, including previous admissions. This was not evident in past studies. The instructions on completing the KPSM were amended following the pilot and now asked patients to comment on their current
hospital admission in the cross-sectional study. The KPSM had a final open-ended question to allow patients to add any further comments.

Patients descriptions of their whole pathway is important to recognise when using a survey for quality improvement. There is the potential for healthcare professionals to interpret findings of aspects of care differently to patients and lead to focusing on the wrong areas for improvement. Agoritsas et al (2005) recognised this in their study and argued that 3 types of questions are useful in quality improvement. These were; global rating scores, reports of usual patterns of care and reports of discrete events. The KPSM achieved this by asking patients to rate aspects of their care through the 13-item scale, provided a global rating of how safe they felt and gave patients the opportunity to record incidents that made them feel safe and unsafe. This demonstrates the potential of the tool to be used in quality improvement methodology.

Compassionate care and communication were the top two codes of descriptors of safety. But when done poorly presented as the top code of descriptor of feeling unsafe. Patients described poor communication so frequently in making them feel unsafe that further coding was undertaken. Patients described key triggers points along their care pathway where communication was poor. These included communication about medication and discharge planning and feelings of not being listened to. These themes emerged in previous studies (Agoritsas et al 2005; Yan et al 2012), and illustrates the significant role that communication plays in making patients feel safe.

The KPSM asked three unique questions, which were not evident in previous studies using surveys. These questions were suggested by patients in the early design of the tool. Theses were;

“Did you inform a member of staff that you felt unsafe?
How did staff respond?
What could staff have done differently ?
The questions provided the opportunity to explore how staff responded at the time to patients’ concerns. Patients emphasized the importance of being listened to. One patient described a situation where she felt unsafe because a doctor had not taken the time to understand and diagnose her problem. These responses illustrate that patients place a high importance on the interactions and relationships with staff in making them feel. In Dixon et al (2015) study the most important factor that positively influenced how safe patients felt was the relationship with their doctor. Martsolf et al (2016) and Carter et al (2017) identified that communication with healthcare professionals was an important factor in making patients feel safe or unsafe. In particular, showing compassion and communicating in a way patients could understand was important to patients in making them feel safe. Hassen et al’s study (2017) aimed to evaluate quality markers for safe care and found that patients and staff identified these differently. Staff identified staffing levels and staff experience, but patients identified staff attentiveness as their top-rated indicator.

An unexpected theme that emerged from the open-ended questions was witnessing challenging behaviour and racial abuse of staff by fellow patients. This was not evident in previous studies and therefore had not been included as an item in the scale. Where patients had documented this in the tool, they had not provided clarity on how staff had responded, or could have responded differently.

The findings from this study contribute to the body of knowledge by demonstrating that patients described feeling safe and unsafe from the relational aspects of their care with staff, and how attentive staff were. But witnessing challenging behaviour adds to the body of knowledge and requires further research.

A number of studies (Agoritsas et al 2005; Evans 2006; Doyle et al 2013; Anhang et al 2014; Lawton et al 2015; O’Hara et al 2017) examined the impact
of patient safety surveys in making improvements in safety. This study did not examine this impact. Further research of the KPSM is therefore required. Most safety research focuses on systems, processes and the competency of staff in improving safety. These have their place in the safety improvement field. This study illustrates there is another dimension to the concept of safety, which is viewed from the experience of patients.

The application of the data analysis plan ensured objective 3; establishing the validity and reliability of the KPSM questionnaire to 158 patients in general medical settings was achieved.

5.8 Hypothesis

The hypothesis for this study was to explore the relationships between patient characteristics (ethnic background, age, gender, social deprivation, family support), mode of admission and patient perceptions of safety.

Step 3 of the data analysis plan focused on testing the relationships between the demographic factors and organisational factors, and patients’ perceptions of safety. General linear modelling was used to ascertain whether variation in patients’ perceptions of safety could be explained by patient characteristics (Pallant 2013). None of these characteristics were associated with the mean patient safety score. The model residuals showed some evidence of departure from normality however the sample size of 158 was sufficiently large for this not to be a major concern (Kwak & Kim 2017). Therefore, objective 4 was achieved.

This study contributes to the body of knowledge by demonstrating that none of these characteristics influenced patients’ perceptions of safety. Within the scoping review the evidence on patient characteristics was inconclusive. Some studies demonstrated that an increased length of stay and patients who were depressed impacted on their safety. There was also variability with age and
socio-economic background. Further research using the KPSM is needed to test the hypothesis, as the results may be different with a larger sample size.

5.9 Limitations of the study

The original plan was to conduct the study within surgical and medical wards within the hospital. The aim of this was to enable generalisability of the results to the wider NHS (Greenhalgh, 2010; Walker & Almond, 2010). During the stages of seeking ethical approval the author experienced a number of challenges which impacted on this and resulted in the study being conducted solely within the medical wards. The author was unable to access the surgical wards at the time of seeking ethical approval. This was because there was no research governance lead within surgery to authorise approval.

Another challenge faced by the researcher related to the process of contacting patients once they had been discharged. The purpose of this was to reduce positive response bias (Walker and Almond, 2010; Greenhalgh, 2010). To achieve this, patients’ records would need to be accessed to obtain their contact details. The researcher was not directly involved with the patients care and could not gain ethical approval for this. The sampling strategy was amended from following up patients on discharge to approaching patients 48 hours prior to discharge. This had the potential risk of increasing a positive response, as patients may have been reluctant to give negative feedback while they were still in hospital (Greenhalgh, 2010).

The sample characteristics were representative of the patient population for the organisation. However, the mean age was 55.7 years, 47.5 percent (n=75) of participants were male and 50.0 percent were female. A total of 90.5 percent (n=143) of participants were admitted through the emergency pathway, while 9.5 percent were planned. While the spread between male and female was almost equal the study findings were biased towards the middle-aged and patients who were admitted through the emergency pathway. It was also biased
towards white British groups as 67.7 percent (n=107) patients were categorised in this ethnic group (Department for Communities and Local Government, 2015). Further work on safety with patients should include younger age groups and those from more diverse backgrounds, in particular patients whose first language is not English, as their perceptions of safety may be very different from this sample. Patients who had a cognitive impairment or history of psychiatric illness were also excluded and further studies are needed to gain insight into these patient groups’ perceptions of safety. Further work should be undertaken to compare patients’ perceptions of safety through the emergency and planned pathways to determine if they are different.

The focus of the study was to explore safety from the patients’ perspectives. However, while this was relevant, the study did not explore whether there was evidence that the areas of safety concern for patients improved. Further studies would need to be undertaken to examine this link.

5.10 Strengths of the study

The application of the WHO International Classification for Patient Safety (2009) as the conceptual framework helped to contextualise the world of safety. This informed what studies were to be included in the scoping review and led to the identification of key themes to influence item development in the KPSM. There was no nationally recognised framework to assess studies using questionnaires. Greenhalgh’s checklist for reviewing questionnaire research was used, in conjunction with Rattray & Jones (2007) framework. Rattray & Jones framework provided a systematic approach in the design, development and implementation in item development was patient-focused and ensured strong face and content validity. The data analysis plan ensured a rigorous approach to data analysis resulting in the tool demonstrating strong internal reliability. The statistical tests applied (exploratory factor analysis, Cronbach alpha, tests for normal distribution) ensured the KPSM was a reliable and valid tool.
5.11 Contribution to knowledge

The aim of this study was to understand what patients' perceptions of safety were within an acute hospital setting, which would inform the development of a measurement questionnaire. The scoping review illustrated that the concept of patient safety was multi-dimensional, with early studies predominantly examining safety from an organisational and healthcare professional perspective. Very few studies examined safety from the patients' perspective, thus illustrating the gap in knowledge and the need for further research. This thesis has attempted to address this gap by undertaking a mixed methods study to understand safety from the patients’ perspective and to use the findings to develop the King’s Patient Safety Measure.

Studies focusing on the design and development of questionnaires illustrated the wide variation in survey design. This insight allowed for a systematic approach to be applied in this thesis, by using the Rattray and Jones framework (2007). This ensured the KPSM was a reliable and valid tool, which has the potential to be applied to clinical practice. Key findings from the study suggest that the KPSM has the potential to be used as an early warning tool and to build resilience within healthcare settings, using feedback from patients. This has been achieved as patients confirmed in the pilot study that the 13-item scale captured the key topics that were important to them. They also confirmed the layout of the KPSM was easy to understand. Much has been claimed about patients not wanting to raise concerns for fear of retribution. This study has demonstrated that if patients are provided with a mechanism through which they are encouraged and supported, they will raise important issues for safety improvement. This was evident from the 98 patients who spent the time completing the open-ended questions. Contemporary research has illustrated this point (Lawton et al 2015, Ricci-Cabello et al 2016, O’Hara et al 2017). The Rattray & Jones framework (2007) provided a systematic approach in the design and development of the tool, with only patient involvement at every stage of development.
One could argue that the focus of this study was on potential harm, rather than on safety. Patients were asked about incidents that made them feel unsafe. This is very much the “find and fix” model of Safety 1 thinking. However, the KPSM also proves the opportunity for staff to learn from mistakes and what went well in real time. Patients are able to give examples in the open-ended questions on what made them feel safe, along with examples of what made them feel unsafe and what staff can do differently to make them feel safe. This approach fits the Safety 2 thinking. The principle of Safety 2 is that all performance, regardless of whether it goes well or fails, operates from the same source. These are the same behaviours and practices of staff (Braithwaite et al. 2015). The focus is to understand how and why things go well, acknowledging that safety is better examined by this approach, rather than focusing on why things fail. Safety 2 examines how people adjust what they do to match the situation, based on availability of resources such as time and manpower.

What the KPSM demonstrates is the variability in performance of staff and services. Therefore, the tool has the potential to act as an early warning system for potential harm, solely based on patient feedback. It enables resilience to be built into care delivery to reduce the risk of harm to patients, otherwise known as resilience engineering (Hollnagel 2014). The KPSM has the potential to address the four components of resilience engineering. These are; learning from what has happened; responding – knowing what to do and being capable of doing it; monitoring what to look for and anticipating – finding out and knowing what to expect.

This study has demonstrated that patients are able to actively participate in the design of a tool which can measure how safe they feel while they are in hospital. Indeed, such a finding is supported by empirical evidence (O’Hara et al, 2017; Ricci-Cabello et al, 2016a; Ricci-Cabello, 2016b; Ricci-Cabello et al, 2017).
This study responds to the challenges of and contributes to the existing body of knowledge in a number of ways:

1. A validated tool (KPSM) was developed to measure how safe patients feel during an acute hospital admission.

2. The findings provide evidence that recognises the contribution that patients can make to the safety agenda of an organisation and enables their voices to be heard.

3. This study provides evidence that interpersonal relationships, in particular communication, are key safety indicators that are important to patients, and which are described differently to healthcare professionals.

4. The findings demonstrate how the use of both quantitative and narrative data within one tool provides a rich source of feedback from patients on what matters in making them feel safe.

5.12 Implications for policy

The Five Year Forward Review (NHS England 2014c) recommended engaging with communities and patients in new ways. As a consequence, NHS England (2015) commissioned a project for commissioners and providers to determine how this could be achieved. The report (NHS England, 2015) made a number of recommendations, including introducing robust mechanisms to enable organisations to listen to patients. The Government’s mandate 2016-17 & NHS Outcomes Framework (HM Government, 2015) set out objectives to 2020 with the aim of reducing variation in care, creating learning organisations and improving services, in particular for vulnerable groups. Objective 2 of the plan set out to create the safest, highest quality health and care service. Patient involvement within this objective related to maintaining and increasing the number of people recommending services and to ensure its effectiveness,
alongside other sources of feedback to improve services. The empirical evidence (Raleigh et al, 2015; Manacorda et al, 2016) has demonstrated limited impact of the Friends and Family test in making improvements, based on the number of completed questionnaires and the overall recommendation of a hospital stay. The Friends and Family test also does not ask patients about how safe they feel. The key lines of enquiry used by the Care Quality Commission to inspect organisations do not ask patients about safety, under the safety domain. Rather, the focus of questioning is from an organisational and healthcare perspective. The argument put forward by O’Hara (2017) was that such an approach was unlikely to target safety improvement from patients’ perspectives. This can be illustrated by the example given to assess discharge planning, where no reference is made regarding the seeking of the patient’s view:

When people move between teams, services and organisations (which may include at referral, discharge, transfer and transition), is all the information needed for their ongoing care shared appropriately in a timely way and in line with relevant protocols?

Gilbert et al (2015) conducted a telephone survey of 19 hospitals across England to explore how patient experience data was being utilised to make improvements in care. They found that there was wide variation in how trusts were making sense and using the data. Patient experience teams were struggling with bringing together data and reporting on it. As a consequence, Gilbert et al (2015) suggested that boards and commissioners may not be getting a full picture of patients’ experience. The Friends and Family test did not ask patients to rate how safe they felt during their hospital stay and did not target areas for improvement. Therefore, improvements in services were limited. In contrast, the KPSM provides a quick and easy method for patients to provide feedback on their safety experiences and how safe they feel.
In 2015 the Health Foundation (Health Foundation, 2015) produced a report, Continuous Improvement of Patient Safety: The Case for Change in the NHS, advocating for a change in the way patient safety is approached within the NHS. The report provided a checklist of safety improvement which included involving patients and their families in safety improvement. A further focus on patient involvement was provided by the Patient Engagement in Patient Safety Framework for the NHS was published (Yorkshire Quality and Safety Research Group & Valid Research, 2016). The purpose of the framework was to provide structure, with examples for thinking about how to engage patients and their families. Three types of patient engagement were identified at the organisational level, which were own care, service provider and across systems. Within each level three ways of patient engagement were described: information, involvement, partnership or shared leadership.

It is clear that hearing the voices of patients and their relatives in safety remains a significant challenge in improving patient safety within the NHS (O'Hara, 2016). O'Hara argues that there is a lack of diversity of patient involvement in healthcare improvement, including patient representation in research. Some of the most vulnerable patients are excluded from research exploring safety because they are frail, suffer from delirium or dementia or unable to speak English and therefore unable to give informed consent. O'Hara argues the existing empirical literature is skewed as a result. Indeed, this is a limitation of this particular study. The approach to safety improvement promoted the identification of past harms and minimising future risks. But what of the patient's voice in examining safety in this way? O'Hara argues that such an approach has made it difficult to fit patient feedback on quality and safety of care into the improvement agenda, as patients do not necessarily articulate their perceptions of safety in this way.

Fitzsimons and Cornwell (2018) argue that there is a divergence in the world of safety between patients and healthcare professionals. Patients include a broader array of non-clinical issues and incidents associated with emotional and
psychological harm. These include problems with communications, staffing levels, including training of staff, care and compassion and the state of the ward environment. Fitzsimons and Cornwell (2018) suggest that healthcare professionals see the immediate risks as clinically important and therefore downgrade testimonies from patients. Patients are experts in their lived experience and offer unique insights into improving the quality of care (Flott et al 2017). The patients who participated in this study described their perceptions and experiences of safety across their pathways of care. There is a paradigm shift in the world of safety improvement (Flott et al 2017) with commissioners and providers now recognising the value of patient feedback to improve services. The empirical evidence demonstrates that feedback from patients can act as an early indicator of potential harm (Agoritsas et al 2005; Evans et al 2006). The patient safety agenda needs to capture the patients’ views and experiences of safety differently to ensure their voices are heard (O’Hara et al, 2017).

The findings from this study have demonstrated that patients’ perceptions and experiences of safety are linked to their interpersonal relationships with healthcare professionals. This is especially in regard to what information is communicated and how it is communicated to them. Caring, kindness and compassion of staff was an important factor in making patients feel safe. However, when these were done badly, patients felt unsafe. Healthcare policy needs to acknowledge that patients experience and describe their world of safety differently from healthcare professionals, and consequently the framework in which to engage them needs to shift to enable their voices to be heard.

5.13 Implications for practice

The KPSM provides the opportunity for patients to become involved, by providing information on their perceptions of safety, during their hospital stay, thereby promoting shared leadership. The feedback from patients during the pilot included the tool was easy to understand and quick to complete,
suggesting the tool would be easy to implement. This provides the opportunity for the King’s Patient Safety Measure to be used within the clinical setting. For example, the tool could be handed out to patients prior to discharge and the responses analysed by staff to help target areas for improvement. Alternatively, the open-ended questions could be included the matron’s round, when speaking with patients. The KPSM has the potential to be used as an early warning trigger tool and for the findings to be used as learning for healthcare staff.

5.14 Future research

This study aimed to explore what patients’ perceptions of safety were within an acute hospital setting, with the aim of developing a measurement questionnaire. More research is needed to further test the tool, in particular with a wider sample size, including younger patients, and those with psychiatric and cognitive impairment, and patients whose first language is not English. An unexpected theme that emerged was patients witnessing violent and aggressive behaviour from other patients. This was not evident in the literature, thus illustrating the need to explore this further, within the acute hospital setting. It was clear that triangulating the codes from the open-ended questions with the results of the 13-item scale provided information on key areas of safety that mattered to patients. Application of the tool in its entirety, or by just using the open-ended questions in matron’s rounds, needs further examination. Essentially, the tool needs to be easy to use in clinical practice.

Recent studies (Doyle et al 2013, Anhang et al 2014) on patient safety have attempted to examine the impact of patient safety measurement tools with health outcomes and the use of resources. It is clear that health outcomes need to be linked to the themes that are important to patients in making them feel safe. The KPSM demonstrated strong reliability in measuring how safe patients felt. The tool has the potential to be used in transformational change of care pathways to determine if patients feel safe and their health outcomes have
improved. The tool may also have the potential to predict potential harm. For example, patients rated staffing levels in the tool, and in the open-ended questions gave examples of poor communication with staff. The study conducted by Ball et al (2018) concluded that when nurses have too many patients to care for and do not have time to complete all the necessary care, missed care increases the odds of poor patient outcomes.

Essentially, the KPSM has three components: the 13-item scale which can target key areas for improvement; question 12 which asks patients to rate how safe they felt during their hospital stay, providing a measure of safety which can be monitored before and after safety improvement has been implemented; and the open-ended questions, providing narrative information and therefore context in how patients perceive safety. The tool provides both narrative and metric data which is quick and easy to collate. The open-ended questions enable patients to describe the responses from staff when patients have raised concerns and what staff should do differently to make them feel safe. This allows staff the opportunity for learning from patients and targeting safety improvement from the patients’ perspective. The KPSM provides a unique tool to assist organisations in identifying and targeting key areas of safety concern for patients. The KPSM provides an opportunity to capture as such the voices of patients in one moment in time, which can quickly be followed up by staff.
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Bibliography


## Appendix 1 Patient experience surveys

<table>
<thead>
<tr>
<th>Authors year</th>
<th>Setting</th>
<th>Intervention</th>
<th>Aims</th>
<th>Methods; participants</th>
<th>Outcome measures &amp; Results</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>Davis et al 2008</td>
<td>United Kingdom Inner city London teaching hospital</td>
<td>Willingness to Ask Safety Questions Survey</td>
<td>Study explored; 1) Surgical patients’ willingness to question healthcare staff about their treatment 2) differences between patients’ willingness to ask factual vs. challenging questions related to quality and safety of their care 3) patient demographic characteristics that could affect patients’ willingness to speak up 4) impact of doctors’ instructions on patients’</td>
<td>Cross-sectional study N=80 patients who had undergone surgery</td>
<td>Patients more willing to ask; factual questions versus challenging questions in all categories women educated patients and patients in employment were more willing to ask questions (p&lt;0.05 Patient involvement strategies which consider patient characteristics need to be developed for</td>
<td>Small scale study Replication and assessment of generalizability of current findings to other patients’ groups needs to be examined</td>
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<tr>
<td>willingness to speak up</td>
<td>patients and staff to promote patient involvement in safety improvement</td>
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<td>Author</td>
<td>Setting</td>
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<td>Methods; participants</td>
<td>Outcome measures &amp; Results</td>
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</table>
| Decourcy et al 2012            | United Kingdom | Scoping review conducted in July 2010, followed by full systematic investigation conducted by two independent researchers in October 201 | To investigate how data has been used and to summaries what has been learned about patients’ evaluation of care as a result | Systematic review      | 41 papers included; 9 annual survey reports, 13 evidence-based articles & reports, 9 multiple survey comparison reports, 3 ethnicity, age & patient experience, 7 sociological studies | Some reports used a single year of data and others used multiple years providing historical comparisons or trend analysis
Socio-demographic variables need to be considered when interpreting results
Many papers did not perform original analyses and... |
results for one trust, only, with no national referencing

41 papers selected

about care
2) patients who reported own health as good more likely to report more positive experience

3) Relationship between staff satisfaction results & patient satisfaction in national surveys

4) patients’ perceptions of adequate staffing levels and amount of dignity and respect correlated with staff’s feelings of work pressure

used reported outcomes from official annual survey reports

Some papers compared different data sets as they were alike and using patient level or trust level aggregated data

Results were mainly displayed descriptively

The question “Overall, how would you rate the care you received?” used by many
papers to determine the importance of different aspects of their care. Asking patients to report in detail would be more appropriate than an inpatient survey itself, a quality improvement tool.
<table>
<thead>
<tr>
<th>Author</th>
<th>Setting</th>
<th>Intervention</th>
<th>Aims</th>
<th>Methods; participants</th>
<th>Outcome measures &amp; Results</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Entwistle et al 2010</td>
<td>United Kingdom</td>
<td>People with recent experience of 5 conditions or interventions associated with a safety problem and people who had raised concerns at the point of care</td>
<td>To explore patients and family’s experiences of and views about speaking up about safety concerns at the point of care and their contribution to their own safety</td>
<td>Qualitative study 71 individual interviews 12 focus groups</td>
<td>Patients’ ability to speak up was influenced by how they assessed the gravity of the threat of harm, the relative importance of their concern given other patients’ needs and staff workload and priorities Key result Potential for patients to contribute to their safety by speaking up about their concerns depended on the quality of the patient-professional relationship</td>
<td>Patients’ assessment of threats to their safety was not validated No assessment of how healthcare professionals responded when patients did speak up</td>
</tr>
<tr>
<td>Author</td>
<td>Setting</td>
<td>Intervention</td>
<td>Aims</td>
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<td>Outcome measures &amp; Results</td>
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<tr>
<td>Jenkinson et al 2002</td>
<td>5 hospitals in one NHS trust in Scotland</td>
<td>Postal questionnaire- Patients asked to evaluate their overall experience of their care &amp; to complete Picker Inpatient survey in specific aspects of care</td>
<td>Determine what 1) aspects of healthcare provision are most likely to influence satisfaction with care &amp; willingness to recommend hospital services 2) explore the extent to which satisfaction is a meaningful indicator of patient experience of healthcare services</td>
<td>Postal questionnaire mailed to patients 1-month post discharge Patients aged 18 years and overrepresenting at the hospitals 2049 questionnaires posted with 65% response rate (n=1332)</td>
<td>Major determinants of satisfaction were physical comfort, emotional support and respect for patient choice. Key results 90% or respondents were satisfied with their experience Age and overall self-assessed health were weakly associated with satisfaction 55% of patients who rated their care as excellent</td>
<td>Patient satisfaction scores present a limited and optimistic picture. Detailed questions about specific aspects of patients' experiences is a more useful in monitoring a hospital's departmental performance</td>
</tr>
</tbody>
</table>
indicated problems on 10% of the issues mentioned in the Picker questionnaire.

Patient satisfaction scores presented a limited and optimistic picture and were therefore limited.
<table>
<thead>
<tr>
<th>Author</th>
<th>Setting</th>
<th>Intervention</th>
<th>Aims</th>
<th>Methods; participants</th>
<th>Outcome measures &amp; Results</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>Jha et al 2008</td>
<td>United States</td>
<td>HCAHPS survey linked to annual survey of American Hospital Association which collects information on a range of information including; nurse-staffing levels, profit status &amp; number of beds</td>
<td>Examined whether key characteristics of hospitals that were believed to improve patient experience were associated with better experiences for patients</td>
<td>Assessed performance of hospitals across multiple domains of patients’ experiences, in particular HCAHPS survey relating to performance on quality of care 4032 hospitals</td>
<td>Moderately high levels of satisfaction with care (67.4%) correlated with measure of patients' experiences Hospitals in bottom quartile of ration of nurses to patients had lower satisfaction</td>
<td>High nurse staff levels may be associated with better experiences for patients Limitations 40% of hospital did not respond. Quality of nonresponding hospitals was slightly lower than hospitals that participated. Potential for no-response bias</td>
</tr>
<tr>
<td>Author</td>
<td>Setting</td>
<td>Intervention</td>
<td>Aims</td>
<td>Methods; participants</td>
<td>Outcome measures &amp; Results</td>
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<tr>
<td>Long et al.</td>
<td>Australian hospital</td>
<td>Discovery interviews conducted with patients</td>
<td>Develop recommendations for patient input into quality improvement</td>
<td>N= 30 aged 18 years and over who had experienced an adverse event</td>
<td>Lack of information was identified as preventing quality improvement</td>
<td>Limitations</td>
</tr>
<tr>
<td>2008</td>
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<td></td>
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<td>Four phases</td>
<td></td>
<td>Very small-scale study</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Development of quality improvement strategies</td>
<td></td>
<td>Hospital wide patient group different to 30 patients involved in interviews asked to validate themes from discovery interviews, along with clinicians and quality managers</td>
</tr>
<tr>
<td>Author</td>
<td>Setting</td>
<td>Intervention</td>
<td>Aims</td>
<td>Methods; participants</td>
<td>Outcome measures &amp; Results</td>
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<tr>
<td>Schoen et al 2005</td>
<td>Australia; Canada; Germany; New Zealand; United Kingdom</td>
<td>2005 Commonwealth Fund International Health Policy Survey</td>
<td>Focus on safety, coordination of care, access and chronic disease management</td>
<td>2250 adults aged 18 years and older who had rated their health as fair or poor; reported that they had a serious illness, injury or disability in last two years</td>
<td>None of the countries was ranked higher or lower across all dimensions of care examined</td>
<td>Poor communication and a failure to coordinate care, especially during interactions with medical staff New Zealand and United Kingdom scored lowest levels for patient engagement Poor</td>
</tr>
</tbody>
</table>
completed the survey  
communication during discharge, in particular with medications was scored low across all countries

Patients with complex care reported failures in their care, especially during discharge, when they saw multiple doctors

Likelihood of coordination failures increased significantly with the number of doctor’s patients saw
# Appendix 2 Patient experience with adverse events studies

<table>
<thead>
<tr>
<th>Author</th>
<th>Setting</th>
<th>Intervention</th>
<th>Aims</th>
<th>Methods; participates</th>
<th>Outcome measures &amp; Results</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>Agoritsas et al 2005</td>
<td>Hospital in Switzerland</td>
<td>Picker Patient Opinion Instrument</td>
<td>N=1433 patients discharged from hospital (response rate 94.4%) Estimate frequency of undesirable events reported by patients</td>
<td>Mailed patient survey Odds ratios and multiple liner regression model</td>
<td>50.6% reported at least 1 event Most frequent was phlebitis 11% Unavailable medical records 9.5% Failure to respect confidentiality 8.45% Hospital acquired infection 8.2%</td>
<td>Report of undesirable events strongly associated with unfavorable ratings of overall care Limitations Patients in Switzerland have a longer length of stay</td>
</tr>
<tr>
<td>Author</td>
<td>Setting</td>
<td>Intervention</td>
<td>Aims</td>
<td>Methods; participants</td>
<td>Outcome measures &amp; Results</td>
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<tr>
<td>Anhang et al 2014</td>
<td>United States of America</td>
<td>Articles that focused on CAHPS</td>
<td>To explore association between patient experience measures and other indicators of healthcare quality; Patient behaviour Clinical processes Clinical outcomes Efficiency safety</td>
<td>Systematic review of 34 articles</td>
<td>Positive association between patient experience &amp; patient adherence to treatment &amp; clinical outcomes No positive association between patient experience &amp; clinical processes</td>
<td>Well-developed patient experience measures should compliment measures of technical care to provide greater detail about the patient pathway where improvements can be made Limitations CAHPS tool</td>
</tr>
<tr>
<td>Author</td>
<td>Setting</td>
<td>Intervention</td>
<td>Aims</td>
<td>Methods</td>
<td>Outcome measures &amp; Results</td>
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<tr>
<td>Doyle et al 2013</td>
<td>United Kingdom</td>
<td>Systematic review</td>
<td>Explore links between patient experience and clinical safety and effectiveness outcomes</td>
<td>Systematic review of 55 studies</td>
<td>Outcome measures</td>
<td>Evidence supports case for inclusion of patient experience as one of central pillars of quality in</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Inclusion criteria</td>
<td>Broad range of patient safety and clinical effectiveness outcomes</td>
<td>Patient experience, patient safety &amp; clinical effectiveness are linked</td>
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<td>Studies that measured association between patients’ reporting their experience and patient safety and clinical effectiveness outcomes</td>
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<td>Results</td>
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<tr>
<td>Patient experience is consistently positively associated with patient safety and clinical effectiveness across wide range of disease areas, study designs, settings population groups and outcome measures.</td>
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<td>healthcare</td>
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<td>Limitations</td>
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<td>Publication bias</td>
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<td>Only included studies showing positive associations between patient experience variables and safety and clinical effectiveness outcomes</td>
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<tr>
<td>Author</td>
<td>Setting</td>
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<td>Aims</td>
<td>Methods; participants</td>
<td>Outcome measures &amp; Results</td>
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<tr>
<td>Evans et al 2006</td>
<td>Australia</td>
<td>Telephone interviews</td>
<td>Seek public opinion of the rate and severity of adverse events experienced in hospital and the perception of safety in hospitals, so that predictors of lack of safety could be identified</td>
<td>Multi staged cluster survey, involving interviews Descriptive analysis to determine adverse event rate Univariate analysis generalized liner model &amp; multivariate analysis to determine joint predictors of safety. P&lt;0.05 represent statistical significance Adults aged 18 years and over N= 2884 Response rate 67%</td>
<td>Perception of safety was affected by their experience of an adverse event</td>
<td>Limitations Survey represents self-reported experiences of an adverse event, using lay judgement Recall bias as using data based on participants recall</td>
</tr>
</tbody>
</table>
## Appendix 3 Patient characteristics

<table>
<thead>
<tr>
<th>Author</th>
<th>Setting</th>
<th>Intervention</th>
<th>Aims</th>
<th>Methods; participants</th>
<th>Outcome measures &amp; Results</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>Idemea et al 2012</td>
<td>United Kingdom</td>
<td>Semi-structured interviews</td>
<td>To understand what patients and families know about problems and failures in healthcare</td>
<td>Qualitative semi-structured open-ended interviews&lt;br&gt;N=39 patients&lt;br&gt;N=80 family members&lt;br&gt;19 interviews involved more than one respondent</td>
<td>Patients and families had considerable knowledge about health service risks and problems &amp; had insight into where can could be improved</td>
<td>Patients and family members need access to structured processes to enable helpful discussions with health care professionals</td>
</tr>
<tr>
<td>Author</td>
<td>Setting</td>
<td>Intervention</td>
<td>Aims</td>
<td>Methods; participants</td>
<td>Outcome measures &amp; Results</td>
<td>Limitations</td>
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<tr>
<td>Jeffs et al 2012</td>
<td>Canada</td>
<td>Semi-structured interviews</td>
<td>To explore patients and family members perspectives on how safety threats were detected and managed during transition of care from an acute hospital to complex continuing care</td>
<td>N= 15 patients</td>
<td>3 key themes</td>
<td>Limitations Small scale study Difficult to draw conclusions</td>
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<tr>
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<td></td>
<td>N= 7 family members</td>
<td>1) lacking information</td>
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<td>Semi-structured interviews</td>
<td>2) getting “funneled through” too soon</td>
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<td>Data analysis</td>
<td>3) difficulty adjusting to the shift from total care to almost self-care</td>
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<td>Directed content analysis</td>
<td>Limitations</td>
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<td></td>
<td>Small scale study</td>
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<td>Author</td>
<td>Setting</td>
<td>Intervention</td>
<td>Aims</td>
<td>Methods</td>
<td>Outcome measures &amp; Results</td>
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<tr>
<td>Rainey et al 2013</td>
<td>2 hospitals in United Kingdom</td>
<td>Interviews</td>
<td>To examine the experiences and views of patients and their relatives to determine potential involvement in promoting their own safety</td>
<td>Interviews conducted over 12-month period and content analysis identified key themes</td>
<td>The ability to speak up about concerns was influenced by the ability of patients; 1) to recognize changes in their clinical condition, 2) ability to self-monitor their care, 3) confidence and trust in healthcare professionals</td>
<td>Limitations: Small scale study, Difficult to draw conclusions</td>
</tr>
<tr>
<td>Author</td>
<td>Setting</td>
<td>Intervention</td>
<td>Aims</td>
<td>Methods; participants</td>
<td>Outcome measures &amp; Results</td>
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<tr>
<td>Rathert et al 2011a</td>
<td>United States of America</td>
<td>Qualitative group interviews</td>
<td>To explore acute care perceptions of patient safety</td>
<td>Group interviews, using followed by an interpretative analytical approach</td>
<td>3 themes identified; 1) communication 2) staffing issues 3) medication administration</td>
<td>Limitations Small scale study Difficult to draw conclusions</td>
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<td></td>
<td>Adults aged 18 and over who had a hospital stay of at least one night within previous 6 months, or were an immediate family member of a patient</td>
<td>N=39</td>
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<td>Patients are acutely aware of care that may pose a risk</td>
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</table>
## Appendix 4 Review of patient perceptions of safety measures studies

<table>
<thead>
<tr>
<th>Author (year)</th>
<th>Country/Setting</th>
<th>Purpose of study</th>
<th>Methods; participants</th>
<th>Data Analysis; tests for reliability &amp; validity</th>
<th>Outcomes</th>
<th>Limitations/ effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sorra et al 2012</td>
<td>United States 73 Acute hospitals</td>
<td>Analysis to examine potential relationships between 2 measures used by AHRQ measures of patient safety culture &amp; experience</td>
<td>Cross-sectional study 73 hospitals that submitted data to both 2008 hospital survey on Patient Safety Culture (Hospital SOPS) comparative database &amp; 2007 Consumer Assessment of Healthcare</td>
<td>Descriptive statistics Hospital SOPS percent positive scores from 2008 were compared with data from 2007 SOPS survey CAHPS scores percent positive scores were compared with 2007 survey</td>
<td>Descriptive statistics SOPS scores of hospitals included in analysis closely match statistics from 2008 comparative data CAHPS scores closely match statistics from 2007 comparative data Hospital SOPS 2008 database average % positive n= 519</td>
<td>Descriptive statistics Compared two sets of data from different time periods, different patient and staff groups, impacting on reliability of data Sample size</td>
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<tr>
<td>Hypothesis - 2 measures are positively related</td>
<td>Providers (CAHPS)</td>
<td>results</td>
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<tr>
<td>Bivariate correlations</td>
<td>CAHPS hospital 2007 database average percent positive n = 972</td>
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<tr>
<td>Calculated correlations between SOPS and CAHPS composite average score, hospital rating &amp; willingness to recommend hospital</td>
<td>Bivariate correlations</td>
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<tr>
<td>Association with lower SOPS composite scores</td>
<td>Larger hospitals r = 0.5, p&lt;0.05</td>
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<tr>
<td>Teaching hospitals r = 0.30, p &lt;0.05</td>
<td>Non-government owned r = 0.42, p&lt;0.05</td>
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<tr>
<td>Examination of covariates &amp; 3 CAHPS measures</td>
<td>Large teaching hospitals associated with lower CAHPS composite average</td>
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<tr>
<td>Small sample size n = 73 hospitals volunteered. Selection bias</td>
<td>Cross-sectional study – cannot illustrate causality</td>
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</tr>
<tr>
<td>Author (year)</td>
<td>Country/ Setting</td>
<td>Purpose of study</td>
<td>Methods; participants</td>
<td>Data Analysis tests for reliability &amp; validity</td>
<td>Outcomes</td>
<td>Limitations/ effectiveness</td>
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</tr>
<tr>
<td>Sorra et al 2012</td>
<td></td>
<td>Off the peg questionnaire or new tool</td>
<td>Bivariate correlations &amp; Multiple regression models</td>
<td>For each SOPS measure with CAHPS measure as dependent variables.</td>
<td>Hospital SOPS measures did not correlate with 2 single item CAHPS measures (hospital rating &amp; willingness to recommend)</td>
<td>Hospitals with higher SOPS scores have higher CAHPS scores - 12/15 SOPS measures were positively correlated</td>
</tr>
</tbody>
</table>
variables – Bed size & ownership

Standardized regression coefficients on same scale as coefficients allowing for comparison

9/12 statistically significant after controlling for hospital.
Positive standardised regression coefficients ranging from Beta = 0.25, to Beta = 0.38

with CAHPS composite average score

Correlation coefficients from $r = 0.30$ to $r = 0.47$.

Composite average score $r = 0.41$, p<0.01

Regression results
3 SOPS measures with largest significant coefficients are – continuous improvement, staffing, & teamwork within units

Positive regression suggests that these 9 predict a higher SOPS score is associated with a higher CAHPS composite
<table>
<thead>
<tr>
<th>Author (year)</th>
<th>Country/ Setting</th>
<th>Purpose of study</th>
<th>Methods; participants</th>
<th>Data Analysis</th>
<th>Outcomes</th>
<th>Limitations/ effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Giles et al 2013</td>
<td>Teaching hospital in North England United</td>
<td>Explore extent to which patients able to provide feedback about contributory</td>
<td>Cross-sectional study Purposive sampling from six units</td>
<td>Content analysis. YCFF used as coding framework Transcripts</td>
<td>Phase 1 13 domains identified by participants – communication, relationships with staff, PMOS</td>
<td>Small sample size &amp; study conducted in one hospital</td>
</tr>
<tr>
<td>Kingdom</td>
<td>factors represented in YCFF</td>
<td>New tool</td>
<td>Develop indicators for each contributory factor in form of questionnaire items</td>
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<td></td>
<td>3 pilot interviews conducted</td>
<td>Phase 1</td>
<td>Patient panel identified contributory factors from YCFF – 13 domains identified</td>
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<tr>
<td></td>
<td>Unstructured interviews n = 18. Narrative approach</td>
<td>Structured interviews n = 15</td>
<td>13 domains from YCFF</td>
<td></td>
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<tr>
<td></td>
<td>Interview transcripts used to</td>
<td></td>
<td>imported into NVivo 8 2 researchers coded comments</td>
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<td></td>
<td>Final PMOS tested for readability (Flesch Reading Ease 65.7 percent &amp; Flesch-Kincaid Grade level 6.9)</td>
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<td></td>
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<td></td>
<td>attitudes of staff New themes- dignity &amp; respect</td>
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<td></td>
<td>Phase 2 3 key areas of concern –</td>
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<td></td>
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<td>Negative statements presented a problem for patients n = 5</td>
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<td></td>
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<td>Unfamiliarity with terminology n = 2</td>
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<td>Patients unable to answer questions they had no experience of (no number given)</td>
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<td></td>
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<td></td>
<td>Useful diagnostic tool at ward level</td>
<td></td>
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<td></td>
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<td></td>
<td>YCFF – based on review of studies conducted with health professionals. Bias towards health professionals’ perceptions of safety. May not truly reflect views of patients</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Phase 2 No reference if patients from Phase 1 participated in Phase 2. Impact on test-retest reliability Cross-sectional study – cannot</td>
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</tr>
</tbody>
</table>

Note: YCFF = Young Carers Family Factors.
<p>| develop items for each domain in PMOS | Draft PMOS revised with research team &amp; patient panel to strengthen content validity | Phase 2 | Think aloud interviews following development of PMOS tool | Staff n = 12 | Patients n = 12 | illustrate causality |</p>
<table>
<thead>
<tr>
<th>Author (Year)</th>
<th>Setting/country</th>
<th>Purpose of study</th>
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<th>Outcomes</th>
<th>Limitations/ effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>McEachan et al 2014</td>
<td>Teaching hospital in North England United Kingdom</td>
<td>New tool To test reliability and validity of PMOS. Factor structure; internal reliability; test-retest reliability; discriminant validity and convergent validity assessed</td>
<td>2 cross-sectional surveys (one with patients and one with staff). Patients completed PMOS survey Staff completed AHRQ safety culture survey 10 wards 250 patients 212 staff</td>
<td>Factor analysis PCA on correlation matrices Kaiser's criterion determined number of factors to retain – loadings of 0.40 or above were retained Cronbach alpha scores of 0.7 and above</td>
<td>Test-retest results; items relating to delays did not show acceptable test-retest reliability. 3 factors significantly discriminated between the hospital units; staff roles and responsibilities; ward type and layout; and equipment. Significant differences between the wards within staff roles and responsibilities factor; the administration ward was shown to be</td>
<td>Some dimensions in PMOS failed to achieve recommended Cronbach alpha score of 0.7. PMOS positive index only related two of the AHRQ survey outcomes</td>
</tr>
<tr>
<td>determined good internal consistency of items</td>
<td>significantly worse, compared to the remaining 11 wards.</td>
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<tr>
<td>Test-retest reliability</td>
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<tr>
<td>Discriminant validity using MANOVA</td>
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<tr>
<td>Convergent validity of PMOS with AHRQ patient safety culture measure</td>
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<tr>
<td>Author (year)</td>
<td>Setting/Country</td>
<td>Purpose of study</td>
<td>Methods; participants</td>
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<td>Limitations/effectiveness</td>
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<tr>
<td>Wolosin et al 2006</td>
<td>Acute hospital setting United States of America</td>
<td>Measures came from Press Ganey Inpatient survey tool used on United States 4 questions What is the current status of patients' perceptions of their personal safety in US hospitals?</td>
<td>Cross-sectional study  Sampling frame  Inclusion criteria = adults patients aged 18 years and above  Gender 62 percent women  n = 637,894 patients  n = 495/500 hospitals</td>
<td>Internal consistency of survey tested by - Cronbach’s alpha for: each scale – 0.84 – 0.95 entire instrument – 0.98 Construct validity determined by factor analysis – 9</td>
<td>Response rate = 25 percent  Q1 Overall perceptions of personal safety  Ratings averaged 87.8 percent, SD 17.7  Q2 Variation by patient, hospitalization and hospital  Variation in safety ratings by age. Mean saving rating overall 90.1 2-way analysis of variance showed significant effects</td>
<td>Selection bias – participating hospitals interested in their patients' views of the care  No reference to develop of tool.  No reference to content validity - Process of identifying how items from</td>
</tr>
<tr>
<td>How do characteristics of patients, hospitalizations and hospitals influence perceived safety?</td>
<td>Analysis of safety rating data taken from Press Ganey Inpatient surveys processed in 2004</td>
<td></td>
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<tr>
<td>How does perceived safety relate to other patient satisfaction issues?</td>
<td>Analysis of safety rating data taken from Press Ganey Inpatient surveys processed in 2004</td>
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<tr>
<td>How can hospitals maximize patients’ perceptions of their safety?</td>
<td>Analysis of safety rating data taken from Press Ganey Inpatient surveys processed in 2004</td>
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</tbody>
</table>

29 items rated on a 5-point Likert scale

Surveys mailed to patients following discharge

Factors mirrored subsections of questionnaire

Convergent validity (average corrected item-scale correlations for each subsection) 0.62 – 0.86

Discriminant validity (items from each scale correlated with items from other scales) 0.40 – 0.59

Multiple on age, gender and their interaction p= 0.001

Patients provided information at admission felt safer, but this declined with increased length of stay

2-way analysis of variance showed patients without roommates (p = 0.001) felt significantly safer

Perceptions of safety negatively correlated (0.31 – 0.43) with hospital bed size and adjusted length of stay. Perceived safety ratings aggregated by hospital. Significant difference by hospital p = <.001 analysis of variance

Average safety rating

Press Ganey Inpatient Survey not clear.

Cross-sectional study – cannot illustrate causality

Multiple regression table not presented to illustrate the overall effect of the independent variables (e.g. gender, sex) on the dependent variables (e.g.
<table>
<thead>
<tr>
<th>Regression analysis - all items significant predictors of patients' reported likelihood to recommend the hospital</th>
<th>77 percent variance in measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flesch Kincaid Index applied.</td>
<td>88.1, SD 3</td>
</tr>
</tbody>
</table>

**Q3** Relationships with other satisfaction measures

Safety ratings correlated positively and highly with ratings of individual care and overall rating of care

Correlation coefficients >0.60

**Q4** How can hospitals maximize patients’ perceptions of safety/security?

Focus on communication safety practices

Patients’ perceptions of safety increases when more information is shared with them

4 questions)
<table>
<thead>
<tr>
<th>Author (year)</th>
<th>Setting/ Country</th>
<th>Purpose; off the peg questionnaire or new tool</th>
<th>Methods; participants</th>
<th>Data Analysis tests for reliability &amp; validity</th>
<th>Outcomes</th>
<th>Limitations/ effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rathert et al 2011b</td>
<td>3 hospitals United States of America</td>
<td>New tool Examine relationships among service quality, patient safety perceptions and patient satisfaction Hypothesis: there is a mediating role for patient safety perceptions</td>
<td>Cross-sectional study Sample Acute care patients with recent hospital stay within last 90 days Hospital 1 n = 486 Hospital 2 n = 279 Hospital 3 n = 231 Inclusion criteria: Aged 18 years</td>
<td>Multiple regression H 1 Service quality positively related to overall satisfaction Step 1 Age, length of stay&amp; health status control variables Step 2 service quality</td>
<td>Response rate 33 % Hospital 1 n = 496 36% Hospital 2 n = 279 30% Hospital 3 n = 231 32% Mean respondent age 64.14 (57 percent women, SD 17.47)</td>
<td>Characteristics of three hospitals not explained. Hospital 1 had a higher sample and response rate compared to the other 2 hospitals. Potential for selection bias Study focused on three key areas: service quality, patient satisfaction</td>
</tr>
</tbody>
</table>
Exclusion criteria:
Psychiatric patients, maternity, patients discharged to facility other than home.

Samples from each hospital compared with full sample frame. Proportionate on discharge unit, gender and age.

Conceptual framework – attribution theory.

<table>
<thead>
<tr>
<th>Questionnaire</th>
<th>H2 Service quality positively related to patient perceptions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Step 1 Age, length of stay &amp; health status control variables</td>
</tr>
<tr>
<td></td>
<td>Step 2 Safety perceptions</td>
</tr>
<tr>
<td></td>
<td>Cronbach alpha score given for each item in each key area</td>
</tr>
</tbody>
</table>

H2 R2 = 0.04
H3 R2 = 0.04

Service quality showed greater variance

H1 R2 = 0.34
H2 R2 = 0.40
H3 R2 = 0.25

H2 Service quality positively related to patient perceptions, therefore hypothesis supported

H1 R2 = 0.55
H2 R2 = 0.55
H3 R2 = 0.50

Authors acknowledge that other variable may influence patients' perceptions of safety.

Cross-sectional study – cannot illustrate causality.

Item generation

Cronbach alpha score stated for each key item, but
<table>
<thead>
<tr>
<th>design – focus on 3 key areas</th>
<th>Patient satisfaction</th>
<th>no evidence of application of factor analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient satisfaction</td>
<td>3 items with 5-point Likert scale developed by research consultants &amp; used regularly by the participating hospitals</td>
<td>Cronbach’s alpha 0.90 – 0.94</td>
</tr>
<tr>
<td><strong>Author (year)</strong></td>
<td><strong>Setting/Country</strong></td>
<td><strong>Purpose of study</strong></td>
</tr>
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</tr>
<tr>
<td>Rathert et al 2011b</td>
<td>United States of America</td>
<td>3 acute hospitals</td>
</tr>
<tr>
<td>Picker Patient Experience questionnaire</td>
<td>Step 2 Overall satisfaction</td>
<td>H4 Patient safety perceptions mediate between service quality and overall satisfaction. Hypothesis partially supported. Hospitals 2 &amp; 3 showed significance in relationship</td>
</tr>
<tr>
<td>----------------------------------------</td>
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</tr>
<tr>
<td>Content &amp; face validity with patient focus groups, then reviewed with healthcare professionals and academics</td>
<td>H4 Patient safety perceptions mediate between service quality and overall satisfaction</td>
<td>Weighting of service quality for each hospital affected the results. This is illustrated by the beta scoring.</td>
</tr>
<tr>
<td>Cronbach’s alpha 0.89 – 0.93</td>
<td>Step 1 satisfaction regressed onto equation in which control variable entered in step 1, service quality in step 2 &amp; safety</td>
<td>H1 beta = 0.591 - 0.182</td>
</tr>
<tr>
<td></td>
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<td>H1 R2 = 0.51 F (3,433) 148.66 p&lt;.001</td>
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<tr>
<td></td>
<td></td>
<td>H2 R2 = 0.58 F (3, 241) = 111.50 p&lt;.001</td>
</tr>
<tr>
<td>Author (year)</td>
<td>Setting/ Country</td>
<td>Purpose of study</td>
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<tr>
<td>Schwappach 2008</td>
<td>1 teaching hospital 860 beds 1 community hospital 170 beds Switzerland</td>
<td>New tool Develop &amp; pilot a brief patient safety survey applicable to inpatient care in Swiss hospitals To ask patients whether they had</td>
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<tr>
<td>experienced specific undesirable events during their hospital stay</td>
<td>validity</td>
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<tr>
<td>Phase 2 Pilot test Patient randomly selected from general and medical wards</td>
<td>frameworks conducted for each patient dependent on their responses in the questionnaire</td>
<td></td>
</tr>
<tr>
<td>Inclusion criteria: minimum of two days in hospital, ability to read and understand German</td>
<td>Event rate for uncertain 1.02 (CI percent 0.76 – 1.29)</td>
<td></td>
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<tr>
<td>N = 125</td>
<td>56 patients reported definitive and uncertain events</td>
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<tr>
<td>Phase 3 Sampled patients who returned survey and reported experience of an incident. Patients n =18 interviewed</td>
<td>Odds ratio increased with every additional day in hospital</td>
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<tr>
<td></td>
<td>OR = 1.03 95 percent CI 1.01 – 1.05, p = 0.012</td>
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<td></td>
<td>Patients who reported at least one definitive event were five times more likely to be concerned or seriously concerned about their safety</td>
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<tr>
<td></td>
<td>OR = 5.85 95 percent CI 2.39 – 14.30, p= 0.0001</td>
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<td></td>
<td>Communication reported by 37 percent patients who teaching hospital.</td>
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<tr>
<td></td>
<td>Distribution between two hospitals not made explicit</td>
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<tr>
<td></td>
<td>Cross-sectional study – cannot illustrate causality</td>
<td></td>
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<tr>
<td>by phone</td>
<td>reported a definitive event Phase 3 Concordance between interviewer classification of undesirable events – 18 events confirmed 9 events discarded 3 unclassified</td>
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<tr>
<td>Author (year)</td>
<td>Setting/ Country</td>
<td>Purpose of study</td>
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<tr>
<td>Schwappach, 2008</td>
<td>Switzerland</td>
<td>Patients' perceptions of the severity of an event were dependent on the actual outcome rather than the potential for harm.</td>
</tr>
<tr>
<td>Author (year)</td>
<td>Setting/Country</td>
<td>Purpose; off the peg questionnaire or new tool</td>
</tr>
<tr>
<td>--------------</td>
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</tr>
<tr>
<td>Sahlstrom M et al 2014</td>
<td>Finnish joint municipal health care &amp; social service authority Finland</td>
<td>New tool Design of a patient safety questionnaire to assess patients' experience of patient safety and its promotion through patient participation</td>
</tr>
</tbody>
</table>
participation in preventing errors, and related literature. Final questionnaire had 4 domains:

Treatment safety, device safety, medication safety, patient participation in promoting safety

Questionnaire developed by researchers

for subscales

Statistical package SPSS 17.0 for windows. Descriptive analysis of variables and statistical significance set at 0.05

Kolmogorov-Smirnov test showed (p <0.05) data were not normally distributed

Categories

(p=.035)

Ages between 51 -65 rated safety higher (m= 3.66)
Day surgery patient rated safety higher m = 3.64
Inpatient rating m = 3.41
Medication safety
Mean score 3.57
Significant differences in ages p= .008
Patients that had experienced errors p = .047
76 – 89 years m = 3.70
66 – 75 years m = 3.26
No report of medication errors regarded safety more positively m= 3.66
Report of medication errors m=3.43

Likert scale. Based on measuring patient safety culture from hospital staff’s perspective (AHRQ). Safety culture definitions are based on healthcare professionals’ perceptions of safety. This study is focused on measuring patients’ perceptions, thus leading to research bias on the statistical analysis of the tool.
<table>
<thead>
<tr>
<th></th>
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<th>totally agree and agree combined</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Totally disagree and disagree combined to achieve to achieve default chi-square test, assuming 20 percent of cells expected count of less than 5</td>
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</tbody>
</table>

Patients involved later stages of tools development. Potential for researcher bias. No reference to factor analysis application.
<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Sahlstrom M et al 2014</td>
<td>Finland</td>
<td>Device safety Experienced to be worst aspect of safety m = 3.32 ratings for device safety varied by gender p = .001 employment p = .012 men m= 3.66 viewed device safety more positively than women m = 3.07</td>
<td>Mean score calculated for each domain Mann-Whitney U and Kruskall-Wallis test used as data did not meet normal distribution assumptions Internal consistency assessed using</td>
<td>Results presented using mean scores. Statistical analysis of sample showed data not normally distributed. More appropriate to present using medium</td>
<td></td>
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</tbody>
</table>

Patient participation Rated most positive aspect of patient safety m = 3.62

Multiple regression table not presented to
Cronbach's alpha

Logistics regression model determined degree to which background variables explained patients' assessment of level of patient safety (odds ratio and 95 percent confidence intervals)

175 power calculation at 80 percent

Differences in clinical settings ($p < .001$)

- Experience of errors $p = .02$
- Day surgery patients rated patient participation more positively $m = 3.76$
- Patient treated in wards $m = 3.47$
- Patients who did not experience errors regarded patient participation more positively $m = 3.69$
- Patients who had experienced errors $m = 3.41$
- Patients who did not know they experienced errors $m = 3.61$

Kolmogorov-Smirnov test not referenced in statistical books. Difficult to interpret application and affect overall effect of the independent variables.
Appendix 5 Review of patient perceptions of safety measures studies April 2015 onwards

<table>
<thead>
<tr>
<th>Author (year)</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Lawton et al 2015</td>
<td>United Kingdom</td>
<td>To investigate; 1) whether the safety information provided by patients was different from that provided by staff 2) whether safety information related to safety</td>
<td>33 hospital wards in 5 acute hospital sites, across 3 hospital trusts Staff N= 648 Completed 4 outcome measures of AHRQ hospital survey of patient safety culture (HSOPC) Patients N= 822 Completed PMOS</td>
<td>Pearson correlations – to assess association between harm-free care score, PMOS and 4 patient safety outcomes from HSOPSC Correlation coefficients of 0.1 small; 0.3 moderate; 0.5 moderate to</td>
<td>Response rate; patients 80% &amp; staff 50% Skew and kurtosis values for variables below 1 Correlation of different measures of quality of care 1) Friends and family test score correlated with PMOS, not significantly with safety HSOPC &amp; safety thermometer 2) Perceptions of patient safety &amp; number of safety</td>
<td>Staff and patient perceptions of safety independently precipitated safety outcomes. Friends and family test significantly correlated with PMOS</td>
</tr>
<tr>
<td>outcomes</td>
<td>44 items</td>
<td>Items presented as statements on a 5-point Likert scale</td>
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<tr>
<td>Measures</td>
<td>2 measures of patient experience and safety – PMOS and Friends and Family test (using 6-point Likert scale)</td>
<td></td>
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<tr>
<td></td>
<td>1 measure of safety culture - AHRQ hospital survey of patient safety culture</td>
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<tr>
<td>Patient safety outcomes</td>
<td>NHS safety thermometer – data downloaded for participating wards</td>
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</tr>
</tbody>
</table>

| Large | Scatter plots – to assess if relationships between variables was linear and whether particular wards represented outliers. |
|       | Spearman’s rank correlations – to ensure patterns of findings were same if assumptions of linearity were not met |

| events reported significantly correlated with % of harm-free care (p<0.001) |
| 3) Negative correlation – as number of safety events reported by staff increased % of harm-free care decreased |
| 4) frequency of reporting events not associated with harm-free care |
| 5) no correlation between perceptions of safety, patient safety grade and PMOS score |
| 6) Number of events reported by staff did not show significant negative correlation – the more safety events reported by staff, lower the PMOS score (r=0.43) |
| 7) High correlations |

| Limitations | 50% target response rate from staff not achieved on some wards |
| Data collection period – 4 months | regressions – to assess predictive value of different measures of safety
MANOVA – to compare trusts across the 4 measures and to identify differences in safety scores | between HSOPSC patient safety grade and perceptions of safety (r=0.91) – two scales were measuring the same thing
Variations in scores between trusts
Friends and family test and HSOPSC outcomes measures did not differ significantly.
PMOS scores demonstrated significant difference |
<table>
<thead>
<tr>
<th>Author (year)</th>
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<th>Methods; participants</th>
<th>Data Analysis; tests for reliability &amp; validity</th>
<th>Outcomes</th>
<th>Limitations/ effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lawton et al 2017</td>
<td>United Kingdom</td>
<td>Evaluate efficacy of patient reporting and action for a safe environment intervention (PRASE)</td>
<td>Multicentre cluster randomised controlled trial Sample: 33 hospital wards within five hospitals PRASE Intervention: 1) PMOS tool 2) proforma for patients to report both safety concerns and positive experiences. PIRT tool ((patient incident reporting</td>
<td>Primary outcome measurements Routinely collected ward level harm free cares core and patient level feedback on safety</td>
<td>Reliability of PMOS was high at 6 &amp; 12 months (alpha &gt;0.9). Linear mixed model showed no significant difference between groups in overall PMOS at 12months. No significant difference in harm free care at 12 months between groups No difference between groups in relation to the ward recommendation to family and friends</td>
<td>Adherence to action plans was poor. Some wards routinely achieved high compliance with harm free care (&gt;90%). Achieving substantial improvement was not possible.</td>
</tr>
</tbody>
</table>
3) Feedback considered in multidisciplinary action planning

100%.

PMOS
Overall score calculated to at least 80% of items by averaging item scores

Secondary outcomes
1) 3 CQUIN questions measured in NHS Inpatient survey
2) NHS Friends and Family test question – How likely are you to recommend this ward to family and friends, if they
needed similar treatment

3) staff perceptions of safety culture using 4 outcome questions from HSOPS

Intervention

Patient feedback to each ward as part of multidisciplinary meeting.

Change cycles lasting 6 months during 12 month period

Data analysis

Ward level
<table>
<thead>
<tr>
<th>linear regression model for safety thermometer</th>
<th>CQUIN HSOPS Cronbach alpha for PMOS (&gt;0.7)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Author (year)</td>
<td>Country/ Setting</td>
<td>Purpose of study; off the peg questionnaire or new tool</td>
</tr>
<tr>
<td>--------------</td>
<td>------------------</td>
<td>----------------------------------------------------------</td>
</tr>
</tbody>
</table>
| O’Hara et al 2017 | United Kingdom | Not a safety measure tool  
Exploratory study of three mechanisms for collecting data on safety concerns from patients during their hospital stay;  
Face to face interviews  
Paper-based forms  
Telephone hot | Exploratory trial using cluster randomisation at ward level  
9 wards  
N=178 patients (response rate 41%)  
Co-design of three mechanisms  
Focus group of patients and focus group of health care staff | Thematic analysis to categorise safety concerns  
Covariance analysis  
Chi-square to explore differences between mechanisms in two categorical dependent variables  
1) likelihood of reporting | Patients in face-to-face interviews at the bedside significantly reported more safety concerns (p<0.01), compared with those using the paper-based form (p<0.01) and patients using the hotline mechanism (p<0.01).  
Significant association between the type of reporting and whether a patient reported one or more safety concerns (p<0.01).  
Patients who reported in face to face interviews 64% | No mechanism differed significantly in terms of  
1) number of reported safety concerns  
2) or preventability  
3) number of safety concerns across the 3 mechanisms |
| line | 2) number of patient reports | reported one or more safety concern.  
49% of all patients who reported a safety concern were in the face to face interviews.  
No statistical difference between the number of classified incidents, or physician-rated preventability. | Most data was collected from patients following discharge, leading to potential recall bias |
<table>
<thead>
<tr>
<th>Author (year)</th>
<th>Country/Setting</th>
<th>Purpose of study; off the peg questionnaire or new tool</th>
<th>Methods; participants</th>
<th>Data Analysis; tests for reliability &amp; validity</th>
<th>Outcomes</th>
<th>Limitations/ effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ricci-Cabello et al 2016</td>
<td>United Kingdom</td>
<td>New tool To develop and validate a patient reported instrument for measuring experiences and outcomes related to patient safety in primary care</td>
<td>Multi stage process Sample 6736 patients in 45 practices. 1244 completed questionnaires (18% response rate)</td>
<td>Item identification &amp; development Systematic review of instruments International expert panel Meta-analysis of qualitative studies 4 patient focus groups 18 cognitive interviews pilot study of tool</td>
<td>Acceptability – median item response rate 91.3% Reliability Internal consistency – Cronbach alpha 0.75% Test-retest reliability 0.7 Practice – level precision &amp; discrimination – low reliability coefficients (&lt;0.7) Validity Structural validity – confirmatory factor analysis provided high structural validity Construct validity</td>
<td>Large scale study, but low response rate Post hoc tests showed over representation of elderly and poly medicated patients Acceptability was low at 60% of participants Test-retest of some items achieved a low score e.g. due to lack of cases</td>
</tr>
</tbody>
</table>
(PREOS-PC) – Covered 5 domains in 11 scales
1) practice activation
2) patient activation
3) experiences of patient safety events
4) harm
5) general perceptions of patient safety

<table>
<thead>
<tr>
<th>Psychometric evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acceptability-evaluated through individual item response rates. Scales calculated as % of maximum score achievable on all items</td>
</tr>
<tr>
<td>Responses missing 50% or more of items in a scale reported as missing</td>
</tr>
<tr>
<td>Internal consistency acceptable where inter-item correlation</td>
</tr>
<tr>
<td>Pairwise correlations supported hypothesis</td>
</tr>
<tr>
<td>of harm</td>
</tr>
</tbody>
</table>
coefficients were at least 0.3 and Cronbach alpha at least 0.7.

Confirmatory factor analysis conducted to examine construct validity.

Discriminant validity tested by examining means of pre-specified group differences of users in line with hypotheses of differences of age, ethnicity, language, and country of
origin, number of long-term conditions and of medications)

Post hoc sensitivity analyses – to examine magnitude of potential response bias

Regression models to compare patient characteristics and scale scores between patients.
Appendix 6 Details of responses to questions and potential problems

<table>
<thead>
<tr>
<th>Question number</th>
<th>Original question</th>
<th>Participants’ answer</th>
<th>Potential problems</th>
<th>Amendments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Was your most recent hospital admission stay planned in advanced or an emergency?</td>
<td>All participants stated they answered the questionnaire based on this hospital experience.</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>2.</td>
<td>How many days have you been in hospital during this stay?</td>
<td>All participants said the question was clear and they answered it correctly</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Question number</td>
<td>Original question</td>
<td>Participants’ answer</td>
<td>Potential problems</td>
<td>Amendments</td>
</tr>
<tr>
<td>-----------------</td>
<td>------------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>3.</td>
<td>Overall comments about items in question.</td>
<td>All participants interpreted the question on what they had experienced during their whole pathway from A &amp; E to the ward. All participants said the fifteen items were important in making them feel safe. All participants rated items based on the care they experienced and how important it was in making them feel safe. Three participants also explained they gave ratings based on the care they witnessed being delivered to other patients.</td>
<td>The wording of the question is misleading. It is asking participants to rate items in order of their importance, whilst participants said they rated them based on their experience. Participants’ answers were not specific to a department but based on their whole patient pathway. One participant said that patients should be able to comment on each of the departments they experience during their hospital stay e.g. A &amp; E; ward, as their perception of how safe they feel is varies</td>
<td>1 participant stated rephrase as = rate items in order of your experience during this hospital stay</td>
</tr>
</tbody>
</table>
depending in which department they are in.
This makes it difficult for organisations to focus down on areas where improvements need to be made and also to acknowledge where safety focus is working well.

<table>
<thead>
<tr>
<th>Question number</th>
<th>Original question</th>
<th>Participants’ answer</th>
<th>Potential problems</th>
<th>Amendments</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.</td>
<td>If yes, please describe what that was? (feel safe)</td>
<td>3 participants did not answer this question, but 1 gave an example at interview; I was looked after very well in CDU. The staff regularly asked if I was comfortable. They brought me to the ward and the nurse handed</td>
<td>8 participants gave examples of what made them feel safe.</td>
<td>None</td>
</tr>
</tbody>
</table>
over to another nurse.

Comments written by other participants were:

“The doctor knew exactly needed to be done, after hearing why I visited. A plan was made with regards to blood tests, x-ray & CT scan. I was informed every step. Very professional.”

“I always felt safe.”

“The presence of security walking around made me feel safe. Also, the staff are very aware”.
<table>
<thead>
<tr>
<th>Question number</th>
<th>Original question</th>
<th>Participants’ answer</th>
<th>Potential problems</th>
<th>Amendments</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.</td>
<td>“I was transported on a trolley because I could not walk properly.”</td>
<td>I always feel in good hands when being admitted to King’s College Hospital”.</td>
<td>“Just knowing you were in safe hands and being treated with respect”.</td>
<td>“Plenty of staff on the ward, so always someone around to help”.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 participant who did not complete this section gave an example of what made them feel safe.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
“A doctor came to speak me and said the CT scan confirmed I did not have cancer. I felt very reassured.”

<table>
<thead>
<tr>
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<th>Original question</th>
<th>Participants’ answer</th>
<th>Potential problems</th>
<th>Amendments</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.</td>
<td>Was there any aspect of your care that you felt unsafe about during your time in hospital?</td>
<td>9 participants ticked no, but 2 participants gave examples of incidents, which made them feel unsafe when interviewed. “I had witnessed a patient attacking a nurse the night before. I was very worried about this. Also, the patient in the bed next to me kept calling out for the nurses and continuously ringing his bell”. “There was a patient in another bay with</td>
<td>Potential non-response</td>
<td>None. This question was kept based on the responses from two patients</td>
</tr>
</tbody>
</table>
challenging behaviour. The nurses should have pulled the curtains around this patient and close the doors to the bay so that other patients do not have to witness this”.

1 participant ticked yes and gave an example in question 7.

<table>
<thead>
<tr>
<th>Question number</th>
<th>Original question</th>
<th>Participants’ answer</th>
<th>Potential problems</th>
<th>Amendments</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.</td>
<td>If, yes, what was it that made you feel unsafe?</td>
<td>9 participants did not complete this question. 1 participant completed this question “Not knowing what medication, I was taking and when I was supposed to be taking it”.</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>
8. Did you inform a member of staff that you felt unsafe? All participants answered no Non-response. None. It was important to establish within the main study whether patients felt able to raise concerns.

<table>
<thead>
<tr>
<th>Question number</th>
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<th>Potential problems</th>
<th>Amendments</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.</td>
<td>How did staff respond?</td>
<td>1 participant wrote N/A 1 participant said, “I always feel safe”. 8 participants did not answer the question</td>
<td>Very low level of response</td>
<td>None. It was important to establish within the main study whether patients felt able to raise concerns.</td>
</tr>
<tr>
<td>10.</td>
<td>What could staff have done differently to make you feel safe?</td>
<td>4 participants answered this question Staff were friendly and helpful. I could not</td>
<td>None, as 4 participants answered.</td>
<td>None</td>
</tr>
<tr>
<td>Question number</td>
<td>Original question</td>
<td>Participants’ answer</td>
<td>Potential problems</td>
<td>Amendments</td>
</tr>
<tr>
<td>-----------------</td>
<td>------------------</td>
<td>----------------------</td>
<td>--------------------</td>
<td>------------</td>
</tr>
<tr>
<td>11.</td>
<td>Please can you say how safe you felt during stay at the hospital?</td>
<td>5 participants rated the hospital 10. 2 participants rated safety as 9 and gave the following reasons; “I could have put 10”. I rated the hospital 9 because of the issue with my medications There was a demented</td>
<td>Variation in responses. Participants rated lower scores based on an experience where they felt less safe.</td>
<td>The likert scale was reduced to a 6-scale rating to simplify responses.</td>
</tr>
</tbody>
</table>
patient calling out during the night. “The care is very good. Staff are very dedicated

3 participants rated the hospital as 8. 2 participants gave reasons for this

“I rated the hospital as 8 because of the incident last night with the patient attacking the nurse and the patient in the bed next to me”.

“I gave a rating of 8 because there were police in A & E and someone was in shackles. There were some drunk people, but security was always there”.
<table>
<thead>
<tr>
<th>Question number</th>
<th>Original question</th>
<th>Participants’ answer</th>
<th>Potential problems</th>
<th>Amendments</th>
</tr>
</thead>
<tbody>
<tr>
<td>12.</td>
<td>Are you male or female?</td>
<td>All participants said the question was easy to understand.</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>13.</td>
<td>What is your ethnic group? (Cross ONE box only)</td>
<td>All participants said the question was easy to understand.</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>
# Appendix 7 Eigenvalues

<table>
<thead>
<tr>
<th>Item</th>
<th>Eigenvalue</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>7.59</td>
</tr>
<tr>
<td>2</td>
<td>1.10</td>
</tr>
<tr>
<td>3</td>
<td>0.81</td>
</tr>
<tr>
<td>4</td>
<td>0.74</td>
</tr>
<tr>
<td>5</td>
<td>0.59</td>
</tr>
<tr>
<td>6</td>
<td>0.52</td>
</tr>
<tr>
<td>7</td>
<td>0.43</td>
</tr>
<tr>
<td>8</td>
<td>0.34</td>
</tr>
<tr>
<td>9</td>
<td>0.29</td>
</tr>
<tr>
<td>10</td>
<td>0.21</td>
</tr>
<tr>
<td>11</td>
<td>0.18</td>
</tr>
<tr>
<td>12</td>
<td>0.12</td>
</tr>
<tr>
<td>13</td>
<td>0.07</td>
</tr>
</tbody>
</table>
## Appendix 8: General linear model with bootstrap

<table>
<thead>
<tr>
<th>Parameter</th>
<th>General linear model</th>
<th>Bootstrap</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SE(β)</td>
<td>t</td>
</tr>
<tr>
<td>Intercept</td>
<td>0.61</td>
<td>7.77</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>-0.42</td>
<td>0.81</td>
</tr>
<tr>
<td>Female</td>
<td>-0.30</td>
<td>0.82</td>
</tr>
<tr>
<td>Missing data</td>
<td>0.00</td>
<td></td>
</tr>
<tr>
<td>IMD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Below 8.49 (Least deprived)</td>
<td>0.44</td>
<td>0.37</td>
</tr>
<tr>
<td>8.5-13.79</td>
<td>-0.08</td>
<td>0.35</td>
</tr>
<tr>
<td>13.8-21.35</td>
<td>0.20</td>
<td>0.25</td>
</tr>
<tr>
<td>21.36-34.17</td>
<td>0.25</td>
<td>0.21</td>
</tr>
<tr>
<td>Above 34.18 (Most deprived)</td>
<td>0.12</td>
<td>0.21</td>
</tr>
<tr>
<td>Missing/invalid postcode</td>
<td>0.00</td>
<td></td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White British</td>
<td>1.05</td>
<td>0.61</td>
</tr>
<tr>
<td>White other</td>
<td>0.96</td>
<td>0.65</td>
</tr>
<tr>
<td>BME</td>
<td>0.99</td>
<td>0.62</td>
</tr>
<tr>
<td>Missing data</td>
<td>0.00</td>
<td></td>
</tr>
<tr>
<td>Admission</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emergency</td>
<td>-0.29</td>
<td>0.26</td>
</tr>
<tr>
<td>Planned</td>
<td>0.00</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>0.00</td>
<td>0.004</td>
</tr>
<tr>
<td>Length of stay</td>
<td>0.00</td>
<td>0.003</td>
</tr>
</tbody>
</table>
Appendix 9 Health Research Authority Letter 11/09/15

11 September 2015

Mrs Jacqueline Sinclair
3rd Floor Hambledon Wing, Central Corridor Denmark Hill
London
SE5 9RS

Dear Mrs Sinclair

<table>
<thead>
<tr>
<th>Study title:</th>
<th>What are patients' perceptions of their safety within an acute hospital setting? A study to inform the development of a measurement questionnaire.</th>
</tr>
</thead>
<tbody>
<tr>
<td>REC reference:</td>
<td>15/EM/0434</td>
</tr>
<tr>
<td>IRAS project ID:</td>
<td>183244</td>
</tr>
</tbody>
</table>

Thank you for your application for ethical review, which was received on 09 September 2015. I can confirm that the application is valid and will be reviewed by the Proportionate Review Sub-Committee on 17 September 2015.

One of the REC members is appointed as the lead reviewer for each application reviewed by the Sub-Committee.
Please note that the lead reviewer may wish to contact you by phone or email between 14 September 2015 and 16 September 2015 to clarify any points that might be raised by members and assist the Sub-Committee in reaching a decision.

If you will not be available between these dates, you are welcome to nominate another key investigator or a representative of the study sponsor who would be able to respond to the lead reviewer’s queries on your behalf. If this is your preferred option, please identify this person to us and ensure we have their contact details.

You are not required to attend a meeting of the Proportionate Review Sub-Committee.

Please do not send any further documentation or revised documentation prior to the review unless requested.

**Documents received**

The documents to be reviewed are as follows:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRAS Checklist XML [Checklist_09092015]</td>
<td></td>
<td>09 September 2015</td>
</tr>
<tr>
<td>Non-validated questionnaire [Patient Questionnaire]</td>
<td>Version1.0</td>
<td>23 August 2015</td>
</tr>
<tr>
<td>Other [CV - David Foster]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participant consent form [Consent form. Version 1.0]</td>
<td>Version1.0</td>
<td>23 August 2015</td>
</tr>
</tbody>
</table>

15/EM/0434
No changes may be made to the application before the meeting. If you envisage that changes might be required, you are advised to withdraw the application and re-submit it.

**Notification of the Sub-Committee’s decision**

We aim to notify the outcome of the Sub-Committee review to you in writing within 10 working days from the date of receipt of a valid application.

If the Sub-Committee is unable to give an opinion because the application raises material ethical issues requiring further discussion at a full meeting of a Research Ethics Committee, your application will be referred for review to the next available meeting. We will contact you to explain the arrangements for further review and check they are convenient for you. You will be notified of the final decision within 60 days of the date on which we originally received your application. If the first available meeting date offered to you is not suitable, you may request review by another REC. In this case the 60 day clock would be stopped and restarted from the closing date for applications submitted to that REC.

**R&D approval**

All researchers and local research collaborators who intend to participate in this study at sites in the National Health Service (NHS) or Health and Social Care
(HSC) in Northern Ireland should apply to the R&D office for the relevant care organisation. A copy of the Site- Specific Information (SSI) Form should be included with the application for R&D approval. You should advise researchers and local collaborators accordingly.

The R&D approval process may take place at the same time as the ethical review. Final R&D approval will not be confirmed until after a favourable ethical opinion has been given by this Committee.

For guidance on applying for R&D approval, please contact the NHS R&D office at the lead site in the first instance. Further guidance resources for planning, setting up and conducting research in the NHS are listed at http://www.rdforum.nhs.uk. There is no requirement for separate Site-Specific Assessment as part of the ethical review of this research.

Communication with other bodies

All correspondence from the REC about the application will be copied to the research sponsor and to the R&D office. It will be your responsibility to ensure that other investigators, research collaborators and NHS care organisation(s) involved in the study are kept informed of the progress of the review, as necessary.

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

15/EM/0434

15/EM/0434 Please quote this number on all correspondence
Yours sincerely
Miss Vic Strutt REC Assistant
Email:
Copy to:
NRESCommittee.EastMidlands-LeicesterSouth@nhs.net
The Research Office, King's College Hospital NHS Foundation Trust

\[\text{Signature}\]
Appendix 10 Health Research Authority Letter 20/09/15

Health Research Authority

East Midlands - Northampton Research Ethics Committee
Royal Standard Place Nottingham NG1 6FS
Telephone: 0115 8839521

20 September 2015

Mrs Jacqueline Sinclair
3rd Floor Hambledon Wing, Central Corridor Denmark Hill
London
SE5 9RS

Dear Mrs Sinclair

<table>
<thead>
<tr>
<th>Study title:</th>
<th>What are patients' perceptions of their safety within an acute hospital setting? A study to inform the development of a measurement questionnaire.</th>
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<tbody>
<tr>
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</tr>
<tr>
<td>IRAS project ID:</td>
<td>183244</td>
</tr>
</tbody>
</table>

The Proportionate Review Sub-Committee of the East Midlands - Northampton Research Ethics Committee reviewed the above application on 17 September 2015.
**Provisional opinion**

The Sub-Committee would be content to give a favourable ethical opinion of the research, subject to clarification of the following issues and/or the following changes being made to the documentation for study participants:

The following changes to be made to the Participant Information Sheet


Add an independent complaints service contact details, PALS (or equivalent organisation)

Clarification on what the sentence ‘The findings will be presented to the hospital....’ Means

The Consent Form to follow the standard format, guidelines can be found at http://www.hra.nhs.uk/documents/2013/09/information-sheet-and-consent-form-guidance.pdf

When submitting a response to the Sub-Committee, the requested information should be electronically submitted from IRAS. A step-by-step guide on submitting your response to the REC provisional opinion is available on the HRA website using the following link: http://www.hra.nhs.uk/nhs-research-ethics-committee-rec-submitting-response-provisional-opinion/

Please submit revised documentation where appropriate underlining or otherwise highlighting the changes which have been made and giving revised version numbers and dates. You do not have to make any changes to the REC application form unless you have been specifically requested to do so by the REC.
15/EM/0434

Authority to consider your response and to confirm the final opinion on behalf of the Committee has been delegated to the Chair

Please contact Ms Vic Strutt, NRESCommittee.EastMidlands-LeicesterSouth@nhs.net if you need any further clarification or would find it helpful to discuss the changes required with the lead reviewer.

The Committee will confirm the final ethical opinion within 7 days of receiving a full response. A response should be submitted by no later than 20 October 2015.

Summary of discussion at the meeting

Informed consent process and the adequacy and completeness of participant information

The Committee commented the Participant Information Sheet did not follow the standard guidelines, and therefore headings are missing

No independent complaints service had been included in the Participant Information Sheet

The Committee queried what was meant by the sentence in the Participant Information Sheet, in section ‘What will be the benefits of carrying out the study’ stating The findings will be presented to the hospital....

The Committee noted the Participant Information Sheet did not cover ‘We cannot guarantee the study will benefit the participants’

The Committee commented on the Consent Form there was no sentence to state ‘I agree to take part’
The Committee agreed the standard format of the Consent Form should be followed.

Documents reviewed
The documents reviewed were:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
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<tr>
<td>Other [CV - David Foster]</td>
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<td>Participant consent form [Consent form. Version 1.0]</td>
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<td>REC Application Form [REC_Form_09092015]</td>
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<td>Version1.0</td>
<td>23 August 2015</td>
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<tr>
<td>Summary CV for supervisor (student research) [Prof. Jane Sandall CV]</td>
<td>Version 1</td>
<td>28 July 2015</td>
</tr>
</tbody>
</table>

Membership of the Committee

The members of the Committee who were present at the meeting are listed on the attached sheet.

15/EM/0434

Statement of compliance
The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

Yours sincerely
Ms Elizabeth Gibbons Chair
15/EM/0434 Please quote this number on all correspondence

Email:
Enclosures: Copy to:

NRESCommittee.EastMidlands-LeicesterSouth@nhs.net
List of names and professions of members who took part in the review
The Research Office, King's College Hospital NHS Foundation Trust

15/EM/0434
East Midlands - Northampton Research Ethics Committee Attendance at PRS Sub-Committee of the REC meeting on 17 September 2015

Committee Members: Also in attendance:

<table>
<thead>
<tr>
<th>Name</th>
<th>Profession</th>
<th>Present Notes</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mr John Aldridge</td>
<td>Retired Senior Lecturer in Nursing</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Mrs Jeanne-Anne Charly</td>
<td>Staff Nurse</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Ms Elizabeth Gibbons</td>
<td>Senior Research Scientist</td>
<td>Yes</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Position (or reason for attending)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Miss Victoria Strutt</td>
<td>REC Assistant</td>
</tr>
</tbody>
</table>
Dear Mrs Sinclair,

Study title: What are patients' perceptions of their safety within an acute hospital setting? A study to inform the development of a measurement questionnaire.

<table>
<thead>
<tr>
<th>REC reference:</th>
<th>15/EM/0434</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRAS project ID:</td>
<td>183244</td>
</tr>
</tbody>
</table>

Thank you for your letter of 19 October 2015, responding to the Proportionate Review Sub-Committee’s request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.
We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Rebecca Morledge, NRESCommittee.EastMidlands-LeicesterSouth@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

**Confirmation of ethical opinion**

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

**Conditions of the favourable opinion**

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

*Management permission (“R&D approval”) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at [http://www.rdforum.nhs.uk](http://www.rdforum.nhs.uk).*

Application System or at [http://www.rdforum.nhs.uk](http://www.rdforum.nhs.uk).
Where a NHS organisation’s role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation. Sponsors are not required to notify the Committee of approvals from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.
It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

**Ethical review of research sites**

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see “Conditions of the favourable opinion” above).

**Approved documents**
The documents reviewed and approved by the Committee are:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
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<td>Version1.0</td>
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<td>Other [CV - David Foster]</td>
<td></td>
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<tr>
<td>Participant information sheet (PIS) [and consent form]</td>
<td>1.2</td>
<td>22 October 2015</td>
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<td>09 September 2015</td>
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<tr>
<td>Research protocol or project proposal [Research proposal. Version 1.0]</td>
<td>Version1.0</td>
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<td>Summary CV for Chief Investigator (CI) [Jacqueline Sinclair CV]</td>
<td>Version:1.0</td>
<td>23 August 2015</td>
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<tr>
<td>Summary CV for supervisor (student research) [Prof. Jane Sandall CV]</td>
<td>Version 1</td>
<td>28 July 2015</td>
</tr>
</tbody>
</table>

**Statement of compliance**
The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements
The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known

please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance

We are pleased to welcome researchers and R & D staff at our NRES committee members’ training days – see details at http://www.hra.nhs.uk/hra-training/

15/EM/0434 Please quote this number on all correspondence
With the Committee’s best wishes for the success of this project. Yours sincerely,

Mr John Aldridge Chair

Email: NRESCommittee.EastMidlands-LeicesterSouth@nhs.net
Enclosures: “After ethical review – guidance for researchers”

Copy to: The Research Office, King’s College Hospital NHS Foundation Trust
20 November 2015
Mrs Jacqueline Sinclair
3rd Floor Hambledon Wing, Central Corridor
Denmark Hill
London
SE5 9RS

Dear Mrs Sinclair

Study title: What are patients' perceptions of their safety within an acute hospital setting? A study to inform the development of a measurement questionnaire.
REC reference: 15/EM/0434
Amendment number:
Amendment date: 18 November 2015
IRAS project ID: 183244

Thank you for your letter of 18 November 2015, notifying the Committee of the above amendment. The Committee does not consider this to be a “substantial amendment” as defined in the Standard Operating Procedures for Research
Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

**Documents received**
The documents received were as follows:

*Document Version Date*

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<thead>
<tr>
<th>Document</th>
<th>Version</th>
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<td>Participant consent form</td>
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**Statement of compliance**
The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

15/EM/0434: Please quote this number on all correspondence

Yours sincerely

George Martin

**REC Assistant**
Email: NRESCommittee.EastMidlands-LeicesterSouth@nhs.net

*Copy to: Sponsor - The Research Office, King's College Hospital NHS Foundation Trust*
Appendix 13 Health Research Authority Letter 30/03/16

Health Research Authority

East Midlands - Leicester South Research Ethics Committee
Royal Standard Place
Nottingham
NG1 6FS
Tel: 0115 8839521

30 March 2016

Mrs Jacqueline Sinclair
3rd Floor Hambledon Wing, Central Corridor Denmark Hill
London
SE5 9RS

Dear Mrs Sinclair

East Midlands - Leicester South Research Ethics Committee

Royal Standard Place Nottingham NG1 6FS

| Study title: | What are patients' perceptions of their safety within an acute hospital setting? A study to inform the development of a measurement questionnaire. |
| REC reference: | 15/EM/0434 |
| Amendment number: | |
| Amendment | 18 March 2016 |
The above amendment was reviewed on 29 March 2016 by the Sub-Committee in correspondence.

**Ethical opinion**

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

**Approved documents**

The documents reviewed and approved at the meeting were:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
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<td>Other [Questionnaire- version 1.2 Date-26.02.16]</td>
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<td>26 February 2016</td>
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</table>

**Membership of the Committee**
The members of the Committee who took part in the review are listed on the attached sheet.

**R&D approval**
All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

**Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members’ training days – see details at http://www.hra.nhs.uk/hra-training/

```
15/EM/0434: Please quote this number on all correspondence
```

Yours sincerely

**Mr John Aldridge Chair**

E-mail:

Enclosures: Copy to:

**NRESCommittee.EastMidlands-LeicesterSouth@nhs.net**

**List of names and professions of members who took part in the review**

**The Research Office, King's College Hospital NHS Foundation Trust**
East Midlands - Leicester South Research Ethics Committee Attendance at Sub-Committee of the REC meeting on 29 March 2016

Committee Members:

Also in attendance:

<table>
<thead>
<tr>
<th>Name</th>
<th>Profession</th>
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<td>Yes</td>
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<td>Senior Research Scientist</td>
<td>Yes</td>
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<tr>
<th>Name</th>
<th>Position (or reason for attending)</th>
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<tbody>
<tr>
<td>Mr George R. Martin</td>
<td></td>
</tr>
</tbody>
</table>
13 April 2016

Mrs Jacqueline Sinclair
3rd Floor Hambledon Wing, Central Corridor Denmark Hill
London
SE5 9RS

Dear Mrs Sinclair

Study title:

REC reference: Amendment number: Amendment date: IRAS project ID:

What are patients' perceptions of their safety within an acute hospital setting? A study to inform the development of a measurement questionnaire.
15/EM/0434

04 April 2016 183244
East Midlands - Leicester South Research Ethics Committee

Thank you for your letter of 04 April 2016, notifying the Committee of the above amendment.

The Committee does not consider this to be a “substantial amendment “as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

Documents received

The documents received were as follows:

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

Yours sincerely

Royal Standard Place Nottingham NG1 6FS

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<td>1.4</td>
<td>26 February 2016</td>
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</tbody>
</table>

15/EM/0434: Please quote this number on all correspondence
George R. Martin REC Assistant

Email: NRESCommittee.EastMidlands-LeicesterSouth@nhs.net

Copy to: R&D - The Research Office, King's College Hospital NHS Foundation Trust
Appendix 15 Trust Letter of Approval

19 April 2016

Research & Innovation Office
King’s College Hospital NHS Foundation Trust First Floor
161 Denmark Hill,
London, SE5 8EF
Direct tel: 020 3299 1980

www.kch.nhs.uk/research R&I central mailbox kch-tr.research@nhs.net

Mrs Jacqueline Sinclair
3rd Floor Hambledon Wing Central Corridor
Denmark Hill
London
SE5 9RS

Dear Mrs Jacqueline Sinclair

Research & Innovation Office

King’s College Hospital NHS Foundation Trust First Floor 161 Denmark Hill,
London, SE5 8EF

Direct tel: 020 3299 1980

www.kch.nhs.uk/research R&I central mailbox kch-tr.research@nhs.net
Study Title: Patients' perceptions of their safety within an acute hospital setting

Ethics ref 15/EM0434
Sponsor: King’s College Hospital Location: Denmark Hill
Study end date as per: 31/7/2017 Target Recruitment: 150
Protocol Version: V1.2

On behalf of King’s College Hospital NHS Foundation Trust, I am pleased to inform you that your project is approved and you may proceed.

The study has been registered as KCH16-061 Please quote this reference in any communications with the R&I Office regarding your project.

As a Trust we are required to meet the national NIHR 70 calendar day metric (valid submission to 1st patient recruited). I can confirm that at the date of R&I approval the clock is at 21 days therefore to achieve the metric you need to consent your first patient by 07-Jun-16

All approved documents are listed at the end of this letter. Please ensure that any amendments to the documents or changes to the study team are notified to the office.

Investigator Responsibilities:

You are expected to recruit to time and target. A condition of the approval is to notify the R&I Office (via the central mailbox) of the date on which you consent your first participant.

The approval is conditional on the project being conducted as described within the application. The project must follow the agreed protocol and be conducted
in accordance with all Trust Policies and Procedures – especially those relating to research and data management.

V5 December 2015

You must notify the office of all changes to the project, such as extension of study activity time at site, amendment to protocol, changes in study team and site closure. For all KCH sponsored/co-sponsored studies, yearly REC progress reports and the end of study report should be submitted to R&I.

You are responsible for ensuring that good research governance, conduct and practice, are maintained throughout the duration of the study.

The Trust maintains oversight of all active projects and you may be subject to review and audit at any point by internal or external bodies.

If the project is a clinical trial under the European Union (EU) Clinical Trials Directive the appropriate EU legislation must be complied with.

In accordance with National and Trust guidelines on safety reporting requirements, you must notify the Sponsor, the R&I Office (via the central mailbox) and submit an Adverse Incidence report on the Trusts’ Datix system for all SUSARS and suspected protocol breaches.

If appropriate it is recommended that you register with the Current Controlled Trials website; http://isrctn.org/

The R&I office will support you throughout the duration of your project. Please contact us at the address above if and when you require further information or guidance.

We wish you every success with your project. Yours sincerely,
Kirsty Hedditch Research Facilitator

**List of Approved Documents:**
Research Protocol v1.2
Participant information sheet & Consent Form v1.4
Questionnaire v1.2
Interview schedule v1;
Appendix 16 Patient Consent Letter Pilot Study

Version: 1.4; Date: 26.02.16

PATIENT INFORMATION SHEET

REC Reference Number: 15/EM/0434

Study Title: What are patients’ perceptions of their safety within an acute hospital setting?

We invite you to take part in this research study

Thank you for taking the time to read this information.

My name is Jacqueline Sinclair and I am a nurse studying for a Doctorate in Healthcare at King’s College, London. I would like to invite you to participate in my research by completing a pilot questionnaire. Following completion of the questionnaire I would like to ask you some questions about the questionnaire. This will help me to understand how easy the questionnaire is for patients to complete, and whether any changes need to made to make it simpler.

If you choose not to take part this will not disadvantage you in any way. Before you decide it is important for you to understand why the research is being done and what your participation will involve. Please take the time to read the
following information carefully and discuss it with others if you wish. Please contact me if there is anything that is not clear or if you would like more information.

The purpose of the study

• To understand what patients perceive safety to be when they are in hospital, and how they experience safety in hospital.

To develop and pilot a questionnaire based tool that can measure patient experience of safety from their perspective. The purpose of this is to help inform and drive safety improvements that are influenced by what is important to our patients.
Why have I been invited to take part?

You are eligible to take part in the study if you:

- Are aged 18 or over
- Have had a recent hospital admission

Do I have to take part in the study?

It is up to you to decide to join the study. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

What will happen to me if I agree to take part?

You are being asked to complete the questionnaire about your current hospital stay and to participate in a short interview.

Once this is done there will be no further involvement for you in this study. The questionnaire should only take approximately fifteen minutes to complete, and the interview no longer than thirty minutes.
How will information about me be kept confidential?

Your personal details including your name will not be recorded on the questionnaire, or interview record. The information you provide will remain confidential and will only been seen by myself, and my supervisors involved with the research. The completed questionnaire and interview record will be stored at the hospital in a locked filing cabinet. Once all the questionnaires have been analysed they will be destroyed.

The information you provide in the questionnaire and interview will be used to inform the design of the final questionnaire. Once you have completed the questionnaire please return this and the signed consent form in the envelope provided.
Are there any benefits for me in participating in the study?

Whilst there will be no immediate direct benefit to you should you decide to participate, the information you provide will help the hospital and staff to have a better understanding about what is important to our patients regarding their safety.

Are there any risks for me in participating in the study?

Whilst there are no identified risks to completing the questionnaire or participating in the interview, it is important to stress that your safety and wellbeing are paramount. If you have found it distressing completing the questionnaire, you can contact the hospital’s Patient Advisory Liaison Service, my academic supervisor, Professor Jane Sandall or myself.

What will happen to the results of this study?

The findings will be presented to the hospitals Patient Safety Committee.

Who is organising and funding the study?

I am self-funding this study.
**Who has approved the study?**

All research in the NHS is reviewed by an independent group of people in a Research Ethics Committee, which is there to protect your rights, wellbeing and dignity. This study has been reviewed and approved by Leicester South Research Ethics Committee.

**Who do I contact if I have any concerns?**

If you have any questions or require more information about this study, please contact me using the following contact details:

Email: Jacqueline.sinclair@kcl.ac.uk Telephone: 020 3299 37124

Jacqueline Sinclair, 3rd Floor Hambledon Wing, King’s College Hospital, Denmark Hill, London SE5 9RS.
Professor Jane Sandall (Academic Supervisor can be contacted if you do not wish to contact Jacqueline Sinclair)

Professor Jane Sandall, Professor of Social Science and Women's Health, Division of Women’s Health and Faculty of Life Sciences and Medicine, King’s College London, Women’s Health Academic Centre, St Thomas’ Hospital, London, SE1 7EH.

Patient Advisory Liaison Service

King’s College Hospital, Denmark Hill, London, SE5 9RS Telephone: 020 3299 3601
Email: kch-tr.pals@nhs.net

If you would like feedback on the study please tick the box ☐
CONSENT FORM FOR PARTICIPANTS IN RESEARCH STUDIES

Title of Project: What are patients' perceptions of their safety within an acute hospital setting?

Name of Researcher: Jacqueline Sinclair

1. I confirm that I have read and understand the information sheet dated: 10.01.16 (Version: 1.4) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

4. I agree to take part in the above study.
Name of Patient     Date     Signature

Name of Person      Date     Signature taking consent

When completed: 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.

Please tick or initial

______________________________________________
Appendix 17 Questionnaire for Pilot

Version : 1.2 Date: 26.02.16

PATIENT SAFETY QUESTIONNAIRE

Please place a tick inside one box using a black or blue ink pen. Don’t worry if you make a mistake. If you do make a mistake then simply fill in the box like so ☐. Then place a tick in the correct box ☐.

Please remember, this questionnaire is about your most recent stay at the hospital. Please do not write your name or address anywhere on the questionnaire.

MISSION TO HOSPITAL

Q1. Was your most recent hospital stay planned in advance or an emergency?

Emergency or urgent ☐ 1 Waiting list or planned in advance ☐ 2

Q2. How many days have you been in hospital during this stay?
YOUR HOSPITAL EXPERIENCE

Q3. Please rate each of the following items by inserting a number between 1 and 10 in each box in order of importance in making you feel safe.

1

10

LEAST IMPORTANT

MOST IMPORTANT
1. I was allocated a bed straightaway ☐

2. Staff listened carefully to what I had to say ☐

3. Staff explained things in a way I could understand ☐

4. I had confidence in the staff treating me ☐

5. Staff were consistent in what they said to me ☐

6. I could have a member of my family or close friend for support when I wanted them ☐

7. Staff were aware of my past medical history ☐

8. My consent was obtained before a test or an investigation ☐

9. Tests were carried out when staff said they would be ☐
10. There were always enough staff to care for me □

11. Staff were familiar with equipment □

12. Staff were familiar with procedures □

13. I was given information about my medication in a way I could understand □

14. My pain was well-controlled □ 15. My discharge was well planned □

Q4. Was there any specific aspect of your care that made you feel safe?
□ Yes 1 □ No 2

Q5. If yes, please describe what that was?

_______________________________________________________________

_______________________________________________________________

Q6. Was there any aspect of your care that you felt unsafe about during your time in hospital?

Yes □ 1 No □ 2
Q7. IF YES, what was it that made you feel unsafe?
_______________________________________________________________
_______________________________________________________________

Q8. Did you inform a member of staff that you felt unsafe?

☐ Yes 1 ☐ No 2

Q9. How did staff respond?
_______________________________________________________________
_______________________________________________________________
_______________________________________________________________

Q10. What could staff have done differently to make you feel safe?
_______________________________________________________________
_______________________________________________________________
_______________________________________________________________

_______________________________________________________________
Q11. OVERALL RATING OF HOSPITAL

Please can you say how safe you felt during your stay at the hospital?

Using a number from 1 to 10 where 1 is that you LEAST felt safe, to 10 is where you felt EXTREMELY safe all the time.

1 ☐ Least safe
2☐
3☐
4☐
5☐
6☐
7☐
8☐
9☐
10 ☐ Extremely safe
ABOUT YOU

Q12. Are you male or female?

Male ☐ 1 Female ☐ 2

Q13. What was your year of birth?

Q14. What is your ethnic group? (Cross ONE box only)

a. WHITE

☐ 1 English/Welsh/Scottish/Northern Irish/British
☐ 2 Irish
☐ 3 Any other white background, write in.....

b. MIXED/MULTIPLE ETHNIC GROUPS

☐ 4 White and Black Caribbean

☐ 5 White and Black African

☐ 6 Any other Mixed/multiple ethnic background, write in.....

c. ASIAN/ASIAN BRITISH

☐ 7 Indian
☐ 8 Pakistani
☐ 9 Bangladeshi
10 Chinese

11 Any other Asian ethnic background, write in.....

d. BLACK/AFRICAN/CARIBBEAN/BLACK BRITISH

12 African

13 Caribbean

14 Any other Black/African/Caribbean, write in....

e. OTHER ETHNIC GROUP

15 Arab

16 Any other ethnic group, write in....

Thank you for completing the questionnaire. Please place in the envelope and hand this into the ward staff.
Appendix 18 Patient Consent Letter Main Study

Version: 1.5 Date: 26.06.16

PATIENT INFORMATION SHEET

REC Reference Number:15/EM/0434

Study Title: What are patients’ perceptions of their safety within an acute hospital setting?

We invite you to take part in this research study

Thank you for taking the time to read this information.

My name is Jacqueline Sinclair and I am a nurse studying for a Doctorate in Healthcare at King’s College, London. I would like to invite you to participate in my research by completing a pilot questionnaire.

If you choose not to take part this will not disadvantage you in any way. Before you decide it is important for you to understand why the research is being done and what your participation will involve. Please take the time to read the following information carefully and discuss it with others if you wish. Please contact me if there is anything that is not clear or if you would like more information.
The purpose of the study

- To understand what patients perceive safety to be when they are in hospital, and how they experience safety in hospital.

To develop and pilot a questionnaire that can measure patient experience of safety from their perspective. The purpose of this is to help inform and drive safety improvements that are influenced by what is important to our patients.

Why have I been invited to take part?

You are eligible to take part in the study if you:

- Are aged 18 or over

- Have had a recent hospital admission

Do I have to take part in the study?
It is up to you to decide to join the study. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

What will happen to me if I agree to take part?

You are being asked to complete the questionnaire about your current hospital stay. Once this is done there will be no further involvement for you in this study. The questionnaire should only take approximately fifteen minutes to complete.

How will information about me be kept confidential?

Your personal details including your name will not be recorded on the questionnaire. The information you provide will remain confidential and will only been seen by myself, and my supervisors involved with the research. The completed questionnaire will be stored at the hospital in a locked filing cabinet. Once all the questionnaires have been analysed they will be destroyed.

The information you provide in the questionnaire will be used to inform the design of the final questionnaire. Once you have completed the questionnaire please return this and the signed consent form in the envelope provided.

Are there any benefits for me in participating in the study?
Whilst there will be no immediate direct benefit to you should you decide to participate, the information you provide will help the hospital and staff to have a better understanding about what is important to our patients regarding their safety.

**Are there any risks for me in participating in the study?**

Whilst there are no identified risks to completing the questionnaire it is important to stress that your safety and wellbeing are paramount. If you have found it distressing completing the questionnaire, you can contact the hospital’s Patient Advisory Liaison Service, my academic supervisor, Professor Jane Sandall or myself.

**What will happen to the results of this study?**

The findings will be presented to the hospital’s Patient Safety Committee. Who is organising and funding the study?
I am self-funding this study.

Who has approved the study?

All research in the NHS is reviewed by an independent group of people in a Research Ethics Committee, which is there to protect your rights, wellbeing and dignity. This study has been reviewed and approved by Leicester South Research Ethics Committee.

Who do I contact if I have any concerns?

If you have any questions or require more information about this study, please contact me using the following contact details:

Email: Jacqueline.sinclair@kcl.ac.uk Telephone: 020 3299 37124

Jacqueline Sinclair, 3rd Floor Hambledon Wing, King’s College Hospital, Denmark Hill, London SE5 9RS.

Professor Jane Sandall (Academic Supervisor can be contacted if you do not wish to contact Jacqueline Sinclair)
Professor Jane Sandall, Professor of Social Science and Women’s Health, Division of Women’s Health and Faculty of Life Sciences and Medicine, King’s College London, Women’s Health Academic Centre, St Thomas’ Hospital, London, SE1 7EH.

Patient Advisory Liaison Service

King’s College Hospital,
Denmark Hill, London, SE5 9RS
Telephone: 020 3299 3601
Email: kch-tr.pals@nhs.net

If you would like feedback on the study please tick the box ☐
CONSENT FORM FOR PARTICIPANTS IN RESEARCH STUDIES

Title of Project: What are patients’ perceptions of their safety within an acute hospital setting?

Name of Researcher: Jacqueline Sinclair

I confirm that I have read and understand the information sheet dated: 26.01.16 (Version: 1.4) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

I agree to take part in the above study.

Name of Patient            Date            Signature
<table>
<thead>
<tr>
<th>Name of Person</th>
<th>Date</th>
<th>Signature taking consent</th>
</tr>
</thead>
</table>

When completed: 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.

- Please tick or initial

[ ] [ ] [ ]

_________________________ __________________________

_________________________ __________________________
Appendix 19 Patient Questionnaire Main Study

Version: 1.3 Date: 26.06.16

PATIENT SAFETY QUESTIONNAIRE

Please place a tick inside one box using a black or blue ink pen. Don’t worry if you make a mistake. If you do make a mistake then simply fill in the box like so☐. Then place a tick in the correct box☐.

Please remember, this questionnaire is about your most recent stay at the hospital.

Please do not write your name or address anywhere on the questionnaire.

ADMISSION TO HOSPITAL

Q1. Was your most recent hospital stay planned in advanced or an emergency?

Emergency or urgent ☐ 1 Waiting list or planned in advance ☐ 2

Q2. How many days have you been in hospital during this stay?

_
YOUR HOSPITAL EXPERIENCE

Q3. Please rate each of the following items by inserting a number between 1 and 6 in each box based on the care you experienced in making you feel safe.

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I was allocated a bed straightaway</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Staff listened carefully to what I had to say</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Staff explained things in a way I could understand</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. I had confidence in the staff treating me</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Staff were consistent in what they said to me</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Version: 1.3 Date: 26.06.16
6. I could have a member of my family or close friend for support when I wanted them ☐

7. Staff were aware of my past medical history ☐

8. My permission was obtained before a test or an investigation ☐

9. Tests were carried out when staff said they would be ☐

10. There were always enough staff to care for me on this ward ☐

11. Staff were familiar with equipment ☐

12. Staff were familiar with procedures ☐

13. I was given information about my medication in a way I could understand ☐

14. I have been in pain during this hospital stay ☐ Yes 1

If yes, please go to question 15. If no, please go to question 16.
15. My pain was well-controlled

☐

16. My discharge plan has started

☐  Yes 1

If yes, please go to question 17. If no, please go the next page.

17. My discharge was well planned

☐

Q4. Was there any specific aspect of your care that made you feel safe?

☐  Yes 1  ☐  No 2

Q5. If yes, please describe what that was?

____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
Q6. Was there any aspect of your care that you felt unsafe about during your hospital stay?

Yes ☐ 1 No ☐ 2

Q7. IF YES, what was it that made you feel unsafe?
______________________________________________________________
______________________________________________________________
______________________________________________________________
______________________________________________________________
______________________________________________________________
______________________________________________________________
______________________________________________________________

Q8. Did you inform a member of staff that you felt unsafe?

☐ Yes 1 ☐ No 2

Q9. How did staff respond?
______________________________________________________________
______________________________________________________________
______________________________________________________________
Q10. What could staff have done differently to make you feel safe?

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

Q11. Please add any further comments that you wish to make about your stay.

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________
Q12. OVERALL RATING OF HOSPITAL
Please can you say how safe you felt during your stay at the hospital?

Using a number from 1 to 6 where 1 is the LEAST felt safe you felt, to 6 is where you felt VERY safe all the time.

1 □ Least safe
2 □ Moderately unsafe
3 □ Mildly unsafe
4 □ Mildly safe
5 □ Moderately safe
6 □ Very safe
ABOUT YOU

Q13. Are you male or female?

Male ☐ 1 Female ☐ 2

Q14. What was your year of birth?

Q15. What is your postcode?

Q16. What is your ethnic group? (Cross ONE box only)

a. WHITE

☐ 1 English/Welsh/Scottish/Northern Irish/British ☐ 2 Irish

☐ 3 Any other white background, write in.....

b. MIXED/MULTIPLE ETHNIC GROUPS

☐ 4 White and Black Caribbean

☐ 5 White and Black African

☐ 6 Any other Mixed/multiple ethnic background, write in.....
c. ASIAN/ASIAN BRITISH

☐ 7 Indian ☐ 8 Pakistani ☐ 9 Bangladeshi ☐ 10 Chinese
☐ 11 Any other Asian ethnic background, write in.....

d. BLACK/AFRICAN/CARIBBEAN/BLACK BRITISH

☐ 12 African
☐ 13 Caribbean
☐ 14 Any other Black/African/Caribbean, write in....

e. OTHER ETHNIC GROUP

☐ 15 Arab
☐ 16 Any other ethnic group, write in....

Thank you for completing the questionnaire. Please place in the envelope and hand this into the ward staff.