Putting the patient in patient safety: qualitative exploration and co-design of a new paradigm

A thesis presented for the degree of
Doctor of Philosophy (PhD)

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Abstract

There has been increasing interest in involving patients in patient safety. Whilst interventions have been introduced to support this, there are still barriers to patient involvement. Currently, there is a focus upon the clinical risk paradigm, where policymakers, academics and healthcare professionals define patient safety; however, evidence suggests that patients and healthcare professionals may conceptualise patient safety differently. This means that patient safety, as it is currently defined, may not be meaningful or accessible to patients. It is therefore necessary to understand, value and incorporate the patient perspective to support genuine patient involvement.

This thesis aims to explore and compare different stakeholder perspectives of patient safety using qualitative methods, and reconcile these in a new patient safety paradigm. Chapter 1 provides the background to patient safety and patient involvement, and addresses the rationale for the thesis. Chapter 2 details the qualitative methods to be used in this research. Chapter 3 presents a systematic review using meta-study methodology to synthesise the current qualitative evidence that explores patient and healthcare professional perceptions of patient safety. Chapters 4 and 5 use constructivist grounded theory to explore patient and healthcare professional perceptions of patient safety within acute medicine for the elderly, elective surgery and maternity, and develop explanatory theory for their conceptualisations of patient safety. Additionally, these chapters allow a comparison of healthcare professional and patient conceptualisations, as well as comparison to existing definitions and models for patient safety. Chapter 6 presents the results of a co-design workshop involving patients and healthcare professionals in elective surgery; this utilises the qualitative findings of the thesis to develop a practical product that, if implemented, will broaden the current patient safety paradigm by identifying, understanding and using the patient perspective. Finally, Chapter 7 discusses the implications of this research for patient safety policy and practice.

Declaration of Originality

I declare that the work in this thesis is my own and all else is referenced. Any contributions by others are acknowledged appropriately.

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When I first started this PhD, I saw it as a means to an end. However, reflecting back now that I am on the brink of submission, I can see the incredible opportunities, both professional and personal, that the last four years have afforded me. To this day, I am not sure why Professor Ara Darzi offered me a clinical research fellowship, but I will remain forever grateful to him for giving me a chance and for the doors he has opened for me.

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When you are undertaking research, you do not consider that it may one day become relevant to you. On his recent admission to hospital, my grandfather poignantly said he was happy to be there because ***he felt safe***. With this, as I near the end of this thesis, the importance and relevance of my work has become very real; indeed this has highlighted its necessity. I dedicate this work to Papa, one of my greatest supporters, who, if he can, will read this from cover to cover and return it with pencil corrections!

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Table of abbreviations

Abbreviation	**Definition**
USA	United States of America
NHS	National Health Service
UK	United Kingdom
NPSA	National Patient Safety Agency
NRLS	National Reporting Learning System
CQC	Care Quality Commission
WHO	World Health Organization
AHSN	Academic Health Sciences Network
HSIB	Healthcare Safety Investigation Branch
PMOS	Patient Measure of Safety
SPO model	Structure-process-outcome model
SEIPS model	Safety Engineering for Patient Safety model
NPSF	National Patient Safety Foundation
NIHR	National Institute for Health Research
CASP Tool	Critical skills appraisal programme tool
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-analyses
HMIC	Health Management Information Consortium
CINAHL	Cumulative Index to Nursing and Allied Health Literature
ICU	Intensive care unit
NICU	Neonatal intensive care unit
YCFF	Yorkshire Contributory Factors Framework
HCP	Healthcare professional
IPA	Intepretative Phenomenological Analysis
NRES	National Research Ethics Service
TPST	The Patient Safety Theory
TCPST	The Clinical Patient Safety Theory
CTG	Cardiotocograph
EBCD	Experience-based co-design
EBD	Experience-based design
NGT	Nominal group technique
PPI	Patient and public involvement
PDSA cycle	Plan-Do-Study-Act cycle
QIF	Quality implementation framework

Chapter 1: Putting the patient in patient safety

1.1 Introduction

Patient safety is a common goal for stakeholders in the NHS: patients expect healthcare to be safe and healthcare professionals strive to deliver this. The term 'patient safety' is becoming typical vocabulary for patients and healthcare professionals; this has been driven by developments in patient safety policy, as well as its emergence into the public domain through campaigns, communications, investigations and public inquiries. With this, there has been an increasing expectation for patients to be involved in patient safety and the safety of their care, with patient roles defined and interventions implemented to facilitate this.

Despite the term patient safety being widely used, its meaning may not be shared between the different stakeholders within healthcare. Indeed, current evidence suggests that patients and healthcare professionals may conceptualise patient safety differently. This means that whilst patients and healthcare professionals share a desire for patient safety, they may view the concept itself through different lenses.

Patient safety is strongly influenced by the clinical perspective; however, failure to recognise the concept through the patient lens poses some fundamental challenges. Firstly, it creates a potential mismatch between patient expectations of patient safety and their experiences of patient safety. Secondly, attempts to involve patients in patient safety use clinically defined means and patient safety activities; this makes patient involvement less accessible for patients if they do not share the same understanding of patient safety.

This thesis seeks to address the challenges that have arisen from situating the patient within a clinical paradigm of patient safety, whilst failing to recognise patients' conceptualisation of safety. In this first chapter, I will set out, in more detail, why this is worthy of study. Looking at the broader literature, I will describe the history of patient safety, the evolution of patient involvement in patient safety and the barriers to involving patients. I will then set out a case for understanding and acknowledging different conceptualisations of patient safety. In doing so, I will argue the need for a new paradigm for patient safety that identifies, understands and uses the perspectives of the patient, thereby truly putting the patient in patient safety.

1.2 History and evolution of patient safety

There are many definitions of patient safety; Vincent (2010) defined patient safety, at its simplest, to mean:

> *"The avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare (p31)."*

The errors and harms suffered by patients in hospital have been recognised and studied for over a century, with early examples including Ignaz Semmelweiss in the 1850s, who reduced mortality related to puerperal fever through the introduction of hand decontamination, Florence Nightingale in the 1860s who made observations about infection and sepsis in the 1860s, and Ernest Codman, a surgeon in Boston in the early 20th century, who was one of few clinicians to explicitly address error (Sharpe and Faden, 1998; Vincent, 2010). Despite these examples, it has taken a long time for medical error, patient harm and patient safety to become a widespread topic of interest, a specific discipline, and a focus for policy, research and funding.

Patient safety as a discipline was established in the 1980s. Rising rates of litigation in the United States of America (USA) led to the establishment of the Harvard Medical Practice Study; initially designed to assess the number of compensable cases in New York State, its ultimate legacy became to study quality and safety, and reveal the true extent of the harm to patients in hospitals (Brennan and Leape, 1991; Leape et al., 1991). It was Lucian Leape who finally confronted the high rates of error in healthcare, applying concepts of psychology and human factors to medical harm and error (Leape, 1994).

The publication of the seminal report *'To Err is Human'* by the Institute of Medicine

(Kohn et al., 1999) brought the issue of patient safety to the forefront, highlighting the scale and seriousness of harm to patients in hospitals. The earlier findings of Brennan and Leape, that between 44,000 and 98,000 people die in hospitals in the USA annually due to medical error, received massive publicity (Brennan and Leape, 1991).[1] Although it was this shocking headline which grabbed the attention of the public, the key message of the report was to set out recommendations to establish patient safety activities as a necessity (Kohn et al., 1999). Additionally, it provided a clear message to the layperson about the extent of harm in hospitals (Elwyn and Corrigan, 2005). The report has therefore often been viewed as the launch of the modern patient safety movement (Vincent, 2010) and, for the first time, patient safety entered the public domain.

1.2.1 Patient safety in the National Health Service

Following this, the National Health Service (NHS) in the United Kingdom (UK) responded to the call to establish patient safety activities. The report, *'An organisation with a memory: learning from adverse events,'* emphasised the need to learn, to understand underlying causes for adverse events, and to take the lead from other high risk industries (Department of Health, 2000; Vincent, 2010). A subsequent publication *'Building a safer NHS for patients: Implementing an organisation with a memory'* (Department of Health, 2001) outlined the UK government's plans for promoting patient safety and represented a commitment to implementing them in the NHS. These two publications ultimately served as catalysts for developments in patient safety in the UK, through the establishment of patient safety bodies, the development of policy and interventions, and the conduct of investigations and public inquiries; the key events are summarised in Table 1.1.

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[1] These figures were subsequently supported by case record reviews in the UK, demonstrating that over 10% of patients experience an adverse event whilst in hospital (Vincent et al., 2001).

Table 1.1: Key events in the history of patient safety

Year	**Event**	**Description**
2001	National Patient Safety Agency (NPSA) is established	The NPSA served to lead and contribute to improvements in and safety of care by informing, supporting and influencing the health sector. It was disbanded in 2012.
	The report from the Bristol Royal Infirmary Inquiry is published	The inquiry investigated concerns about the quality of paediatric cardiac surgery. It was noteworthy for openly scrutinising surgical performance, adopting systems approaches to analysis, and bringing error and healthcare professional fallibility into the public domain (Vincent, 2010).
2003	National Reporting and Learning System (NRLS) is established	The NRLS is a central database of patient safety incident reports. It is analysed to continuously improve the safety of patient care.
2004	The Health Foundation 'Safer Patients Initiative' is launched	This was the first major quality improvement programme in the UK focussing on organisation wide approaches to patient safety.
	'7 steps to Patient Safety' guide is launched by the NPSA	This guide presented evidence, examples and best practice for managing patient safety through seven core activities.
2004-2007	Healthcare Commission conducts 14 investigations into healthcare failures across the NHS	Created in 2004, the Healthcare Commission was responsible for assessing of care provided by the NHS. It was replaced by the Care Quality Commission (CQC) in 2009.
2008	The World Health Organization (WHO) launches the 'Safer Surgery Checklist'	This is a checklist, used worldwide and adapted for different surgical settings, which has been shown to significantly reduce both morbidity and mortality (Haynes et al., 2009).
2009	The Department of Health publishes its first list of 'never events'	Examples include: wrong site surgery, wrong implant/prosthesis, misplaced nasogastric tubes.
	The Care Quality Commission (CQC) is established	The CQC monitors, inspects and regulates services to make sure they meet fundamental standards of quality and safety; the results are publicly available and include performance ratings.
2013	A Public Inquiry into deaths at Mid Staffordshire NHS Trust is published by Sir Robert Francis	The report examined the causes of failings in care and made 290 recommendations, particularly outlining

	QC	a statutory duty of candour.
	The Keogh Report is published	This was a comprehensive review of NHS urgent and emergency care.
	The Berwick Report is published by The National Advisory Group on Safety of Patients in England	Led by Don Berwick, the report was commissioned in light of the Francis Inquiry to make zero harm a reality
	Charles Vincent proposes a new framework for measuring and monitoring safety in healthcare (Vincent et al., 2014)	The framework uses five dimensions to assess the safety of organisations: past harm, reliability, sensitivity, anticipation and preparedness, integration and learning.
2013-2015	The Morecambe Bay Inquiry is conducted	This inquiry examined the management, delivery and outcomes of maternity and neonatal care.
2014	15 'Patient Safety Collaboratives' are established	PSCs are led by England's Academic Health Sciences networks (AHSNs). They focus on supporting and facilitating improvement across the NHS.
	'Sign up to Safety' is launched by NHS England	'Sign up to Safety' is a national patient safety campaign with the mission to strengthen patient safety in the NHS. It aims to listen, learn and take action to improve patient safety.
2017	Healthcare Safety Investigation Branch (HSIB) is launched	HSIB is a team of safety investigators, funded by the Department of Health and hosted by NHS Improvement, but operating independently of them, CQC and NHS organisations.

Each of these events has had significant implications for patient safety as an emerging topic within the public domain. Communications and reports by bodies such as the Care Quality Commission (CQC) are publicly available, and include ratings on the quality and, specifically, safety of healthcare organisations. Heavily reported by the media (Campbell, 2010; Matthews, 2018), the concept of patient safety has been thrust before the public, and thus brought into everyday discourse.

1.2.2 Evolution of the patient role in patient safety

Following *'To Err is Human'* and the related developments in the UK, significant progress was made to improve safety in healthcare; the public emergence of this topic was also coupled with an explicit commitment to enhancing the patient role in patient safety. Steps were taken to ensure patients were more specifically involved in safety with the publication of *'Building a safer NHS for patients: implementing an organisation with memory'* (Department of Health, 2001), which explicitly highlighted the need to examine a clear role for patients in helping to promote and attain safety goals. This ultimately led to the development of the National Patient Safety Agency (NPSA), whose work at the time included promoting patient/public involvement in safety and producing publicity campaigns and other literature. Additionally, in a seminal paper that discussed patient safety and the patient role, Vincent and Coulter suggested that patients' central position makes them uniquely aware of error and able to provide new perspectives, and that by developing an active patient role, patients could help to ensure care is effective, appropriate and safe (Vincent and Coulter, 2002).

The subsequent sections will therefore address patient involvement (more broadly, as well as in relation to patient safety), the patient role in patient safety, the feasibility of patient involvement, interventions for involving patients in patient safety and, critically, the barriers to patient involvement.

1.3 What is patient involvement and why involve patients in patient safety?

Many terms are used interchangeably in relation to involvement (e.g. participation, engagement) and there is often a lack of consensus around the meaning of the term 'patient involvement' (Ocloo and Matthews, 2016). However, when considering involvement, I subscribe to the definition by INVOLVE who define it as an activity *"being carried out '**with**' or '**by**' members of the public rather than '**to**', '**about**' or '**for**' them"* (INVOLVE, 2012).

Patient involvement can relate to a range of different activities within healthcare including decision-making and research. Involving patients in decisions about their care is at the core of high quality care; it underpins health policy and the work of healthcare professionals (Holme, 2009; McDonald et al., 2013). Patient involvement has been shown to have beneficial effects upon processes and outcomes of care (Longtin et al., 2010; McDonald et al., 2013), with evidence for enhancing patient satisfaction and increasing the likelihood of positive organisational change (Crawford et al., 2002). A range of initiatives has been established within the NHS by the Department of Health to involve patients, in order to improve the quality of care. This has been triggered by failings in healthcare and high profile public inquiries; indeed, a legal duty to involve patients was established in the NHS Act 2006 (Ocloo and Fulop, 2011). It is therefore not surprising that patient involvement has also been applied to patient safety, with key documents outlining how patient involvement should be applied to the safety of healthcare (National Health Service Executive, 1999; Department of Health, 2006; Department of Health, 2009).

The justifications for involving patients in patient safety have been extrapolated by commentators from wider literature addressing patient involvement in healthcare more generally and are widely documented. Firstly, patients are motivated to be involved in order to achieve good outcomes and avoid harm (Barber, 2002; Lyons, 2007; Holme, 2009). Secondly, they are central to their care and the only witness to the entire care process, thus providing a complete picture of their journey (Barber, 2002; Vincent and Coulter, 2002; Lyons, 2007; Schwappach, 2010; Rathert et al., 2011a). Thirdly, they provide a different perspective on safety from that of healthcare professionals (Weissman et al., 2008). Given these justifications, it has been suggested that patient involvement in patient safety may prevent adverse events and harm (Institute of Medicine, 2001; Awe and Lin, 2003; Shaw et al., 2004; Bergeson and Dean, 2006; Coulter and Ellins, 2006; Howe, 2006; Rainey et al., 2015).

There is some limited evidence that safety improves when patients are involved with their care (Berwick, 2013) and that patient centred care is positively related to patient safety (Vincent and Coulter, 2002; Burroughs et al., 2007; Rathert and May, 2007; Rathert et al., 2011a). It has been postulated that the association between patient involvement and improvements in safety relates to heightened vigilance and effective communication, with identification of adverse events as, or even before, they happen (Weingart et al., 2011). A recent randomised controlled trial of an involvement intervention concluded that involvement by means of reporting and feedback was both feasible and acceptable and had the potential to be effective in reducing patient harm (Lawton et al., 2017). Whilst it seems reasonable to speculate that involving patients may prevent adverse events and harm (Longtin et al., 2010), few studies have fully addressed the evidence for involving patients in patient safety (McDonald et al., 2013) and clear evidence for patient involvement is lacking.

Nonetheless, patient involvement in patient safety has remained a key agenda for the NHS; there is a specific commitment to involving and engaging patients in safety within the Berwick Report (Berwick, 2013) and, more recently, a framework for patient involvement has been published in conjunction with the Sign up to Safety campaign (Sign up to Safety Patient Engagement in Patient Safety Group, 2016).

Having understood the background to patient involvement and why patients should be involved in safety, I will now explore the literature on how patients could be involved in patient safety, considering the specific roles for patients.

1.4 How could patients be involved in patient safety? The patient role in patient safety

The potential opportunities for patient involvement in patient safety are broad and widely discussed in the literature (Vincent et al., 2001; Vincent and Coulter, 2002; Peat et al., 2010; McDonald et al., 2013). Many potential patient roles have been identified, for example helping to reach an accurate diagnosis, choosing treatment/providers, reporting adverse events or incidents, or checking treatment (Vincent and Coulter). In 2010, a ten year review of the modern patient safety movement examined the progress of patient involvement in patient safety, noting the particular emergence of advocacy groups and a trend towards considering the role patients could have in preventing mistakes in real-time. This showed that the patient safety movement was developing a *"human face"* and involving patients; however, involvement was limited passive roles and did not include the far-reaching potential roles that had been identified (Wachter, 2010). This was similarly evidenced in a qualitative interview study where patients identified their role in patient safety as simply following instructions and considered themselves to be passive (Rathert et al., 2011a). This suggested that patients were possibly not willing and/or able to take on the spectrum of described roles.

In an evidence scan, The Health Foundation summarised the ways patients have been involved in patient safety (The Health Foundation, 2013). They categorised the main approaches as, (i) collecting retrospective feedback from patients (to use as tools for professionals or to directly guide improvement), (ii) asking patients to help plan broad service and (iii) encouraging patients to identify risks when receiving care.

These approaches are considered to exist along a continuum, ranging from the patient having a less active to a more active role; this is illustrated in Figure 1.1.

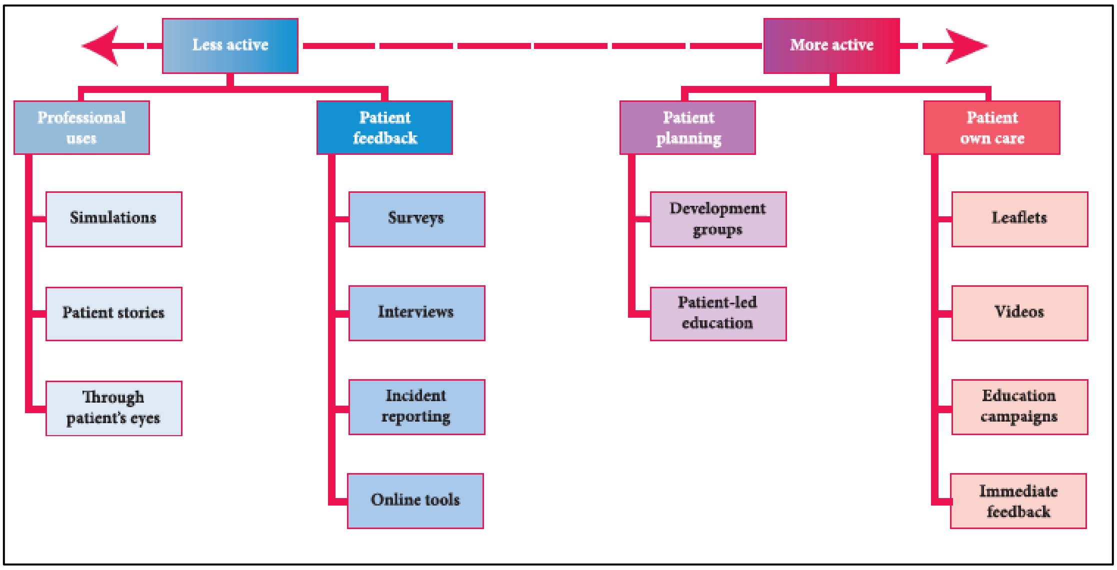
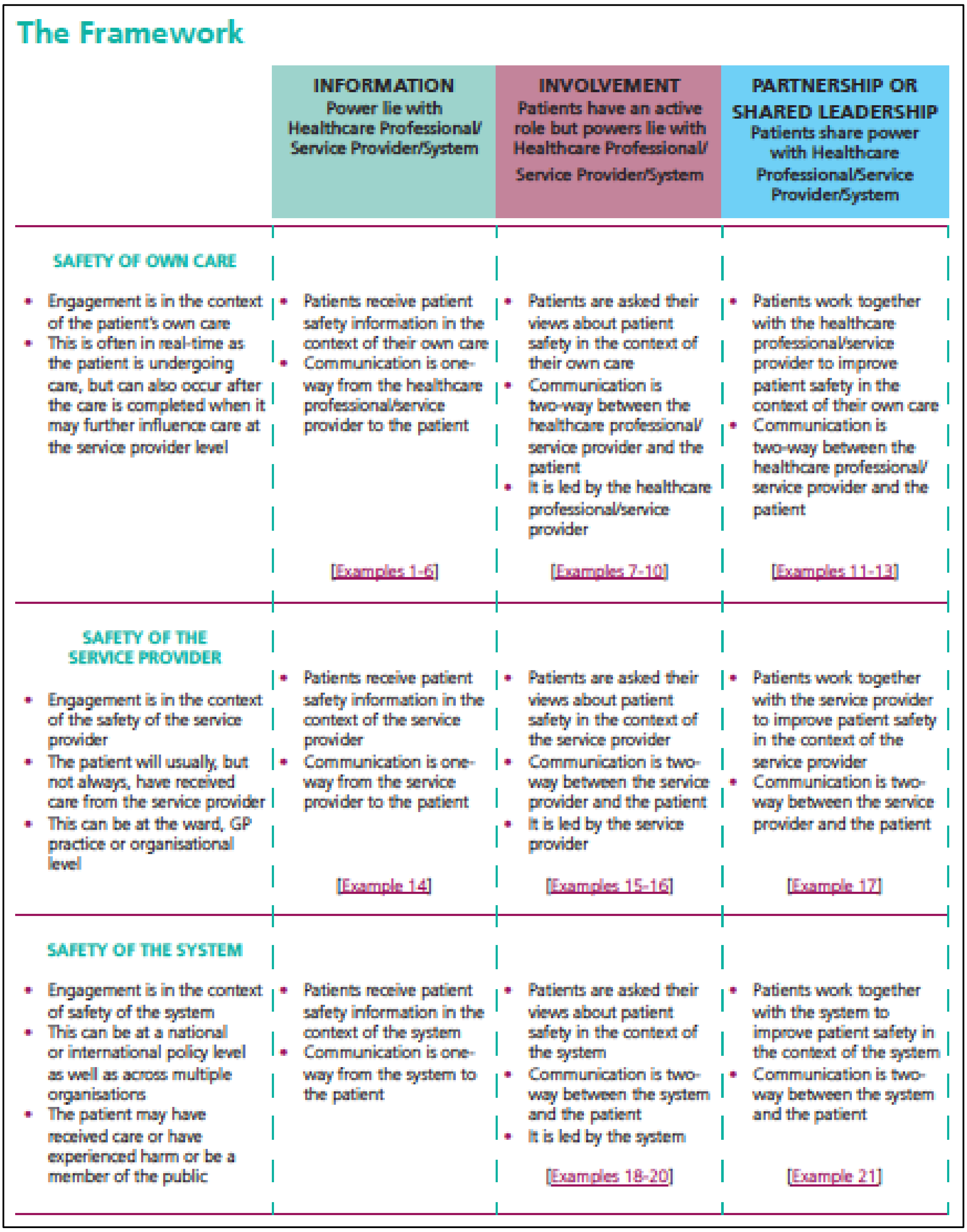


Figure 1.1: Spectrum of roles for patients in patient safety
(From The Health Foundation (2013))

It could be argued, however, that this representation of patient involvement is not sufficiently comprehensive; at the active end of the spectrum, there is inadequate representation of the roles previously discussed by Vincent and Coulter (2002). Sign up to Safety have more recently offered a more extensive framework for patient engagement in patient safety in the NHS, which describes roles at three levels of engagement (information, involvement, partnership or shared leadership) and three levels of the healthcare system (own care, service provider, system), shown in Figure 1.2.



The Framework

	INFORMATION Power lie with Healthcare Professional/ Service Provider/System	INVOLVEMENT Patients have an active role but powers lie with Healthcare Professional/ Service Provider/System	PARTNERSHIP OR SHARED LEADERSHIP Patients share power with Healthcare Professional/Service Provider/System
SAFETY OF OWN CARE • Engagement is in the context of the patient's own care • This is often in real-time as the patient is undergoing care, but can also occur after the care is completed when it may further influence care at the service provider level	• Patients receive patient safety information in the context of their own care • Communication is one-way from the healthcare professional/service provider to the patient [Examples 1-6]	• Patients are asked their views about patient safety in the context of their own care • Communication is two-way between the healthcare professional/ service provider and the patient • It is led by the healthcare professional/service provider [Examples 7-10]	• Patients work together with the healthcare professional/service provider to improve patient safety in the context of their own care • Communication is two-way between the healthcare professional/ service provider and the patient [Examples 11-13]
SAFETY OF THE SERVICE PROVIDER • Engagement is in the context of the safety of the service provider • The patient will usually, but not always, have received care from the service provider • This can be at the ward, GP practice or organisational level	• Patients receive patient safety information in the context of the service provider • Communication is one-way from the service provider to the patient [Example 14]	• Patients are asked their views about patient safety in the context of the service provider • Communication is two-way between the service provider and the patient • It is led by the service provider [Examples 15-16]	• Patients work together with the service provider to improve patient safety in the context of the service provider • Communication is two-way between the service provider and the patient [Example 17]
SAFETY OF THE SYSTEM • Engagement is in the context of safety of the system • This can be at a national or international policy level as well as across multiple organisations • The patient may have received care or have experienced harm or be a member of the public	• Patients receive patient safety information in the context of the system • Communication is one-way from the system to the patient	• Patients are asked their views about patient safety in the context of the system • Communication is two-way between the system and the patient • It is led by the system [Examples 18-20]	• Patients work together with the system to improve patient safety in the context of the system • Communication is two-way between the system and the patient [Example 21]

Figure 1.2: Patient Engagement in Patient Safety – A Framework for the NHS

(Sign up to Safety Patient Engagement in Patient Safety Group, 2016)

This more comprehensively represents the extensive range of roles patients may have in patient safety within the NHS. This may represent more recent move towards acknowledging patient inclusion in patient safety. This suggests that, overall, patient safety policy is moving in the right direction towards more meaningfully involving patient in patient safety. It is unclear, though, to what extent patients are actually involved in patient safety. In the next section, I will explore the literature that considers the feasibility of patient involvement in patient safety, and, particularly, the acceptability, willingness and ability of patients to be involved.

1.5 Is patient involvement in patient safety feasible?

Having established why and how patients could be involved in patient safety, it is necessary to consider whether it is feasible. A range of factors including interest, motivation, willingness, capacity and ability have an impact on whether patients involve themselves in patient safety (Howe, 2006). In this section I particularly explore whether patients are willing and/or able to take on the suggested patient roles.

Patient involvement in patient safety assumes that patients are ready to have a role in error prevention (Longtin et al., 2010). Patients have been identified as highly motivated to reduce risk and improve outcomes (Barber, 2002; Lyons, 2007; Holme, 2009) and studies have shown that patients are willing to engage in safety behaviours (Davis et al., 2008; Davis et al., 2011). It has been shown through systematic review that patients share positive attitudes about engaging in their safety and supporting general educational campaigns (Schwappach, 2010). An exploratory quantitative questionnaire study showed that patients support the idea of patient involvement in medication safety (Mohsin-Shaikh et al., 2014). Patients view involvement positively; they welcome the opportunity to ask questions and have their questions addressed as this provides reassurance and understanding of what is happening in their care (Hrisos and Thomson, 2013).

There is, however, evidence of a disparity between willingness and subsequent engagement with safety behaviours; patients are influenced by the type of safety behaviour, the role of healthcare staff with which they are interacting, and whether they are encouraged to engage (Schwappach, 2010; Davis et al., 2011). Patients report concerns about the methods of involvement and dislike actions that check or challenge healthcare professionals; they feel this questions or criticises the professional integrity of staff and portrays them as ‘bad’ patients, and consequently potentially compromising their quality of care (Hrisos and Thomson, 2013). For example, in a survey study, 84 percent of patients reported that they would be comfortable asking a nurse to verify patient identity, but only 45 percent comfortable asking a nurse if they had washed their hands (Waterman et al., 2006). Interestingly, even healthcare professionals in the patient role demonstrate similar reluctance at engaging in safety behaviours (Davis et al., 2012c); particularly, physicians reported they would be less willing to engage in asking challenging questions to other physicians or notifying them of problems in their care, despite reporting willingness to support patients in these behaviours.

Considering their ability to be involved in patient safety, patients believe that they could have a role and are able to prevent adverse events. In a questionnaire survey, 91 percent of patients thought they could prevent medical error and 98 percent believed they should be educated by hospitals to do so (Waterman et al., 2006). A systematic review of hospital-based patient reporting showed that patients have the ability to report on safety events in hospital (Ward and Armitage, 2012). In a similar way, in developing the Patient Measure of Safety (PMOS) in hospital and primary care settings, it was shown that patients are able to identify factors considered to be contributing factors to safety incidents (as described by the Yorkshire Contributory Factors Framework (Lawton et al., 2012)) (Giles et al., 2013; Hernan et al., 2016). Additionally, patient views on care have been shown to correlate with patient safety outcomes, as measured by percentage harm-free care; furthermore, patients offer a unique perspective on patient safety, distinct from that of staff (Lawton et al., 2015).

Patients have also been shown to report events that healthcare professionals would consider insignificant (Ward and Armitage, 2012). In structured interviews, ambulatory oncology patients were asked if they had experienced a recent unsafe episode in their care; of 193 patients, 83 reported a total of 121 incidents, but only 20 of these were considered adverse events, close calls or errors, and 101 (52 percent) were instead identified as lapses in service quality (Weingart et al., 2007). It was concluded that this means that patients may be able to offer valuable insights for promoting safety, but would require specific questioning or guidance to identify events considered to be of clinical importance (Ward and Armitage, 2012). O'Hara et al. (2018) similarly recognised a lack of progress in using patient feedback in patient safety because the information they provide does not fit within our professionally developed systems for safety and risk.

Overall, this demonstrates to an extent that patients are willing and able to have roles and be involved in patient safety. This, however, does not appear to translate into clinical and patient safety practice. It has been remarked, *"the most remarkable feature [of the safety movement] is surely the lack of attention paid to the patient"* (Vincent and Coulter, 2002). Plans for improving safety often ignore the patient perspective and patients are often viewed as merely *"passive victims"* (Vincent, 2010), when patients should be viewed as a source of expertise and experience, with an active role, as partners or co-producers (Vincent and Coulter, 2002). This suggests that there are barriers to patient involvement.

1.6 What are the barriers to patient involvement in patient safety?

There are multiple barriers to patient involvement in patient safety. These have been broadly grouped as patient factors, staff factors, patient-professional relationship factors, organisational factors and other factors. Each of these will be discussed in turn.

1.6.1 Patient factors

Socio-demographic characteristics are a fundamental barrier to patient involvement in patient safety (Vincent and Coulter, 2002; Longtin et al., 2010; Davis et al., 2011; Davis et al., 2012b; Doherty and Stavropoulou, 2012; Ocloo and Matthews, 2016). Issues such as inequality, discrimination and social exclusion have been cited as key barriers to patient involvement (Ocloo and Matthews, 2016). Many groups are purposefully or inadvertently excluded from involvement on the basis of equality and discrimination (e.g. gender, ethnicity, culture, belief, sexuality, age, disability, class), of where people live (e.g. homeless, residential homes, prison, travellers), of communication issues (e.g. deaf, blind, non-verbal, non-English speakers), of unwanted voices or of poor health literacy. As an example, Davis et al. (2011) found that patients were more likely to be involved in patient safety behaviours if they were female, educated and employed.

Cognitive characteristics can be a barrier to involvement; these include the patient's temperament (Vincent and Coulter, 2002), their confidence (Longtin et al., 2010) and their perception of self. In particular, patients often view themselves as subordinate (Doherty and Stavropoulou, 2012) or mere objects in care (Bishop and Macdonald, 2014), meaning they do not feel entitled to be involved. Additionally, their own perceptions around levels of harm, the relative importance of speaking up, and the likelihood of their involvement making a difference, reduces the likelihood of their involvement (Schwappach and Wernli, 2010b; Schwappach and Wernli, 2010a).

Health literacy is a barrier, as patients need sufficient knowledge and health literacy in order to be involved. Patients found it difficult to be involved and address complex issues if they lacked knowledge about their care or medical information/knowledge more generally (Vincent and Coulter, 2002; Howe, 2006; Longtin et al., 2010; Bishop and Macdonald, 2014) or if they lacked experience of or beliefs about different types of error (Peat et al., 2010).

Finally, a patient's health status is also a barrier to involvement. Their ability to be involved depends upon disease characteristics (Davis et al., 2012a), illness severity including pain (Howe, 2006; Schwappach and Wernli, 2011; Doherty and Stavropoulou, 2012), co-morbidity (Longtin et al., 2010) and various psychological components to ill health include vulnerability, powerlessness and feelings of humiliation (Howe, 2006).

Overall, individual patient characteristics vary considerably. It must be recognised that there are many different factors, which may pose a barrier to patient involvement in patient safety. Because of this, the preventative role of the patient in error and harm must be met with caution due to variations in patient capacity to participate, particularly to avoid disadvantaging those who cannot or will not be involved; even where patients have the ability to be involved, caution must be exercised to avoid shifting responsibility to the patient and to also avoid provoking guilt and blame upon a patient if an error occurred nonetheless (Wachter, 2010).

1.6.2 Staff factors

From the healthcare professional perspective, patient involvement is generally viewed positively, but support varies between types of safety behaviour and there is disparity between perceived importance and willingness to accept or promote such behaviours (Davis et al., 2012c). Staff welcome patient questions as it demonstrates they have an interest in their care; they also note that 'speaking up' behaviour can identify and fix potential problems early on (Hrisos and Thomson, 2013). There is, however, a degree of resistance from healthcare professionals (Ocloo and Matthews, 2016), with the existence of professional defensiveness or a cultural barrier to patient involvement in patient safety (Howe, 2006). This relates to fear from staff about the potential negative impact of detailed open discussion and inquiry into patient safety, both for the staff members (removing professional protection and confidentiality from error) and for patients (in terms of undermining their trust in healthcare professionals (Howe, 2006; Vincent, 2010). Additionally, staff are under time pressures which limit their ability to engage with, and involve patients in, patient safety (Schwappach et al., 2011).

1.6.3 Patient-professional relationship factors

Ability and willingness to be involved in safety is affected by aspects of the patient-professional relationship, including the quality of patient professional interaction, the way staff behave and relate to patients, and the anticipated response from staff to patient involvement in patient safety. Patients are more likely to be involved if healthcare professionals are responsive, interested and approachable, if they take time to listen, offer clear, simple, open and honest interactions, establish good communication and form human connections with patients (Howe, 2006; Entwistle et al., 2010; Hovey et al., 2010; Bishop and Macdonald, 2014; De Brun et al., 2016).

Alternatively, patients would avoid involvement in patient safety because of fear of its impact on the patient-professional relationship or on the quality of care (Entwistle et al., 2010; De Brun et al., 2016); for example, patients have a fear of asking questions in case staff are too busy or they cause offence (Bishop and Macdonald, 2014). This is strongly related to issues of power and trust within the patient-professional relationship. Where patients have an assumed trust in staff and the safety of care, they do not want to undermine this (Hovey et al., 2010; Pittet et al., 2011; Rathert et al., 2011a; Rathert et al., 2011b). Historical paternalism and hierarchy still remains (Howe, 2006), along with the associated power imbalances this creates (Pickard et al., 2002; Howe, 2006; Doherty and Stavropoulou, 2012; McDonald et al., 2013); these imbalances in power are a barrier to patient involvement. Patient involvement challenges the power play in the acute care paradigm where patients usually hand over control (Rathert et al., 2011a; Rathert et al., 2011b). Patients are therefore more likely to be involved if safety behaviours are compatible with the traditional patient-professional relationship (Schwappach and Wernli, 2010b). In order to counter this, changes would be required in the patient-healthcare professional relationship to break down these power barriers and enhance patient involvement.

From the healthcare professional perspective, in a vignette study, staff generally approved of patient involvement even if it impacted the professional-patient relationship and regardless of how the situation made them feel personally; however, they did perceive potentially negative effects on the provider-patient relationship (Schwappach et al., 2013). Professionals felt that the various patient involvement in safety behaviours could be seen as critical, anxiety provoking, challenging of professional integrity, burdensome on time/workload, and ultimately damaging of the trust within the professional-patient relationship (Hrisos and Thomson, 2013). Overall, different factors within the patient-professional relationship can be both barriers and facilitators to patient involvement in patient safety.

1.6.4 Organisational factors

Organisational factors also act as barriers to involving patients in patient safety. Shortage of resources, limits on the time of staff and the workload of the system reduce the opportunity for interaction and patient involvement (Schwappach and Wernli, 2011; Doherty and Stavropoulou, 2012; Bishop and Macdonald, 2014; Ocloo and Matthews, 2016). Furthermore, a lack of structural-procedural mechanisms to give patients the opportunity and means to be involved is a barrier; for example, patients require established processes to be in place to report on their experiences of safety, and these must be easy, structured and simple to engage with (De Brun et al., 2016). Additionally, lack of visible evidence for organisational learning and change are barriers to involvement (De Brun et al., 2016).

1.6.5 Other factors

There is a general lack of evidence for patient involvement in patient safety, which also serves as a barrier to its success. In the past it has been noted that, surprisingly, patient perspectives are often not included in the development of involvement roles for patients (Entwistle et al., 2005). Additionally, there has been little research into the potential negative effects of patient involvement (Peat et al., 2010). Despite multiple calls for specific research on patient involvement in safety, it has remained *"contentious and untested"* (Lawton and Armitage, 2012). A more recent systematic review further supports this view, highlighting the lack of *"high quality evidence informing real world implementation"* and minimal formal evaluation of patient safety involvement for its impact upon rates of adverse events and safety outcomes (Berger et al., 2014).

1.7 The perspective barrier in patient safety

There is, however, a significant barrier to patient involvement that is yet to be addressed: the perspective barrier. In a thought paper addressing the role of patients and citizens in patient safety, O'Hara and Isden (2013) commented on the *"fundamental paradox of considering 'the patient perspective' on safety within the current clinical risk paradigm."* They recognised that there are differences between patient and clinical understanding of patient safety, which limits patient involvement to simply following expert and clinically defined rules. In further understanding the challenges posed by the perspective barrier in patient safety, it is first necessary to understand more about the clinical perspective and what is known so far about the patient perspective. In the subsequent sections, I will further explore the clinical paradigm of patient safety, the patient perspective on patient safety, and the differences between them.

1.7.1 The clinical perspective of patient safety

At the start of this chapter, I offered one of the simplest, but most widely used, definitions of patient safety by Vincent (2006). There are, however, other accepted definitions for patient safety. For example, the World Health Organization (WHO) offers a similar simple definition:

> *"The prevention of errors and adverse effects to patients associated with healthcare."*

In another example, Emanuel et al. (2008) define patient safety as:

> *"A discipline in the health-care sector that applies safety science methods towards the goal of achieving a trustworthy system of health-care delivery. Patient safety is also an attribute of health-care systems; it minimizes the incidence and impact of, and maximizes recovery from adverse events."*

Expanding upon these definitions, there are a range of different theories and models for patient safety that are commonly used within the clinical and academic paradigms of patient safety. Patient safety activities and improvements are often based upon these models. Table 1.2 describes some existing clinical theories and models of patient safety.

Table 1.2: Existing clinical models and theories of patient safety

Theory or model of patient safety	Description
Donabedian's Model *(Donabedian, 1966; Donabedian, 1978; Donabedian, 1980; Donabedian, 1988)*	Donabedian's quality model describes how structure and process are linked to outcomes; this quality assurance model or structure-process-outcome (SPO) model has been applied to patient safety. In this model, structure refers to the organisation, material resources and human resources; process refers to processes of care or how tasks and clinical processes are organised and performed; outcomes refer to clinical results and impacts of and patient satisfaction with care (Carayon et al., 2006).
Seven Levels of Safety *(Vincent et al., 1998)*	Vincent further developed James Reason's Organisational Accident Model (Reason, 1997), which showed the latent conditions, error producing conditions, active failures, and defences and barriers, which are implicated in safety incidents. The 'seven levels of safety' framework describes the contributory factors and influences on safety under seven broad headings: patient factors, task factors, individual (staff) factors, team factors, working conditions, organisational factors, and institutional context. This model outlines objective components that contribute to safety.
Safety Engineering for Patient Safety (SEIPS) Model *(Carayon et al., 2006)*	The SEIPS model provides a framework for understanding the structures, processes and outcomes in healthcare; it is influenced by the discipline of human factors. Within this work system model there are five components, which interact with and influence each other: technology and tools, organisation, person, tasks and environment. These interactions result in different outcomes for performance, safety, health, and quality of working life. The SEIPS model therefore builds upon the Donabedian model, by emphasising structure and allowing linkage of various elements of the SPO model
A model for patient safety *(Emanuel et al., 2008)*	Emanuel identified that many components of and models for patient safety have been articulated, but a single model for thorough adoption has not been available. They developed a patient safety model which considers the why, what, where, how and who of patient safety, and builds on the work of Donabedian (1978), Vincent et al. (1998) and Carayon et al. (2006). They developed an overarching model dividing healthcare systems into four main domains: those who work in it, those who receive it (patients), infrastructure (healthcare delivery processes), and methods for feedback or improvement. They purport that their model shows the component elements of patient safety and how they interact.
A framework for measuring and monitoring safety *(Vincent et al., 2014)*	Vincent developed a framework to guide clinical teams and organisations in maintaining safety. It identifies five dimensions of safety, developed from scoping reviews of high-risk industries and models of safety, which are assembled in a framework for the assessment of whether a healthcare organisation is safe. They describe the framework as encompassing *"the principal facets of safety."* The five domains are: past harm, reliability, sensitivity to operations, anticipation and preparedness, and learning and integration.

Safety-I and Safety-II *(Hollnagel et al., 2015)*	Hollnagel et al. (2015) recognised the current patient safety ‘orthodoxy’ as based on a linear cause-and-effect, component failure model; however, incidents and accidents are not linear, due to the complexities of the healthcare system. In their White Paper, safety is defined as *“the system quality that is necessary and sufficient to ensure that the number of events that can be harmful to workers, the public, or the environment is acceptably low,”* which most people consider to represent the absence of incidents. This is defined as *Safety-I*, a state in which as few things go wrong as possible; the focus is on causes, contributory factors and risk assessment, and humans are considered a liability or hazard as the most variable component. They propose a move to *Safety-II*, a state in which as many things as possible go right; the focus is on everyday performance variability adapting to respond to variable conditions, with humans the necessary resource to deliver this.

The commonality between these definitions and models is objectivity; they generally consider measurable factors, parameters, structures and processes contributing to safety. With these definitions in mind, it is therefore unsurprising that in patient safety healthcare professionals tend to be focussed on failure at points, quantifiable events and analysable issues or processes (Vincent, 2010).

1.7.2 The patient perspective of patient safety

There is evidence to indicate that the term patient safety is unfamiliar and not forefront in patients' minds. A 1997 telephone survey by the National Patient Safety Foundation (NPSF) at the American Medical Association aimed to understand the experiences and opinions of American adults on patient safety issues in the healthcare environment. When asked what came to mind when thinking about patient safety, 28 percent didn't mention anything about safety in the healthcare environment; this suggests that the vocabulary of patient safety is confusing. The top responses included exposure to infection (20 percent), general care received (13 percent) and qualifications of healthcare professionals (11 percent) (Harris and Associates, 1997). Similarly, in a 2006 UK-based study by Ipsos MORI to explore perceived risks from interaction with health and care professionals, risks relating to safety and harm did not come to mind spontaneously. When prompted, the risks that came to mind included financial concerns, waiting times and communication issues (IpsosMori, 2012). This finding in the 1997 NPSF survey is perhaps unsurprising given that it came before the publication of *'To Err is Human'*; however, given the focus on patient safety in the public domain in subsequent years, it is perhaps more surprising that patient safety appeared to be an unfamiliar topic to participants of the Ipsos MORI survey.

In other empirical studies, patients appear to define patient safety differently. Patients appear to associate patient safety with quality of care, meaning that failures in quality of service may indicate to patients an unsafe environment; for example, patient-reported issues around patient safety or unsafe care included problems with parking, concerns about security, waits, delays, care processes, and interpersonal dynamics such as poor communication or patient-professional interactions (Weingart et al., 2007; Rathert et al., 2011a; Hor et al., 2013). De Brun et al. (2016) found that patients struggle to distinguish the concept of safety from other aspects of care. O'Hara et al.

(2017) similarly found that patients may be unfamiliar with what is meant by safety, and thus in exploring the concept of safety instead asked patient to describes concerns in their care. Given this, overall it appears that patient safety is a term that may be unknown, unfamiliar or confusing to patients.

1.7.3 Comparing the clinical and patient perspective

Where patients are able to discuss safety, patients' criteria for safety appear to diverge from the criteria of clinicians and academics (Rathert et al., 2011c; Hor et al., 2013), with patients predominantly aligning quality of care and their experiences with patient safety. In the earlier discussion around patients' ability to be involved and particularly report on adverse events, evidence from a structured interview study about unsafe episodes of care was presented that showed that more than one in five patients reported an unsafe care experience; however, clinicians rated only 1 percent of these to represent care related injuries (Weingart et al., 2007). This was similarly found by O'Hara et al. (2018), with 65 percent of concerns expressed by patients in a study not traditionally classified as patient safety incidents. The clinical perspective is often used to determine the validity of patient reports (Weingart et al., 2007; Weissman et al., 2008; Hor et al., 2013). However, this and the previous section suggests that patient safety, as defined in the clinical paradigm, is an inadequate term that does not capture patients' full experience (De Brun et al., 2016).

Overall, there is no clear patient definition of, understanding of, or model for patient safety, though there is some limited evidence that patients have their own unique perspective of the concept of patient safety centred on quality and experience. In contrast, there are clear clinical/academic definitions of and models for patient safety, which are predominantly concerned with objective events or processes.

1.8 How is patient involvement in patient safety enhanced through interventions?

In order to enhance patient willingness and ability to be involved in patient safety, and to try to address some of the discussed barriers, many interventions and initiatives have been designed and implemented. In exploring the role of patients in promoting safety, Holme (2009) identified a number of explicit initiatives designed to enhance involvement. These include: World Alliance for Patient Safety (World Health Organization), Patients for Patient Safety, the patient safety champion network launched by the NPSA, NHS Choices and the Patient Choice Survey. Campaigns such *'It's OK to ask'* or *'Clean your hands'* (by the former NPSA) educate and encourage patients to be involved; leaflets developed by the Patient Association also identify ways that patients can be involved and enhance their safety. Interventions have been designed and implemented in order to encourage patients to engage in safety behaviours, with a scoping review identifying 437 research papers on the topic (Peat et al., 2010); the cited interventions aim to tackle some of the barriers to involvement.

Two examples of practical interventions are the 'P.I.N.K. Video' and the 'Patient Safety Briefing'. The 'P.I.N.K. Video' is a short animated safety briefing, shot through the eyes of the patient; it encourages patients to participate, inform, notice and know (CPSSQ, 2008); in an evaluative study of the 'P.I.N.K Video', it was found to be received favourably and raised awareness for patients of their potential roles in patient safety and encouraged them to be more involved (Pinto et al., 2013). Similarly, Guy's and St Thomas' Hospital have implemented a patient safety briefing video that advises patients about prevention of falls, blood clots, infection and pressure areas, sharing medication history, confirming identity, understanding discharge instructions and encouraging the discussion of any concerns (Haelo, 2014).

A systematic review of evaluations of the effectiveness of interventions designed to promote patient involvement found there were improved safety outcomes for the intervention groups, though the evidence was limited and of poor quality (Hall et al., 2010). A Health Foundation evidence scan found that feedback, planning and education initiatives lead to short term process improvements, but longer term impacts or changes in outcome are uncertain; there is little comparative evidence for different intervention strategies and minimal evidence on the extent of impact upon error reduction, safety climate improvements or overall safety (The Health Foundation, 2013).

Overall, despite a growing number of interventions to enhance involvement of patients in patient safety, and some evidence to support their efficacy, concern still remains about the effectiveness of interventions. In particular, interventions are criticised for their lack of explicit rationale or theoretical basis, limited attempts at formal evaluation and minimal patient involvement in their development (Peat et al., 2010). There is, therefore, limited evidence for their success. More significantly, these interventions are focussed upon the clinical perspective of patient safety, meaning they do not facilitate meaningful involvement of patients in patient safety.

1.9 Summary and rationale for the thesis

The previous sections have explored the rationale for patient involvement in patient safety, potential patient roles, the feasibility of patient involvement, the barriers to patient involvement, and interventions attempting to facilitate involvement or enhance patient safety. One significant barrier to patient involvement in patient safety, differing perspectives of patient safety, has been identified. This section will summarise why this is a barrier and provide the rationale for developing a new paradigm in patient safety to overcome this barrier.

Currently, defining patient safety and the associated issues of risk and harm, is left to healthcare professionals, policymakers and academics/researchers (Coulter and Ellins, 2006; Travaglia and Braithwaite, 2009; Ocloo, 2010; Hor et al., 2013). The NHS predominantly takes a ‘Safety 1’ approach to patient safety (O'Hara and Lawton, 2016). Overall, patient safety activities and efforts to involve patients in patient safety revolve around a clinical paradigm, abide by the care setting/professional role boundaries that compartmentalise care, and use clinical terms and clinical means to quantify the key outcome of ‘past harm’ (Hollnagel et al., 2013; O'Hara and Isden, 2013; Vincent et al., 2014; O'Hara and Lawton, 2016). This is particularly problematic because patients have a different perspective of patient safety, focussing on quality and experience

The Health Foundation has recognised this *“fundamental paradox of considering the ‘patient perspective’ on safety within the current clinical risk paradigm”* (O'Hara and Isden, 2013); introducing the patient into the clinical paradigm poses some challenges. When patients offer feedback, their comments and insights do not fit the rigid models, frameworks or approaches for patient safety. Patients view their experience of care as a journey, not as isolated events within specific settings with specific professionals (O'Hara and Isden, 2013; O'Hara and Lawton, 2016). They feedback on quality and experience, and not upon measurable events (e.g. pressures sores or infection); however, the value of patient stories and experiences as a reliable source of evidence in relation to safety is called into question (O'Hara and Isden, 2013). Safety concerns expressed by patients are often dismissed and defined as merely relating to patient experience. It is therefore suggested that whilst patients are capable of commenting on *"soft issues,"* their concerns do not provide valuable information relating to patient safety (O'Hara and Isden, 2013).

Contrary to this, earlier sections clearly outlined the value of patient involvement and patient perceptions have been described as a *"good first indicator of deeper systems issues"* (Rathert et al., 2011a). Indeed, the combination of patient experience and perspective with clinical expertise may reveal more risk and opportunities to prevent it (O'Hara and Isden, 2013). Patients can reveal issues and concerns which are overlooked by clinical reporting systems, offering a unique and distinctive perspective on patient safety; they can also provide insight into how care is experienced by patients and therefore what can be done to improve patient experience and patient safety, complementing existing methods and processes in patient safety (O'Hara et al., 2018). This value is recognised in NHS policy, where there is a significant focus upon involving the patient in patient safety; this standard has been set by Berwick (2013):

> *"The goal is not for patients and carers to be the passive recipients of increased engagement, but rather to achieve a pervasive culture that welcomes authentic patient partnership – in their own care and in the processes of designing and delivering care. This should include participation in decision-making, goal setting, care design, quality improvement, and the measuring and monitoring of patient safety. Patients and their carers should be involved in specific actions to improve the safety of the healthcare system and help the NHS to move from asking, "What's the matter?" to, "What matters to you?" This will require the system to learn and practice partnering with patients, and to help patients acquire the skills to do so."*

Despite this, patient safety definitions and approaches still exclude patients and the public (Ocloo, 2010), and purely clinical approaches to patient safety are evidently not meaningful or accessible to patients. Our preoccupation with measurement in the clinical paradigm reduces the patient role to *"compliance with rules defined by experts"* (O'Hara and Isden, 2013), which may not be understood or be of meaning or significance to patients. De Brun et al. (2016) also found that patients' conceptualisations of safety influenced their patient safety reporting behaviours; this means that patient understanding and prioritisation of a safety issue influenced whether they reported on it, meaning that their difference in understanding of safety was a major barrier to involvement within the clinical paradigm. Overall, by situating the patient in the clinical paradigm of patient safety and failing to recognise the patient conceptualisation, we may not be meeting a patients own expectations of patient safety, be involving them in patient safety activities that hold any meaning to them or indeed involving them in activities that they even understand.

There is evidence of some co-creation around patient safety issues (e.g. in designing safer environments) (O'Hara and Isden, 2013), however there are growing calls for incorporating the patient perspective within patient safety more broadly. Patients are seeking to challenge the predominantly clinical paradigm of patient safety (Ocloo, 2010), the limitations of the biomedical model in health and illness have been widely discussed and there is now increasing acceptance of lay interpretations (Ocloo and Fulop, 2011), and there is awareness of the need for a patient safety framework that is patient-centred (Sharpe and Faden, 1998). Despite this, the medical model remains a powerful determinant in defining patient safety approaches (Sharpe and Faden, 1998; Ocloo, 2010).

In considering the patient in patient safety, O'Hara and Isden (2013) concluded that there should be a move towards a new risk paradigm that *"values, accommodates and acts"* on the patient perspective. This recommendation is empirically supported in data by Hor et al. (2013), drawing on patient healthcare experiences to describe safety as *"the ongoing practical accomplishment of actors in their everyday work,"* a co-accomplished concept that is continually renegotiated and redefined by staff and patients in their interaction, rather than a concept that exists as specifications or preconditions. De Brun et al. (2016) also concluded that an approach that values the patient perspective is required; this could involve either moving away from using the term ‘safety’ entirely or reconceptualising it to incorporate patients’ experiences. Most recently, O'Hara and Lawton (2016) have championed a more radical and expansive view of safety (including risk, harm and the presence of safety), which values and gives credence to different perspectives.

Despite such extensive calls to develop a more expansive and inclusive patient safety paradigm, the patient safety movement continues to paradoxically involve the patient in the clinical paradigm and fails to acknowledge the patient conceptualisation. Our current approach is at odds with the modern vision for patient safety, which advocates understanding what matters to the patient (National Advisory Group on the Safety of Patients in England, 2013) and values the *“non-clinical voice”* (O'Hara and Isden, 2013). It is now necessary to establish a stronger narrative around patient safety in the public domain that accepts the perspectives of different stakeholders, and in particular the patient. This thesis seeks to achieve this goal for authentic patient partnership in patient safety by understanding and valuing the patient conceptualisation of patient safety alongside the current clinical paradigm. Therefore, this thesis aims to understand and acknowledge different conceptualisations of patient safety in order to define a new paradigm in patient safety that identifies, understands and uses the perspectives of the patient, thereby truly putting the patient in patient safety.

1.10 Thesis aims and research question

To conclude this chapter I will outline the aims, research questions and the overall structure of this thesis.

This thesis aims to understand and acknowledge different conceptualisations of patient safety in order to define a new paradigm[2] in patient safety that identifies, understands and uses the perspectives of the patient, thereby truly putting the patient

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[2] The use of the term paradigm denotes the aim to develop new theory in relation to the conceptualisations of patient safety and subsequently an approach to patient safety that values both the patient and healthcare professional perspective.

in patient safety. To further delimit this, I will specifically consider patient and healthcare professional conceptualisations of patient safety in secondary care.

In order to achieve this I will use qualitative methods; in qualitative research the intent is to explore and understand the meaning individuals or groups ascribe to a central phenomenon (Creswell, 2009), which is appropriate for the given aim of this thesis. In qualitative study, researchers state research questions and not objectives or hypotheses; these take the form of broad central questions and associated sub-questions (Creswell, 2009). Therefore, the two main research questions for this thesis are:

1. How is patient safety conceptualised?
2. How can patient and healthcare professional conceptualisations of patient safety be reconciled in a new paradigm?

These main research questions are supported by the following sub-questions:

1. What is the patient conceptualisation of patient safety?
2. What is the healthcare professional conceptualisation of patient safety?
3. How are the patient and healthcare professional conceptualisations of patient safety similar or different?
4. How do patient and healthcare professional conceptualisations of patient safety vary between different clinical specialties in secondary care?

Considering the structure of this thesis, in Chapter 2, I describe the underpinning research design and qualitative methods to be used. In Chapter 3, I undertake a systematic review of the existing qualitative evidence exploring patient and healthcare professional perceptions of patient safety. This evidence is synthesised using a qualitative meta-synthesis method, meta-study. In Chapter 4 and 5, constructivist grounded theory is used to further explore and conceptualise the patient and healthcare professional perspective of patient safety within acute medicine for the elderly, elective surgery and maternity, and explanatory theory is developed. In Chapter 6, experience-based co-design is used to translate the qualitative findings of this research into clinical practice, developing a practical product that could applied in clinical practice in order to expand the current patient safety paradigm and value the patient perspective of patient safety in clinical practice. Finally Chapter 7 discusses the implications of the work for patient safety policy and practice.

Chapter 2: Research design underpinning the thesis

2.1 Introduction

Research design incorporates philosophy, strategies of inquiry and specific research methods (Creswell, 2009); the problem, audience, and researcher influence the choice of research design. In particular, the researcher must consider their own philosophical assumptions (their paradigm or worldview), the strategy of inquiry that relates to this, and the methods that translate this into practice.

I will start by outlining my personal researcher biography; this will allow me to consider what influences my philosophical assumptions, and to reflect upon my role in and influence upon this body of work as the researcher. Following this, I will describe the paradigms that underpin research and state my own philosophical assumptions that guide this thesis. Finally, I will justify the use of a qualitative research approach and discuss the procedures for ensuring rigour in the research.

2.2 Researcher biography

I qualified as a medical doctor in 2012 and have worked clinically over the past six years in a range of specialties including medicine for the elderly, general surgery, gastroenterology, obstetrics and gynaecology, general practice and emergency medicine. I also have experience of working in the private practice setting.

I have had a varied exposure to the field of patient safety, both clinically and academically. From the beginning of my medical education, I was taught the four principles of biomedical ethics (Beauchamp and Childress, 2012), which espoused that we should practice with beneficence and non-maleficence, meaning that we should do good and do no harm. I was not overtly taught about patient safety as a discipline at medical school, although we were regularly told we would pass our clinical exams if we could demonstrate we were ‘safe’. My first true understanding of patient safety came as a result of changes driven by the establishment of the Care

Quality Commission and recommendations in the wake of the Mid Staffordshire scandal in 2013. I have since taught these topics to medical students, and patient safety is now common discourse in my day-to-day role and an increasing priority for the Department of Health.

The growing relevance of patient safety to my day-to-day clinical practice was a stimulus for my research in patient safety and brought me to work as a clinical research fellow with the National Institute for Health Research (NIHR) Imperial Patient Safety Translational Research Centre. The researchers with whom I have worked have also provided influence to my understanding of patient safety.

Finally, I have my own personal experiences of healthcare, as an inpatient, outpatient and, more recently as a relative within the context of elderly medicine; these experiences influence my personal perspective of patient safety.

I therefore began this research acknowledging my personal, academic and clinical influences. These will be discussed further as I explore the philosophical underpinning of this thesis and my role as a researcher.

2.3 Philosophical underpinnings of research and paradigms

All research has a philosophical foundation relating to the nature and attainment of knowledge, which influences its conduct (Creswell, 2009; Creswell and Plano Clark, 2011); researchers must be aware of the assumptions they make about gaining knowledge and be explicit about them (Creswell and Plano Clark, 2011). A variety of philosophical perspectives have been described (Guba and Lincoln, 1994; Creswell, 1998; Crotty, 1998; Lincoln and Guba, 2000; Schwandt, 2003); however, there is no real consensus on how to classify them and terminology is often inconsistently applied. Given the variation in classification and terminology, I have chosen to focus on the commonly cited work of Guba and Lincoln (1994) who describe four research paradigms: positivism, post-positivism, critical theory, and constructivism.

A paradigm or worldview is defined as a basic set of beliefs that guide action (Kuhn, 1970; Guba, 1990; Guba and Lincoln, 1994). This set of beliefs is concerned with first principles or ultimates, which must be accepted on faith and are not open to proof; they define the nature of the world, one's place in it and one's relationship to it and its parts. The basic beliefs defining paradigms are based on three interconnected questions outlined by Guba and Lincoln (1994):

1. <u>The ontological question:</u> What is the nature of reality, and what is there that can be known about it? What do we believe about the nature of reality?
2. <u>The epistemological question:</u> What is the nature of the relationship between the known, the inquirer and what can be known? How do we know what we know?
3. <u>The methodological question:</u> How can the inquirer find out what she believes can be known? How should we design the study?

Beliefs surrounding ontology, epistemology and methodology shape how a researcher sees the world and acts within it; a researcher's epistemology, ontology and methodology are contained within their paradigm (Denzin and Lincoln, 2005). I will initially address ontology, epistemology and methodology in turn, before attending to the paradigms encompassed by these.

2.3.1 Ontology

Ontology encompasses a spectrum of perspectives on the nature of reality. At one end of the spectrum, naïve realism describes a reality, which is real, apprehendable, objective and unchangeable. On the opposite end of the spectrum, relativist ontology assumes there are multiple realities that are based upon experience, and are local and specific in nature; this means reality is the product of a person or group, though there may be common elements. In between these lies critical realism, which assumes reality is real but imperfectly apprehendable, and historical realism, which assumes a virtual reality which has been moulded by social, political, cultural and other values over time (Guba and Lincoln, 1994).

2.3.2 Epistemology

Epistemology encompasses a spectrum of perspectives on how we know what we know about the nature of reality; this is constrained by the assumptions made about the nature of reality (e.g. a real reality needs objective detachment to discover it). From the dualist[3] objectivist[4] epistemological approach, the researcher and the subject are assumed to be independent and the subject can be studied without the researcher influencing or being influenced by it. Values and biases are prevented from influencing outcomes and findings are replicable and true; this means that the researcher can objectively determine how things really are. A modified dualist objectivist approach assumes it is possible to approximate reality, so that findings are probably true. On the opposite end of the spectrum, from the transactional[5] subjectivist[6] epistemological approach, the researcher and subject are linked; in this, the findings are created by the research, leading to a blurring of the lines between epistemology and ontology (Guba and Lincoln, 1994).

2.3.3 Methodology

Research methodologies vary according to researcher ontology and epistemology. Experimental manipulative methodologies focus on hypothesis verification with controlled confounding conditions; these are used by an objective researcher pursuing an apprehendable reality. In contrast, dialogic and dialectical methodologies are transactional; in these, there is discourse between individuals holding different points of view, but who wish to establish the truth through reasoned argument. Hermeneutical and dialectical methodologies create interpretations or constructions through interactions between and among the researcher and subjects (Guba and Lincoln, 1994).

2.3.4 Paradigms

Different paradigms hold different beliefs in relation to ontology, epistemology and methodology. These are summarised in Table 2.1, developed from Guba and Lincoln (1994):

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[3] Dualist = the world consists of two fundamental entities, mind and matter

[4] Objectivist = the conviction that reality is mind independent

[5] Transactional = Investigator and subject are linked

[6] Subjectivist = the conviction that reality is mind dependent

	Positivism	**Post-positivism**	**Critical Theory**	**Constructivism**
Ontology	Naïve realism	Critical realism	Historical realism	Relativism
Epistemology	Dualist/ objectivist	Modified dualist/ objectivist	Transactional/ subjectivist	Transactional/ subjectivist
Methodology	Experimental/ manipulative	Modified experimental/ manipulative	Dialogic/ dialectical	Hermeneutic/ dialectical

Table 2.1: Paradigms and their ontology, epistemology and methodology

Differences between paradigms are not simply philosophical; they have implications for the practical conduct of research. The positivist paradigms (e.g. positivism, post-positivism) are associated with ‘scientific’ thinking and quantitative research approaches, where the aim is to produce evidence for a knowledge claim; so-called interpretivist paradigms (e.g. constructivism, critical theory) are based on human subjectivity and how subjects perceive and understand the world (Allsop, 2012).

In conducting research, researchers must address the worldview they bring to a study, define the components of that worldview and how this shapes the strategy of inquiry (Creswell, 2009). The next section attends to my own personal worldview and its application to this body of work.

2.4 Defining my paradigm

Worldviews are shaped by an individual’s discipline, the beliefs of their academic supervisors and research group, and by their own past research experiences; I have considered the influences on my own worldview.

Firstly, I have been educated and trained within a predominantly positivist paradigm. I have a background in the so-called ‘hard sciences’ (biology, chemistry, mathematics). Secondly, medicine predominantly teaches us about statistics, quantitative methods, and the use of evidence-based medicine derived from gold standard randomised controlled trials; additionally, most health research is carried out in the positivist paradigm, which is dominant within biomedical research (Allsop, 2012). Therefore, there is a predominant acceptance of realist ontology, of a single truth (e.g. a right way to manage a patient), and an objectivist epistemology, meaning it is apprehendable through objective measurement. Thirdly, our education about qualitative research methods is limited. Overall, I am therefore strongly influenced by a positivist paradigm within my clinical practice.

I recognise, however, that medicine is not always 'one size fits all.' Individual patients are unique and they respond differently to treatment. Patients are also more than just their conditions that we treat; they are human beings that we interact with on an individual basis, who respond differently to their circumstances due to a range of factors (e.g. gender, culture, sociology). Different patients will see the same situation in different ways, meaning multiple perspectives may exist on a single issue. I learnt to treat patients without prejudice, listening, understanding and valuing the perspectives of others. I accept that there are multiple realities for patients, and that these are based on their experiences, known through subjective means and subject to the influence of interaction with me as their doctor. In this was, I am accepting of relativist ontology and transactional subjectivist epistemology, and I am therefore also influenced by interpretivist paradigm.

My ability to value and recognise two different and contrasting paradigms in my clinical practice has implications for my research. Traditionally, health researchers favour a single paradigm and are commonly split between positivism and constructivism (as an interpretivist paradigm) (Broom and Willis, 2002), as is evident within the discussion of my personal clinical worldview. Ontologically, one cannot accept the existence of both a single reality and multiple realities, and epistemologically one cannot study these objectively and subjectively (Broom and Willis, 2002; Allsop, 2012). Taking a purist philosophical stance, different paradigms are logically inconsistent or mutually exclusive (Lincoln and Guba, 1985; Leininger, 1992; Lincoln and Guba, 2000; Broom and Willis, 2002; Allsop, 2012); researchers must use one or another and cannot accept any other way of knowing. In conducting this body of research, I therefore face a philosophical dilemma in relating to two opposing paradigms, which must be further analysed and resolved.

In the battle between positivism and constructivism, proponents of positivist approaches to health research criticise constructivism, arguing that biological phenomena have a real existence, and are purely physiological:

> *"What can be more 'real' than cancer, diabetes or the pain from a broken leg? They are physiological conditions." (Allsop, 2012)*

As such interpretivist approaches are suggested to have no role. In practice, however, it is noted that nursing, health and sociological research actually occupies a middle ground between positivist and interpretivist paradigms and recognises that there are both subjective and objective components to health and disease (Broom and Willis, 2002; Keele, 2012). In a practice example, this means that whilst pain may be objectively 'real,' the sufferers of pain also differently and subjectively experience it. Therefore, health researchers, more generally, share the same tension between positivism and interpretivism as I do.

2.4.1 Pragmatic approach to paradigms

The separation of different epistemological and ontological positions has been criticised as creating an artificial dichotomy (Broom and Willis, 2002) and it is suggested that the usefulness and appropriateness of paradigms and their associated qualitative or quantitative research approaches should be tied to the research question, as well as the philosophical stance of the researcher (Broom and Willis, 2002; Allsop, 2012). Attempts to resolve the tension include acceptance of a certain amount of pragmatism when applying a paradigmatic approach to research design, by focussing on their relevance to the nature of the specific research questions (Oakley, 2000; Bryman, 2001). This means researchers should choose the best means to answer a research question, which may include a mixed methods approach, rather than being solely driven by a philosophical perspective.

2.4.2 Dialectical pluralism

Pragmatism in paradigmatic thinking has been further addressed by the philosophical process or meta-paradigm of dialectical pluralism (Johnson, 2008; Johnson, 2017). Johnson (2008) initially discussed dialectical pluralism in relation to mixed methods research, as a philosophy or process that would allow researchers with different worldviews to come together. He recommends that paradigms for mixed methods research be inclusive and fluid, adapting to the specific research question. He refers to the philosopher Kant when discussing the impossibility of subscription to a single paradigm, who believed that quantitative and qualitative knowledge are both necessary categories of human understanding. Johnson (2008) therefore tells us that philosophy is important, but as a partner to mixed methods research and not its dictator.

Dialectical pluralism allows the interaction of multiple ontologies, epistemologies, methodologies, values and methods (Johnson et al., 2014) and recommends that researchers concurrently and equally value multiple paradigms (Johnson, 2017). Ontologically, it is committed to the existence of many kinds of reality (subjective, intersubjective, objective). Epistemologically it is committed to dialectical (learning from different and even contradictory ideas), dialogical and hermeneutical (interpretive) processes for knowledge discovery and construction, and allows engagement with multiple epistemologies. It is committed to multiple methodologies and methods, to be decided on a project-to-project basis (Johnson et al., 2014). Therefore, it asks researchers to consider what is relevant to each research question, purpose and the associated stakeholders (Johnson, 2017). It is applied predominantly in relation to mixed methods research to allow multiple researchers and their individual perspectives to interact and learn from each other; however, its originator recommends that it can and should have a broad use, meaning it should be usefully applied whenever one must listen to and value multiple paradigms.

Paradigmatic pragmatism and dialectical pluralism therefore help to resolve the tensions between the positivist and interpretivist paradigms that I equally relate to. I can value each paradigm and see a place for them in different types of research. I recognise, though, on choosing one over another for this body of work, that I must be mindful of the influence of the other in the conduct of my research.

In finally identifying a worldview to orientate this thesis, I have considered both my own background and influences, but also the research question. In this body of work, the research questions require me to understand the perspectives of multiple participants on patient safety, a phenomenon that exists within their healthcare experience; this aligns with an interpretivist paradigm. Considering my philosophical assumptions, I have chosen to orientate this research within the interpretivist paradigm or, more specifically, the constructivist paradigm, which I will go on to describe and justify.

2.5 Constructivist paradigm

Constructivism is concerned with understanding a phenomenon as others experience it, rather than merely explaining; it is therefore interpretative and has grown out of the philosophy of phenomenology (which is concerned with the way things appear to individuals in their experiences) and hermeneutics (which says that access to the world of experience is always through interpretation) (Constantino, 2008). Its basic assumptions are that knowledge is socially constructed by those participating in the research process, and that the researcher attempts to understand the experiences of others (Schwandt, 2000; Mertens, 2005). The findings of constructivist research are a product of the values of the researcher, and are therefore a co-construction of the participant and researcher (Mertens, 2005).

In understanding constructivism as a paradigm, I draw upon the work of Guba and Lincoln (1994). Constructivism accepts a relativist ontology, in which realities are multiple and constructed by people through interaction; these can be individual or shared, and this necessitates gathering different perspectives. It accepts a transactional and subjectivist epistemology, that knowledge is socially constructed and mind dependent; research findings are the result of interaction between the researcher and the subject, so that findings are co-created. It relies upon hermeneutical and dialectical methodology, meaning that understanding of peoples' experiences is elicited through interaction between the researcher and subject, interpretation and co-construction. The study should take place in the natural setting of the subject and the phenomenon, and there must be recognition of the researcher (values, relationship to participants, closeness to subject). It is consistent with a qualitative strategy of inquiry, using methods such as semi-structured interviewing.

This has implications for the conduct of the thesis. Given its constructivist paradigmatic orientation, in answering the research question, I must seek multiple perspectives within the hospital inpatient setting, using a qualitative strategy of inquiry. As the researcher I am involved in the co-creation of findings, and I must therefore recognise my clinical and academic roles, and subsequently my own understanding of patient safety, and their potential influence upon the findings.

2.6 Qualitative strategy of inquiry

Considering my own philosophical assumptions and values, alongside the research aims, a qualitative strategy of inquiry is used throughout the thesis, with constructivism providing the general philosophical orientation. The aim of qualitative research is to develop concepts that aid the understanding of a phenomenon in its natural setting, using the meanings, experiences and views of participants (Pope and Mays, 1995). Qualitative research can provide context and meaning to human behaviour, eliciting the ‘insider’ view, rather than the ‘outsider’ view of quantification (Guba and Lincoln, 1994). It is particularly used when variables and the theory base is unknown; the concept under exploration may be immature, inaccurate, un-described or lacking in theory (Morse, 1991).

The researcher is located in the world and uses a series of interpretive practices to make the world visible and transform it into a series of representations; this means the researcher studies a phenomenon in its natural setting and attempts to make sense of it in terms of the meanings individuals attach to it (Denzin and Lincoln, 2005). This is done through the collection and study of empirical materials (e.g. case study, personal experience, interview, text) and emphasises understanding qualities, meaning and processes that are not experimentally measured (e.g. in terms of quantity, intensity, frequency).

This thesis seeks to understand and explain perspectives of patient safety; this involves exploring, interpreting and presenting the meaning of patient safety, as the central phenomenon, to individuals or groups (Creswell, 2009). Therefore the thesis aim and associated research questions are amenable to exploration using a qualitative strategy of inquiry.

2.7 Rigour in qualitative research

This section broadly addresses the principles of rigour that must be attended to when conducting qualitative research; the specific methods for each study will be described in detail in the relevant chapters.

Rigour relates to the integrity of study conduct and is necessary to ensure the credibility of study findings (Noble and Smith, 2015). Qualitative research is frequently criticised for failing to demonstrate sufficient rigour; criticisms include poor justification of methods, lack of analytical transparency, and researcher bias (Sandelowski, 1993; Rolfe, 2006; Noble and Smith, 2015). Traditionally, evaluation of rigour has focussed on reliability, validity and generalisability, which are terms more related to the positivist paradigm or quantitative research (Long and Johnson, 2000; Noble and Smith, 2015). Qualitative research has faced the challenge of a lack of consensus around evaluating rigour; however, Lincoln and Guba (1985) have offered alternative criteria.

Lincoln and Guba (1985) propose that the rigour be assessed by trustworthiness (credibility, transferability, dependability and confirmability) and authenticity criteria. Credibility means achieving consensus amongst informed and qualified persons; this refers to ensuring what is reported by researchers matches the phenomenon under study. Transferability means increasing understanding of a phenomenon to apply elsewhere. Dependability means ensuring transparent processes and a paper trail, so that one can have confidence in the findings. Confirmability means acknowledging the influence the researcher and ensuring interpretations remain grounded in the original data. Authenticity means ensuring a balanced presentation of all perspectives (Guba and Lincoln, 1994; Long and Johnson, 2000; James, 2008; Noble and Smith, 2015).

Various methods have been suggested for maintaining rigour within qualitative research. Cohen and Crabtree (2008) synthesised and published criteria for good qualitative research, which include recognising and accounting for researcher bias, methods for ensuring validity and methods for verification or reliability. Noble and Smith (2015) also list various strategies for ensuring the trustworthiness of findings including accounting for personal biases, engaging in critical reflection of self and methods, keeping meticulous records of methods and interpretative decisions, including verbatim quotes to support findings, engaging with other researchers to reduce bias, using respondent validation or member checking, and using data triangulation of multiple data sources to produce understanding. Table 2.2, developed from Noble and Smith (2015), with reference to Long and Johnson (2000), shows how these strategies relate to the principles of rigour.

Principle of rigour	**Strategy**
Credibility **Confirmability** **Authenticity**	- Engaging in reflexivity and reflection on own perspectives e.g. impact of preconceptions, motivations, and influences, and the researcher role in the process and findings - Peer debriefing to identify hidden biases - Ensuring the representativeness of the findings to the phenomenon including external audit, member checking, and the use of verbatim data extracts
Dependability	- Ensuring transparency around research processes - Keeping record of methods and decisions - Engaging with other researchers
Transferability	- Provide rich detail of the context to facilitate evaluation of conclusions and transferability to other settings

Table 2.2: Principles of rigour and related strategies

The specific application of these principles is discussed in the context of each study.

Through my personal researcher biography, I have identified important considerations in relation to the confirmability principle, namely my own personal biases. I have identified that I am a clinician and I therefore approach the topic of patient safety from a clinical lens; in addition to this, education in the positivist paradigm influences me to believe in a single reality. Relating this to the research subject in this thesis, this would orientate me to believe in a single definition of patient safety, biased by my clinical background, to pertain to strict clinical and academic definitions (as discussed in Chapter 1). I have, however, also demonstrated an orientation to the interpretivist paradigm in my clinical work, accepting that health and disease, and healthcare experiences, are not simply objective, but have a subjective component that is different to different people. I am therefore also able to accept and value the existence of other different concepts of patient safety, beyond the clinical and academic definitions. Nevertheless, in conducting this research, I have been mindful of my clinical lens. Continual reflexivity and discussion with my supervisors has served to reduce its influences upon the findings of this thesis.

2.8 Conclusion

In this chapter, through exploration of my personal worldview and the aims of this research, I have identified that this thesis adopts a constructivist orientation and uses a qualitative strategy of inquiry. In particular, I have reflected upon my personal researcher biography and analysed how this influences my personal worldview and subsequently the paradigm within which I conduct my research. This is particularly important when considering maintaining rigour in my work and I have discussed the types of strategies that ensure rigour in qualitative research.

Chapter 3: Patient and healthcare professional perceptions of patient safety - a systematic review and meta-study of the qualitative evidence

3.1 Introduction

There is evidence and commentary suggesting that patients and healthcare professionals perceive patient safety differently. This poses a challenge for involving patients in patient safety; their role in the clinically defined patient safety paradigm is unclear. Developing a new patient safety paradigm that values both the patient and healthcare professional perspective requires an understanding of how they each conceptualise patient safety. This study seeks to begin addressing this by exploring the current literature about perceptions of patient safety.

This study aims to understand patient and healthcare professional perceptions of patient safety by considering how they define patient safety or, recognising that the term may be unfamiliar, how patient safety is conceptualised more broadly. It seeks to achieve this by systematically reviewing the current qualitative literature that explores perceptions of patient safety. I specifically focus upon studies using qualitative methods because this is the best way of exploring unconstrained views, free from pre-determined hypotheses or definitions (Pope and Mays, 1995). I use a qualitative meta-synthesis methodology, meta-study (Paterson, 2001), to synthesise the qualitative findings to generate new insights into perceptions of patient safety.

This chapter begins with an overview of qualitative meta-synthesis and the chosen methodology. It goes on to detail the study itself and the results.

3.2 Background to qualitative meta-synthesis

3.2.1 History and background of qualitative meta-synthesis

The Cochrane Collaboration was established in the 1990s for the systematic review and appraisal of evidence for its quality and effectiveness, and helped to establish the systematic review of randomised controlled trials as the 'gold standard' in defining evidence-based practice (Guyatt et al., 2000; Marks and Sykes, 2004). The term systematic review is often considered synonymous with the term 'meta-analysis' (Walsh and Downe, 2005), and current methods of evidence synthesis favour quantitative forms of evidence and omit qualitative data (Dixon-Woods et al., 2005). As many forms of evidence exist, it is limiting to only consider randomised controlled trials as a source of evidence when not all outcomes favour assessment using this methodology (Dixon-Woods et al, 2005). This, however, changed with the establishment of The Cochrane Qualitative Research Methods Group in 1998 and with recognition by the NHS Centre for Reviews and Dissemination of the value of diverse types of evidence.

Reliance on randomised controlled trials as evidence is fading and the role of qualitative research is now explicitly considered (Jones, 1995; Dixon-Woods et al., 2001; Centre for Reviews and Dissemination, 2008). Published themed collections of qualitative research and narrative review have attempted to summarise and contribute to knowledge and understanding of studied phenomena (Campbell et al., 2003). However, lack of attention to the integration of qualitative findings has implications for both knowledge development and utilisation of qualitative research. This has driven the interest in synthesising qualitative research (Campbell et al., 2003), which can bring together themes and concepts to generate entirely new insights (Jensen and Allen, 1994; Beard et al., 1997; Sandelowski et al., 1997; Finfgeld, 1999; Malpass et al., 2009).

Stern and Harris (1985) first coined the term qualitative meta-synthesis; they described it as the amalgamation of a group of qualitative studies, with the aim to develop a theory or model to explain their findings. The term does not signal any one technique or method (Sandelowski and Barroso, 2011); instead, meta-synthesis is an iterative process that is determined by the relationship of individual studies to each other (Malpass et al., 2009). Where meta-analysis serves to integrate studies and increase certainty in cause and effect, meta-synthesis is interpretive and hermeneutic, in that it uses philosophy and methodology of interpretation to seek to understand and explain phenomenon (Walsh and Downe, 2005). In this way, qualitative meta-synthesis brings together findings on a chosen theme, going beyond description, summary or aggregation seen in narrative review or meta-analysis, so that the results can be seen as being more than the sum of the parts. Furthermore, synthesis can extend beyond analysis by considering how the researchers interpreted data, the design and quality of the studies and the theory they employ (Campbell et al., 2003). Through triangulation of data, method and theory, it is possible to generate a new collective and expanded theory of a phenomenon that is more socially relevant, complex and more complete (Paterson, 2001; Honein-Abouhaidar et al., 2014).

3.2.2 Critique of qualitative meta-synthesis

Qualitative research is often criticised for creating multiple separate pools of knowledge around the same phenomenon. For findings to have impact in practice and policy, they must be situated within a larger interpretive context, be presented accessibly, and be usable (Sandelowski et al., 1997). Researchers recognise that individual studies can be informative, but like individual pieces of a puzzle, they do not contribute significantly to our understanding of a whole phenomenon; therefore to advance knowledge and influence practice, synthesis is necessary (Jensen and Allen, 1996). Silverman (1997) argues for meta-synthesis, stating that qualitative researchers risk marginalisation from policymakers and clinicians if their work remains isolationist and esoteric and thus seemingly incapable of influencing strategy or practice. Despite this, meta-synthesis remains a contentious method, as it rests on the assumption that it is acceptable to generalise findings beyond individual studies. Post modernists reject any generalisation of individual studies and would therefore reject synthesis. There are concerns that in generalising and synthesising across studies, important differences and value in terms of context will be lost (Campbell et al., 2003), as well as the uniqueness and integrity of individual projects, which moves away from the aims of qualitative research (Sandelowski et al., 1997).

Fundamental issues of diversity in ontology, epistemology, methodology, theoretical viewpoint, quality, and context, may prevent synthesis (Sandelowski et al., 1997). Relativists will argue that synthesising studies with different epistemologies is not desirable or feasible, as each individual study represents a unique view, influenced by different theory or methods (Sandelowski et al., 1997). Additionally the meta-synthesis process can be viewed as reductionist, meaning that there cannot be one theory as a singular explanation of a phenomenon (Walsh and Downe, 2005). Alternatively, given that truths may be seen as multiple within the qualitative research paradigm, it is legitimate to bring together a variety of perspectives and approaches in meta-synthesis (Walsh and Downe, 2005). Rather than being reductionist, it can be regarded as an ever expanding boundary breaking exercise (Sherwood, 1997a), which opens up new insights and understandings, values richness and thickness of description (Walsh and Downe, 2005), and moves qualitative research away from being so singular by situating it within a larger research field (Sandelowski et al., 1997). In this way, the process of meta-synthesis is a constructivist approach and the product of the meta-synthesis is a social construction (Paterson, 2001).

3.2.3 Conducting a meta-synthesis

Meta-synthesis has been applied to a diverse range of areas including transformational leadership (Pielstick, 1998), experience of chronic illness (Thorne et al., 2002), diabetes (Paterson et al., 1998), concepts of caring in nursing (Sherwood, 1997b), adaptation to motherhood (Beck, 2002) and midwifery care (Kennedy et al., 2003). Meta-synthesis in these contexts has been approached in many different ways, but little work has been done to directly compare the products of different synthesis techniques and few of them have been extensively applied to health literature (Walsh and Downe, 2005).

Meta-synthesis uses the reports of primary research studies and their presented themes as data; from this, the aim is to develop higher order themes (Walsh and Downe, 2005). The data is discussed in terms of constructs (Malpass et al., 2009): first order, second order and third order constructs. First order constructs are the views of a study participant; they represent their understandings of an experience. Second order constructs are developed by the researchers of the primary studies, and are expressed as themes; they represent the researchers' understanding of the multiple participants' understandings of an experience. It is these second order constructs that meta-synthesists are interested in and utilise as primary data. These are used to develop third order constructs, which are the product of a meta-synthesis; they represent the meta-synthesist's understanding of researcher understandings of study participant understandings. The concept of constructs is summarised in Figure 3.1.

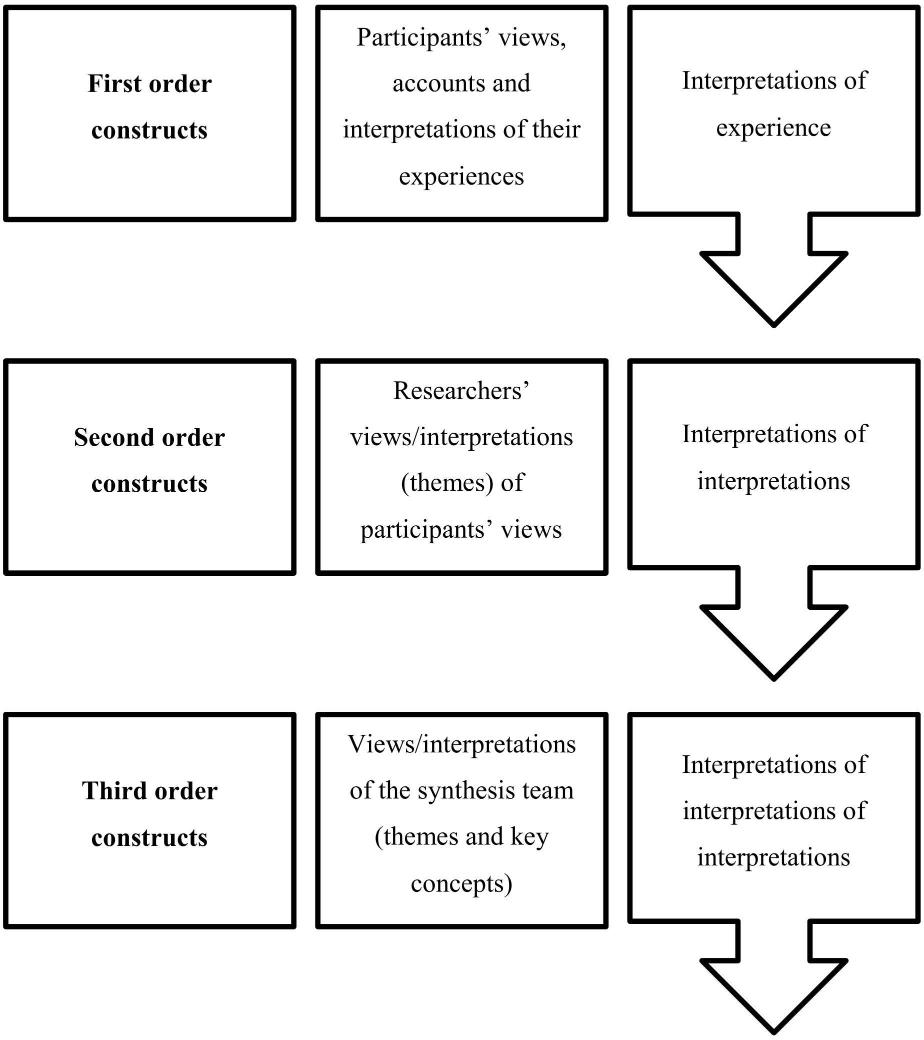

Figure 3.1: Definitions of first, second and third order constructs
Developed from Malpass et al. (2009), who draw on the work of Britten et al. (2002) and Noblit and Hare (1988)

There is a lack of clarity with respect to many aspects of conducting a meta-synthesis, including defining the research question, sampling/the number of studies to include, appraisal of included studies and selection of synthesis technique (Dixon-Woods et al., 2005); however, commentary exists, offering opinion on how to approach some of these aspects (Barroso et al., 2003; Walsh and Downe, 2005; Malpass et al., 2009).

3.2.3.1 Research question

As with other forms of evidence synthesis, the research question frames the meta-synthesis; questions are often framed quite broadly, although a range of approaches are advocated (narrow or precise question, versus a broader or more inclusive question) (Walsh and Downe, 2005). Importantly, the question must be broad enough to allow for finding refutational studies, which reach an oppositional conclusion from the main body of work in that area (Walsh and Downe, 2005).

3.2.3.2 Searching and study inclusion

There is little advice available on identifying studies for inclusion in a meta-synthesis; however, the aim should be to identify all of the relevant studies in a field and not simply a sample (Barroso et al., 2003). As such, it is suggested that the search may need to extend beyond established databases and include books, unpublished theses, backtracking of references and speaking to experts (Walsh and Downe, 2005).

3.2.3.3 Meta-synthesis techniques

The most influential and well-known method for meta-synthesis is meta-ethnography. This is an interpretive approach that translates studies into one another, with the objective of developing new interpretations and conceptual insights (Shaw, 2012). The method, described by Noblit and Hare (1988), uses seven stages to synthesise studies using comparable methodologies. Meta-study, defined by Paterson (2001) is considered to be an extension to meta-ethnography; it additionally considers how research findings are produced in relation to the authors' use of methods and theory. The subsequent section will consider meta-study in more detail.

3.3 Meta-Study: Theoretical background to the method

Meta-study is a systematic analysis and synthesis research method (Paterson, 2001). In contrast to other approaches to synthesis, it additionally considers how research findings are produced in relation to the individual study authors' use of methods and theory. It is an interpretive qualitative research approach in the constructivist paradigm, where the researcher's role is to understand how people construct knowledge about the phenomenon under study (Guba and Lincoln, 1994). Within a meta-study it is therefore accepted that there is no singular objective reality; instead there are co-existing (and sometimes competing) realities, which are related to the single phenomenon under study. From this constructivist approach, the researcher conducting the meta-synthesis is interpreting primary research reports, translating the work of others to reveal similarities and differences, and developing theory (Paterson, 2001).

The meta-study method provides a wish list for best practice, but notably, full compliance is not considered either desirable or practicable; the method offers a structure for understanding findings in the context that produced them (Garside, 2008). Meta-study is comprised of three analytical components (meta-data-analysis, meta-method and meta-theory), which provide a unique angle from which to deconstruct and interpret a body of qualitatively derived knowledge and then synthesise the findings (Paterson, 2001); these meta-study components and their relationship to the aspects of primary qualitative research are illustrated in Figure 3.2.

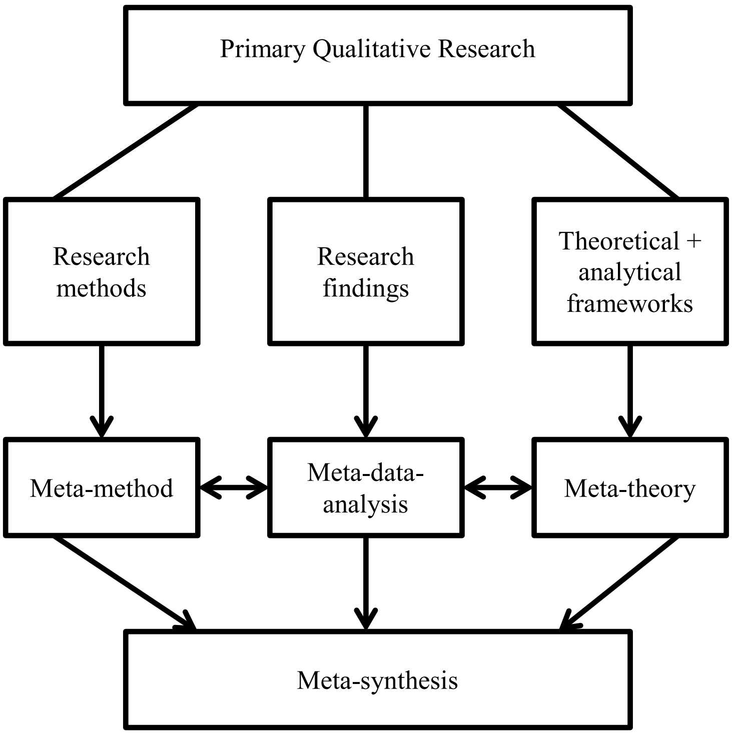

Figure 3.2: The components of meta-study

From Paterson (2001)

The analysis involves identifying commonalities, differences, patterns and themes within the data and reconciling methods and theories within the body of research (Honein-Abouhaidar et al., 2014). The overall aim is to generate new or expanded theory about a phenomenon, by following distinct analytical and synthesis steps, which will be described in turn.

3.3.1 Meta-data-analysis

Meta-data-analysis is *"a systematic means of combining the findings of several qualitative research studies concerning a specific phenomenon"* (Paterson, 2001, p67). It is the analysis of processed data by systematic comparison of the findings of multiple reports with a common focus or properties. Many interpretive methods can be employed within meta-data-analysis, including meta-ethnography (Noblit & Hare), grounded theory or thematic analysis (Paterson, 2001). Paterson (2001) favours meta-ethnography, as it is helpful in revealing similarities, differences and lines of arguments. It involves reading the studies in detail, and noting how a phenomenon is described using concepts, key metaphors, categories and phrases; the themes are extracted from each study and compared.

3.3.2 Meta-method

Meta-method is the *"study of the epistemological soundness of the existing research, as well as the ways the methodological applications may have influenced the findings that are generated"* (Paterson, 2001, p71). The purpose of the process is to determine how the interpretation and implementation of qualitative research methods have influenced the findings of and emergent theory from research. It is not a method for critique but a method for understanding the methodologies applied to studying a phenomenon, how these may have shaped the understanding itself and how they have changed over time. It involves identification and extraction of the components of research design and data collection for each study; subsequently, the research designs of primary research reports are compared and contrasted to ascertain trends in the methodologies and any outcomes associated with specific research reports.

3.3.3 Meta-theory

Meta-theory is the critical exploration of the theoretical frameworks that have provided direction to research (Paterson, 2001). Theory can be present in a study in several ways, through theory-testing research, theory-generating research, theory-evaluating research or theory-framed research. The theories observed can be grounded theory, substantive/mid range theory or grand theory. Meta-theory is a creative and systematic way of analysing theory and its effects on research within a specific field of study. The purpose is to analyse the implications of theory on a body of research so that existing theory can be critically interpreted, tested or even developed into new theory.

3.3.4 Meta-synthesis

In the context of meta-study (itself a meta-synthesis method), the term meta-synthesis refers to the final step that generates new collective and expanded theory of a phenomenon (Paterson, 2001; Honein-Abouhaidar et al., 2014). This extends beyond the analysis of the three previous individual stages, to identify truths about the phenomenon under study; this is achieved by acknowledging in combination how the primary researchers interpreted data, the design and quality of the studies and the developed theory. Meta-study commonly draws upon synthesis techniques used in meta-ethnography (Noblit and Hare, 1988):

- Reciprocal synthesis, where concepts of one study easily encompass another (i.e. identifying similarities)
- Refutational synthesis, where concepts are contested across papers (i.e. identifying differences)
- Line of argument synthesis, which accepts that different researchers will study different aspects of a phenomena and therefore by arranging these in order it will be possible to offer a fuller account of a phenomenon.

3.3.5 Maintaining trustworthiness and credibility

For a meta-study to be considered trustworthy and credible, it must attend to the principles of rigor (Paterson, 2001); this was considered, more generally, in Section

2.7 in relation to qualitative research, and is addressed here, more specifically, in relation to meta-study.

Overall, rigor in meta-study necessitates awareness of one's own role and biases, engaging in reflexivity, undertaking the synthesis in a transparent manner, remaining faithful to the original research reports, and consideration of establishing a meta-study research team (Paterson, 2001; Shaw, 2012). In a meta-study research team, three researchers are recommended who are involved in identification and appraisal of studies, discussion of the studies in depth, and all stages of the synthesis (Paterson, 2001). It is vital to be transparent about the procedures followed and interactions of the team; clear documentation of the discussions and interpretations of the team ensure this and provide reassurance that the original papers are fairly and appropriately represented (Paterson, 2001). Shaw (2012) describes three models for research team collaboration: true collaboration, where researchers are equal partners; hierarchical, where there is a principal investigator; or spider web, where the meta-synthesis is undertaken within a network.

Beyond the role of the team in maintaining trustworthiness and credibility, utilising a team honours the inherent constructivist nature of meta-synthesis, in dealing with and reflecting upon multiple perspectives; a team can support the development of collective understanding (Shaw, 2012). Additionally, having a multi-disciplinary research team can provide support with understanding the breadth of methodological, content and theoretical knowledge that is encountered; experience in qualitative research is necessary, along with passion and time to commit to the research area (Shaw, 2012).

3.3.6 Quality assessment

A range of quality assessment tools is available for the spectrum of research methodologies. There are a number of instruments and frameworks specifically for the assessment of the quality of qualitative research. However, the Critical Appraisal Skills Programme (CASP) Tool (CASP, 2006) is widely used in systematic reviews because it is easy to use and can be applied to different types of qualitative design. Despite qualitative reviews being outside of the scope of the Cochrane Collaboration, the Cochrane Collaboration Qualitative Methods Group notes that critical appraisal is pertinent and supports the CASP tool as an appropriate method (Hannes, 2011).

Some researchers consider quality assessment necessary (Walsh and Downe, 2005), and argue that as a feature of meta-analysis it should also feature in meta-synthesis (Campbell et al., 2003; Walsh and Downe, 2005). However, on-going challenges for quality assessment in the context of meta-synthesis exist. Firstly, there is currently no consensus on how to assess the quality of qualitative research (Paterson, 2001; Dixon-Woods et al., 2006). Questions remain over how quality judgements are used in the inclusion/exclusion of studies and how the assessment of quality is incorporated within the synthesis itself (Dixon-Woods et al., 2006), although it has previously been used to 'test' the contributions of studies to a meta-synthesis (Malpass et al., 2009). There exists a tension between the reporting of quality and the relevance of this, with reluctance to make exclusions based on quality alone (Dixon-Woods et al., 2006). Secondly, there is often variation between different reviewers when judging quality and inclusion, regardless of the chosen appraisal method (Dixon-Woods et al., 2006). Conclusions and agreement can be difficult to achieve (Walsh and Downe, 2005), often as editorial policy can limit detailed information on methods and analysis in the individual primary studies (Paterson, 2001). Overall, there is a need for on-going research and debate to determine the purpose of appraisal and the implications variability in quality has for synthesising studies (Dixon-Woods et al., 2006).

3.4 Study methods

Meta-study was chosen as the meta-synthesis method for this study. Having understood the background to qualitative meta-synthesis and, in particular, the meta-study method, it is necessary to consider the application of this to this particular study.

The strengths of meta-study have been discussed; however, a summary justification for the use of it in this study is offered here. Firstly, meta-study provides a structured systematic method for analysis and synthesis, yet also offers flexibility. Secondly, meta-study is compatible with my constructivist perspective because it seeks to better understand how people construct knowledge about their experiences; therefore it is suited to answering the research question. Finally, meta-study has been applied successfully to other similar health research, including investigation of older adults' definitions of health (Song and Kong, 2015), the role of spirituality in palliative care (Edwards et al., 2010) and benefits and barriers to colorectal cancer screening participation (Honein-Abouhaidar et al., 2014). Honein-Abouhaidar et al. (2014) opted for this method as it allows for particular focus on the experience of people and aims to better understand how people construct knowledge (in this case, understanding the determinants of screening test participation). Particularly they sought to understand factors involved in individuals' perceptions and experiences of colorectal cancer and screening. Their aim to explore perceptions and experiences of a phenomenon, mirrors my aim to understand how patients and healthcare professionals perceive and experience conceptualise patient safety. This example of the use of meta-study in the context of perceptions and understandings in healthcare therefore supports my use of meta-study in a similar context.

The study method, including the stages of meta-study, is graphically represented in Figure 3.3 and then described below. The meta-study followed the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement guidelines (Moher et al., 2009).

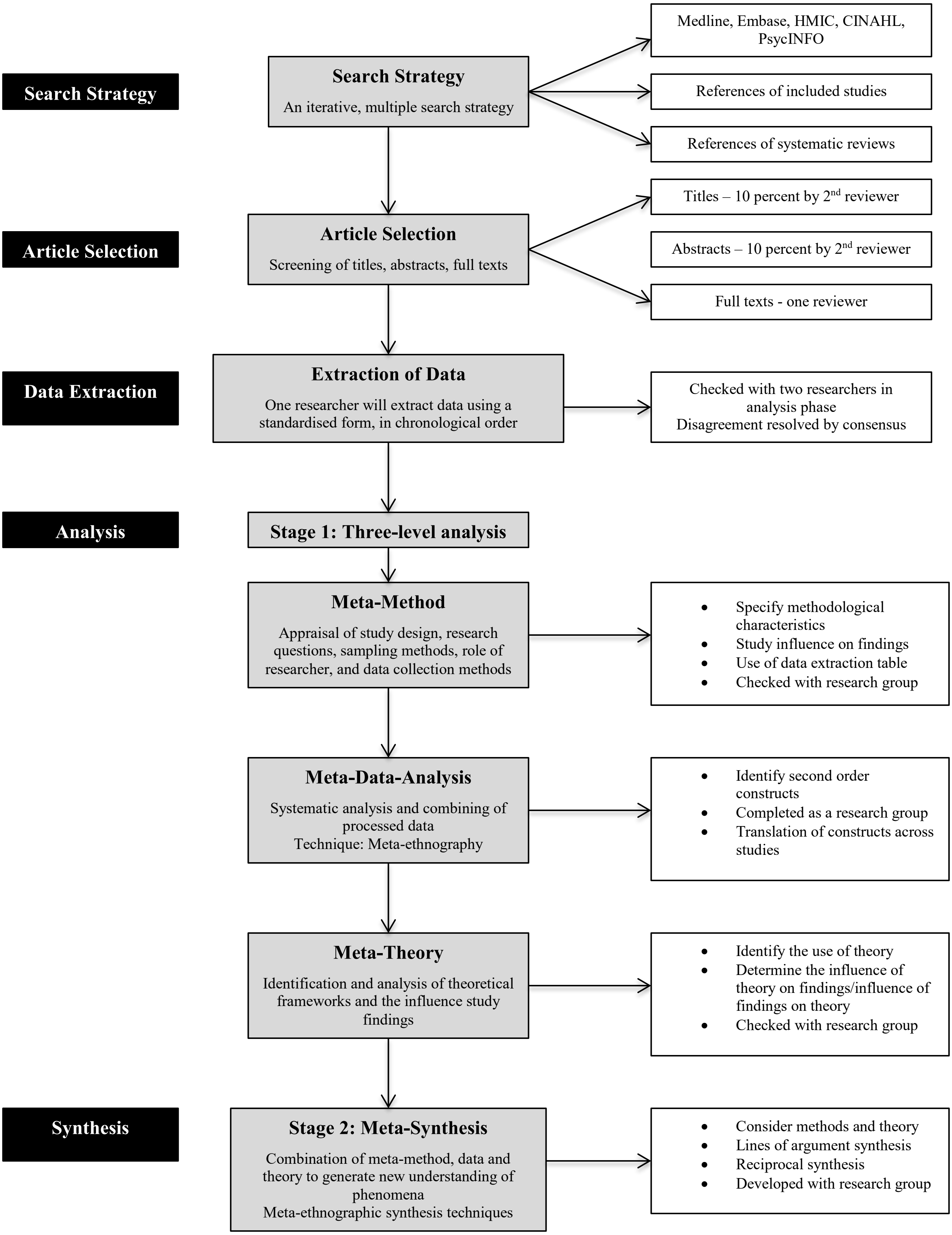

Figure 3.3: The meta-study method applied in this study

Developed from Honein-Abouhaidar et al. (2014)

3.4.1 Formulating the research question

In determining the research question for a systematic review, guidelines recommend the main features that should be considered are the study population, intervention, comparison and outcome (Centre for Reviews and Dissemination, 2008). However, it is important to note that these criteria do not directly apply in the context of qualitative research. This study aims to understand patient and healthcare professional perceptions of patient safety; the study takes a broader definition of the patient and as such seeks to include patients, members of the public (as past, present or future users of healthcare), and carers or relatives of patients. The study therefore asks:

- What is the patient, public, carer or healthcare professional perception of patient safety?

Considering the research question in more detail, the populations under study were any of the following:

- Patients (of any clinical speciality)
- Members of the public
- Carers or relatives of patients
- Healthcare professionals (of any discipline).

The outcome under study was the perception of patient safety. For this review, participant perceptions of patient safety were determined in two ways, as:

- Participant understanding/definition of patient safety, where participants give a distinct, explicit definition of patient safety
- Factors that participants discuss which contribute to their conceptualisation of patient safety.

3.4.2 Achieving rigour

Recommendations made by Shaw (2012) and Paterson (2001) were applied to promote rigour in the meta-study. A meta-study research team was established, using a hierarchical model of collaboration (Shaw, 2012), with EB as principal investigator (a clinician with knowledge in patient safety and qualitative research), and SA and DDL as the other team members (social scientists with advanced knowledge in patient safety and qualitative research). The research team were involved in all stages of the meta-study and met regularly to discuss the study and interpretations; a timeline of activities is discussed later. This team approach supported the inherent nature of the study, which involves multiple perspectives; this fostered shared refinement of the collective understandings from studies and protected against individual biases that may impact the synthesis. Additionally the knowledge and experience of the research team contributed to the required methodological, content and theoretical knowledge.

Throughout the study, processes and decisions were documented; additionally the team engaged in continual reflection on thoughts, on the findings of the primary studies, on the interpretations of studies, and on the meta-study findings.

3.4.3 Selecting databases

The following databases were searched:

- Embase Classic+Embase
- Ovid MEDLINE®
- PsycINFO
- Health Management Information Consortium (HMIC)
- Cumulative Index to Nursing and Allied Health Literature (CINAHL).

Additionally, The Cochrane Database of Systematic Reviews and PROSPERO (International prospective register of systematic reviews) were searched for any existing systematic reviews.

3.4.4 Developing the search strategy

The search strategy was developed using the facets of the research question:

- Patient/public/carer or healthcare professional

- Perceptions
- Patient safety

A list of search terms was produced by identifying synonyms and key words for each facet. Search terms were truncated and combined using Boolean operators. In particular, the adjacent function (‘adj’) was used to support the association between the facets. The search was limited to identify the terms within the title and abstract. An additional limit on publication date from 1999 onwards was set; this is in reference to the publication of the seminal work ‘To Err is Human’ (Kohn et al., 1999), often seen as the launch of the modern patient safety movement, and consistent with similar reviews (Khajavi et al., 2013; Harrison et al., 2015). The final search strategy can be seen in Table 3.1.

1	(patient* or inpatient* or outpatient* or consumer* or client* or public or user* or citizen* or carer* or relative* or caregiver* or care giver* or next of kin or parent* or famil*).ti,ab.
2	(doctor* or clinician* or physician* or resident* or surgeon* or medic* or nurs* or staff or professional* or personnel* or trainee* or midwi* or pharmacist* or physiotherapist* or therapist* or provider*).ti,ab.
3	(perception* or perspective* or belief* or attitude* or understanding or opinion* or view* or awareness or interpretation* or defin* or experience* or conceptuali*).ti,ab.
4	1 adj2 3
5	2 adj2 3
6	4 or 5
7	(safety or error* or adverse event*).ti,ab.
8	6 adj3 7
9	Limit 8 to year= “1999-current”

Table 3.1: Search strategy

3.4.5 Selecting studies

Search results were merged in a reference manager and duplicate records were removed. Titles were examined against the inclusion and exclusion criteria (Table 3.2) by EB, with clearly irrelevant records removed at this stage.

Inclusion Criterion	**Definition**	**Rationale**
Participants must be: members of the public, patients, carers or healthcare professionals	The study includes any of the following: members of the public, patients, carers, or healthcare professionals.	People who interact with, have the potential to interact with, or work within healthcare are the target population.
The study should explore and report on participant perceptions of patient safety	The study reports: participant understanding/definition of patient safety – distinct explicit definition, and/or identification and discussion of factors participants identified as contributing to their perceptions of patient safety.	The study aims to explore perceptions of patient safety.
The study is a qualitative study, with themes supported by verbatim quotes	Qualitative studies include: a stand alone qualitative study, or part of a mixed methods study that reports significant qualitative findings, or survey studies with open ended questions analysed using qualitative analysis methods. Study themes should be supported by verbatim quotes.	This study aims to explore perceptions, which is best done with qualitative research. Verbatim quotes provide supporting evidence of the researcher's conclusions.
Exclusion Criterion	**Definition**	**Rationale**
Not in English		
Non empirical data	This includes: conference abstracts, reviews, editorials, systematic reviews.	These lack sufficient methodological information about the study or are subject to bias or are not original empirical data.
Studies that use prompts to explore patient safety perceptions	This includes studies that use definitions of patient safety or error, or scenarios, to prompt discussion about patient safety.	These may influence participant perceptions.
Studies that solely explore perspectives of other related patient safety phenomena	This includes: patient safety culture, causes of patient safety incidents, specific types of patient safety incident/error, incident reporting, error disclosure, pharmacovigilance/ adverse event reporting, patient involvement in safety and patient safety interventions.	These are similar related phenomena; however, the study focused solely on perceptions of patient safety as a broader concept.

Table 3.2: Inclusion and exclusion criteria

Abstracts of the remaining studies were then examined against the inclusion and exclusion criteria. To ensure clarity of the inclusion and exclusion criteria, a second reviewer (GM) independently reviewed 10 percent of titles and abstracts. An inter-rater reliability analysis using the Kappa statistic was performed to determine consistency of title and abstract inclusion/exclusion among raters; any disagreement was resolved through discussion to achieve consensus. Full text screening was conducted by EB against the inclusion/exclusion criteria (Table 3.2) and reviewed with the research team prior to commencing data extraction and the meta-study analytic stages. The reasons for exclusion were recorded. The references lists of all included papers and identified systematic reviews were hand-searched for additional papers.

3.4.6 Extracting data

Data extraction was completed by EB using a table derived from Paterson (2001). Studies were managed in separate groups defined according to the participant type (healthcare professional or patient), and in chronological order to determine how methods and understanding of a phenomenon may have developed over time (Paterson, 2001; Malpass et al., 2009). The categories of extracted data are included in Appendix 1. Accuracy of data extraction was checked at a research team meeting by review of the reports of the included studies and the extraction tables.

3.4.7 Assessing quality

In consideration of the current controversies around the approach to qualitative appraisal and its role in meta-synthesis (discussed in Section 3.3.6) this was not undertaken.

3.4.8 Conducting the meta-study

The multidisciplinary research team, as defined previously, regularly met to conduct stages of the meta-study. A timeline of research team meetings and their content is shown in Appendix 2. In between face-to-face meetings, discussion and review of study steps was undertaken via email communication. For each stage of the meta-study, considered in turn below, the role of the research team is stated.

Meta-method was undertaken by EB. Using the data extracted, a further table was developed to appraise the recorded data for each study against the initial appraisal questions defined by Paterson (2001) and shown in Table 3.3. This allowed comparison of the included studies and facilitated the consideration of methodological themes, also defined in Table 3.3. The research team reviewed this table, and discussed and reached agreement on the methodological themes, ensuring rigour, clarity and trustworthiness.

Initial Appraisal		Methodological Theme
Research Question	• Do the research question and the methodological conduct of the study fit? • How does the research question impact the outcomes of the study? • Were the best methods used for the research question?	• Is there a predominance of research method? • Has this affected the findings or their interpretation over time? • What questions have been asked over time? Do they address a gap or limitation within a field?
Setting	• How does the researcher-participant relationship influence research findings? • What is the impact of researcher discipline, setting and timing of data collection?	• Is there a predominance of research settings over time? • Is there a predominance of researcher characteristics over time?
Sampling	• How was it done and what influence does this have on the findings? • What is the demographic profile of those studied? Who was excluded and why?	• Who has been included and excluded over time? • Are there clear limitations?
Data Collection	• What is the method? • What questions are asked and how are they framed?	• Are their prevailing methods over time? • How have methods changed? • How might they have influenced research over time?

Table 3.3: Meta-method initial appraisal questions and methodological themes
As defined by Paterson (2001)

Meta-data-analysis was conducted for each of the two study aims in turn, subdivided into patient and healthcare professional groups, during a face-to-face research team meeting. The data used in the meta-data-analysis were the research themes presented within the original study, referred to as second order constructs (Paterson, 2001); these represented the primary researcher's understanding of the participants' understandings of patient safety. Second order constructs were assessed against the primary data they represented; primary researchers would, in some cases, present higher-level concepts, which would therefore not always sufficiently capture the richness of the data they discussed. In such cases, where necessary, we developed our own sub-categories to achieve greater granularity (Paterson, 2001). To facilitate this, a data table was developed within Excel. Each study was entered across a row; constructs formed the column headings, and in each cell a definition of the construct was written for that study where applicable. Once complete, a summary definition (also referred to as a translation (Paterson, 2001)) was written for each second order construct across all the studies it appeared in. An example of this meta-data-analysis is given in Appendix 3. Regular reflection was undertaken to avoid rapid or overly 'tidy' categorisation of constructs.

Finally, the research team met to conduct the meta-synthesis. We discussed the constructs, meta-theory and meta-method; through this, we determined how the studies were related to one another and used line of argument and reciprocal synthesis techniques to develop fuller explanations of the phenomenon defined by the aims.

3.5 Results

The final search was run on 25th April 2016. A total of 7237 records were identified and a further 36 were identified from hand-searching nine relevant systematic reviews (Masso Guijarro et al., 2010; Khajavi et al., 2013; Lewis et al., 2013; McVeety et al., 2014; Mollon, 2014; Daker-White et al., 2015; Duarte Sda et al., 2015; Harrison et al., 2015; Lang et al., 2016); 3866 records remained for title screening after de-duplication. There was good agreement between both reviewers on title screening (Kappa 0.77; $p<0.001$); both reviewers subsequently screened 10 percent of abstracts (Kappa 0.65; $p<0.001$). Two hundred and twenty-one (221) proceeded to full text review; eight additional studies were identified from hand searching. Nineteen studies were included in the meta-study, six healthcare professional and 13 patient studies (see Figure 3.4 for Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) diagram).

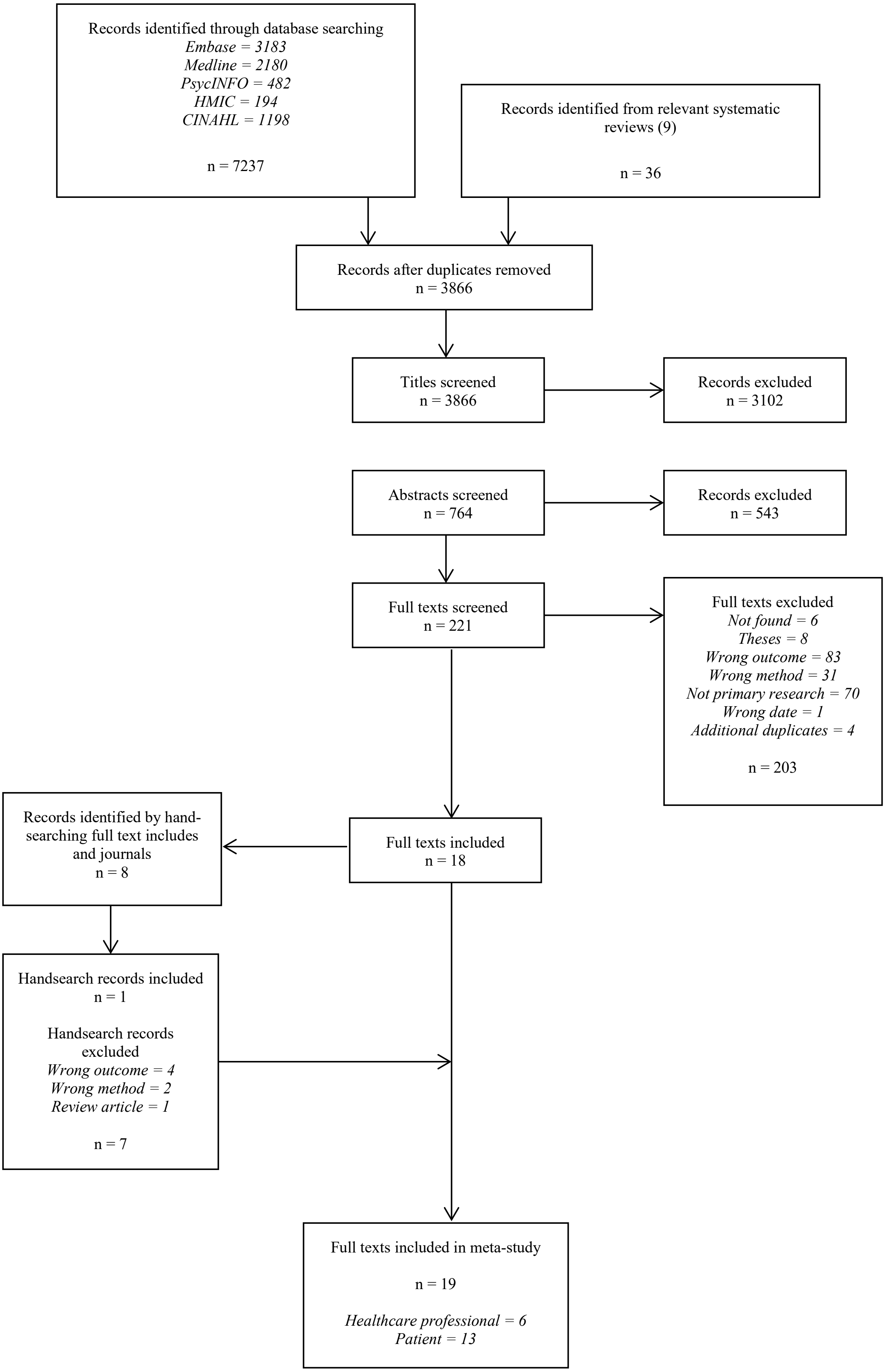

Figure 3.4: Preferred Reporting Items for Systematic Reviews and Meta- Analyses Diagram

3.5.1 Characteristics of the included studies

The authors, titles and aims of the 19 included studies are shown in Table 3.4. Of these studies, six addressed healthcare professionals perceptions of patient safety. Thirteen addressed patient/public/carer perceptions; of these studies, 11 had patients as participants, one (Lyndon et al., 2014) had parents as participants in the context of neonatal intensive care, and one study (Rathert et al., 2011a) included not only patients, but also parents of children and family of adult patients. No studies considered the perspective of members of the public.

Table 3.4: Included studies - authors, titles, and aims

	Author	**Title**	**Aim**
Healthcare Professional	**Vaismoradi et al. (2011a)**	Patient safety: nursing students' perspectives and the role of nursing education to provide safe care	To explore nursing student perspectives of patient safety and the role of education
	Jones (2014)	Residents' perspectives on patient safety in university and community teaching hospitals	Not clearly stated (identifies lack of investigation of resident perceptions of patient safety
	Dias et al. (2014)	The nurses' understanding about patient safety and medication errors	To assess understanding of nurses of patient safety and medication errors
	Valiee et al. (2014)	Critical care nurses' perception of nursing error and its causes: a qualitative study	To assess nurses' perceptions about nursing error and its causes
	Aveling et al. (2015)	Why is patient safety so hard in low-income countries? A qualitative study of healthcare workers' views in two African hospitals	To identify and explain obstacles to ensuring patient safety
	Kanerva et al. (2016)	Nursing staff's perceptions of patient safety in psychiatry inpatient care	To explore nursing staff perceptions of patient safety
Patient	**Van Vorst et al. (2007)**	Rural community members' perceptions of harm from medical mistakes: a High Plains Research Network (HPRN) Study	To assess experiences of medical mistakes
	Rathert et al. (2011a)	Putting the 'patient' in patient safety: a qualitative study of consumer experiences	To explore perceptions of safety (experiences of safety and influence on perception of care)
	Vaismoradi et al. (2011b)	Patients' understandings and feelings of safety during hospitalisation in Iran: a qualitative study	To explore understandings and feelings of safety during hospitalization
	Kooienga and Stewart (2011)	Putting a face on medical errors: a patient perspective	To explore perceptions of error
	Scott et al. (2012)	Do older patients' perceptions of safety highlight barriers that could make their care safer during organisational care transfers?	To explore the concept, explanations and terms used when talking about safety in organizational care transfers
	Holliman and Bernstein (2012)	Patients' perceptions of error during craniotomy for brain tumour and their attitudes towards pre-operative discussion of error: a qualitative study	To explore perception of potential medical error
	Stenhouse (2013a)	'Safe enough in here?' Patients' expectations and experiences of feeling safe in an acute psychiatric inpatient ward	Reports on the theme of safety arising from a large narrative study of being a patient on an acute ward

	Lyndon et al. (2014)	Parents’ perspectives on safety in neonatal intensive care: a mixed-methods study	To explore conceptualization of safety in NICU
	Hernan et al. (2014)	Patients’ and carers’ perceptions of safety in rural general practice	To identify perceptions of patient safety
	Lovink et al. (2015)	Patients’ experiences of safety during haemodialysis treatment – a qualitative study	To explore feelings and experiences of safety during haemodialysis
	Rhodes et al. (2016a)	Trust, temporality and systems: how do patients understand patient safety in primary care? A qualitative study	To explore patients’ understandings of safety in primary care
	Rhodes et al. (2016b)	Sensemaking and the co-production of safety: a qualitative study	To understand how individuals make sense of their experiences of primary care and how that reshapes conceptualisations of patient safety
	Collier et al. (2016)	Patients’ and families’ perspectives of patient safety at the end of life: a video-reflexive ethnography study	To explore how patient safety and harm is defined

3.5.2 Meta-method results

The patient and healthcare professionals studies were appraised separately; therefore the meta-method results are presented in turn.

3.5.2.1 Patient studies

There were thirteen patient studies published between 2007 and 2016; the full table of characteristics is shown in Appendix 4.

A total of 685 participants took part in the studies; 46 participants were parents of babies in the neonatal intensive care units (Lyndon et al., 2014), 11 participants were parents of children (Rathert et al., 2011a) and 10 were family members of adult patients with a chronic condition or recent acute care experience (Rathert et al., 2011a). Importantly, the analysis by (Rathert et al., 2011a) did not discuss similarities or differences between the patient safety perceptions of different patient groups, parents or family members; their results represent the perceptions of the participants as a whole. No studies looked at the perception of members of the public. The characteristics of the participants were variably reported, with the youngest participant 18 years and the oldest 89 years. Table 3.5 summarises the initial appraisal of the studies, which are fully addressed in the subsequent paragraphs.

Nine studies aimed to explore perceptions or understandings of patient safety (Rathert et al., 2011a; Vaismoradi et al., 2011b; Scott et al., 2012; Lyndon et al., 2014; Hernan et al., 2015; Lovink et al., 2015; Collier et al., 2016; Rhodes et al., 2016a; Rhodes et al., 2016b), three studies aimed to explore patient safety through experiences or perceptions of mistakes/error (Van Vorst et al., 2007; Kooienga and Stewart, 2011; Holliman and Bernstein, 2012) and one study reported on the theme of safety arising from a larger narrative study of experience of the inpatient psychiatry ward (Stenhouse, 2013a). Five studies asked participants about their definitions or understandings of patient safety (Rathert et al., 2011a; Vaismoradi et al., 2011b; Scott et al., 2012; Lovink et al., 2015; Rhodes et al., 2016a), four studies asked about feeling safe or unsafe (Vaismoradi et al., 2011b; Scott et al., 2012; Lovink et al., 2015; Collier et al., 2016), one study asked about knowledge and perception of error (Holliman and Bernstein, 2012), one study asked about the broad experiences of admission (Stenhouse, 2013a) and four studies did not report the questions they asked (Van Vorst et al., 2007; Kooienga and Stewart, 2011; Hernan et al., 2014; Lyndon et al., 2014).

The studies were heterogeneous in their clinical setting. Six studies took place in the community/GP setting (Van Vorst et al., 2007; Kooienga and Stewart, 2011; Scott et al., 2012; Hernan et al., 2014; Rhodes et al., 2016a; Rhodes et al., 2016b) and the remainder in acute care (Rathert et al., 2011a), medical or surgical wards (Vaismoradi et al., 2011b), neurosurgery (Holliman and Bernstein, 2012), psychiatry (Stenhouse, 2013a), neonatal intensive care unit (Lyndon et al., 2014), outpatient haemodialysis (Lovink et al., 2015) and end of life care (Collier et al., 2016). Similarly, studies were heterogeneous with respect to the country, with four studies in the USA (Van Vorst et al., 2007; Kooienga and Stewart, 2011; Rathert et al., 2011a; Lyndon et al., 2014), four in the United Kingdom (Scott et al., 2012; Stenhouse, 2013a; Rhodes et al., 2016a; Rhodes et al., 2016b), two in Australia (Hernan et al., 2014; Collier et al., 2016) and one in each of Canada (Holliman and Bernstein, 2012), Iran (Vaismoradi et al., 2011b) and the Netherlands (Lovink et al., 2015)

The study designs varied and included community-based participatory research (Van Vorst et al., 2007), grounded theory (Rathert et al., 2011a), descriptive studies (Kooienga and Stewart, 2011; Lovink et al., 2015), appreciative inquiry (Scott et al., 2012), narrative study (Stenhouse, 2013a), constructivist grounded theory (Lyndon et al., 2014) and video-reflexive ethnography (Collier et al., 2016). A variety of data collection methods were seen; six studies used semi structured interviews (Vaismoradi et al., 2011b; Holliman and Bernstein, 2012; Scott et al., 2012; Lovink et al., 2015; Rhodes et al., 2016a; Rhodes et al., 2016b), one study used written survey with open ended questions (Van Vorst et al., 2007), two studies used semi-structured focus groups (Rathert et al., 2011a; Hernan et al., 2014), one study used unstructured interviews (Stenhouse, 2013a), one study used a telephone survey with open ended questions (Kooienga and Stewart, 2011), and two studies used mixed methods including field notes, interviews, observations and video-reflexive sessions (Lyndon et al., 2014; Collier et al., 2016). A broad range of analysis methods were used including combined template/editing approach (Van Vorst et al., 2007), grounded theory (Rathert et al., 2011a), thematic analysis (Kooienga and Stewart, 2011;

Vaismoradi et al., 2011b; Holliman and Bernstein, 2012; Scott et al., 2012), narrative analysis (Stenhouse, 2013a; Hernan et al., 2014), constant comparison (Rhodes et al., 2016a; Rhodes et al., 2016b), constructivist grounded theory (Lyndon et al., 2014), content analysis (Lovink et al., 2015) and ethnography (Collier et al., 2016).

Having initially appraised each study, I then considered the methodological themes. There was no predominant research method; a range of methods was used to understand participants' subjective experience of patient safety. Commonly, individual semi-structured interviews or focus groups were used to explore perceptions; there was no evident trend in data collection methods over the chronology of the included studies. Across all studies, the research questions sought to address a gap in knowledge about patient perceptions and understanding of patient safety. The earlier studies were more generalised in their setting, whilst more recent studies focussed on a more specific clinical setting or specialty. The role and influence of the researcher was relatively poorly addressed, with eight studies failing to address this. Additionally the timing and setting of data collection was not commonly reflected upon, although a reader could draw inferences.

Table 3.5: Patient studies - meta-method

Study	**Research Question** ***Do the research question and the methodological conduct of the study fit? How does the research question impact the outcomes of the study? Were the best methods used for the research question?***	**Setting** ***How does the researcher-participant relationship influence research findings? What is the impact of researcher discipline, setting and timing of data collection?***	**Sampling** ***How was it done and what influence does this have on the findings? What is the demographic profile of those studied? Who was excluded and why?***	**Data Collection** **What is the method? What questions are asked and how are they framed?**
Van Vorst et al. (2007)	The community-based action participatory research approach integrates the knowledge and expertise of the participants in each study phase, grounding it in real life participant experience. Research question refers to 'medical mistakes' but does so to discuss patient safety events; this may limit study outcomes.	The researcher-participant relationship is not discussed therefore its influence is unknown. The impact of researcher discipline is unknown, as this is not clearly stated. Additionally the impact of the timing of data collection cannot be determined.	No specific sampling method was used. Recruitment was via newspaper adverts and approach by community members. The self-selected nature of the population may mean that this is not representative of the population. Limited data on the demographic profile is published, with no information on exclusions.	Survey with opened ended qualitative questions. The questions asked are not reported.
Rathert et al. (2011a)	Focus groups with semi-structured interview questions to explore perceptions. Participant responses may be limited by the use of focus groups, rather than individual interviews. The research question is broad and therefore does not restrain outcomes.	The backgrounds of the researchers are stated; however their research roles and relationships are not, so its impact is unclear. Interviewing took place in a neutral setting; the weekday evening data collection may limit who can attend.	No specific sampling method was used. Recruitment was via random digit dialling, which limits participation to those with a telephone and may under-represent the elderly. The demographic profile is clearly stated, with a predominance of women (74 percent). Participants with a one-night stay in the last 6 months were recruited across four groups: parents of children, family	Focus groups with semi-structured interview questions. The questions are clearly reported; they seek to determine the meaning of patient safety to patients, key issues and factors patients equate with safety.

			of adult patient, chronic care patient, and acute care patient. No exclusions are stated.	
Vaismoradi et al. (2011b)	Individual semi-structured interviews were used to explore understandings and feelings. This method suits the broad research question.	The researcher-participant relationship is not discussed therefore its influence is unknown. The impact of researcher discipline is unknown, as this is not clearly stated. Data collection took place at an unknown time at the patient's bedside; this non-neutral setting could influence outcomes. The Iranian culture and context may limit generalisability.	Purposive sampling from both sexes and different wards of to ensure maximum variation sampling; therefore the sample should be broad and not limiting. Some demographic information is stated. No exclusion criteria (apart from medical contraindication) are stated.	Individual semi structured interviews. The stated major focus of the questions is participant understanding of patient safety and feeling safe.
Kooienga and Stewart (2011)	Telephone interviews with open ended questions sought to explore perceptions of error. Reponses may be limited by the lack of rapport using telephone interviewing.	The researcher-participant relationship is not discussed therefore its influence is unknown. The impact of researcher discipline is unknown, as this is not clearly stated. Data collection took place 2-3 weeks after take part in another study, which itself may have impacted the study. The use of telephone interviews creates a neutral setting but may impact rapport.	Purposive sample of community members who agreed to tell their stories; recruited from a larger sample participating in a randomised experiment. Interest was indicated by ticking a box and providing a number. The sample is therefore broad but limited to those opting in, with a phone and those who are reachable. Limited demographic information is reported.	Qualitative telephone interview with open-ended questions. The questions asked are not reported.
Scott et al. (2012)	Appreciative inquiry, a method for organisational development, was used to develop a semi-structured interview, particularly using the Discover and Dream process. This allows exploration	The researcher-participant relationship is not discussed therefore its influence is unknown. The impact of researcher discipline is unknown, as this is not clearly stated. The timing and setting of	No specific sampling method was used. The sample was broad; some limited demographic information is reported. Exclusions were made if participant less than 18 years,	Semi-structured interviews, some dyadic were used. A topic guide was developed with open ended questions following the Discover and Dream process to explore: types of organisational care

	of past experiences and future needs; this is appropriate for the research question. The research questions have an additional focus on barriers and safeguards to provide patient defined safe care. Dyadic interviewing enriches the outcomes, but may also limit people's responses.	data collection is unknown.	unable to consent or had no experience of organisational care transfers.	transfer, feeling safe, what safety means and what would make people feel safer.
Holliman and Bernstein (2012)	Semi structured interviews were used to explore perceptions of error in the context of neurosurgery. This allows exploration of perceptions; they additionally explore more specific topics unrelated to the review.	The discipline of DH is unknown; MB is the centre neurosurgeon. This may influence the results, as the participants know the surgeon conducting the research. The timing and setting of data collection is not reported.	No specific sampling method was used. Some limited demographic information is reported. Participants came from a single centre. Exclusions were made is participants were less than 18 years, not cognitively intact, emotionally fragile, or unable to speak adequate English.	Semi structured interviews were used. Questions were asked relating to perceptions of error.
Stenhouse (2013a)	Qualitative unstructured interviewing was used to understand the patient perspective of inpatient admission. It arises from a larger narrative study about the experiences of patients on an acute ward. This approach allows participants to structure their own narrative how they choose and produces accounts that are close representations of their experience. Safety arose as	The researcher-participant relationship is not discussed therefore its influence is unknown. The impact of researcher discipline is unknown, as this is not clearly stated. Data collection took place at two and six weeks post discharge; developing rapport facilitated deeper exploration of participant feelings in the second interview. Interviews took place in the	No specific sampling method was used. Participants were excluded if they had a risk of violence to the researcher or were on a criminal section of the Mental Health Act.	Open unstructured interviews. The main question was around general experience of being a patient on an inpatient ward; the experience and perspective of safety arose as a narrative within this.

	a specific narrative within this more general study.	participant’s own home, which may encourage discussion.		
Lyndon et al. (2014)	Parallel convergent mixed methods study, with constructivist grounded theory approach for interviews allow development of conceptualisation of safety in the NICU. The method allows systematic study of human experience.	The disciplines and roles of the researchers are clearly stated; the effect of clinician investigators was considered in all aspects of the study. Where participants viewed the researchers as part of the hospital were among the most open with criticisms of care. Interviews took place in a setting away from the ward – either a meeting room or at the parents home, creating a safe space for the participant.	All patients were screened for parent eligibility and were approached in research centre hours if eligible. No other specific sampling method was used. The possible sample was small, due to parents being limited on their time on NICU, making them less accessible for recruitment. Recruitment and participation during admission may be affected by concern for social desirability bias – parents may fear offering criticism that could negatively impact care. Parents were excluded if they did not speak English. Full demographic information is reported.	Semi structured interviews. The questions asked are not reported.
Hernan et al. (2014)	Semi-structured focus groups were used to explore perceptions of safety in the GP setting. Both narrative analysis and grounded theory style constant comparative methods are alluded to. Focus groups may constrain what participants share.	The researcher-participant relationship is not discussed therefore its influence is unknown. The impact of researcher discipline is unknown, as this is not clearly stated. The location and timing of interviewing is not reported.	No specific sample method was used. A varied sample is reported with demographic profiles reported. No exclusion criteria are reported.	Semi-structured focus groups. The questions asked are not reported.

Lovink et al. (2015)	A descriptive exploratory study is used to explore experience of safety in outpatient haemodialysis.	The disciplines of the researchers are reported. One researcher is also a dialysis nurse at one participating hospital; the tensions of the dual role are recognised so this individual was not involved in recruitment or informed consent. Interviews were undertaken outside of work hours and out of uniform. The separation between roles was emphasised at the beginning. There are limitation due to this dual role, including influence upon participation and responses. Interviews too place in a private room before, during or after treatment or at home; this allowed for greater in depth discussion, though the proximity to treatment may influence information given.	Purposive sampling was used to seek maximum variation based on hospital type, gender, years of treatment, and comorbid conditions. Nonetheless a homogenous sample was noted. Exclusions were made on basis of Dutch language skills.	In depth individual semi-structured interviews. A topic list was used based on literature and expertise of the researcher. The main questions considered participant experience of safety; prompts included definitions of safety, feeling (un)safe, perceived risks, and roles in safety.
Rhodes et al. (2016a)	Exploratory semi-structured interviews are used to explore understandings of patient safety in primary care.	The researcher-participant relationship is not discussed therefore its influence is unknown. The impact of researcher discipline is unknown, as this is not clearly stated. Interviews took place at a mutually convenient time and place, usually the patient's home.	People with multi-morbidities were oversampled, as they are known to be vulnerable to safety incidents. No exclusion criteria are reported; demographic profiles are given.	Semi-structured interviews with an iterative topic guide. Interviews began with broad questions and as it was an exploratory study, interviewees largely introduced topics. Topics raised in early interviews were explored in later ones.

Rhodes et al. (2016b)	Semi-structured interviews are used to understand how individuals make sense of their experiences of primary care and how that reshapes conceptualisations of patient safety.	The researcher-participant relationship is not discussed therefore its influence is unknown. The impact of researcher discipline is unknown, as this is not clearly stated. Interviews took place at a mutually convenient time and place, usually the patient's home.	People with multi-morbidities were oversampled, as they are known to be vulnerable to safety incidents. No exclusion criteria are reported; demographic profiles are given.	Semi-structured interviews with an iterative topic guide. Interviews began with broad questions and as it was an exploratory study, interviewees largely introduced topics. Topics raised in early interviews were explored in later ones.
Collier et al. (2016)	Videoreflexive ethnography is used to explore how patients and their families define patient safety at the end of life.	AC is an experienced community palliative care nurse and ethnographer; AC engaged in self-critique of to ensure clinical experience did not influence study findings. Participants conduct their own filming and generate their own accounts when able.	Purposive sampling was used with snowballing; no setting or diagnosis was preferenced. The study aimed to be as flexible as possible on participants could take part on their terms, recognising vulnerability and deterioration. No exclusions were given and demographic profiles are reported.	Several types of data were used: semi-structured interviews, field interviews, ethnographic field notes and video-reflexive sessions. Patients were asked what makes the place feel safe or unsafe.

3.5.2.2 Healthcare professional studies

There were six healthcare professional studies published between 2011 and 2016; the full methodological characteristics are shown in Appendix 4. A total of 165 healthcare professionals took part in the studies. Four of the studies focussed on nurses alone (a total of 58 trained nurses and 17 student nurses), one study focussed on residents[7] alone (33 residents) and one study focussed on a variety of hospital staff. The age and other characteristics of the participants were variably reported. Table 3.6 summarises the initial appraisal of the studies, which are fully addressed in the subsequent paragraphs.

Three studies aimed to explore perspectives or understanding of patient safety (Vaismoradi et al., 2011a; Dias et al., 2014; Kanerva et al., 2016), one study aimed to explore perceptions of nursing error (Valiee et al., 2014), one study aimed to identify and explain obstacles to ensuring patient safety (Aveling et al., 2015), and one stated no specific aim but identified a lack of investigation of resident perceptions of patient safety as the rationale for the study (Jones, 2014). All six studies sought to explore these aims by asking participants about their understanding and perceptions of patient safety, risks and error. All six studies explored patient safety in the hospital inpatient setting, but they were heterogeneous with respect to the range of clinical specialty settings. Two studies did not explicitly state the clinical specialty (Vaismoradi et al., 2011a; Jones, 2014), one study took place in intensive care/critical care/dialysis units (Valiee et al., 2014), one study took place within psychiatry (Kanerva et al., 2016) and two studies took place across a breadth of clinical specialities (Jones, 2014; Aveling et al., 2015). Similarly, studies were heterogeneous with respect to the country with two studies conducted in Iran (Vaismoradi et al., 2011a; Valiee et al., 2014), one study in the USA (Jones, 2014), one study in Brazil (Dias et al., 2014), one study in east Africa (Aveling et al., 2015) and one study in Finland (Kanerva et al., 2016). All but one study (Jones, 2014), which used an interactive group interview, used individual semi-structured interviews to collect data, which were analysed inductively either by thematic or content analysis.

Having initially appraised each study, I then considered the methodological themes.

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[7] Resident is a term from the USA that refers to a junior doctor (i.e. a fully qualified doctor, but still in training towards achieving consultant status).

Sampling methods, study type, and the impact of setting, sampling, researcher role and data collection methods were widely unreported. The research questions asked were very similar and aimed to address gaps in understanding of healthcare professional perspectives of patient safety. The impact of researcher and setting was poorly discussed; a broad range of settings was evident but gaps remain. Over the chronology of the studies, no changes in study aims or data collection methods were seen.

Table 3.6: Healthcare professional studies - meta-method

Study	**Research Question** *Do the research question and the methodological conduct of the study fit? How does the research question impact the outcomes of the study? Were the best methods used for the research question?*	**Setting** *How does the researcher-participant relationship influence research findings? What is the impact of researcher discipline, setting and timing of data collection?*	**Sampling** *How was it done and what influence does this have on the findings? What is the demographic profile of those studied? Who was excluded and why?*	**Data Collection** **What is the method? What questions are asked and how are they framed?**
Vaismoradi et al. (2011a)	Grounded theory semi structured interview study was used to explore perspectives regarding patient safety. The study also sought to explore the role of nursing education in developing their safety capabilities; this may constrain outcomes.	The roles of the researchers are stated but there is no discussion of the relationship to the participants and potential biases. The timing and setting of the data collection is note reported.	Purposive sampling was done, based on maximum variation approach; however only one group of nursing students in the context of Iranian culture is included. No exclusions are reported. The demographic profiles are given.	Semi-structured interviews. Students are asked to explain their idea of the meaning of patient safety
Jones (2014)	Interactive group interviews were used. The research question is not clearly stated; however the study recognises a gap in investigation of resident perspectives of safety.	The researcher-participant relationship is not discussed therefore its influence is unknown. The impact of researcher discipline is unknown, as this is not clearly stated. The timing and setting of data collection is also not reported.	Residents were selected based on the prevalence of their specialty, their regular interaction and opportunities for shared clinical experiences. No exclusions are reported. Limited demographic information is reported.	Interactive group interviews with 2 participants. Eight questions were asked; this includes describing what patient safety is, risk, and factors that can promote and threaten safety.
Dias et al. (2014)	A qualitative exploratory descriptive cross-sectional study was used to assess understanding of the inter-related issues of patient safety and medication errors. The study is limited by the	The researcher-participant relationship is not discussed therefore its influence is unknown. The impact of researcher discipline is unknown, as this is not clearly stated. The	The sampling method is not reported. No exclusions are reported. Demographic information is given.	Individual semi structured interviews. Participants were asked about their understanding of patient safety, as well as

	focus on medication error type.	timing and setting of data collection is also not reported.		additional questions specific to medication errors.
Valiee et al. (2014)	Semi-structured interview study was used to explore perceptions of nursing error and its causes.	The researcher-participant relationship is not discussed therefore its influence is unknown. The impact of researcher discipline is unknown, as this is not clearly stated. The timing and setting of data collection is also not reported.	Purposive sampling was used; its influence is not discussed. No exclusions are reported. Extensive demographic information is reported.	Deep semi structured interviews. Participants were asked about experience, definitions and causes of error.
Aveling et al. (2015)	Semi-structured interview study was used to assess obstacles to patient safety.	The roles of the researchers are reported; however there is no discussion of the relationship to participants and potential influences/biases. The timing and setting of data collection is also not reported.	Purposive sampling used; its influence is not discussed though the aim was to include participants from a wide range of grades and areas of practice. No exclusions are reported. The role of the participant only is reported.	Semi-structured interviews. No specific questions are reported but interviews covered perceptions of patient safety and challenges in delivering safe care.
Kanerva et al. (2016)	Semi-structured interview study was used to explore perceptions of patient safety.	The roles and disciplines of the researchers are unknown; discussed in limitations that participants may not raise issues as they would assume that the researcher would know them having worked in the area, therefore participants were asked to elaborate if they suggested the interviewer would know what they were describing. The timing and setting of data collection is also not reported.	All nurses working on a randomly chosen morning were contacted with information and asked to participant. The authors reflect the sample comes from only one district within a specific culture, which could influence outcomes, although the challenges (and therefore perceptions) are considered universal. No exclusions are reported. Demographic profiles are reported.	Semi-structured interviews. No specific questions are reported but participants were given the opportunity to freely describe patient safety as they see and understand it.

3.5.3 Meta-data-analysis results

This section presents the results of the meta-data-analysis. Each study outcome (definitions of patient safety and factors contributing to the conceptualisation of patient safety) is considered in turn. Patient and healthcare professional studies are again analysed separately.

3.5.3.1 Definition of patient safety: patient studies

Four patient studies (Vaismoradi et al., 2011b; Lyndon et al., 2014; Lovink et al., 2015; Collier et al., 2016) reported participant definitions of patient safety; the identified second order constructs and their translations, as constructed by the research team, are seen in Table 3.7.

Second order construct	**Translation or summary definition of second order construct**
Physical safety Lovink et al. (2015)	Receiving safe treatment, without complications; pre-requisite to emotional safety
Awareness of emotional needs and wellbeing Vaismoradi et al. (2011b); Lovink et al. (2015); Collier et al. (2016)	Looking after patients' emotional and wellbeing needs; expression of feelings and emotions; feeling safe or interpersonal safety indistinct to physical safety
Interaction between staff and carers Lyndon et al. (2014)	Patient safety as a combination of clinical team actions and parent contributions to the care of the baby (Paediatrics)

Table 3.7: Patient definitions of patient safety - second order constructs and translations

Where patient safety was defined, three types of safety were identified: physical safety, emotional safety and safety arising from the interactions between staff and carers. Physical safety was defined as receiving safe treatment without complications and was seen as a pre-requisite to emotional safety (Lovink et al., 2015). The predominant safety type was that of feeling safe through looking after emotional wellbeing needs and through interpersonal relationships (Vaismoradi et al., 2011b; Lovink et al., 2015; Collier et al., 2016); this was considered indistinct to physical safety (Collier et al., 2016). In the paediatric setting, patient safety was seen as a combination of the actions of the clinical team and the contributions of the parents to the care of the baby (Lyndon et al., 2014).

3.5.3.2 Definition of patient safety: healthcare professional studies

Six healthcare professionals studies reported definitions of patient safety; the identified second order constructs and their translations, as constructed by the research team, are seen in Table 3.8.

Second order construct	**Translation or summary definition of second order construct**
Do no harm Dias et al. (2014); Jones (2014); Valiee et al. (2014)	Treating patients without harm, physically or mentally
Complex and multi-faceted Aveling et al. (2015)	Multifaceted; problems cannot be linked to a single cause
Physical safety Vaismoradi et al. (2011a); Dias et al. (2014)	Preventing physical harm, suffering or complications
Psychological safety Vaismoradi et al. (2011a); Dias et al. (2014)	Maintaining good communication, privacy and confidentiality, and mental integrity. Preventing distress
Safety from self Kanerva et al. (2016)	Preventing harm from own mental and physical health (mental health context)
Safety from others Kanerva et al. (2016)	Preventing harm from other patients (mental health context)
Adherence to standards of care Jones (2014)	Adhering to standards of care, procedures and routines prevents error
Professional skills and competence Dias et al. (2014)	Patient safety is dependent on staff professional skills and qualities
Professional duty Aveling et al. (2015)	There is a professional duty to prevent things going wrong
Environmental Dias et al. (2014)	Patient safety is depending on maintaining a suitable physical environment
Organisational Dias et al. (2014); Aveling et al. (2015)	Patient safety is dependent upon adequate organisational structures, systems and resources

Table 3.8: Healthcare professional definitions of patient safety - second order constructs and translations

Patient safety was predominantly defined as the concept of doing no harm (Dias et al., 2014; Jones, 2014; Aveling et al., 2015), which meant treating patients without causing them harm, both physically and mentally. Patient safety was defined as multi-faceted (Aveling et al., 2015) and several different types of safety were identified as components of patient safety. Physical safety was defined as preventing physical harm, suffering or complications (Vaismoradi et al., 2011a; Dias et al., 2014). An additional concept of psychological safety was included within definitions of patient safety, defined as maintaining good communication, respecting privacy and confidentiality, maintaining mental integrity and preventing distress (Vaismoradi et al., 2011a; Dias et al., 2014). Within the mental heath based study, additional concepts of safety, safety from self and safety from others, were included (Kanerva et al., 2016). Healthcare professionals additionally defined patient safety by including actions and attributes they believed to be required for maintaining safety. These included adhering to standards of care, routines and procedures to prevent error (Jones, 2014), having and working within professional competence and skills (Dias et al., 2014; Valiee et al., 2014), maintenance of a suitable physical environment (Dias et al., 2014) and the presence of organisational structures, systems and resources (Dias et al., 2014; Aveling et al., 2015). Patient safety was also recognised as an inherent professional duty to prevent things from going wrong (Aveling et al., 2015).

3.5.3.3 Factors contributing to the conceptualisation of patient safety: patient studies

Thirteen patient studies included factors contributing to the conceptualisation of patient safety; patients identified factors that both threatened and promoted patient safety, which are described below. The final second order constructs and their translations, as constructed by the research team, are seen in Table 3.9.

Table 3.9: Factors perceived by patients as contributing to patient safety - second order constructs and translations

Second order construct	Translation or summary definition of second order construct
Physical environment Collier et al. (2016); Rhodes et al. (2016b)	The perceived safety and quality of built environment affects patient safety, including the design, age and accessibility of infrastructure
Cleanliness; Infection Prevention & control Vaismoradi et al. (2011b)	Clean environment and protection against transmission of disease promotes patient safety
Psychological environment and atmosphere Lyndon et al. (2014); Rhodes et al. (2016b)	Noise, lack of privacy and normalcy (Paediatrics) threaten patient safety
	Psychological components of the environment impact safety including the atmosphere and welcome
Safe place Stenhouse (2013a)	Being in hospital means being in a place where patients are safe from themselves, others and the outside world (Psychiatry)
Procedures Lovink et al. (2015); Collier et al. (2016)	Risks specifically related to aspects of treatment threaten patient safety
Protocols Holliman and Bernstein (2012); Lyndon et al. (2014); Collier et al. (2016); Rhodes et al. (2016a); Rhodes et al. (2016b)	Protocols exist to prevent error and promote patient safety
	Protocols may be perceived as invisible and as constraining on practice, which may undermine safety. They are seen to protect doctors and not patients
Medication administration and reconciliation Rathert et al. (2011a)	Accurate administration and reconciliation on admission/discharge promotes patient safety
Care plan Vaismoradi et al. (2011b); Rhodes et al. (2016a)	Having a stable care plan as soon as possible and being informed of it. Endangered if undetermined or delayed
	Holistic, individualised care plan promotes patient safety
	Timely investigation, diagnosis and referral promotes patient safety
Responsibility Stenhouse (2013a); Hernan et al. (2014)	Responsibility for error is individual
	Responsibility for error and safety is with the individual
Openness Hernan et al. (2014)	Desire explanations and apologies when error occurs
Duty	Application of mental health law and hospital duty of care promotes patient safety

Stenhouse (2013a)	
Competence Holliman and Bernstein (2012); Lyndon et al. (2014); Rhodes et al. (2016a); Rhodes et al. (2016b)	Level and consistency of competence impacts patient safety
	Expectation of technical and medical competence required for patient safety
	Value of technical competence in patient safety context dependent; underpinned by medical education and regulation
Role of nurse Vaismoradi et al. (2011b); Stenhouse (2013a); Lyndon et al. (2014); Lovink et al. (2015)	Nurses are pivotal to patient perceptions of patient safety; determined by nurses' skills and qualities
Manner Van Vorst et al. (2007); Rhodes et al. (2016a); Rhodes et al. (2016b)	Poor manner impacts patient safety, including lack of attention to personal needs, lack of caring attitude or unapologetic attitude
	Non-technical skills and interpersonal competence promote patient safety
Nurse-doctor cooperation Vaismoradi et al. (2011b)	Nurses and doctors working as a team promote safety
Interprofessional communication Holliman and Bernstein (2012)	Lack of communication can produce error and impact patient safety
Teamwork Holliman and Bernstein (2012)	Lack of teamwork can produce error and impact patient safety
Not to be forgotten Vaismoradi et al. (2011b); Lovink et al. (2015)	Frequent contact, checking, proximity and presence of nursing staff promotes patient safety
Staffing level Rathert et al. (2011a)	Patient safety is threatened by understaffing, staff not being visible, not checking up on patients, and having competing demands
Responsiveness Scott et al. (2012); Lyndon et al. (2014); Collier et al. (2016)	Listening and responding quickly to needs promotes patient safety; in Neonatal Intensive Care Unit this also means providing moment to moment care
	Not meeting basic care needs, and failing to adequately respond to and manage symptoms threatens patient safety
Communication of information Van Vorst et al. (2007)	Unsatisfactory communication to patient of status and treatment plan, and not listening to information from the patient threatens patient safety
Quality of communication between patients and staff Kooienga and Stewart (2011); Rathert et al. (2011a); Scott et al. (2012); Hernan et al. (2014); Lyndon et al. (2014); Collier et al. (2016); Rhodes et al. (2016a)	Lack of respect, prejudice and blame; unprofessional style
	Communication that promotes patient safety is open, timely, accurate, positive inclusive of family, involved, patient centred, with a good doctor-patient relationship and continuity

Patient expectations Van Vorst et al. (2007)	Patient safety is threatened when there are unmet expectations, dismissed requests or knowledge/expectations that contradicted professional judgment
Care transition Collier et al. (2016)	Harm occurs at care transitions
Vulnerability Hernan et al. (2014)	Vulnerability (especially in chronic disease) and power imbalances put patients at risk
Continuity of Care Rhodes et al. (2016a)	Patients feel safer seeing the same General Practitioner and being known by them
Trust Van Vorst et al. (2007); Holliman and Bernstein (2012); Scott et al. (2012); Hernan et al. (2014); Lyndon et al. (2014); Rhodes et al. (2016a)	Patients inherently trust in skills and knowledge, which promotes patient safety
	Error events lead to loss of faith or trust
Patients affecting patient safety Stenhouse (2013a); Rhodes et al. (2016b)	Patient safety is threatened by other patients: by other mental health inpatients, by infection and by the mood of others
Support from patients Vaismoradi et al. (2011b)	For female patients, being supported by others promotes patient safety
Role of significant other Rathert et al. (2011a)	Relatives and others promote patient safety by preventing problems, assisting patients and acting as an advocate
Patient agency Vaismoradi et al. (2011b); Lyndon et al. (2014); Lovink et al. (2015); Rhodes et al. (2016a)	Patients promote patient safety by maintaining Patients need to maintain some control over routines and treatment; want active role in care and to be involved in decisions; see themselves as agents in safety
Psychosocial Rhodes et al. (2016a); Rhodes et al. (2016b)	The social/relational elements of interaction, generated from the expectations and experience of care, impact patient safety by making people feel safe
Gate keeping/access Rhodes et al. (2016a); Rhodes et al. (2016b)	Safety is impacted by gatekeeping functions, access to appointments and interpretations of urgency; this is mediated by finance

Often patients discussed the concept of patient safety through discussions of what made them feel safe (Rathert et al., 2011a; Vaismoradi et al., 2011b; Scott et al., 2012; Stenhouse, 2013a; Hernan et al., 2014; Lyndon et al., 2014; Lovink et al., 2015; Collier et al., 2016; Rhodes et al., 2016a). The range of associated factors is subsequently discussed.

Patients identified factors that both threatened and promoted their safety. Concerns about the safety and quality of built environment threatened patient safety (Collier et al., 2016), whilst cleanliness and infection prevention and control measures promoted patient safety (Vaismoradi et al., 2011b). Specific environmental threats were named in the context of paediatrics in relation to noise, and lack of privacy/normalcy (Lyndon et al., 2014). Within mental health, the hospital itself as a physical space was considered to be a safe place for patients (Stenhouse, 2013a).

Procedures and their associated risks were identified as a threat to patient safety (Lovink et al., 2015; Collier et al., 2016). Related protocols (Holliman and Bernstein, 2012; Lyndon et al., 2014; Collier et al., 2016; Rhodes et al., 2016a), and particularly medication procedures, were considered to exist in order to promote patient safety in relation to procedures (Rathert et al., 2011a). Establishing a clear care plan with prompt investigation and diagnosis promoted safety (Vaismoradi et al., 2011b; Rhodes et al., 2016a), whilst any delay or an undetermined plan threatened safety (Vaismoradi et al., 2011b). Gatekeeping and limits to access to care, which may be mediated by financial constraints, were considered to impact safety (Rhodes et al., 2016a). Safety was thought to be the responsibility of individual staff members (Hernan et al., 2014) and in particular nurses were considered accountable for creating safety (Stenhouse, 2013a; Hernan et al., 2014).

The role of the nurse, identified as the most accountable professional, mediated patient perceptions of safety. Feelings of safety were determined by the skills and qualities displayed by nurses (Vaismoradi et al., 2011b; Stenhouse, 2013b; Lyndon et al., 2014; Lovink et al., 2015; Rhodes et al., 2016a) and a range of skills and qualities were deemed important contributory factors in promoting or threatening safety. Patients expected nurses to be competent, and identified concerns about the level and consistency of competence as a threat to patient safety (Lyndon et al., 2014);

therefore, assessment of the nurse as technically competent promoted feelings of safety (Rhodes et al., 2016a). The manner of staff or the way they conducted themselves was identified as impacting upon patient safety. Poor manner, (for example when nurses failed to pay attention to personal needs, lack a caring attitude and have an unapologetic attitude) was seen as a threat to patient safety (Van Vorst et al., 2007), whilst having a good manner and interpersonal skills promoted feelings of safety (Rhodes et al., 2016a). The responsiveness of staff was an important factor contributing to patient safety; listening and responding quickly and providing moment to moment care promoted safety (Scott et al., 2012; Lyndon et al., 2014), whilst failure to respond to basic care needs and symptoms threatened safety (Collier et al., 2016). Patients desired frequent checking, proximity and presence of nurses and quick attention to their needs to feel safe (Vaismoradi et al., 2011b; Lovink et al., 2015). The failure to address and meet patient expectations affected the perception of patient safety (Van Vorst et al., 2007). Inter-professional team working contributed to patient safety (Vaismoradi et al., 2011b), whilst lack of communication and teamwork was seen to cause error and threaten safety (Holliman and Bernstein, 2012).

Trust in healthcare professionals was seen as important for establishing patient safety. Patients inherently trust healthcare professionals due to their skills and knowledge (Holliman and Bernstein, 2012; Scott et al., 2012; Hernan et al., 2014; Lyndon et al., 2014; Rhodes et al., 2016a). Error in care resulted in damage to their trust of healthcare professional (Van Vorst et al., 2007; Hernan et al., 2014).

Communication was a factor that mediated patient perceptions of patient safety. In relation to the communication of information, patients felt unsafe if there was unsatisfactory communication of the plan to the patient and a failure to listen to information shared by the patient (Van Vorst et al., 2007). The quality of communication was key for patient safety. A lack of respect, an unprofessional style and prejudice threatened safety (Kooienga and Stewart, 2011) and good quality communication promoted safety (Van Vorst et al., 2007; Rathert et al., 2011a; Scott et al., 2012; Hernan et al., 2014; Lyndon et al., 2014; Collier et al., 2016; Rhodes et al., 2016a).

Relationships between the patient, healthcare professionals and others were perceived as contributing to patient safety. Long term relationships and continuity of care, through seeing the same General Practitioner and being known by them made patients feel safer (Rhodes et al., 2016a). Patients perceived that harm occurs at care transitions (Collier et al., 2016), where information about them may be lost in translation.

The vulnerability of patients due to ill health and power imbalances was perceived as threatening patient safety (Hernan et al., 2014). The support of other patients and relatives was felt to promote patient safety (Rathert et al., 2011a; Vaismoradi et al., 2011b). In the context of mental health, patients perceived their safety to be threatened by other patients (Stenhouse, 2013a).

Patients saw themselves as an important factor in establishing patient safety; through maintaining agency and having an active role in their care, they deemed themselves as safety agents promoting patient safety (Vaismoradi et al., 2011b; Lyndon et al., 2014; Lovink et al., 2015; Collier et al., 2016; Rhodes et al., 2016a). Their perceived feelings of safety were impacted by the social elements of interaction with healthcare professionals and how this influences what patients think or feel; it was seen to mediate the safety of their physical health as patients were concerned by the judgments and responses of healthcare professionals (Rhodes et al., 2016a).

3.5.3.4 Factors contributing to patient safety: healthcare professional studies

Four healthcare professional studies included factors that contributed to the conceptualisation of patient safety; they identified factors that both threatened and promoted patient safety. The final second order constructs and their summary definitions/translations are seen in Table 3.10.

Second order construct	Translation or summary definition of second order construct
Individual workload Valiee et al. (2014)	Volume of work i.e. Heavy workload threatens patient safety
Tiredness Aveling et al. (2015)	Being tired threatens quality and safety of care
Workforce numbers Valiee et al. (2014); Aveling et al. (2015)	Low staffing levels threaten patient safety
Constraints on hours Jones (2014)	Reduction in time to safely complete patient care tasks
Volume of patients Jones (2014); Valiee et al. (2014); Aveling et al. (2015)	High volume of patients threatens patient safety
Acuity of patients Jones (2014); Valiee et al. (2014)	Very ill patients threaten patient safety
Motivation Valiee et al. (2014)	Lack of motivation secondary to pressure can lead to nursing error
Protocols Kanerva et al. (2016)	Ensure staff know procedures in every day work and emergencies
Environment/ infrastructure Valiee et al. (2014); Aveling et al. (2015); Kanerva et al. (2016)	Poor design of environment and poor infrastructure standard
Human-technology interface Jones (2014)	Inadequate Information Technology and electronic health record integration
Resources/ equipment Valiee et al. (2014); Aveling et al. (2015)	Lack of/old materials and equipment
Patient safety culture Aveling et al. (2015); Kanerva et al. (2016)	Activities, events and atmosphere on the ward affect patient safety
	Failure of governance structures to aligned with achieving patient safety
Transitions of care Jones (2014)	Failure of critical information transfer threat to patient safety
Interprofessional relationships and communication Jones (2014); Valiee et al. (2014); Aveling et al. (2015)	Lack of teamwork, coordination and communication
Individualised care Kanerva et al. (2016)	Holistic personalised care crucial for patient safety
Continuing professional development Kanerva et al. (2016)	Maintenance of clinical skills essential for patient safety
Supervision Jones (2014)	Lack of adequate staff supervision threatens patient safety
Experience and knowledge Valiee et al. (2014); Aveling et al. (2015)	Lack of experience or knowledge when new threatens patient safety
Training Valiee et al. (2014); Aveling et al. (2015)	Inadequate or inconsistent training
Legal rights of patient Kanerva et al. (2016)	Laws guiding care that protect patients rights – including restraint and seclusion in mental health

Table 3.10: Factors healthcare professionals perceived as contributing to patient safety - second order constructs and translations

Workload was perceived as negatively contributing to patient safety (Jones, 2014; Valiee et al., 2014; Aveling et al., 2015); this included having a heavy workload, being tired, low staffing levels, reduced time to care due to constraints on working hours and the volume and acuity of patients. The use of protocols was identified as an opportunity to promote patient safety by ensuring everyone knows the procedures for everyday work and emergencies (Kanerva et al., 2016). Inadequate IT/electronic health records (Jones, 2014), poor design and standard of environment/infrastructure (Valiee et al., 2014; Aveling et al., 2015; Kanerva et al., 2016), and lack of or old equipment all threatened patient safety (Valiee et al., 2014; Aveling et al., 2015).

Patient safety was perceived to be promoted by the activities and atmosphere on the ward, creating a positive patient safety culture (Kanerva et al., 2016). This was threatened when hospital governance structures were not aligned with achieving patient safety (Aveling et al., 2015).

On an individual staff level, lack of motivation was identified as leading to nursing error and therefore represented a threat to patient safety (Valiee et al., 2014). Interprofessional teamwork and communication was identified as contributing to patient safety (Jones, 2014; Valiee et al., 2014; Aveling et al., 2015); studies identified that the opposite (lack of teamwork, coordination and communication) threatened patient safety.

Communication at organisational care transfers where critical information is being transferred (Jones, 2014), was deemed a particular threat. An individualised holistic patient care plan was considered crucial to promoting patient safety within mental health; additionally laws guiding the rights of patients, restraint and seclusion promoted patient safety in this setting (Kanerva et al., 2016).

3.5.4 Meta-theory results

3.5.4.1 Patient studies

Four studies used theory in a variety of different ways, either using existing theory or generating new theory. Two studies (Scott et al., 2012; Lovink et al., 2015) applied existing theory to underpin, understand and explain their findings. Two studies (Lyndon et al., 2014; Collier et al., 2016) developed new theory from the results of their studies.

Scott et al. (2012) made reference to Reason's Swiss Cheese Model in the introduction and noted that there has been no theoretical exploration of how patient perceptions contribute to models of patient safety. They conclude that communication and responsiveness were considered key to patients in the provision of safe care in organisational care transfers. They therefore recommended application of these patient identified factors as additional defences, barriers or safeguards within the Swiss Cheese Model to the reduce the chances of a hazard becoming a patient safety incident, thus incorporating the patient perspective into a recognised model of accident causation.

Lovink et al. (2015) applied the monitoring and blunting model (Miller, 1995) to contextualise and explain the study findings and to make recommendations for care. Monitoring is defined as the extent to which patients attend to threatening signals, whilst blunting is the avoidance of threatening signals. The study found that some patients looked to control their situation (monitors) whilst others left everything to the nurses (blunters). Applying this theory to the results, they recommended that patients should be given information in a way that is tailored to their coping strategies. This tailoring was considered to possibly contribute to overall feelings of safety, through the maintenance of control.

Lyndon et al. (2014) used constructivist grounded theory to develop a theory that conceptualised parental perceptions of safety and safety concerns in the NICU. Parents viewed safety as a combination of clinical teams' actions and parents' contributions to monitoring and improving baby's condition across three dimensions: physical, developmental and emotional. The theory demonstrated how concerns often overlap at the intersection of domains; all three domains intersected at the central processes of 'watching over my baby' and 'making decisions.'

Collier et al. (2016) broadly discussed the theoretical approach underpinning their study and developed a patient safety model from the results. A sociocultural perspective on patient safety was used; this approach allows consideration of the 'taken for granted' social elements of patient safety and challenges the perspective of mainstream patient safety by embracing organisational complexities and including user perspectives of patient safety. The patient safety model demonstrated the broad definitions given by patients and families, plus the differences to the organisational definitions. Patients and families framed harm, and as a consequence safety, as emerging from how clinical tasks, interpersonal communication, the environment and socio-cultural context are intertwined.

3.5.4.2 Healthcare professional studies

There was no theory used or developed in the included healthcare professional studies.

3.6 Meta-synthesis results

This section details results of the meta-synthesis, which brings together the findings of the meta-data-analysis, meta-method and meta-theory, to create an expanded understanding of perceptions of patient safety as the phenomenon under study.

3.6.1 Definition of patient safety

The translated second order constructs identified through meta-data-analysis have been brought together in a line of argument synthesis to create a wider explanation of the phenomenon of healthcare professional and patient definitions of patient safety respectively.

3.6.1.1 The patient perspective

Patient safety from the patient perspective is delineated into interrelated types of safety. Broadly, patient safety is comprised of physical safety and emotional or psychological safety (including the concepts of wellbeing, emotional needs and feeling safe). Physical and emotional safeties are interdependent; feeling safe in a psychological sense is indistinct to physical safety, with physical safety a requisite to emotional safety. Additional safeties arise in the context of paediatrics, where it is the product of the actions of the clinical team and the parents.

3.6.1.2 The healthcare professional perspective

As an overarching abstract concept, patient safety is considered to be complex and multifaceted, with the main focus as doing no harm. Several types of patient safety are named: in the general inpatient setting these are physical and psychological safety, but it is noted that there are alternative safeties that arise within the mental health context, namely safety from self and safety from others. There are several care concepts included within definitions of patient safety which serve to promote or protect patient safety; these can be subdivided into actions inherent to the practice of healthcare professionals (their adherence to standards of care, maintaining competence and upholding professional duty) and attributes of the environment in which they work (the environmental and organisational infrastructures). This is illustrated in Figure 3.5.

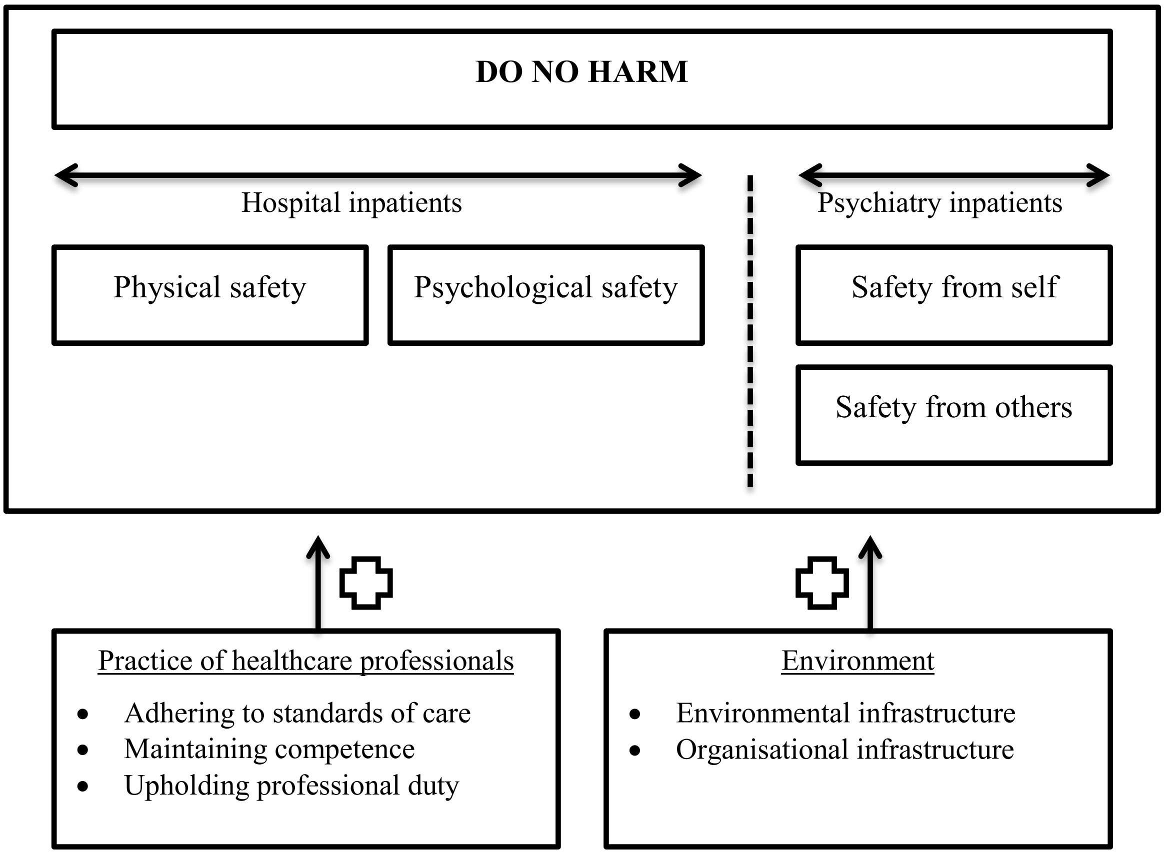

Figure 3.5: The healthcare professional perspective of patient safety

3.6.2 The conceptualisation of patient safety

Sections 3.5.3.3 and 3.5.3.4 identified factors that contribute to patient and healthcare professional conceptualisations of patient safety and, from these, second order constructs were defined. The meta-synthesis sought to synthesise the second order constructs and therefore explain how patient safety is conceptualised.

For each of the groups of studies (patient and healthcare professional) the meta-study team used reciprocal synthesis, which clusters similar concepts together, to organise the second order constructs. Through this, the team defined eighteen factors contributing to the conceptualisation of patient safety; examples of these factors are ‘Environment’ and ‘Workload.’ These factors were then compared across the patient and healthcare professional groups and organised within a unified theoretical framework describing factors contributing to the conceptualisation of patient safety. The factors were compared to each other and organised under five themes: system, staff, patients, processes of care, and relational aspects of care. The full theoretical framework is presented in Table 3.11; each factor is defined, and the table identifies whether the factor was derived from patient and/or healthcare professional perspective, and gives references the associated original empirical studies.

Table 3.11: Theoretical framework for the conceptualisation of patient safety

HCP = Healthcare professional

Theme	Factor	Explanation of the factor	Who?
SYSTEM	**Atmosphere** Stenhouse (2013a); Lyndon et al. (2014); Rhodes et al. (2016b)	The hospital as a 'safe place' with a welcoming atmosphere, noise control, privacy and normalcy.	Patient
	Organisational functions Rhodes et al. (2016a); Rhodes et al. (2016b)	Gatekeeping functions, access to appointments, and finance.	Patient
	Resources Jones (2014); Aveling et al. (2015)	Adequate equipment, materials, Information Technology and electronic health record integration.	HCP
	Safety culture Aveling et al. (2015); Kanerva et al. (2016)	Existence of governance structures, with associated activities, events and atmosphere at ward level.	HCP
	Workload Jones (2014); Valiee et al. (2014); Aveling et al. (2015)	Determined by staffing levels, volume and acuity of patients, working hours. Impacts tiredness, motivation, safety and quality of care.	HCP
	Environment Vaismoradi et al. (2011b); Valiee et al. (2014); Aveling et al. (2015); Collier et al. (2016); Kanerva et al. (2016)	Quality, design and cleanliness of built environment.	Both
	Protocols and Procedures Rathert et al. (2011a); Lyndon et al. (2014); Lovink et al. (2015); Collier et al. (2016); Kanerva et al. (2016); Rhodes et al. (2016a); Rhodes et al. (2016b)	Procedures have inherent risks; protocols exist for safety in everyday work and emergencies (e.g. medication administration). However, patients believe they can limit discretion and undermine safety.	Both
STAFF	**Professional qualities and competence** Van Vorst et al. (2007); Vaismoradi et al. (2011b); Holliman and Bernstein (2012); Stenhouse (2013a); Lyndon et al. (2014); Lovink et al. (2015); Rhodes et al. (2016a); Rhodes et al. (2016b)	Demonstration of consistent technical competence and possession of core attributes (including mannerisms, attitudes, clinical skills and knowledge).	Patient
	Acquisition of skills/training Jones (2014); Valiee et al. (2014); Aveling et al. (2015); Kanerva et al. (2016)	Acquisition or maintenance of skills through training, appropriate supervision and accumulation of experience/knowledge.	HCP
	Responsibility Stenhouse (2013a); Hernan et al. (2014); Kanerva et al. (2016)	The legal, ethical and individual responsibilities of healthcare professionals e.g. Human Rights law, mental health law, duty of care.	Both
PATIENTS	**Impact of self and others** Rathert et al. (2011a); Vaismoradi et al. (2011b); Stenhouse (2013a); Lyndon et al. (2014); Lovink et al. (2015); Rhodes et al. (2016a); Rhodes et al. (2016b)	Control over or input into care and its safety, with support from significant others/fellow patients, without threat from others.	Patient

PROCESSES OF CARE	**Responsiveness** Rathert et al. (2011a); Vaismoradi et al. (2011b); Lovink et al. (2015)	Presence and proximity of nursing staff providing timely management of basic care needs/symptoms, and frequent contact/checks.	Patient
	Care Planning Vaismoradi et al. (2011b); Rhodes et al. (2016a)	Quick determination of a care plan, including investigation, referral and diagnosis. Includes having and being informed of a care plan.	Patient
	Individualised care Kanerva et al. (2016)	Holistic personalised care plan, including in mental health.	Both
RELATIONAL ASPECTS OF CARE	**Patient-staff relationship** Van Vorst et al. (2007); Scott et al. (2012); Hernan et al. (2014); Lyndon et al. (2014); Rhodes et al. (2016a)	Foundation of inherent trust; recognition and alleviation of power imbalances.	Patient
	Psychosocial Van Vorst et al. (2007); Rhodes et al. (2016a); Rhodes et al. (2016b)	The feeling of safety and the minimisation of emotional harm; this includes the social elements of interaction, the expectation and experience of interaction, and what people think/feel.	Patient
	Teamwork and interprofessional working Vaismoradi et al. (2011b); Holliman and Bernstein (2012)	Working and cooperation within teams, including multiprofessional teams.	Patient
	Communication Van Vorst et al. (2007); Kooienga and Stewart (2011); Rathert et al. (2011a); Holliman and Bernstein (2012); Scott et al. (2012); Hernan et al. (2014); Jones (2014); Lyndon et al. (2014); Valiee et al. (2014); Aveling et al. (2015); Collier et al. (2016); Rhodes et al. (2016a)	Communication to the patient, family, within the care team, and outside of care team. It should be professional, respectful, unprejudiced, timely, accurate, open, and patient centred. It includes listening, establishing ideas/concerns/expectations, and information transfer at transitions of care or between team members/other teams.	Both

Overall, the theoretical framework synthesises existing literature on factors perceived by patients and/or healthcare professionals as contributing to patient safety, in an attempt to explain how patient safety is conceptualised more broadly. The framework thematically organises factors that contribute to the conceptualisation of patient safety.

3.7 Discussion

This is the first systematic review and qualitative synthesis of studies examining patient (including members of the public, relatives or carers) and healthcare professional perceptions of patient safety. When asked to define patient safety, healthcare professionals can offer an expansive definition, identifying not only types of safety but also conditions necessary for safety. The healthcare professional perspective aligns with definitions seen in academia and health policy. Patients, in contrast, only describe types of safety, predominantly physical safety and emotional or psychological safety (including the concepts of wellbeing, emotional needs and feeling safe). These are inter-related, with physical safety as a pre-requisite for emotional safety. Psychological safety (the feeling of safety) and physical safety are indistinct to patients, meaning feeling safe and being safe are equally important and intertwined within their definition of patient safety.

Importantly, it is evident that patients' ability to package their understanding of patient safety into a definition is limited. Despite the frequent use of the term 'patient safety' in healthcare, patients may not attach real meaning to it or associate it with their own experiences. This has important implications for the way that we frame questions about safety in research and, more broadly, how we discuss patient safety with patients and involve them in the safety of their care. Given this, recognising that patient safety may not be understood, studies often explored the topic by asking about the patient experience and seeking reflections upon perceived safe or unsafe care, rather than asking about 'patient safety' or seeking a definition; from this, a wider view or conceptualisation of patient safety is elicited. Patient participants were able to discuss the concept of patient safety in relation to their experiences and identify a range of positive and negative factors perceived as contributing to patient safety.

This study provides limited evidence for the public, relative or carer perception of patient safety. Very few study participants were relatives or carers of patients (67 out of a total of 685 participants). One study (Lyndon et al., 2014) focussed solely on the perspectives of parents of babies in the neonatal intensive care unit. In this setting, patient safety was importantly seen as the product of the combined actions of the patient and the clinical team, a concept that appeared unique to this study. However, there were also several factors identified as contributing to the conceptualisation of patient safety that overlapped with the other included studies that focussed on the perceptions of patients (for example atmosphere, procedures and protocols, professional qualities and competence). One further study, (Rathert et al., 2011a) also included the perspectives of parents of children and relatives of adults with chronic conditions or recent experience of acute care. This study, however, did not present the perspectives of these groups separately and it is therefore not possible to draw any specific conclusions about the perspectives. Furthermore, no studies were identified that examined the public perception of patient safety. Therefore, from this study, it is not possible to draw specific conclusions about public perceptions of patient safety due to a lack of available evidence.

Considering both patient and healthcare professional perceptions of patient safety, eighteen factors contributing to the conceptualisation of patient safety were defined (Table 3.11); these factors were subsequently grouped into five themes to develop a theoretical framework for the conceptualisation of patient safety. Within this framework, the similarities and differences between patient and healthcare professional perceptions were demonstrated. Patients identified nine unique factors, with a predominance towards those related to communication, relationships and professional qualities, as has been alluded to in earlier research (Weingart et al., 2007; Rathert et al., 2011a; Rathert et al., 2011c), and processes of care. Healthcare professionals identified four unique factors, with a predominance towards factors that are tangible and measurable (Vincent, 2010), for example skills/training, workload and resources. Patients and healthcare professionals demonstrated a shared understanding of five factors: environment, protocols and procedures, responsibility, individualised care, and communication.

3.7.1 Feeling safe

Of particular interest, the patient conceptualisation of patient safety included patient safety as a psychosocial phenomenon; patients focussed upon the psychological feeling of safety. This concept was evident within both the meta-data-analysis and the meta-method. The meta-method showed that patients were more able to discuss patient safety with reference to feelings of safety, with some interviews adapting their line of questioning to ask patients what made them feel safe or unsafe. The concept of feeling safe is represented within the meta-synthesised patient definition of safety and also within the theoretical framework by the ‘psychosocial’ factor (defined as a relational concept which emphasises feeling safe and avoiding emotional harm (Rhodes et al., 2016a; Rhodes et al., 2016b)). This starkly contrasts biomedical models of safety and the concept of physical safety or being safe; it was evident that healthcare professionals do not consider psychosocial aspects of safety within their conceptualisation of patient, tending to be preoccupied with the more tangible concept of being safe. It is therefore the patient focus upon the concept of feeling safe that is key in the distinction between the patient and professional conceptualisation of patient safety. This therefore warrants further study.

The concept of feeling safe has been explored by other existing studies. For example, a grounded theory study of Intensive Care Unit (ICU) patients developed a model of the psychosocial needs of patients around a core category of feeling safe (Hupcey, 2000); other studies have similarly focussed on the needs of ICU patients (Compton, 1991; Elpern et al., 1992; Russell, 1999). Lasiter (2011) sought to increase the understanding of feeling safe for older adults admitted to ICU in the USA. They developed a theoretical model of older adults' perceptions of feeling safe, which described feeling safe as arising from a process beginning with specific requisites to expected or actual staff actions/interactions. Four requisites were defined (initiative, oversight, predictability and proximity), describing the nature and characteristics of staff and their duties. This work was extended by Lasiter and Duffy (2013), to identify factors influencing feeling safe and expand current knowledge around what feeling safe meant for older adults. There is a degree of similarity between the factors identified in this meta-study and these examples.

It is perhaps a limitation of the meta-synthesis that these studies were not identified in the literature search. There is, however, an important distinction to be made between the theories of feeling safe discussed in the previous paragraph and the findings of the meta-study in this chapter. In the studies discussed above, feeling safe is explored from the perspective of patient experience, patient needs and recovery from illness; in contrast, the concept of feeling safe described in this meta-study has arisen through explorations of patient understanding of the discipline of patient safety. It is not clear to what extent these pre-existing theories of feeling safe relate to the concept of patient safety; they therefore may not be adequate to understand the patient conceptualisation of patient safety in relation to feeling safe. This chapter therefore contributes important new knowledge in relation to patient feelings of safety within this specific context.

Considering the discipline of patient safety, there has been previous recognition of a distinction between physical and emotional safety (Russell, 1999). Despite this, there has been a lack of in depth exploration around and practical action to address the emotional component of safety. Mollon (2014) therefore sought to understand patient safety from the patient perspective and therefore undertook a concept analysis to explore and define the critical attributes of the concept of feeling safe. For the purposes of the study, feeling safe was defined a priori as *"an emotional state where perceptions of care contribute to a sense of security and freedom from harm."* Thirty-one studies (including the work by Hupcey (2000), Lasiter (2011) and Lasiter and Duffy (2013)) were identified. From the included studies, forty characteristics were recognised as relating to the concept of feeling safe. Examples of these are: relationships, checking, presence, safety and security, competence care, trust, being cared for, knowledge and control. Four main categories or defining attributes for feeling safe were then defined, shown in Table 3.12; subsequently, a theory of feeling safe was developed explaining the antecedents and defining attributes necessary for feeling safe.

Category	**Definition**
Trust	An inherent property, born out of the expectations of the staff and relationships
Cared for	This included responsiveness, checking, following up, getting timely help, anticipating needs, and availability
Presence	This included physical presence, proximity and availability
Knowledge	Possession by staff and provision of to the patient

Table 3.12: Categories explaining the concept of feeling safe.
Developed from Mollon (2014)

There are similarities between the defining attributes identified by Mollon and the results of the meta-study. Factors from the theoretical framework (Table 3.11) that explain the patient conceptualisation of patient safety (e.g. professional qualities and competence, responsiveness, patient-staff relationship) are comparable to the attributes 'Trust,' 'Cared for' and 'Knowledge' (Table 3.12). The findings of the meta-study therefore support Mollon's findings about the contributory factors for feeling safe.

There are, however, limitations to Mollon's work which the meta-study goes some way to address. Firstly, despite seeking to explore patient safety from the patient perspective, many of the studies included by Mollon (2014) explored feeling safe from the perspective of caring, wellness and recovery (rather than aiming to pursue a more expansive concept of patient safety). This was justified by recognising that safe can mean many things depending on your frame of reference and that including these studies would achieve recognition of an aspect of safety away from the physical concept. The meta-study has begun developing a more expansive concept of patient safety and an understanding of the concept feeling safe specifically in relation to patient safety, and therefore extends Mollon's findings. Secondly, in the study's discussion, Mollon recognised that there remains a lack of empirical referents for the concept of feeling safe, meaning that it was still not possible to fully define and quantify the concept. The meta-study, in contrast, has clearly identified factors that contribute to the patient conceptualisation of patient safety, which is importantly focussed upon the psychological component, feeling safe; these factors therefore represent potential empirical referents for the concept of feeling safe. The meta-study therefore further extends Mollon's work by taking the first steps towards fully developing the patient conceptualisation of patient safety as the concept of feeling safe and defining how it is comprised.

3.7.2 Study findings in relation to current research, policy and practice

Current research, policy and practice remains one sided, with patient safety framed from a clinical perspective. Predominantly, promotion and improvement of safety involves identifying and minimising past risk (Vincent et al., 2014), sometimes referred to as the 'Safety 1' approach (Hollnagel et al., 2013). Considering the Monitoring and Measuring Safety Framework (Vincent et al., 2014) discussed in Chapter 1, the key focus is on measurement and practical tangible means for assessing safety that are within the control of the organisation and clinicians. Similarly, The Yorkshire Contributory Factors Framework (YCFF) (Lawton et al., 2012) distils nineteen measurable factors that contribute to patient safety incidents into a hierarchical framework of contributory factors, from proximal (sharp end) to distal (latent) factors. From this, the Patient Measure of Safety (PMOS) tool was subsequently developed to involve patients in patient safety by allowing them to feedback on the safety of their care; it incorporates the factors from the YCFF that patients are able identify at a ward level (Giles et al., 2013; McEachan et al., 2014).

YCFF and PMOS are existing tools that could be considered as representative of current understandings of patient safety from academia/policy and patient perspectives respectively; as such, these tools have been compared to the findings of this meta-study. To demonstrate any similarities the differences between these current understandings of patient safety and the patient conceptualisation of patient safety evident from this study, Table 3.12 maps and compares the factors perceived by patients as contributing to patient from this meta-study to the factors in the YCFF (Lawton et al., 2012), and the individual question items from the validated PMOS (McEachan et al., 2014). Making comparison to the individual question items from PMOS allows a more granular assessment of any similarities and differences. The table identifies whether the meta-study factor is represented in YCFF and/or PMOS, and to which factor or item these relate.

Table 3.13: Comparison of meta-study factors with factors from Yorkshire Contributory Factors Framework and items from Patient Measure of Safety questionnaire

Factor	**By whom?** Patient or Patient & HCP	**YCFF**	**PMOS**	**PMOS Item**
Atmosphere	Patient	Yes (Physical environment)	Partly	1 – Dignity 20 – Noise levels
Organisational functions	Patient	Yes (External policy)	No	-
Environment	Both	Yes (Physical) environment	Yes	11 – Position of nurses station 12 – Lighting 13 – Clutter 14 – Space 20 – Noise 21 – Lighting 22 – Temperature 23 – Cleanliness 24 – Space

Protocols and Procedures	Both	Yes (Policies and) procedures	No	-
Professional qualities and competence	Patient	Yes (Individual factors)	Yes	9 – Able to use equipment 19 – Able to carry out tasks 25 – Poor attitude of staff 27 – Staff know what doing
Responsibility	Both	Yes (Lines of responsibility)	Partly	17 – Clear who was in charge 26 – Knew which consultant in charge 37 – Knew which nurse responsible for care
Impact of self and others	Patient	No	No	-
Responsiveness	Patient	No	Yes	15 – Able to deal with treatment needs 16 – Prompt answering buzzer 18 – someone available to deal with every aspect of my care 33 – Always someone available trained to give treatment
Care Planning	Patient	No	Partly	4 – Got answers to all questions about care 6 – Staff knew about changes in plan of care 29 – Conflicting information about care

Individualised care	Both	No	No	-
Patient-staff relationship	Patient	No	No	-
Psychosocial	Patient	No	No	-
Teamwork and interprofessional working	Patient	Yes Team factors	Yes	5 – Able to get advice from other teams 31 – Staff worked as a team
Communication	Both	Yes Communication systems	Yes	4 – Got answers to all questions 40 – Always felt listened to 42 – Correct information sharing 29 – Conflicting information about care

There are clear similarities and differences between the patient perspective identified in this meta- and the patient perspective represented by PMOS. In Table 3.13, some PMOS question items measure concepts related to the following factors defined within the meta-study: environment, professional qualities and competence, responsiveness, teamwork and interprofessional working, and communication. For some factors identified in the meta-study (atmosphere, responsibility, and care planning), there are PMOS question items which are partly related; for example: 'Atmosphere' includes noise and privacy/dignity which are measured by PMOS items, but also includes other concepts such as being welcoming and normalcy, which are not represented by PMOS items.

The findings of this meta-study indicate that patients have a more expansive conceptualisation of patient safety than the PMOS allows them to report. For example, several factors identified by patients are not represented by items within PMOS: organisational functions, protocols and procedures, impact of self and others, responsiveness, individualised care, patient-staff relationship and psychosocial safety.

YCFF and PMOS tool may continue to propagate the Safety 1 approach, by focussing on identifying and measuring past risk, and parameters that are clinically defined. Indeed, in their own critique of PMOS, Giles et al. (2013) recognised that patients have a more holistic view of issues relating to their safety. A further limitation of PMOS is that it is based upon the YCFF, which in turn is based upon reviews of studies conducted with healthcare professionals. This means that PMOS might not truly reflect the views of patients. Attempts were made to mediate this through an additional unstructured qualitative interview approach; despite this, as evidenced from the mapping exercise, PMOS does not fully capture the patient perspective of patient safety.

Here it is necessary to recognise that the comparisons made between the framework developed in this meta-study (in Table 3.11) and YCFF and PMOS must be applied with caution. This is because the factors in the meta-study represent conceptualisations of patient safety, whereas YCFF and PMOS represent contributory factors in patient safety incidents or measures of patient safety; therefore the concepts being compared are not truly equivalent. Nonetheless, as PMOS is the only available measure of safety for the patient perspective, it is a useful baseline from which to compare existing representations of the patient perspective. Secondly, it is also important to recognise that some concepts are not amenable to measurement and questioning, which may account for some of the apparent limitations of PMOS to represent the patient conceptualisations of patient safety seen in this meta-study.

Overall, whilst PMOS does offer patients an important way to be involved and contribute to patient safety, it is evident that it may not measure factors important to the patient in patient safety, and therefore may not fully represent the patient conceptualisation of patient safety. Beyond this tool, currently, the patient conceptualisation of patient safety is inadequately represented by existing frameworks, theories and models for patient safety. This therefore supports the need for further understanding and subsequent recognition of the patient conceptualisation of patient safety in policy, and the development of tools and practices that adequately take the full patient perspective into account.

3.7.3 Future work

It is evident that the concept of feeling safe is important in the patient conceptualisation of patient safety, whilst healthcare professionals subscribe to objective clinical definitions situated within academia and health policy. The patient conceptualisation includes patient safety as a psychosocial phenomenon; it is the patients' focus upon the concept of feeling safe that is key in the distinction between the patient and professional conceptualisation of patient safety. Some theories and models for feeling safe already exist; however, these are focussed upon patient needs and experience, and it is not clear to what extent these relate to patient safety.

Overall, the current patient safety paradigm does not consider the patient conceptualisation of safety, particularly the psychosocial aspects and feeling safe, favouring objective evidence of safety contained within models, frameworks and measures. This demands further exploration to determine exactly how the patient perspective of patient safety and the concept of feeling safe are comprised.

Importantly, what makes patients feel safe may be different to those things that preoccupy clinicians and policymakers in our current patient safety paradigm (Rhodes et al., 2016b). This has implications for our use of the term patient safety and for the involvement of patients. Steps have been taken to engage with patients and create transparency in patient safety in the NHS; however, current methods of engagement and involvement of patients in patient safety perpetuate the clinical perspective (O'Hara and Lawton, 2016) by using terms that are evidently not understood by patients and failing to take into account their broader conceptualisation of safety. Patient safety policy therefore needs to move on from restricting patient involvement to offering feedback within our current definitions of patient safety (O'Hara and Lawton, 2016), and must develop models of patient safety and approaches to patient involvement that take the broader patient conceptualisation, including the concept of feeling safe, into account.

There is much rhetoric within patient safety policy which advocates for this need to recognise and value the patient perspective. Berwick (National Advisory Group on the Safety of Patients in England, 2013) calls for *"a pervasive culture that welcomes authentic patient partnership."* The Health Foundation advocates for a "*new risk 'paradigm'"*, where we identify, understand and use the perspectives of patients and the public in defining and improving patient safety (O'Hara and Isden, 2013). It has been suggested that patient safety and patient involvement is at a *"crossroads"* whereby policy either continues to fit the patient perspective into the clinical/academic safety paradigm or embarks on a new approach that invites the patient perspective, offering opportunities to define what patient safety is to them and recognising and embracing a more expansive view of safety (Hor et al., 2013; O'Hara and Lawton, 2016).

This study has provided further evidence that patients and healthcare professionals conceptualise patient safety differently; these differences pose a challenge to involving the patient in the current clinically defined patient safety paradigm. Considering this and the calls from within patient safety policy, it is therefore necessary for future work to expand the current (or even create a new) patient safety paradigm that truly values different perspectives, where we move away from clinically derived definitions, and invite patients to contribute in establishing what patient safety is, its boundaries and how it is comprised.

3.8 Strengths and limitations

To my knowledge, this study is the first systematic review and qualitative synthesis of patient and healthcare professional perceptions of patient safety. A clear research question was defined and an extensive search strategy was employed to identify relevant empirical studies. It uses meta-study, which is highly systematic technique for analysis and synthesis. The study has transparently applied the method and adhered to the recommended principles of rigour.

There are some limitations to this study. Firstly, only published articles are included; the search was comprehensive and included hand searching, but it is possible that literature may have been missed. Secondly, qualitative meta-synthesis is criticised as it rests on the assumptions that it is acceptable to generalise findings beyond individual studies. There are concerns that uniqueness, integrity, important differences and value in terms of context will be lost (Sandelowski et al., 1997; Campbell et al., 2003). Despite this, as is seen in this review, it allows the opening up of new insights and understandings (Walsh and Downe, 2005) and is necessary in advancing knowledge of a whole phenomenon (Jensen and Allen, 1996). Thirdly, qualitative meta-synthesis techniques may be criticised in relation to their trustworthiness and credibility. I ensured that the data remained true to source by checking data extraction within the research team and regular discussion and reflection during the interpretation of the findings. To limit potential researcher biases, the procedures, methods and analysis have been stated transparently and were undertaken as a research team, with regular discussion and reflection (Paterson, 2001; Walsh and Downe, 2005).

The search terms used, specifically the synonyms for ‘patient safety’ were limited; there are many other terms that could have been used (including, but not limited to, incident, misdiagnosis, misadventure, or different types of safety e.g. medication safety). Broad search terms were employed as the study sought to specifically understand definitions of patient safety as a broad concept, and specifically patient safety as is currently defined and recognised within policy and clinical practice. As a result, this study may not include understanding of specific types of safety and may miss appropriate literature that used alternative terms for patient safety. Additionally, literature that explores patient safety from the patient perspective that uses their conceptualisations and language in the titles/abstracts, rather than these familiar clinical and policy terms may have been overlooked. Overall, this may mean that the meta-study does not represent the entire understanding of patient safety from all angles and approaches; nonetheless, it importantly demonstrates significant deficits in our current patient safety models and provides sufficient evidence and justification for exploring different conceptualisations of patient safety further.

There was heterogeneity of study setting (country and clinical specialty); of note, six out of the thirteen patient studies focussed on the community/primary care setting, where patient safety and conceptualisations of patient safety may be different to secondary care and other care settings. Overall, this places a limit on the generalisability of the synthesis, especially to the NHS, and it is difficult to draw conclusions around how clinical specialty impacts conceptualisation of patient safety and to what extent the finds of this meta-study relate to primary, secondary and other care settings.

Considering the study participants, it is not possible to determine from this study the impact of ethnic diversity, thus placing limits on its ability to understand how safety may be culturally and socially bound. Detailed information is provided, however, about each study to maximise potential for generalisability. Only 67 out of 685 study participants were relatives or carers of patients, and no studies included members of the public; due to limited available evidence, this study is therefore not able to draw conclusions about the public, relative or carer perceptions of patient safety, and therefore focuses upon the patient perception.

There are limitations to the framework developed in Section 3.62, shown in Table 3.11; it is purely descriptive, with factors organised thematically. From this study it is not possible to draw conclusions about relationships between these themes and factors to develop an explanatory model or theory about the conceptualisation of patient safety. Despite this, overall, the framework indicates that there are real differences between the patient and healthcare professional conceptualisation of patient safety, and is therefore an important contribution to our understandings of different perspectives of patient safety.

Despite the limitations, this study supports the viewpoints in the literature that patients and healthcare professionals have different perceptions of patient safety, and it strengthens the call to further understand and then broaden the conceptualisations of patient safety by incorporating the patient perspective.

3.9 Conclusion

This study has explored definitions of patient safety and how patient safety is conceptualised more broadly through identifying factors perceived as contributing to patient safety, from both the patient and healthcare professional perspective. There is evidence of both similarities and differences in perceptions of patient safety between patients and healthcare professionals. Differences exist in the specific definitions of patient safety offered by patients and professionals and, more generally, in the factors that contribute to their conceptualisations of patient safety. In considering the contributory factors, these were grouped and then organised thematically within a theoretical framework for the conceptualisation of patient safety; this, however, remains descriptive as it was not possible to postulate relationships between themes and factors to develop an explanatory model or theory for the conceptualisation of patient safety.

To strengthen these conclusions, further work is required to understand conceptualisations of patient safety and provide further evidence, within the specific context of the NHS, of differences between patient and healthcare professional conceptualisations of patient safety. To achieve this, further qualitative work should be conducted that aims to explore and compare conceptualisations of patient safety within the NHS, and also consider the impact of cultural, sociological and clinical factors. This would therefore provide the evidence to support and develop a new patient safety paradigm that values different perspectives, which is relevant to the NHS.

Chapter 4: How do patients conceptualise patient safety?

4.1 Introduction

This thesis has thus far presented the similarities and differences between the patient and healthcare professional perspective of patient safety from the existing evidence; the differences pose a challenge for meaningfully and accessibly involving patients in the currently clinically orientated patient safety paradigm. Chapter 3 used meta-study to identify, review and synthesise the existing qualitative evidence exploring both how 'patient safety' was defined and, more broadly, how patient safety was conceptualised. Through the meta-study, patient and healthcare professional definitions of patient safety have been identified and synthesised; additionally, factors perceived as contributing to patient safety were identified. Patients were not familiar with the term 'patient safety' and struggled to package their understanding of the concept into a definition; however, patients were able to discuss patient safety in the context of their experiences of care, particularly describing the processes in healthcare that made them feel safe or unsafe. The key distinction between the patient and healthcare professional conceptualisation was the patient focus upon feeling safe, a psychosocial phenomenon; this is distinct from biomedical models of safety and the healthcare professional focus upon objective tangible measures of safety and the concept of being safe.

The theoretical framework created through meta-synthesis thematically grouped factors named by patients and healthcare professionals as contributing to their conceptualisation of patient safety. Whilst this provides a useful summary of how patient safety is conceptualised more broadly, and where there are differences between the patient and healthcare professional perspective, the framework has limitations. Firstly it is based upon heterogeneous studies (both in relation to clinical context and country), which may limit its generalisation to the NHS. Secondly, the themes are purely descriptive; from this it was not possible to draw conclusions about the relationship between themes and factors and develop an explanatory theory of the conceptualisation of patient safety. Therefore, whilst the findings of the meta-study support the existence of different perspectives and add to the call to develop a more expansive patient safety paradigm, valuing these differences, they do not provide sufficient evidence to support, develop and implement a new patient safety paradigm relevant for the NHS.

To support policy developments in expanding or defining a new patient safety paradigm, further qualitative work is necessary to definitively understand how patient safety is conceptualised in the NHS, by both patients and healthcare professionals to consider how this may be affected by different clinical settings, and to develop theory that explains this. As the first step in achieving this, the study presented here aims to understand how patients conceptualise patient safety across three clinical specialties: acute medicine for the elderly, elective surgery and maternity.

4.2 Defining the research question

In a qualitative study, a researcher states research questions, and not objectives or hypotheses. Defining the research question guides the focus of a study, influences methods and bounds what will be studied (Corbin et al., 2008). Qualitative research questions allow exploration of multiple factors and perspectives that contribute to the phenomenon under study (Creswell, 2007); they take the form of broad central questions and associated sub-questions (Creswell, 2009). Additionally this allows for adaptation and flexibility in the study as data is generated.

Considering this, the central research question for this study was:

How do patients conceptualise patient safety?

This was supported by the following sub-questions:

1. What are patients' perceptions of patient safety, including their knowledge, understanding and experiences of patient safety?
2. How do these perceptions contribute to the patient conceptualisation of patient safety?

3. What is the impact of clinical setting (acute medicine for the elderly, elective surgery, maternity) upon the conceptualisation of patient safety?

The next section will discuss the qualitative methodology, constructivist grounded theory (Charmaz, 2006), that was used to answer this research question.

4.3 Methodology

4.3.1 Grounded Theory

Grounded theory (Glaser and Strauss, 1967) is a qualitative research design in which the researcher generates a general explanation or theory about a process, action or interaction (Strauss and Corbin, 1998; Creswell, 2007; Creswell et al., 2007). It is both a method and a product, and is described as a truly inductive systematic method designed to move data to substantive theory to explain a social process, with the resulting theory grounded in the data (Willig, 2001). The theoretical influences of grounded theory are based within pragmatist philosophy[8] and symbolic interactionist sociology[9] (Corbin and Strauss, 2015). These ideas have influenced grounded theory methodology over time, and are explained in a set of assumptions with methodological implications

The emergence of grounded theory challenged the dominance of logico-deductive methods (those that simply tested hypotheses, relied on pre-existing constructs or categories, or applied existing theories), by setting out to gather data and develop theory directly derived from or grounded in the data (Glaser and Strauss, 1967; Dey, 1993; Willig, 2001; Walker and Myrick, 2006). By being grounded in data, theory that is produced is purported to be uninfluenced by preconceptions, theories or researcher influences (Willig, 2001); it discovers 'what is' or the one truth of a social

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[8] Pragmatism is the philosophical study of action, process and meaning (Charmaz, 2000).

[9] Symbolic interactionism tells us that individuals structure the external world through their perceptions and interpretations of it; meaning therefore arises from experience and social interaction, and is contextual and changes over time (Blumer, 1969; Blumer, 1986; Dey, 1999; Starks & Trinidad, 2007). In this way, symbolic interactionism proposes that reality is socially constructed and related to the interpretation of action (Charmaz, 1990).

process (Glaser, 1992; Locke, 2011).

Grounded theory as a method uses a number of key strategies. The strategies include constant comparative analysis, negative case analysis, theoretical sensitivity, theoretical sampling, theoretical coding and theoretical saturation; these are defined in Table 4.1, and their application to the work in this chapter will be discussed in more detail in the Methods section.

Strategy	**Definition**
Constant comparative analysis	The process of moving back and forth through the data during coding in order to identify similarities and differences amongst emerging categories, in order to link and integrate categories to form a theory
Negative case analysis	The seeking out if negative cases, or instances that do not fit, within a theory in order to qualify, enhance and develop the complexity of the data upon which a theory is based
Theoretical sensitivity	The interaction of the researcher with the data to reach a theory by asking questions of the data, comparing it and search for opposites
Theoretical sampling	The collection of further data in light of emerging categories in order to test an emerging theory against incidents that confirm or challenge it
Theoretical coding	The application of a coding paradigm or coding framework to data, which guides the research in their analysis of the data
Theoretical saturation	The goal for data collection and analysis, this is the point at which no new categories emerge

Table 4.1: The key strategies of grounded theory

Developed from Willig (2013)

4.3.2 Constructivist Grounded Theory

Constructivist grounded theory is a grounded theory methodology defined by Charmaz (2006). She describes a grounded theory method aligned with constructivism, assuming a relativist ontology, meaning there are multiple social realities, and research knowledge is co-created between the researcher and the researched (Guba and Lincoln, 1994; Schwandt, 1994; Charmaz, 2000).

Constructivist grounded theory refutes the existence of a discoverable objective reality, and the role and influence of the researcher is valued; the researcher is recognised as more than a witness, and therefore as an interpreter of data (Charmaz, 2006). The results of constructivist grounded theory are described as a construction of reality, rather than reality itself (Charmaz, 2006). It is therefore accepted that the resulting theory is just one particular interpretation of the phenomenon under study, rather than the truth (Willig, 2001). This approach addresses the concerns of reflexivity within grounded theory by recognising the perspective of and questions asked by the researcher (Dey, 1999).

4.3.3 Rationale for choosing constructivist grounded theory

This study aims to understand how patient safety is conceptualised by patients and the public, including exploring their experiences; constructivist grounded theory was chosen to achieve this. The section explores the rationale for choosing it.

My earlier work in Chapter 3 suggested that patient conceptualisations of patient safety is process based; grounded theory can be used to study individual processes, interpersonal relationships and the effects between individuals and larger social processes (Charmaz, 1996). Other researchers have also recognised the nature of patient safety as a social process (Lyndon, 2008; Lyndon and Kennedy, 2010; Lyndon et al., 2012) and have similarly used grounded theory to study the phenomenon. Considering this, grounded theory is therefore appropriate for this study.

Constructivist grounded theory, specifically, was selected as it aligns with my epistemology and ontology (discussed in Chapter 2). Constructivism, and therefore constructivist grounded theory, accepts the existence of multiple realities and seeks multiple individual accounts (Charmaz, 2006).

Importantly, the fundamental aim of constructing theory also influenced the selection of grounded theory. For social scientists, theory helps to make sense of a complex phenomenon through a process of deduction and induction. Theory allows researchers to gather information, organise it, give it meaning and meaningfully express it (Reeves et al., 2008; Corbin and Strauss, 2015). Theory can subsequently be practically applied for managing problems or reaching desired goals (Corbin and Strauss, 2015). This thesis seeks to understand how patient safety is conceptualised and to develop a new patient safety paradigm; in constructing theory about how patients and the public conceptualise patient safety, methods for engaging them and involving them in ways that align with their conceptualisations can therefore be developed.

Other interpretative methodologies exist, which have also been considered for this body of work, for example Interpretative Phenomenological Analysis (IPA). IPA aims to investigate the experiences of an individual, how they make sense of them, and the meanings those experiences hold (Smith, 2004). It draws upon the fundamental principles of phenomenology (concerned with the way things appear to individuals in their experience), hermeneutics (the belief that access to the world of experience is through interpretation) and idiography (referring to in depth analysis of single cases or perspectives) (Smith and Osborn, 2003; Langdridge, 2007).

I have considered IPA as a methodological tool for this body of work. Phenomenology primarily aims to explore an individuals' lived experience of a phenomenon, how they make sense of it and the meanings those experiences hold for them; patient safety cannot be characterised (yet) as a lived experience. Considering the hermeneutic aspect of IPA, I will be making an interpretation of the participants' interpretations of what patient safety is. This, however, is recognised and managed with the use of a constructivist approach. Finally, considering idiography, I am not aiming to produce rich detailed individual descriptions; rather I am seeking to achieve consensus across multiple individual narratives (Charmaz, 2006) and develop an abstract theory that explains how patient safety is conceptualised. IPA is therefore not appropriate considering the study aim.

4.4 Methods

4.4.1 Design

In depth, semi-structured, individual interviews were used to collect data; these are described as personal and intimate encounters that *"elicit detailed narratives and* *stories"* (Dicicco-Bloom and Crabtree, 2006; Whiting, 2008), by asking participants pre-set open-ended questions from a topic guide (Dicicco-Bloom and Crabtree, 2006; Jamshed, 2014). A topic guide allows systematic and comprehensive exploration of a topic, whilst also keeping it focussed upon the studied phenomenon (Dicicco-Bloom and Crabtree, 2006); it is generally comprised of core questions and associated questions or prompts, which therefore permit some flexibility to pursue interesting or important areas that arise (Smith and Osborn, 2003; Creswell, 2007). As this is a flexible method of data collection for generating rich narratives of the phenomenon under study, it was an appropriate approach for the exploratory aim of the study.

The topic guide was developed from general literature review and through reflection upon the outcomes of Chapter 3. It was adapted for each of the three included clinical settings: acute medicine for the elderly, elective surgery and maternity. It consisted of core open questions and subsequent prompts, to be used if the participant could not answer the initial questions or to develop a more comprehensive response; this is referred to as *"funnelling"* (Smith and Osborn, 2003). The topic guide was flexible and revised as interviews took place; this reflected my developing understanding of their conceptualisations of patient safety. The topic guides broadly covered:

- Demographic details
- Knowledge and understanding of 'patient safety'
- Experience of patient safety, including feeling safe and unsafe
- Importance of patient safety to the patient
- The patient role in patient safety
- Discussions about patient safety, including being given information by healthcare professionals, asking questions or reporting concerns
- Friend, family and carer perceptions of patient safety

Considering the results of Chapter 3, the interview framed questions in a way that would be more accessible to patients. They were initially asked about the definition of the term 'patient safety'; however, recognising that patients may not attach real meaning to the term or associate it with their own experiences, the interview was designed to ask patients about their experiences of safety in their care. As it became clearer about how patients conceptualise safety, the topic guide was amended to ask what made them feel safe or unsafe. The full topic guide can be found in Appendix 5.

4.4.2 Setting and participants

The study took place at St Mary's Hospital, a large central London teaching hospital. Current inpatients were recruited to the study as they are currently using and experiencing healthcare, and therefore have first-hand experiences of patient safety. A broad range of clinical specialities was included – acute medicine for the elderly, elective surgery and maternity (postnatal ward); this was to both assess the impact of clinical setting upon conceptualisation of patient safety but also to improve the generalisability of the outcome.

There were additional reasons for including the particular specialties. Patients in acute medicine for the elderly (defined as over 65 years and admitted as a result of an acute medical emergency) are at high risk of adverse events (Tsilimingras et al., 2003; Sari et al., 2008; Panagioti et al., 2015); they represent a vulnerable patient group, whose perspectives may not be captured by mainstream patient surveys (O'Hara and Isden, 2013). As a 'harder to reach' group, who may not be able to speak up for themselves, for whom physical and mental frailty may be a barrier to participation (O'Hara and Isden, 2013) or for whom involvement in research poses more risk or ethical challenge, they have traditionally been neglected in research (McMurdo et al., 2011). Elective surgical patients are more 'well' and may experience care, and as such patient safety, differently because of their different route to admission and clinical status. Finally women in the postnatal setting represent a 'well' population, who are often well educated about labour and delivery through the process of antenatal care and, similar to the elective surgical patients, may experience care and patient safety differently.

Participants were eligible if they were:

- A patient in acute medicine for the elderly, elective surgery or maternity (postnatal ward).
- 18 years or older

- Clinically well/stable enough to participate (as determined by clinical staff)
- Able to given informed consent

No exclusions were made on the basis of language. Access to an interpreter was offered for those who required it to participate.

4.4.3 Sample size

Typically, in grounded theory, data collection and analysis takes place concurrently, with methods such as theoretical sensitivity, negative case analysis or theoretical saturation (as discussed above) used to broaden and refine data collection and analysis. Data collection and analysis continues until no new variation for existing categories emerges, the categories are 'saturated' and explain the bulk of the data; therefore, a sample size is not pre-determined. In this study abbreviated grounded theory (Willig, 2001) was used. This means that data is only analysed according to grounded theory (using coding and constant comparison) and grounded theory methods are not applied to data collection.

Abbreviated grounded theory was employed for two reasons. Firstly, theoretical saturation is seen *"as a goal rather than a reality"* (Willig, 2013). With the generation of theory, there is the constant possibility of emergent perspectives arising at any time in the research process, which would change or develop the theory; in this way theory generation may be seen as a never-ending process (Dey, 1999). Abbreviated grounded theory places a limit upon this process. Secondly, abbreviated grounded theory is advocated where there are time or resource constraints (Willig, 2013).

Given this, it was necessary to define an appropriate sample size. The aimed sample size for each group was 6-8 participants. This number was chosen with reference to research which has shown that thematic saturation is achieved with between 6 and 12 interviews (Guest et al., 2006). This initial sample size was reviewed and found to be adequate.

4.4.4 Ethical considerations

Ethical approval was granted for this study by National Research Ethics Service (NRES) Committee North West – Greater Manchester South (Reference: 15/NW/0694). The main ethical issues related to informed consent, risks of the study, confidentiality and data management.

Participants were required to give informed consent to participate. Following the receipt of the information sheet, patients were given twelve hours to decide if they were willing to take part. To give informed consent, the participant had to have capacity; this meant they had to demonstrate understanding of the purpose and nature of the study and the possible risks and befits, be able to retain and weigh up the information about the study, and freely communicate a decision.

The study did not offer any direct benefit to the participants (beyond contribution to improving patient safety) and patients were advised that their participation or non-participation would not affect the standard of care they were receiving and was entirely voluntary. Participants were free to withdraw at any point without providing a reason and without it affecting the care received. There was a small chance of participants finding the issues raised by the study to be difficult and worrisome; support mechanisms were identified in the event of this occurring (e.g. discussing issues with clinical team, ward manager or Patient Advice Liaison Service). Additionally, interviewing can be emotionally demanding for the researcher; for me as the interviewer, my supervision team formed an important debriefing and support mechanism during data collection.

Some personal data was collected for the purposes of contacting participants to arrange interview and to inform patients of study results. All data collected was kept in a combination locker in a locked office. Study data is stored for 10 years to allow reference to data requested regarding published research. Participants were advised that their responses would be confidential, except in the circumstance where serious unreported patient safety events, on-going safety issues or clinical concerns were identified that could present on-going risk to the participant or others; in this situation, it was advised that confidentiality would be broken, although anonymity could still be preserved.

4.4.5 Recruitment

Hospital inpatients were recruited directly from the wards. When recruiting patients on a ward level, permission was sought from clinical ward managers to approach patients. Ward staff members (doctors, nurses and midwives) were asked to identify appropriate patients (those who were clinically well/stable enough to participate). Potential participants were approached, the study was explained and they were issued with a participant information sheet (Appendix 6). Patients were given a minimum of 12 hours to decide if they wished to participate, after which the researcher returned, consent was taken (Appendix 7) and the interview conducted at that time or a mutually agreed time. If the participant remained undecided and wanted more time, the researcher returned 24 hours after the initial approach.

4.4.6 Data collection

Written informed consent was sought from all study participants for participation in the interviews. The informed consent discussion and interview took place at a convenient location, in an appropriate language; translators were made available for patients requiring it to be able to participate. At the beginning of each interview, participants were given an explanation of the interview and overall study. They were reminded that the content of the interview is confidential and anonymous. An audio recording was made of the interview. The interviewer took field notes reflecting verbal responses and reflections to be used to adapt the topic guide/study direction. The audio recordings were professionally transcribed and the transcripts were reviewed for accuracy.

4.4.7 Data analysis

Data analysis, using constructivist grounded theory (Charmaz, 2006), was undertaken after data collection was complete and not concurrently. Grounded theory was applied to the original data only, and not to the process of collecting data, which is known as abbreviated grounded theory (Willig, 2001). The transcripts were read and re-read, prior to commencing analysis. Interview data were analysed on paper, by hand, at all stages. In analysing the data, the transcripts for each participant cohort were initially analysed in their separate groups during coding.

Coding is an iterative, inductive and reductive organisational process for exploring and comparing data (Walker and Myrick, 2006). It is the defining of broken down data through naming it with a label (Willig, 2001; Walker and Myrick, 2006). Labels should categorise, summarise and account for the data (Charmaz, 2006). There are three levels of coding in constructivist grounded theory: initial coding, focussed coding, and theoretical coding. These are the fundamental processes that take the researcher from possession of a transcript to a theory (Strauss, 1987; Walker and Myrick, 2006). Two techniques, constant comparison and memo writing, which are fundamental to coding procedures, were employed.

In the subsequent sections, I will firstly explain constant comparison and memo writing. Then, I will explain and describe the levels of coding and the procedures used. Finally, I will discuss the development of theory from data and how this was achieved.

4.4.7.1 Constant comparison method

Fundamental to developing a grounded theory is the constant comparison method; this is defined as an iterative process through which the researcher compares data with data, data with code, code with code, code with category, category with category, and category with concept (Charmaz, 2014). Constant comparison creates momentum in the analysis by seeking similarities and differences within and between categories (Willig, 2001), and serves to determine if the data supports and continues to support the developed categories (Holton, 2007).

Constant comparison was used throughout the three stages of coding. In doing this, I continually returned to the data. I also sought negative cases (instances that did not fit); consistent with abbreviated grounded theory, negative cases arose within the data rather than through further theoretical sampling. Negative cases encourage refinement of categories and the development of subcategories, and ensures the complexity and diversity of data is captured (Willig, 2001).

4.4.7.2 Memo writing

Memo writing is a component of analysis and theory construction; memos can take many forms but they share the common purpose of tracing how the theory developed (Willig, 2001). Charmaz (2006) views memos as the space in which a researcher can reflect upon what they have *"seen, sensed, heard and coded."* They form the basis of a researcher's analytical notes to explain, fill out, compare and connect categories. It starts from the beginning of the research process, but is particularly important from the focussed coding stage when you are seeking analytical directions. Clustering is a useful technique for beginning memo writing; it is a non-linear, visual and flexible way of understanding and organising material (Rico, 1983), similar to conceptual or situational mapping (Clarke, 2003; Clarke, 2005). It moves towards showing how ideas fit together, and forms a structure around which you can write. Memo writing, utilising the clustering technique, was employed during focussed and theoretical coding, and during theory development.

4.4.7.3 Initial coding

Initial coding is the first stage of coding in constructivist grounded theory. In initial coding each data segment is named; it can be done word-by-word, line-by-line, incident-to-incident, or using a combination of these (Charmaz, 2006). This process fractures the data (Charmaz, 2006; Walker and Myrick, 2006). According to Charmaz (2006), initial coding requires a researcher to remain close to the data, to be comparative and to be open to the many possibilities within the data; as such, the codes remain provisional in order to improve fit. Codes are not preconceived; rather they are created through the researcher's interaction with the data. Initial coding should be fast and spontaneous; this gives the researcher a fresh view of the data and prevents over-thinking. It forces the researcher to think about the data in new ways, findings new patterns and ways that may even differ from participants' interpretations. Some codes will be obvious and fit easily, whilst others will require revisiting. It is recommended that the researcher try to see actions in the segments of data that she is coding; this can be aided through the use of words that reflect actions or the use of gerunds (words of '-ing form'). Additionally *in vivo* codes are helpful in preserving participant meaning in coding.

Following recommendations by Charmaz (2006), I remained close to the data, moved quickly through it and continually compared data with data to refine codes; this ensured participant meanings were retained and avoided me importing my own language to the data. In addition, the use of short codes, *in vivo* codes and gerunds preserved both action and participant meaning; additionally codes maintained the participant perspective, by using pronouns like *"I"* and *"me."*

A second researcher (AM), a healthcare professional with experience in qualitative data analysis but no background in patient safety research, initial coded 25 percent of the transcripts. Multiple coding is similar to the quantitative concept of inter-rater reliability and is used to reduce the subjectivity of the process of qualitative data analysis (Barbour, 2001), and confers rigour. It is considered useful to have other researchers analyse segments of data and review coding frameworks (Barry et al., 1999), not for the level of agreement between researchers, but the content of discussions around disagreement and the insights discussing coding can have for refining the codes (Barbour, 2001). Importantly it encourages the consideration of other interpretations and greater interrogation (Barbour, 2001). EB and AM met to review and discuss their coding. There was evident concordance between the two researchers; furthermore the process served to clarify, expand and refine developing codes by providing new insights.

4.4.7.4 Focussed coding

In the second stage, focussed coding, the most significant or frequent initial codes are used to help organise larger segments of data. Focussed codes are more directed, selective and conceptual (Glaser, 1978; Charmaz, 2006); strong analytical directions identified within initial coding form the basis of focussed coding. Memos are then used to raise focussed codes to conceptual categories. Glaser and Strauss (1967) define a category as *"a conceptual element in a theory."* They are the codes that best represent what is happening in your data and form part of the developing analytical framework. A conceptual category moves beyond the descriptive and explains processes in the data; categories often subsume common themes in several codes. As with codes, categories may be *in vivo*, maintaining the language of participants or theoretical.

In this stage, I moved across interviews in order to compare patients' experiences.

Through this process of comparing data with data, focussed codes were developed that explained ideas, events or processes across the data (Charmaz, 2006). I examined which initial codes made the most sense in order to categorise the data as a whole. I continually compared data to the developing focussed codes, which helped to refine them. Examining focussed codes and using memos, I developed conceptual categories. This was aided by a technique called clustering, which is a practical paper exercise that allows flexible organisation of data.

4.4.7.5 Theoretical coding

Theoretical coding follows focussed coding and develops possible relationships between conceptual categories developed in focussed coding. Theoretical codes integrate and weave fractured coded data back together (Glaser, 1978) to tell a coherent analytical story and move that story in a theoretical direction (Charmaz, 2006). Glaser (1978) used 18 theoretical coding families to aid this process; Charmaz (2006) does not directly recommend this and it is criticised similarly to axial coding advocated by Strauss and Corbin (1990) for being prescriptive and deductive, by encouraging the search for particular patterns within the data rather than starting from the data itself Willig (2001). Theoretical codes clarify context and conditions in which a phenomenon is evident (Charmaz, 2006) and characterise the social reality of the phenomenon (Charmaz, 1990).

Memo writing and clustering paper exercises were used to develop the relationships between conceptual codes, thereby assisting theoretical coding and subsequent theoretical category development. Conceptual maps showing the theoretical categories, conceptual categories and their sub-categories were developed for each participant cohort; these were then compared, with the aim of developing a unified theory that explained how patient safety was conceptualised.

4.4.7.6 Theory development and theoretical sorting

Theory is distinct from descriptions; descriptions are words that create a mental picture of a phenomenon (Corbin et al., 2008), whereas theory is abstract and explanatory (Charmaz, 2006; Corbin et al., 2008). In earlier grounded theory works, the identification of the *"basic social process"* was considered fundamental to theory development (Glaser and Strauss, 1967; Glaser, 1978); basic social processes are defined as those processes that shape the actions and understandings of the participants (Charmaz, 2006). In this stage, I sought to uncover the processes underlying the conceptualisation of patient safety; this was achieved through theoretical sorting.

Theoretical sorting considers the possible relationships between categories and how they could be integrated into theory (Glaser, 1978; Charmaz, 2006; Walker and Myrick, 2006). It reconstructs multiple narratives and explains the processes that underlie a phenomenon (Dey, 1999). Charmaz (2006) explains that for constructivists, categories serve as *"interpretive frames"* and are an abstract means of understanding relationships. Using sorting and diagramming of categories and memos, the previously developed categories were compared and ordered/grouped, considering how their arrangement reflected the studied phenomenon and the logic of the categories themselves (Charmaz, 2006). Relationships were postulated between theoretical categories and a theory was developed.

4.4.8 Maintaining rigour

Rigour in qualitative research was addressed in Chapter 2. Rigour is implicitly built into grounded theory method, provided it is transparently stated (as above) and applied (Cooney, 2011). Rigour was additionally maintained with reflexive memo-ing and self-reflection (Tracy, 2010). The origin of the data and codes was tracked throughout the analysis and illustrative quotes are presented to support the analysis.

4.4.9 Transcription notation

In the subsequent sections, I will use illustrative quotes to support themes identified. Table 4.2 provides an explanation for notation used.

Notation	**Meaning**
…	Natural pause
[sic]	Participant has said something that is not grammatically correct, rather than an error in transcription
Bold text	Participant emphasis on a word/phrase
{ }	Indicates action e.g. gesturing, laughing
--	Quote shortened/part removed

Table 4.2: Transcription quotes notation

4.5 Results

This results sections is divided into the following sub-sections: demographic details, conceptualisations of patient safety, exploring and understanding experiences that led to feelings of safety, theoretical and conceptual categories, and The Patients' Safety Theory (TPST).

4.5.1 Results 1: Demographic details

A total of 24 participants were interviewed between the 3rd November 2015 and the 30th November 2016. The demographic details of each participant group are presented here.

Eight 'acute medicine for the elderly' patient participants were recruited from one acute medical ward and two care of the elderly wards with the assistance of the Older Persons Acute Liaison team, and ward doctors and nurses. Five male and three female patient participants with an average age of 85.9 years (range 81-94 years) were interviewed. The full demographic details are given in Table 4.3. Interviews took place at the bedside and lasted an average of 32.3 minutes (range 16-90 minutes).

No.	Gender	Age	Ethnicity	Admission	Family support	Job
1	M	94	White British	Fall	Friends	Delivery
2	F	90	White Irish	Pneumonia	Children	Photographic specialist
3	M	82	White British	Fall	Partner	Messenger
4	F	81	White Irish	Fall	None - Partner in care	Book keeper
5	M	83	White British	Pneumonia	Partner	Legal administrator
6	M	86	Other White	Nausea and vomiting	Daughter	Tutor
7	F	90	Other White	Fall	Children	Company director

8	M	81	Black Caribbean	Cardiac problem	Wife	Porter

Table 4.3: Demographic details - acute medicine for the elderly patient participants

Eight patient participants on the postnatal ward were recruited to the maternity cohort with the assistance of midwives and doctors. Eight female patient participants with an average age of 33.9 years (range 27-39 years) were interviewed. The full demographic details are given in Table 4.4. Interviews took place at the bedside and lasted an average of 24.5 minutes (range 14-39 minutes).

No.	**Gender**	**Age**	**Ethnicity**	**Admission**	**Parity**[10]	**Job**
1	F	37	Other White	Normal vaginal delivery, after pre-term, pre-labour rupture of membranes.	2	Publishing
2	F	37	White British	Elective lower segment caesarean section for twins. Short cervix with cervical cerclage and pre-term labour.	2	Lawyer
3	F	33	Black African	Elective lower segment caesarean section for twins, with hypertension and proteinuria.	3	Not working
4	F	39	Black African	Elective lower segment caesarean section, hypertension.	3	Carer.
5	F	33	White British	Emergency lower segment caesarean section breech and rupture of membranes. Baby admitted to Neonatal Intensive Care Unit.	1	Marketing
6	F	36	White British	Emergency lower segment caesarean section for failure to progress.	1	Teacher
7	F	27	Asian	Normal vaginal delivery, with postpartum haemorrhage.	2	Nanny
8	F	29	Black British	Emergency lower segment caesarean section for failure to progress.	1	IT/Business analyst

Table 4.4: Demographic details - maternity patient participants

Eight elective surgical patient participants were recruited from two surgical wards with the assistance of ward doctors and nurses. Five male and three female patient participants with an average age of 64.8 years (range 33-87 years) were interviewed. The full demographic details are given in Table 4.5. Interviews took place at the bedside and lasted an average of 36.6 minutes (range 16-67 minutes).

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[10] Parity relates to the number of pregnancies carried to a viable gestation.

No.	Gender	Age	Ethnicity	Admission	Family support	Job
1	F	87	Asian	Elective aneurysm repair	Relatives	Worked for church
2	M	60	White British	Elective incisional hernia repair	Friends	Unemployed
3	F	73	Arab	Elective sigmoid colectomy	Husband, nieces	Did not work
4	F	44	White British	Elective vein stenting	Family and friends	Tutor
5	M	76	White British	Elective right hemi-colectomy	Wife	Retired civil servant
6	M	65	White British	Elective vascular bypass	Family	Hotel receptionist
7	M	33	White British	Elective vascular	Wife	Steel erector
8	M	80	Asian	Elective amputation	Family	Waiter

Table 4.5: Demographic details - elective surgical patient participants

4.5.2 Results 2: Conceptualisations of patient safety

In this section, I explore participants' definitions and broad conceptualisations of patient safety. The results for the three patient participant groups are combined.

Participants were first asked to define or explain what they thought patient safety was. For many participants, this was not a familiar concept:

> *"No. I never heard of that one." (Elderly 1)*
>
> *"I don't know if I can answer that." (Surgery 1)*
>
> *"The problem here is really that I can't understand what **you** mean about safety in this case." (Elderly 7)*

Participants alluded to the idea of there being different concepts to patient safety, recognising that they, as patients, may have a different perspective of patient safety to a researcher or a healthcare professional:

> *"I know what I mean but I don't know what you mean." (Surgery 8)*

Participants identified patient safety as having both objective and subjective components. As well as safety being a *"reality"* or a tangible state ('I am safe'), patient safety was also a personal state, related to how people feel ('I feel safe'):

> *"I can say in two different parts…that's personally or how people feel, or the fact they're facing it, the reality around… About myself in particular, I am – yeah, I feel safe." (Maternity 5)*

Whilst some participants voiced explanations of safety that were similar to academic and clinical definitions of safety, emphasising an objective component (the idea of 'being safe'), the distinguishing feature of the initial patient conceptualisation of safety was the subjective component. To patients, patient safety meant feeling safe. Participants wrestled with the competing notion that they could be and/or feel both safe and unsafe in hospital. The initial conceptualisation of patient safety is illustrated in Figure 4.1, and the objective and subjective conceptualisations of safety are each discussed in detail in turn.

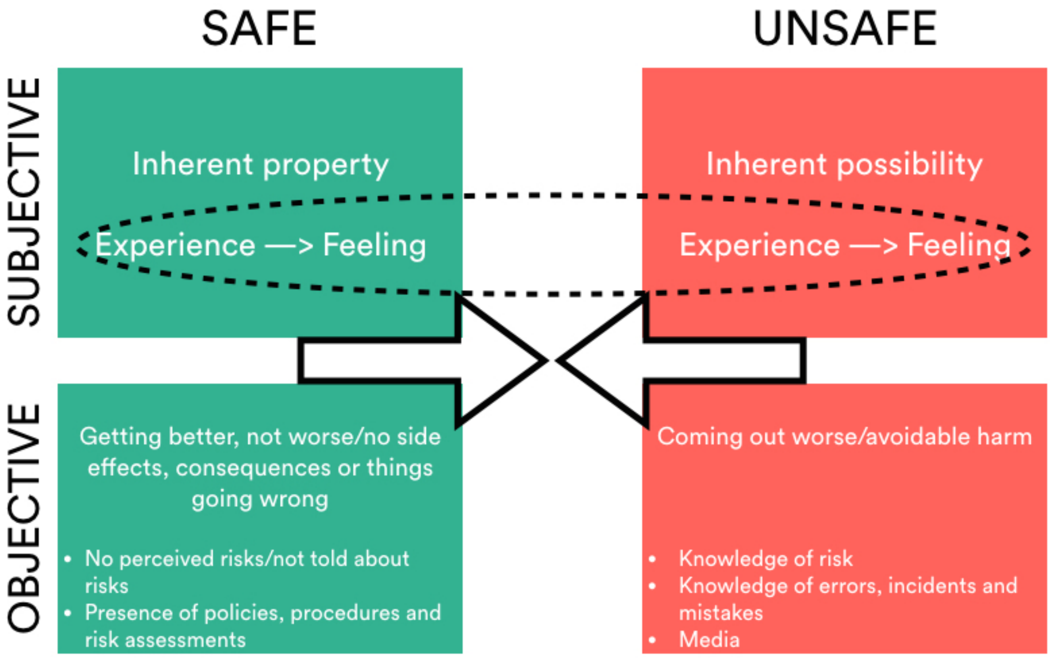

Figure 4.1: The conceptualisation of patient safety – Objective and Subjective

4.5.2.1 Objective conceptualisation of safety – 'being safe'

The objective conceptualisation of patient safety comprised tangible, knowable, observable concepts; this included evidence of being safe and unsafe (through patient outcomes), awareness of specific risks of hospital, and mechanisms (policies, procedures and protocols) that exist to prevent harm. This conceptualisation paralleled academic definitions and models of patient safety, and some participants provided definitions or discussed patient safety in similar terms to our commonly used academic definitions of safety. Participants demonstrated awareness of the risk of harm when in hospital *("coming out of hospital worse off than when you came in"* (Maternity 2)) and that patient safety was about avoiding this harm through the presence of policies, procedures and risks assessments. Equally, knowledge of patient safety incidents or reports from others about harm in hospital provided objective evidence that you may not be safe in hospital:

> *"I think you're safe. But mind you, there have been incidents that have happened in hospitals too, haven't there?" (Elderly 4)*

Comments on this objective component of patient safety (the risks and patient safety mechanisms e.g. policies, procedure, protocols), however, were minimally volunteered. Participants, when struggling to discuss the term 'patient safety,' were prompted to think about the risks of being in hospital, or what they may have seen in the media about patient safety or problems in hospital. This yielded the majority of their objective conceptualisations of patient safety. Some perceived no risks, *"No I just didn't think about it. It didn't even cross my mind to think about that" (*Elderly 2), or assumed that there were none because they had not been told about them. The majority extensively named risks they knew of or had seen in the media. Table 4.6 shows the risks mentioned, and who mentioned them (marked with an X).

Risk	Elderly	Maternity	Surgery
Emotional		X	
Environment	X	X	
Harm	X		
Infection	X	X	X
Lack of resources		X	X
Medication/treatment	X	X	X
Mobility/falls	X		
Other patients	X		X
Staff		X	
To belongings			X
Waiting	X		
Wrong surgery	X		X
Media reported risks			
Avoidable deaths/harm		X	
Failure of care		X	X
Finances	X		X
Food			X
Infection		X	X
Lack of communication			X
Neglect/safeguarding	X	X	
Never events			X
Risk from others	X	X	
Staff		X	
Weekend effect			X

Table 4.6: Participant awareness of risks in hospital

4.5.2.2 Subjective conceptualisation of patient safety – 'feeling safe'

Participants conceptualised safety subjectively, where the term subjective pertains to feelings or interpretations or beliefs. When describing patient safety in the context of their hospital admission, patients drew upon their feelings, statements like *"I feel safe when"* or *"X makes me feel safe."* They described feelings of safety, and discussed what made them feel safe or unsafe in hospital. Patient safety was therefore conceptualised as a feeling; the feeling of safety arose from the experiences they had in their care, for example, the things they witnessed, or that were done to them:

> *"I sort of take it from my own experience in how I see things and experience it." (Surgery 8)*

Firstly, participants held an inherent subjective belief that when in hospital, you would be safe; this belief arose without the need for evidence to substantiate this. Safety was considered an inherent property of a hospital and healthcare:

> *"I don't think it's anything you really think about, because I just – it's a safe place, in my opinion, so it didn't even cross my mind." (Maternity 4)*

Interestingly, participants also believed that there was a competing inherent possibility of harm, which again arose without the need for substantive evidence:

> *"Even if you're in the hospital, you're not safe." (Surgery 8)*

In summary, from the patient perspective, patient safety was regarded as an inherent belief, but also importantly as a subjective state, a feeling; feelings of safety were invoked by experiences in care. Uniquely, patient safety, for patients, is therefore a subjective experiential phenomenon.

As an aspect of patient safety that has appeared unique to the patient conceptualisation of patient safety, this study therefore further explored this particular component of the patient conceptualisation of patient safety, by exploring and understanding experiences that led to feelings of safety/feeling safe (or unsafe)[11].

4.5.3 Results 3: Exploring and understanding experiences that led to feelings of safety

In this section, I further explore and attempt to understand the types of experiences that led to feelings of safety. I begin by describing the development of conceptual maps, first for each participant cohort, and then a unified conceptual map combining the participant cohorts.

4.5.3.1 Developing conceptual maps

Initial codes that described feelings of safety and the experiences in their care (incidents, actions, interactions, processes) that led to those feelings were examined and compared in focussed coding. Categories were developed: categories organised the initial codes (the different types of experience and, additionally, any descriptors

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[11] A note on terminology: Feelings of safety and feeling safe are considered synonymous. The feeling of safety is a subjective state, which would be expressed by saying "I feel safe."

that related to how actions or processes were undertaken). Categories were then organised, to form conceptual categories (with associated sub-categories) by considering how they were related through memo writing and clustering. Conceptual categories defined the types of actions and processes which participants experienced that gave rise to feelings of safety; therefore, conceptual categories explained patients' feelings of safety as arising from specific experiences in their care. Examples of conceptual categories included 'Performing clinical tasks and procedures,' 'Being my advocate' and 'Reporting my concerns.'

Through theoretical coding, the conceptual categories were examined and relationships developed between them. Conceptual categories (the types of actions and processes that gave rise to feelings of safety) were organised according to the main actor implicated in those actions or processes. The identified actors were: the organisation, staff, patient, and friends family and carers. These formed the theoretical categories; these explained patients' feelings of safety as arising from specific experiences involving specific actors in their care.

As discussed in the method section, through the stages of coding, conceptual maps were developed to help describe and explain the data. The relationship between sub-categories, conceptual categories and theoretical categories is more easily understood with the aid of a conceptual map. An excerpt from one of these maps is given as an illustrative example, in Figure 4.2; it illustrates how sub-categories, conceptual categories and theoretical categories are related. Conceptual maps for each participant cohort can be found in Appendix 8.

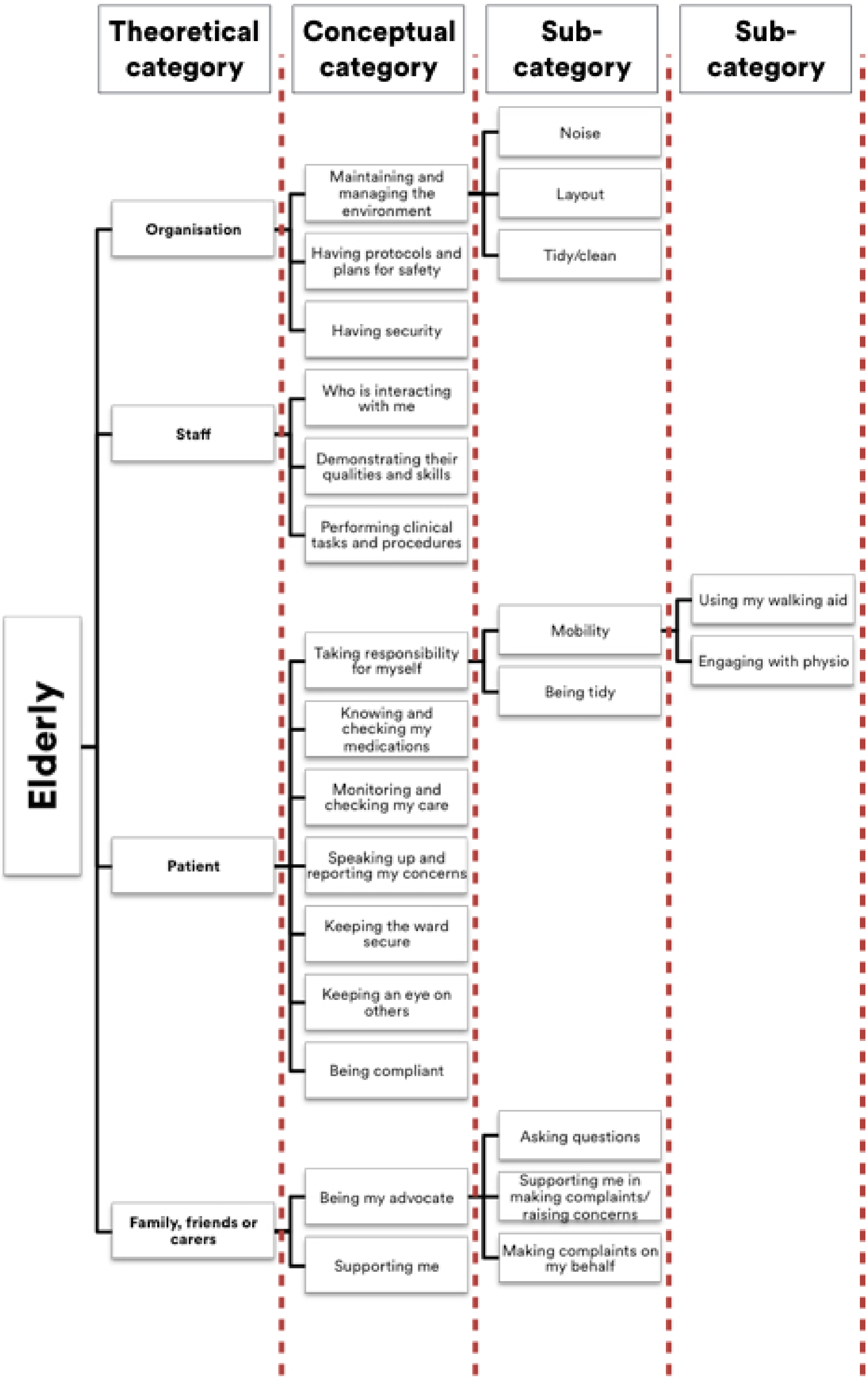

Figure 4.2: Example conceptual map demonstrating categories

4.5.3.2 Developing a unified conceptual map

Initially, conceptual maps were developed separately for each participant cohort (Appendix 8). These were then overlaid to facilitate the development of a unified conceptual map, representing all three participant groups. In the first stage of development, all categories and sub-categories from each participant group were presented in a single conceptual map; these were colour coded to demonstrate from which participant cohort a particular category arose (Orange = Elderly, Blue = Maternity, Green = Surgery). These are shown in Figures 4.3, 4.4a-d, 4.5 and 4.6; for ease of presentation and viewing, the single conceptual map is sub-divided into the individual theoretical categories: organisation (Figure 4.3), staff (Figure 4.4a-d), patient (Figure 4.5), and friends, family and carers (Figure 4.6). Furthermore, due to the number of categories within the staff map, for ease of presentation and viewing, each conceptual category (shown in Figure 4.4a) is presented in a separate map (4.4b, 4.4c and 4.4d).

This single conceptual map (Figure 4.3, 4.4a-d, 4.5 and 4.6) allowed an assessment of the similarities and difference between the three participant groups. The common elements, based on multiple patient groups, were combined into a single unified conceptual map, which is discussed in depth in Section 4.5.4.

In Section 4.5.5, I will go on to discuss where the differences in conceptualisation of patient safety lie between the three participant cohorts. These are evident from the conceptual maps in the subsequent figures where categories arose in only one patient participant group (i.e. are coloured by only one colour).

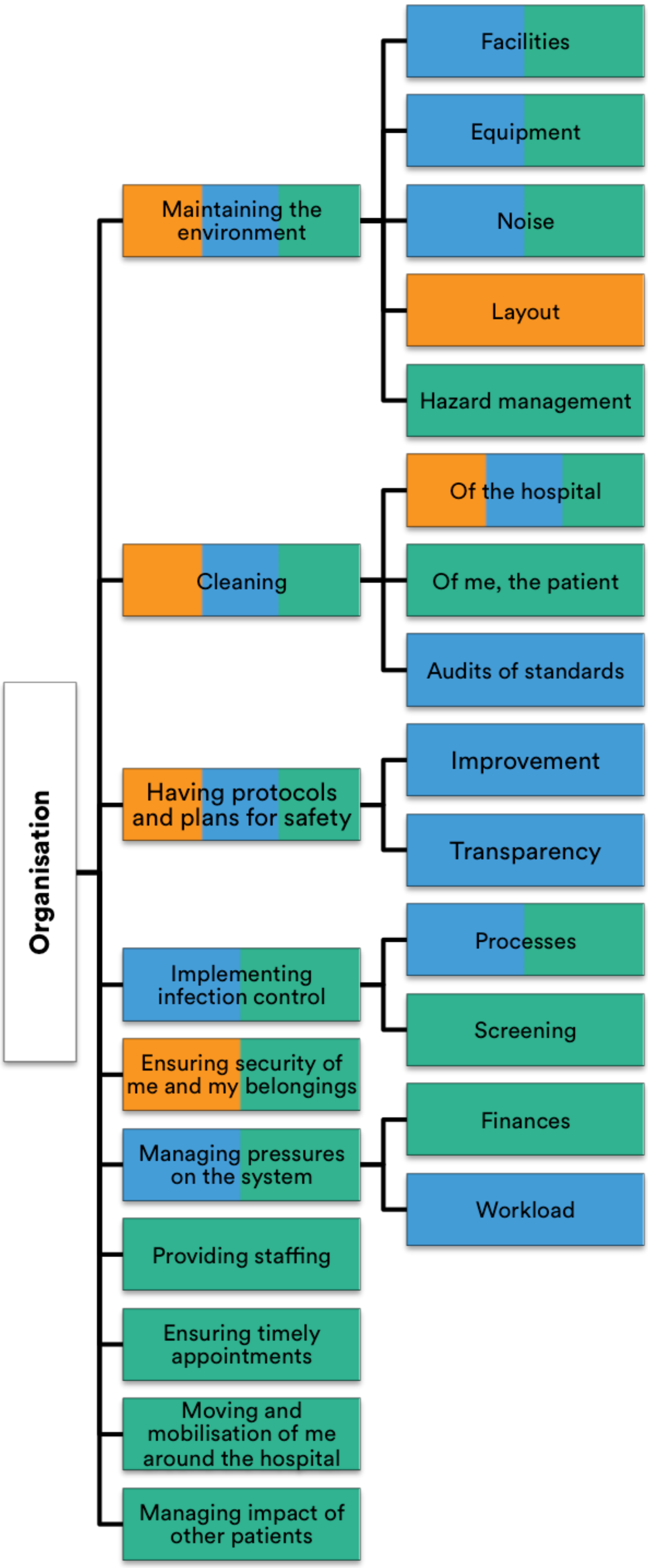

Figure 4.3: Conceptual map – Organisation

(Key: Orange = Elderly, Blue = Maternity, Green = Surgery)

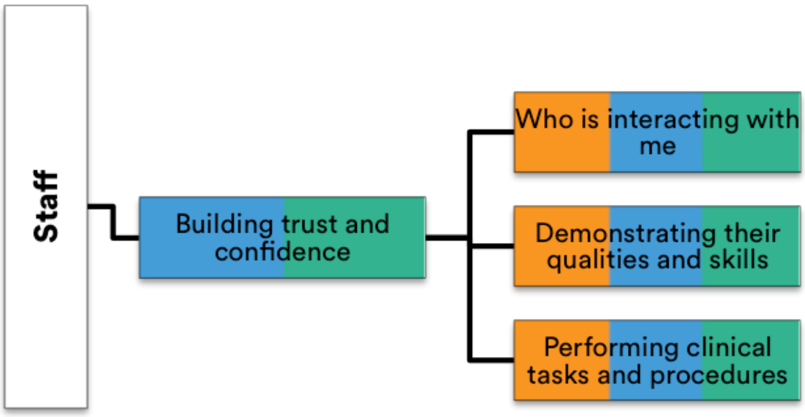

Figure 4.4a: Conceptual map – Staff – Overview of conceptual categories

(Key: Orange = Elderly, Blue = Maternity, Green = Surgery)

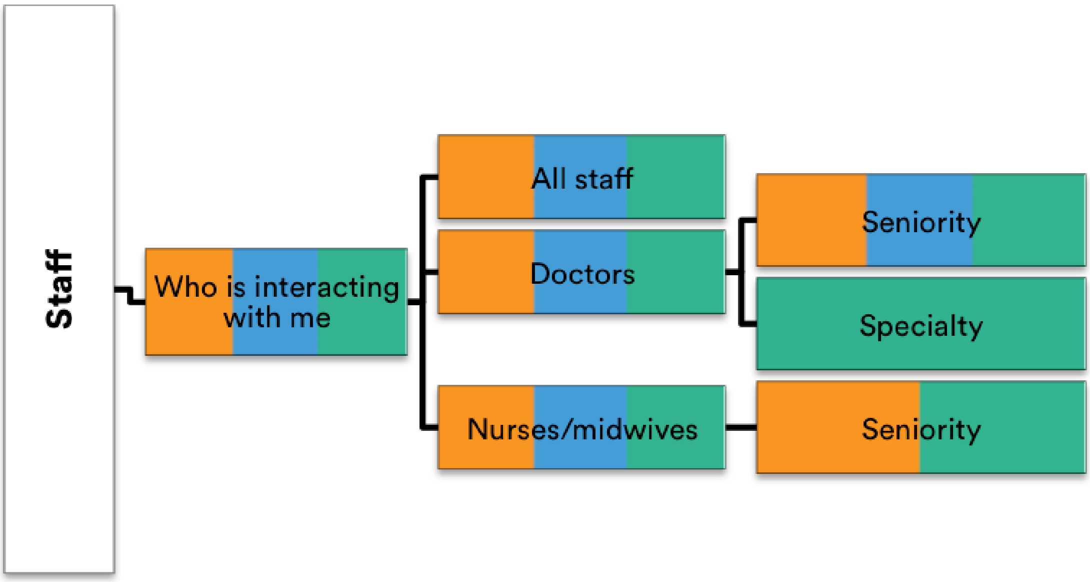

Figure 4.4b: Conceptual map – Staff – 'Who is interacting with me'

(Key: Orange = Elderly, Blue = Maternity, Green = Surgery)

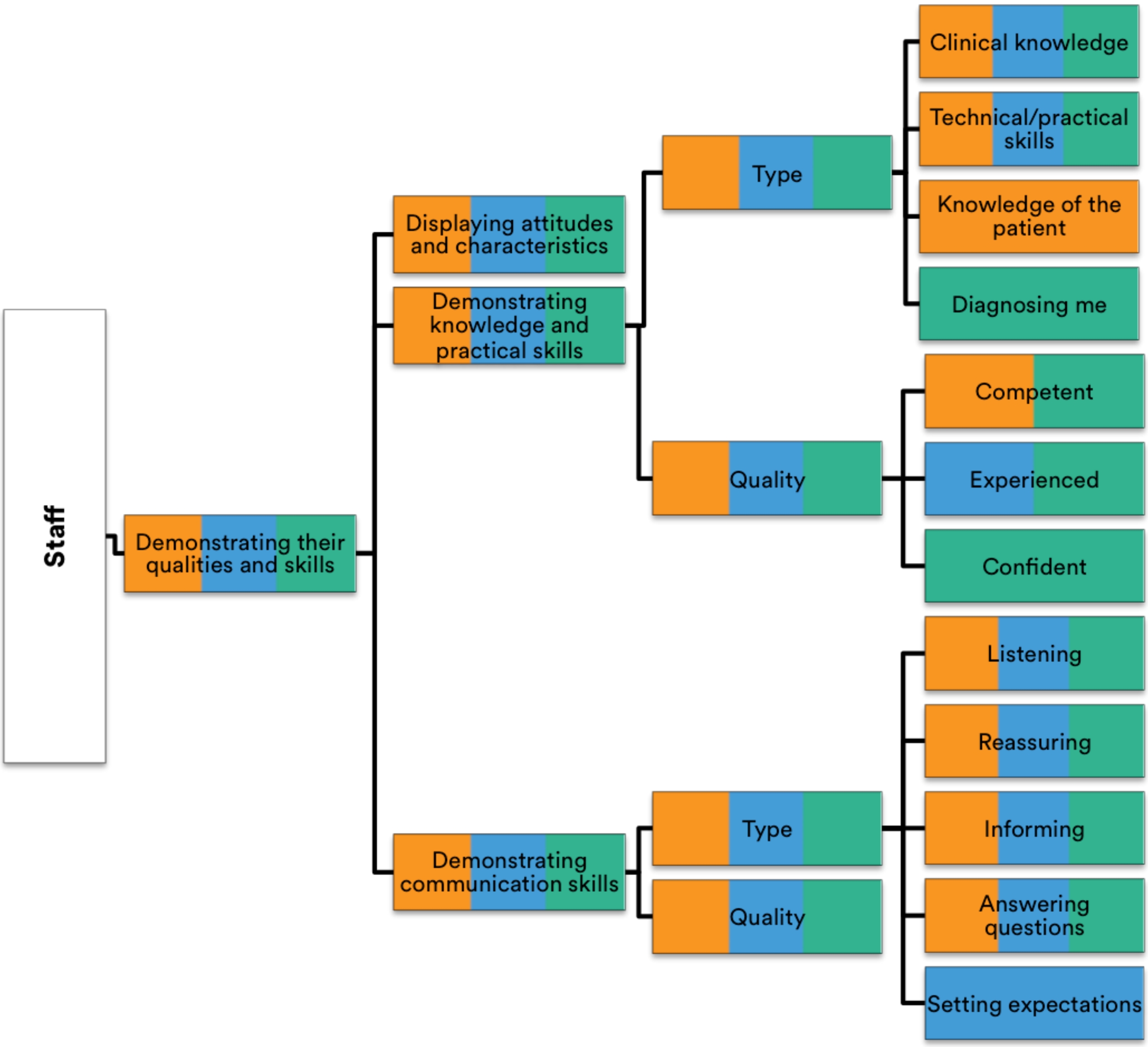

Figure 4.4c: Conceptual map – Staff – 'Demonstrating their skills and qualities'

(Key: Orange = Elderly, Blue = Maternity, Green = Surgery)

Figure 4.4d: Conceptual map – Staff – 'Performing clinical tasks and procedures'

(Key: Orange = Elderly, Blue = Maternity, Green = Surgery)

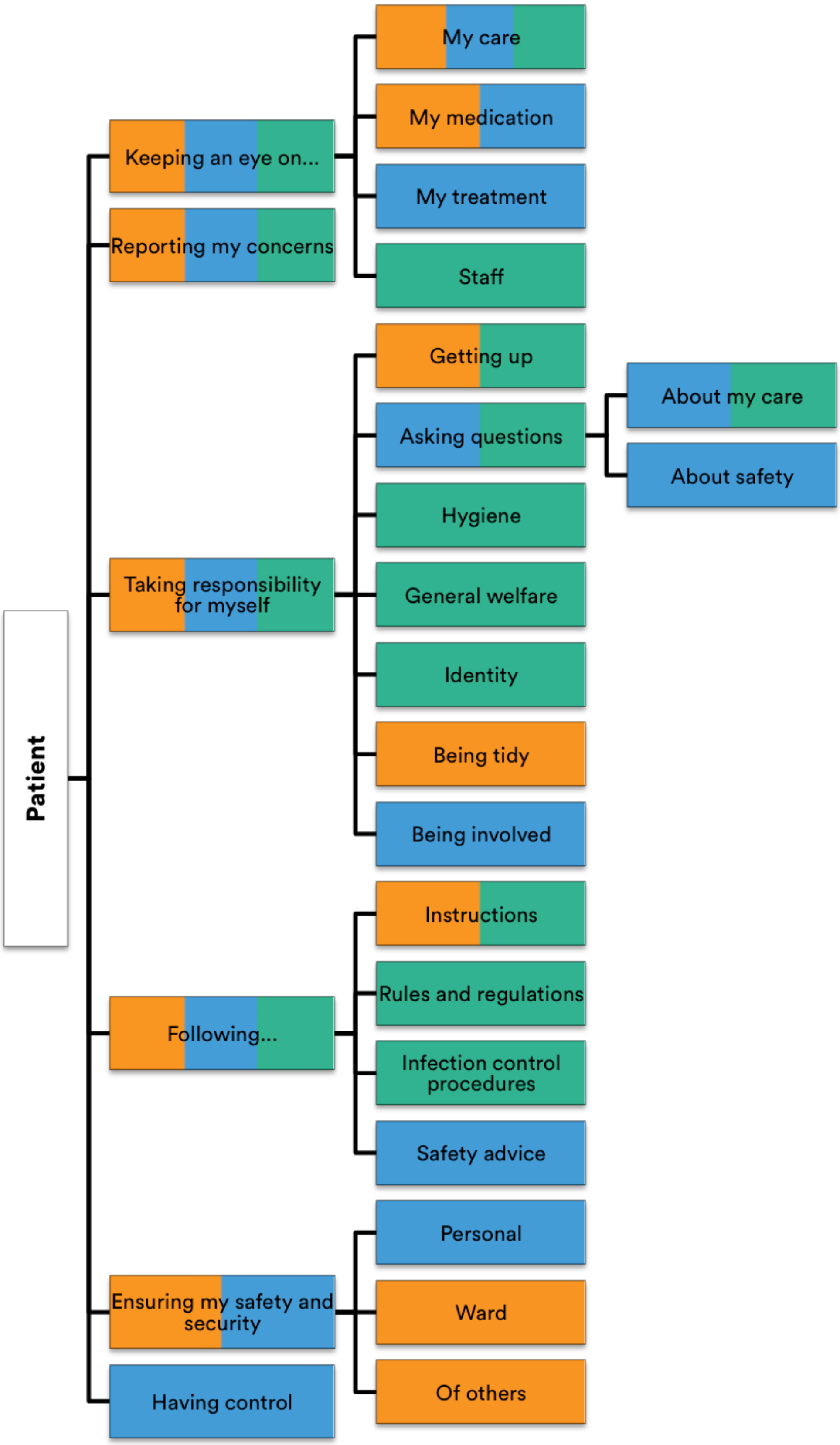

Figure 4.5: Conceptual map – Patient

(Key: Orange = Elderly, Blue = Maternity, Green = Surgery)

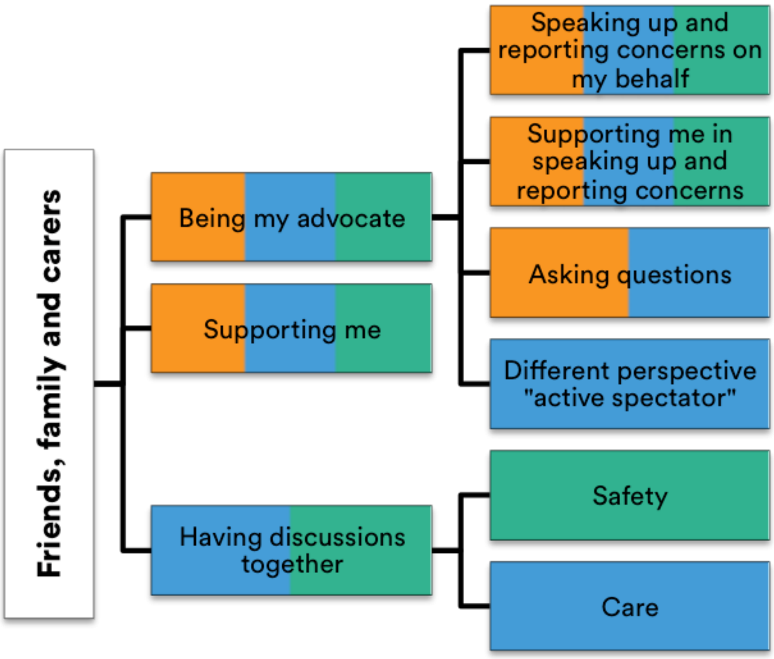

Figure 4.6: Conceptual map – Friends, family and carers

(Key: Orange = Elderly, Blue = Maternity, Green = Surgery)

4.5.4 Results 4: Unified theoretical and conceptual categories

In this section, categories identified as being common to all patient participant groups (across the three specialties) are discussed. Each theoretical category and its associated conceptual categories/sub-categories are discussed in turn, with illustrative quotes to show how these were derived from the data. For each theoretical category (Organisation, Staff, Patient, Friends/Family/Carers), a single organising conceptual map is presented to visually illustrate this.

4.5.4.1 Organisation

The theoretical category ‘Organisation’ contains categories that describe experiences created at the level of the hospital/NHS Trust. Whilst staff, including healthcare professionals, are involved in maintaining the environment and cleaning, the processes described here occur at a higher organisational level.

4.5.4.1.1 ‘Organisation’ conceptual map

Figure 4.7 illustrates the single organising conceptual map for the 'Organisation' theoretical category, summarising the results discussed below.

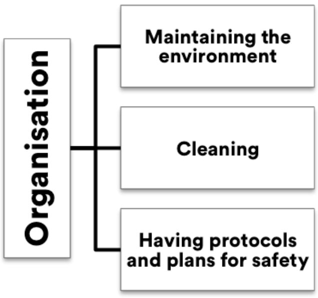

Figure 4.7: 'Organisation' conceptual map

4.5.4.1.2 Maintaining the environment

Patients' feelings of safety arose from their experiences of the physical spaces in the hospital: the ward and other areas, the hospital facilities, and the clinical equipment. They felt safe if they were using facilities and equipment that were being looked after, checked and maintained.

> *"I suppose also ensuring that the various machines work etc. all the sort of things are, you know, it's safe and it doesn't cause problems." (Surgery 5)*
>
> *"Well just being on the ward and sort of feeling safe on the ward and feeling safe when you use the utilities and everything else." (Maternity 2)*

One participant (Surgery 4) made reference to the existence of *"health and safety"* type protocols and processes, and explained that these could relate to *"you [as the patient] or the actual area you're in";* this made a distinction between actions that happened to or for the patient, and actions that happened to or for maintaining the environment. Indirect activities upon the environment they were in, contributed to their feelings of safety.

4.5.4.1.3 Cleaning

Patients felt safe when they could see the ward was being cleaned (observing the process, seeing the cleaners) or by observing that the ward itself was clean:

> *"And every day I've seen people come round and clean… so, yeah, it does make you feel sort of safer and better." (Surgery 4)*
>
> *"Seeing that there are cleaners all the time…yeah, just seeing that the place is clean…" (Maternity 8)*

One participant commented that an apparent lack of substantial cleaning made him feel unsafe. He remarked that it was difficult to make a true judgement, as he did not know what was good enough:

> *"The cleaning...I don't see them going round. I feel the cleaning is cursory. But again, for all I know, that's good enough because that's all it needs." (Surgery 2)*

For this participant, observation of cleaning alone was not necessarily sufficient to give him feelings of safety. Having some awareness of the standards and protocols would enhance the patient's feelings of safety.

4.5.4.1.4 Having protocols and plans for safety

Over and above observing cleaning and cleanliness, in discussing maintenance of the environment and cleaning, the existence of protocols and plans had a role in their feelings of safety. Protocols and plans were assumed to exist at an organisational level; these would dictate processes such the maintenance and cleaning of the environment.

> *"I would have thought you'd have like your general health and safety policies and procedures, which are probably loads and sort of risk assessments and things like that." (Surgery 4)*
>
> *"Well I'd imagine ... the Director of the hospital has lots of plans, and you know?" (Elderly 5)*

The extent to which these plans could contribute to their feelings of safety, though, was limited by their transparency. There was a sense that many processes were 'behind the scenes' to patients, yet known to staff: *"they all know about it and they just do it automatically"* (Surgery 2). Because patients were not in the know about the correct process or protocol, they could not judge how well something had been done, which then made them feel unsafe. Some participants were aware that checks and audits took place because they were publicised on boards in the ward, for example for falls or pressure sores. These meant things could not be *“obscured from the public”* (Maternity 1) and made patients feel safer.

4.5.4.2 Staff

The theoretical category ‘Staff’ contains sub-categories that describe processes involving staff. Feelings of safety were intrinsically linked to trusting and having confidence in the staff. A participant described she felt safe *“because if you are in a hospital you trust the people around you”* (Maternity 7). Trusting staff meant, *“you buy into that person, you put all of your faith into their ability to do their job”* (Maternity 5). Patients’ trust in staff and feelings of safety depended on various aspects of the staff themselves including who they are and how they treat you:

> *“Depends on the way they treat you really, isn’t it? Depends on how they treat you, it depends on who you got treating you, so sadly sometimes, it’s the wrong person, that's the way I see it.” (Elderly 8)*

Overall, patient feelings of safety in relation to staff depended upon who patients were looked after by or interacted with, what the staff were like and what the staff were doing. These are discussed in turn.

4.5.4.2.1 ‘Staff’ conceptual map

Figure 4.8 illustrates the single organising conceptual map for the ‘Staff’ theoretical category, summarising the results discussed above.

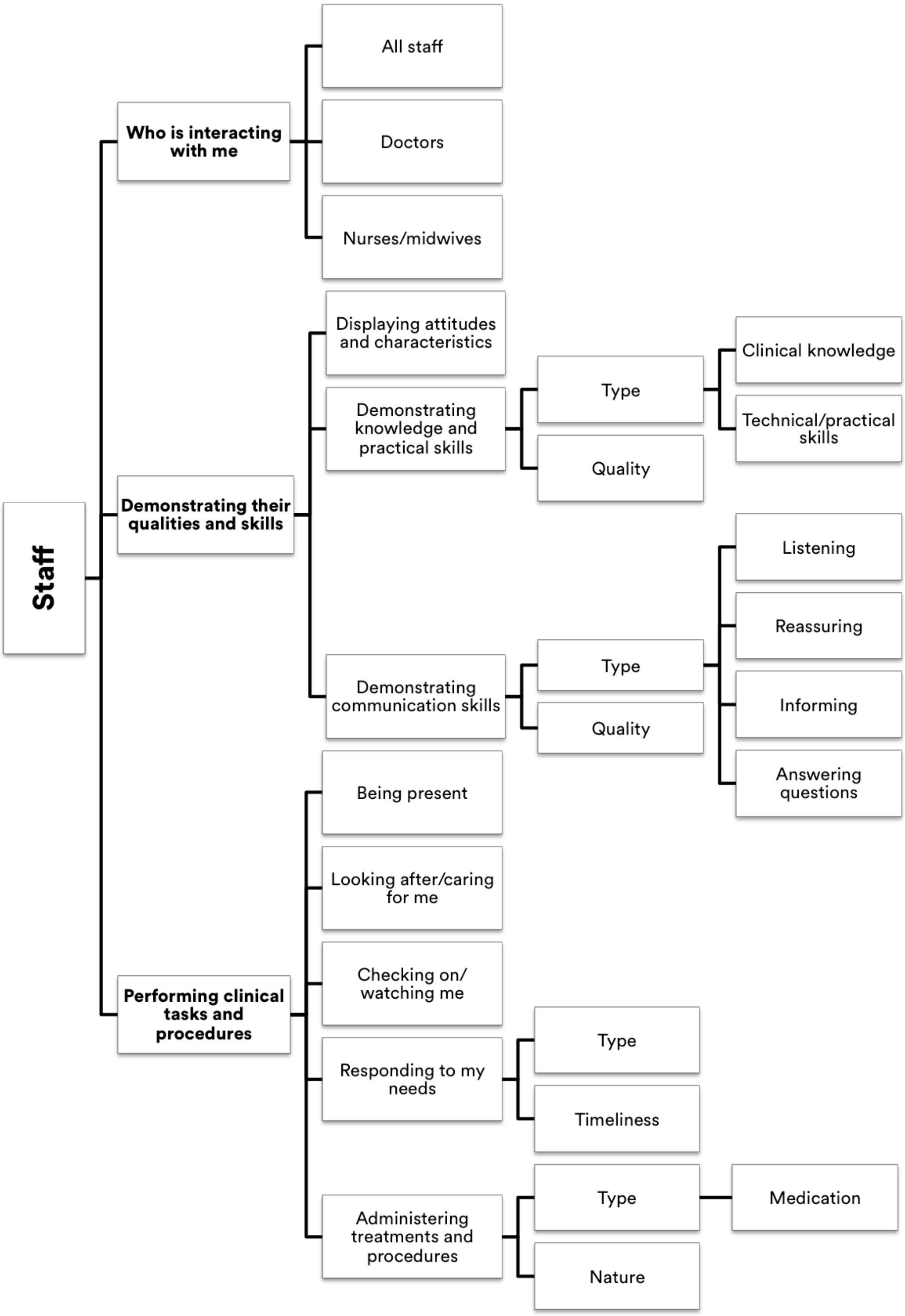

Figure 4.8: 'Staff' conceptual map

4.5.4.2.2 Who is interacting with me

Interaction with staff made patients feel safe. Both within and across patient participant groups, patients reported different members of staff as being important for their feelings of safety. The specialty of the staff member made a difference; for example, patients felt safer through knowing they were seeing the correct specialty staff member for their specific problem. Knowing that the right person, with the right knowledge, was being consulted made patients feel safe. Patients described how different members of staff had responsibility for different aspects of care, *"its different qualifications and different job roles innit [sic] really?"* (Surgery 7). Doctors, for example, would *"treat you"* (Maternity 4) and *"do all the operating"* (Surgery 7), whereas the nurses fulfilled the caring aspects, for example spending time with patients, giving them care/looking after them, watching out for them, and being 'hands on'. Because of this, it was vital that everyone played his or her part in patient safety:

> *"...it can't just be left to one person because they won't have a holistic view over it because it can encompass so many things." (Maternity 2)*

Nurses and midwives embodied the predominant clinical presence for patients and were usually the first member of staff a patient met; as they were *"always with us"* (Maternity 7), (unlike doctors who were only present *"in the morning"* (Surgery 6)), midwives/nurses had the most significant role in making patients feel safe on a day to day basis, as well as through fulfilling various nursing specific aspects of their care.

Despite the significance of the day-to-day role of nurses and midwives, patients still regarded the doctor to be at *"the top level"* (Elderly 4) in relation to their feelings of safety. This stemmed from their perceived superior knowledge and level of study. Additionally, the seniority and experience of the doctor were also important. One patient commented on the importance of *"the correct level of contact with junior, mid and senior...a drizzle of each*" (Maternity 2), recognising that they each had their roles to play. They did not necessarily want to see their lead consultant all of the time, but wanted to know they were available. Two participants reported no confidence in more junior staff:

> *"Registrars talk out their backside [sic], they don't know what*

> *they're doing." (Surgery 2)*

> *"The doctors [consultant] are giving the instructions but presumably the less senior ones didn't make sure [they were followed through]." (Surgery 3)*

These views arose from experiences of errors in care, both actual and perceived, and subsequently led to losses of trust in the skills of anyone but a consultant. The ability of more senior staff was valued and patients would therefore defer to their opinions and skills; for example, even where a registrar was recognised as having a lot of experience of siting epidurals, a patient still requested for a consultant to attend and would wait:

> *"I just asked the person who was going to do it, 'Have you done many of these?' and she said, 'Well I'm not a consultant but I have done many.' And I said, 'I'm really sorry but if you don't mind a consultant doing it, I'm just very afraid of the epidural,' and she said, 'That's fine but he's **ten minutes away**.' And I said, 'Okay, that's fine, I can wait ten minutes.'" (Maternity 1)*

Participants also reported deferring to the opinion of consultants they specifically knew and who knew them and their history; familiarity and past experiences of care with an individual healthcare professional develops confidence and trust:

> *"[Dr M] has seen me for the past years and years and has followed up my chronic kidney disease and I know he is around and I know Dr J, he will contact him and discuss with him the results and that makes me feel safe." (Elderly 7)*

However, overall, there was a consistent belief that all members of staff patients interacted with, regardless of their specific role or level, contributed to their feelings of safety. This is because they felt that their safety was the responsibility of and in the minds of all staff, and that all job roles would include an element of safety practices within them:

> *"It has to be in the minds of all levels, no matter what it is that you do. It might be you have a certain role and a certain job but that would have to have a patient safety element, so that comes together like a chain almost." (Maternity 2)*

4.5.4.2.3 Demonstrating their qualities and skills

Patients described the personal attitudes and characteristics that staff displayed that made them feel safe. These were evident, not through what staff did, but how they performed tasks and delivered care:

> *"My experience with them from the day I was referred to them to today, they handled it beautifully. they handled it beautifully. The surgeon, you see, because at first I had to see the surgeon and he was- his manners, his- the way he dealt with me…" (Surgery 3)*

Participants described the key characteristics of a healthcare professional associated to feelings of safety: altruistic, interested, and motivated. The perceived altruistic motivations for doing a job in healthcare (rather than the money) gave patients feelings of safety:

> *"The jobs they are doing, not just to get paid, because they love work, they give life to people, they care for people, that is important" (Surgery 1).*

One participant, though, observed that the attitude of some healthcare assistants demonstrated they did not care and were just there for the money. Participants also felt safe when staff were professional, nice, friendly, gentle, compassionate and kind. An elderly patient described the way a nurse washed him, failing to show kindliness, dignity or compassion, made him feel unsafe:

> *"First of all, the way that she had asked me, not saying, "Good morning," or anything, you understand? Pushing me. I watch out and with this thing she poured the cold water all over the body and "Turn here, turn here." I'm naked. I have difficulty sometimes to turn my head right or left, you understand? At the moment. Maybe in a week or so I will able to, or maybe I will never have the ability to, but ... a certain kindliness, that's all." (Elderly 6)*

Participants reported feeling safe when healthcare professionals demonstrated competence in practical skills and clinical knowledge. Clinical knowledge was important for patients to feel safe; it represented something that the patients themselves did not have: *"I guess they've got the knowledge that you don't have, I suppose"* (Maternity 6). Patients felt safe when staff displayed and then applied clinical knowledge to correctly diagnose and manage their conditions. A participant described feeling unsafe when nurses at one hospital did not recognise that her difficulty in breathing could be related to asthma, but the doctors at another hospital knew her conditions and recognised the cause of the symptoms:

> *"The nurses, when a patient can't breathe, the nurses didn't know it was asthma. They said, 'Oh you can still talk so you don't have asthma'. Things like that…I feel safe with doctors who know what is actually going on." (Elderly 7)*

As well as demonstrating clinical knowledge, staff needed to display practical clinical skills. This included siting intravenous lines, dressing wounds, managing drains, doing procedures. Patients felt unsafe if a member of staff could not do a procedure that they thought they should be able to do:

> *"One of the nurses couldn't put the IV in, that's a qualified staff nurse couldn't put the IV in." (Surgery 7)*

It was not just possession of the skill, but also the quality of the performance of the skill that contributed to patients' feelings of safety. Patients expected staff to perform skills correctly, accurately, and confidently. If staff could not do something, patients expected them to seek help.

For patients to feel safe, staff needed to demonstrate good communication skills. They discussed the quality of communication (*"how the people talk to you,"* Elderly 8), but predominantly focussed on the type of communication (e.g. listening, acknowledging, reassuring, answering questions) that was needed in the patient-professional interactions to feel safe. One participant summarised this:

> *"It's the contact that you have with the professionals, it's the way that they interact with you, it's putting your mind at ease, having patience with questions, answering them and then following up on them, and feeling as though, you know, you are, you are being listened to." (Maternity 2)*

Patients also needed to be informed about what was happening to feel safe; this included information their diagnosis, treatment and any planned investigations. The ward round was identified as one way that patients could be updated and patients could then ask questions. Two elderly patient participants described how incidences of not being told about their treatment or about planned investigations caused them to feel worried and unsafe:

> *"Well, a little bit. We should have been told that we were going over there, we were going over there for something, or we were going in this place where you sit right down, where you have something done, but there was nothing told. They just said, get on this thing and lay down. I've been in those scans before, but I didn't know what it was all about." (Elderly 3)*
>
> *"Well, to be honest with you, this here, I don't know what's gone on here, so I worry about that. And if I was getting any treatment, some – I would like to know the ins and outs of it, what effect it would have on me and that and what it would do, you know." (Elderly 4)*

4.5.4.2.4 Performing clinical tasks and procedures

Patients described the clinical tasks and procedures that staff undertook that made them feel safe. Patients felt safe when staff were present. Being present meant staff were either available to them or visible:

> *"You are safe, but ...there are people around. There are the people who could look after you." (Elderly 6).*
>
> *"Just the presence of people. There's the ward manager and the midwives, the nurses, the healthcare assistants, so it's a constant flow of faces, familiar faces, when you're here for a certain number of days that just makes you feel that they're there for you and your wellbeing and your safety." (Maternity 5)*

This had a slightly different meaning in maternity where, when in labour, women expected somebody to be physically attending them at all times. The *"flow"* of people in and out of one woman's room made her feel unsafe as she felt no one person was looking after her:

> *"But the fact I was just there and there was no one person looking after me, and there were lots of people coming in and out of the room, I felt like I was just in a waiting area." (Maternity 1)*

Another described being left alone, attached to lines and having an epidural, which meant she could not move and, with the door closed, she could not attract attention when she started to feel unwell:

> *"But that point of waiting for like somebody to walk past then not being able to call, which is just – it's a small oversight, but it can make a big difference." (Maternity 8)*

The patient felt unsafe being left, but additionally felt that the failure to have a member of staff continually present led to her situation escalating to an emergency, where it may not have otherwise.

Patients felt safe in the knowledge that they would be looked after/cared for in hospital (*"Everyone's going to look after you,"* Maternity 5). Their experiences of being looked after or cared for had both psychological and physical components. It meant the staff showing concern about how the patient felt emotionally and providing them with what they needed:

> *"I feel like they always ask me or because they are very concerned about how I feel." (Maternity 7).*

It also meant physically caring for the patient, including attending to their activities of daily living. Their feelings of safety would be threatened by failing to fully meet their caring needs, as described by one patient:

> *"Another thing is they do wash me fabulously well but nobody ever like, I tried to do it myself, wash my teeth. I have a toothbrush that I use and this water and so on but the most hygienic it's not. I have some Listerine and I can do this but compared to how the whole body is washed..." (Elderly 7)*

Patients felt safe when they were being checked on and watched. Checking on a patient meant asking how they were feeling or how their symptoms were, and included monitoring of treatment or post-operative monitoring.

> *"They ask like how you're feeling or what you're going through and try to understand, they can suggest things to make certain things better. That to me is part of your patient safety even though it's not branded as it or within patient safety stuff now so that's, yeah." (Maternity 8)*

It also included being reviewed by a doctor to assess progress during admission. One patient expressed the importance of being informed when they might be reviewed for feeling safe, or if this was not possible, providing reassurance that they had not been forgotten, are being tracked from a distance and how to trigger a patient review if it was needed:

> *"So I think having a more upfront conversation to say, 'I may not be here regularly but I will be watching and tracking this, and if you have any concerns, this is how you can escalate them to me.'" (Maternity 1)*

The reassurance, assumption or observation that patients were being watched by staff made them feel safe. It was an assumed role of the nurses and patients felt safe because if they were being watched, they thought *"nothing could happen to you"* (Elderly 2).

Patients felt safe when staff responded to their needs. They described the different needs (generic, symptoms, help, urgent help) they expected staff to attend to ensure feelings of safety, and also that they expected staff to fulfil those needs in a timely manner. Patients felt safe simply knowing that they could use their call bell and call for someone to attend to them; however these feelings were denigrated if staff took a long time to respond. Patients also felt safe because they knew staff would respond quickly to urgent or emergency situations: *"Because like if you have problems they can rescue or like give you straight whatever you need,"* (Maternity 7). Elderly patients compared hospital with home, describing how at home they felt unsafe because if something happened to them they had nobody around to help them, whereas in hospital they *"[felt] safe from the point of view that they won't let you down"* (Elderly 7).

One patient described a poor experience in another hospital where his pain needs had been poorly managed. He was able to express these concerns at pre-assessment and they were addressed; a plan was made around what analgesia would work best in the post-operative period. In hospital he experienced being reviewed by the pain team, as well as being managed by the nurses.

> *"They listen, they're asking and they respond. They listened, they tried different things and I trusted them, you know. I didn't trust them at [the other hospital]. I wouldn't go there if it was [sic] the last hospital around for surgery. No." (Surgery 2)*

The positive response to his concerns and pain needs meant he trusted the staff and felt safe. His poor experience at the other hospital had made him feel unsafe, to the extent that it mediated his ideas about engaging with them in future healthcare encounters.

Administering treatment referred to initiating, managing, monitoring and following up treatment for a condition (particularly medication). Being treated for their condition made patients feel safe. One patient described doctors failing to initiate any treatment, leading to deterioration in her clinical condition and her feelings of safety:

> *"I arrived on a Friday with asthma, until Monday evening I hadn't had any nebuliser, any oxygen, any inhaler, nothing and I was collapsing going to the bathroom quite a lot." (Elderly 7)*

Getting the right treatment was important for feelings of safety; this meant both getting the right treatment for the specific condition, *"managing their condition and their treatment"* appropriately (Maternity 1), and then *"making sure you get the right medicine,"* (Elderly 4), meaning you are physically administered the correct drug. Patients were aware that it was possible to be administered the wrong drug; processes like hearing *"them saying what each thing is"* (Elderly 4) and being informed throughout the drug administration processes made them feel safe. A patient described the experience of being given a medication through the wrong central line port:

> *"I'll tell you what makes me feel unsafe. They have tubes here {pointing to neck}. One night, one of the nurses put medicine in the wrong tube. She nearly frightened me to death." (Surgery 3)*

Therefore it was not just being given the correct treatment or drug, it was also the process of giving treatment correctly that made patients feel safe. This extended to other treatments and procedures like dressings. Through experience, patients knew when something was not right: *"I just thought that don't feel right"* (Surgery 7); when they expect staff to be able to do something properly and they fail to, this leads to a loss of confidence and loss of feelings of safety.

4.5.4.3 Patient

Patients felt that there were things they did, or could do, that contributed to their feelings of safety; these are discussed in the subsequent sections.

There were also some patients though who felt that they could not contribute; there were a number of reasons for this. Firstly, some patients felt they had no control over the processes that were important for their feelings of safety (for example, clinical tasks or cleaning). Secondly, some felt they lacked the expertise or knowledge about healthcare and hospitals to contribute to safety. Finally, some reported assuming a passive role in hospital and relinquishing control, meaning they had no role in contributing to their own feelings of safety.

> *"Because most of it's in other people's hands, you know, drips, putting things in and out, cleaning correctly, you know. Their cleanliness, I'm not in control of that," (Surgery 2)*
>
> *"I don't know if I really have the medical expertise…. I guess I could be in a position to suggest something they do to make you feel like it's more safe but I'm … yeah I don't think I know enough about hospitals to make suggestions on them," (Maternity 6)*
>
> *"When you go to hospital you let go, you just let go, you let things happen to you. I know I am looked after." (Elderly 7)*

For those who felt they could act, they described that monitoring and checking their care, reporting their concerns, taking responsibility for themselves and being compliant made them feel safe.

4.5.4.3.1 'Patient' conceptual map

Figure 4.9 illustrates the single organising conceptual map for the 'Patient' theoretical category, summarising the results discussed above.

Figure 4.9: 'Patient' conceptual map

4.5.4.3.2 Keeping an eye on and checking my care

Participants reported that they could contribute to their own feelings of safety by keeping an eye on and checking their own care:

> *"I think you can't just sit by and let things happen. You've got to be aware of what's going on around you… Being observant, and processes, and what's going on, and what's happening, and what people are doing." (Surgery 5)*

Participants checked their medications; this included asking what something was, what it was for and the timings of medications.

> *"I think everyone's got their role including yourself. I think, you know if you're not happy you should ask questions and sort of don't sit there and worry about it or anything. This morning when she came up with a new tablet for me and it was like oh what's this one then because no one had said I'd be taking that today. I think it's everyone's responsibility to a part." (Surgery 4)*

Participants also monitored the tasks staff were doing and how they were doing it; they got a sense of whether something was being done right by the way staff were doing it:

> *"…it depends on what the person do, and how she or her do*

> *it, you see? You know if it's right." (Elderly 8)*

4.5.4.3.3 Reporting my concerns

Participants reported that they could contribute to their feelings of safety by reporting their concerns; this was closely related to monitoring and checking care. There was some sense of duty around reporting concerns, *"I **have** to open my mouth or to raise my voice up,"* (Maternity 4). In engaging with reporting and speaking up, patients believed that this would lead to change; for example, if a particular action or process was making them feel unsafe, speaking up about this would change the course of the action:

Participants identified reporting an event that had made them feel unsafe as the means through which staff and system learning would occur:

> *"I'd have to say something to somebody, otherwise nobody will learn, so I should say something." (Maternity 3)*

In contrast, however, some participants felt that they just had to accept error and events that made them feel unsafe:

> *"You have to let bygones be bygones. You don't have to talk, as simple as that." (Elderly 8)*

4.5.4.3.4 Taking responsibility for myself

Participants reported that they could contribute to their own feelings of safety by taking responsibility for themselves and aspects of their care. This included exercising due caution when mobilising *("my stick, to use it and to use it properly,"* Elderly 3) and generally looking after themselves:

> *"It's sort of generally like looking after yourself as well and making sure you are getting up and about if they want you to and keeping clean and things like that and sort of like just your general wellbeing and safety in that respect, so like have your tags on and things like that." (Surgery 4)*

In Maternity, participants felt that they had the ability to, as well as a responsibility for, being involved in their own care and the care of their baby; by being involved in the tasks that led to their feelings of safety, they too could enhance this feeling. They could ensure, for example, timely treatments (which were discussed earlier as being implicated in patients feelings of safety). However, they also acknowledged that whilst patients could contribute in this way, there needed to be *“boundaries*” and *“reasonable expectations of patients”* (Maternity 1) and that the burden of these tasks fell with staff.

4.5.4.3.5 Following advice, rules and regulations

Finally, participants reported that they could contribute to their own feelings of safety by *“do[ing] what I am told”* (Elderly 4), being compliant with advice that is there to ensure their safety, and *“follow[ing] the rules and regulations”* (Surgery 8) that are in place for the perceived purpose of making them feel safe.

4.5.4.4 Friends, family or carers

Participants identified that their friends, family or carers made them feel safe in hospital by being their advocate and also being a source of support.

4.5.4.4.1 ‘Friends, family or carers’ concept map

Figure 4.10 illustrates the single organising conceptual map for the ‘Friends, family or carers’ theoretical category, summarising the results discussed above.

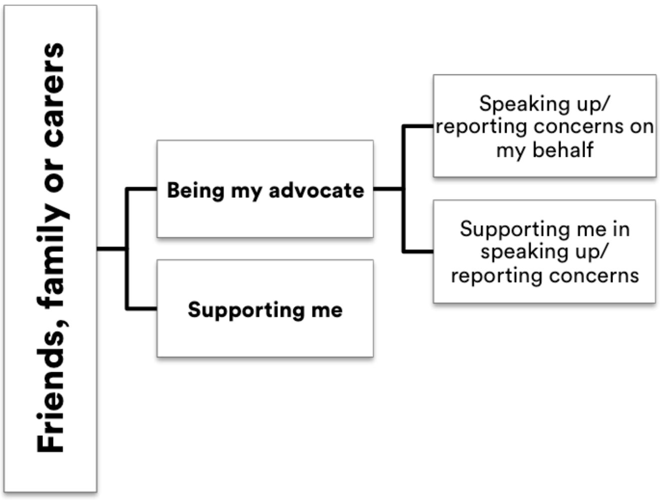

Figure 4.10: ‘Friends, family or carers’ conceptual map

4.5.4.4.2 Being my advocate

Friends, family and carers had advocacy roles that contributed to patients' feelings of safety. Firstly, they could speak up and report concerns on behalf of the patient, where they did not feel able:

> *"He [my husband] is very capable of dealing with it in a way I am not. I get embarrassed and this, that and the other so he takes over and deals with it. Although he doesn't…I mean, he saved my life. If it wasn't for my husband, I would have been dead." (Surgery 3)*

Secondly, they could provide support for the patient to be able to report their concerns. Participants identified needing an advocate for support, as they would provide validation or additional proof of their concern, and due to their vulnerability:

> *"If it's only yourself you might think you're imagining it or something, you know." (Elderly 4)*
>
> *"Without that support you feel more vulnerable so you're going to be less able perhaps to speak up about other things." (Maternity 2)*

For the elderly patient participants in particular, an advocate protected their interests and preserved their autonomy. Without that, there was the perception that the hospital *"can do what they like with you and put you into a home or whatever,"* (Elderly 4) and the prospect of this led to feeling unsafe.

In Maternity, the role of the partner was discussed as being unique. Different to the other cohorts, the partner is (usually) always present during labour; the partner is a *"witness"* or *"spectator"* who is there for support and safety (Maternity 2). The partner can take an active role and speak up if concerns are identified; the partner is a *"sound mind"* (Maternity 5), when the woman is less able or less coherent because she is on *"strong painkillers or just exhausted*"; this lead to feelings of safety.

4.5.4.4.3 Supporting me

Friends, family and carers contributed to patients' feelings of safety by providing them with support – both emotional and physical. They contributed to looking after patient and making them feel safe and comfortable in hospital:

> *"They sort of look after you, so they make sure you're feeling comfortable and things like that and bring you in bits if you need it and take bits home if you want so, yeah, I think they do have a part to play as well." (Surgery 4)*

Friends, family and carers also provided emotional and psychological support and reassurance, which helped patients feel safe. One participant said that her partner's role in reassurance though was limited due to his limited knowledge: *"I know he didn't know much – I kind of didn't believe him"* (Maternity 6).

4.5.5 The impact of different clinical contexts

In examining the conceptual maps in Figure 4.3, 4.4a-d, 4.5 and 4.6 it is evident that some of the experiences in care that lead to feelings of safety are unique to specific clinical contexts. Table 4.7 provides a list of the categories of experiences that are unique to each speciality, and the theoretical category they relate to.

Clinical Specialty	**Category**	**Theoretical Category**
Surgery	Providing staffing	Organisation
	Ensuring timely appointments	
	Moving me around the hospital	
	Managing the impact of other patients	
	Managing financial pressures	
	Ensuring security of myself and my belongings	Organisation/Patient
	Managing my treatment plan	Staff
	Interprofessional communication	
	Having discussions together	Friends, family or carers
Elderly	Ensuring security of me and my belongings	Organisation
	Planning my discharge	Staff
	Promoting my mental health	
	Preventing falls	
	Mobility	
	Interprofessional communication	
	Ensuring my safety and security	Patient
Maternity	Managing workload pressures	Organisation
	Continuity of care	Staff
	Engaging in safety behaviours	
	Providing psychological support	
	Ensuring my safety and security	Patient
	Having control	
	Having discussions together	Friends, family or carers
	Having priority over me	Baby
	Being equal priority to me	

Table 4.7: Unique categories of experiences that lead to feelings of safety

Some of these categories represent generic experiences, which could feasibly arise in any clinical specialty (e.g. 'Providing staff' or 'Ensuring security of me and my belongings'). Equally, these could represent experiences that are specific to certain clinical specialties. From this study, it is unclear whether these are unique or simply not identified in all participant cohorts; to determine this, this could be tested through theoretical sampling, which serves to obtain data in order to explicate conceptual and theoretical categories (Charmaz, 2006).

Some categories appear to be particularly specialty specific include 'Planning my discharge,' 'Preventing falls' and 'Mobility' within the elderly cohort. In the maternity cohort, an additional actor, 'Baby,' was identified as influencing their feelings of safety (Figure 4.11).

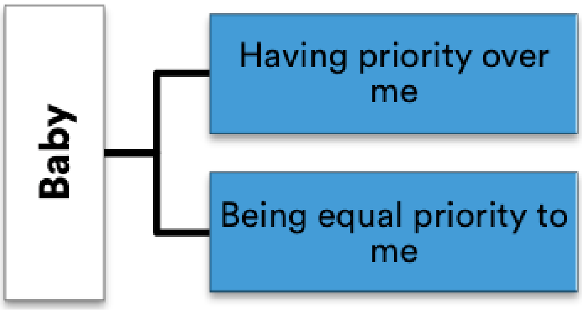

Figure 4.11: Conceptual map – Baby

Women expressed feelings of safety when the care of their baby was prioritised; there were conflicting views around this, with some participants reporting the baby should take priority over them and others reporting the baby should be of equal priority to them.

Both of these examples in medicine for the elderly and maternity suggest that there may be real differences in the conceptualisation of patient safety and what gives rise to feelings of safety between clinical settings. This could be further clarified through theoretical sampling, and could lead to further development of theory specific to individual clinical settings.

4.5.6 The Patients' Safety Theory

In the last section, I presented theoretical categories, and their associated conceptual categories and sub-categories, developed during initial, focussed and theoretical coding. These, in essence, provided a thematic description of the data. The final stage of analysis was to postulate relationships between the theoretical categories and to develop an explanatory theory of the patient conceptualisation of patient safety.

In relating the theoretical categories, which explain patients' feelings of safety as arising from specific experiences involving specific actors in their care, these specific experiences were re-examined. I considered the nature and characteristics of the experiences, including whether they were active (including/involving the patient) or passive (done to or separately from the patient), whom the processes involved, and the relationships between those involved. Consistent with constructivist grounded theory and rejecting the focus on a 'single basic social process,' a number of processes were identified that are experienced by patients, which give rise to *patients' safety* (the patient conceptualisation of patient safety) or feelings of safety. Overall, through exploring the relationships between theoretical categories and combining the identified processes that are experienced by patients and give rise to their feelings of safety, I have developed The Patients' Safety Theory, illustrated in Figure 4.12.

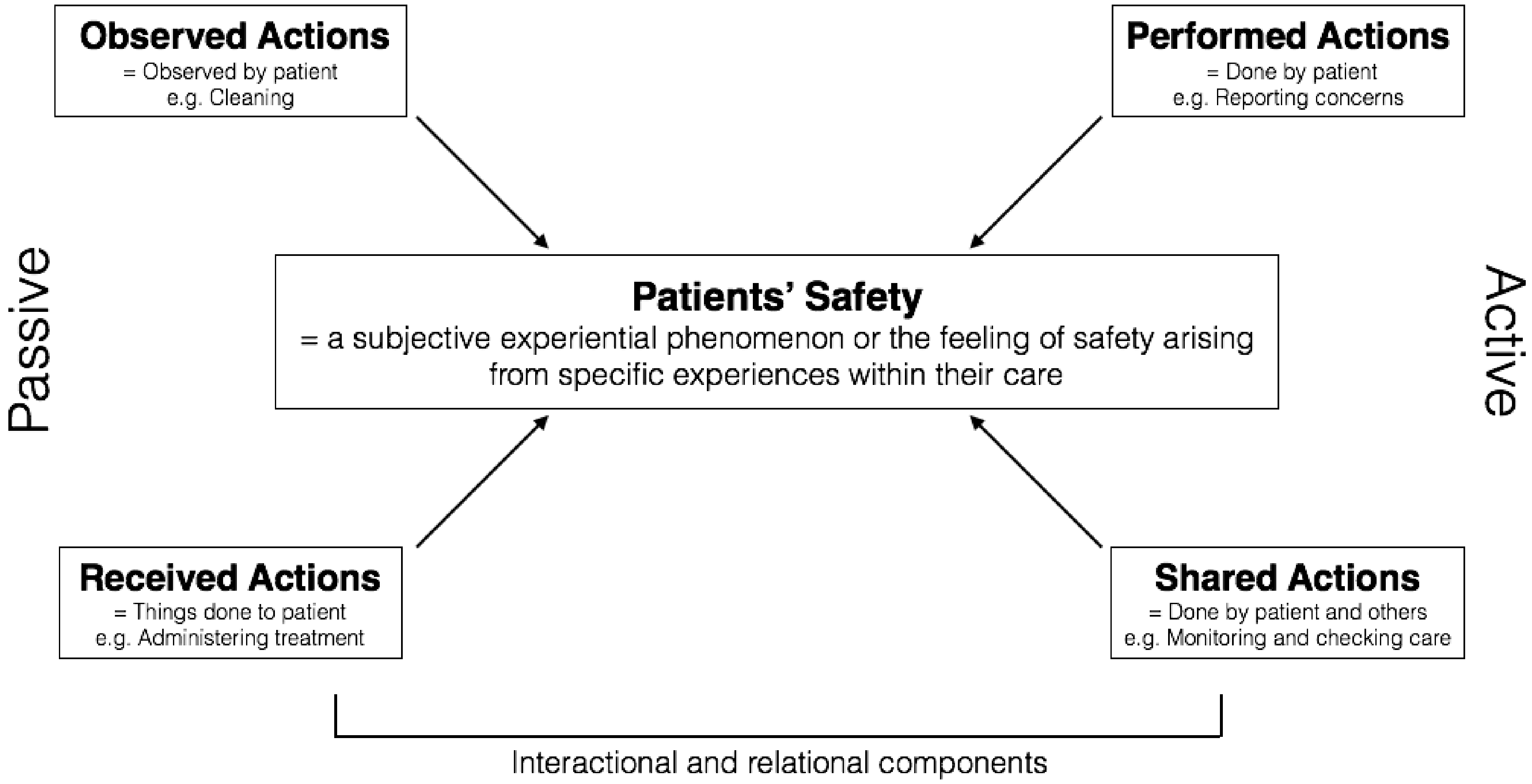

Figure 4.12: The Patients' Safety Theory

The Patients' Safety Theory (TPST) describes *patients' safety*, the patient conceptualisation of patient safety, as a subjective experiential phenomenon or the feeling of safety arising from specific experiences with actors within their care. The theory illustrates the types of process that patients experience which give rise to their feelings of safety. These can be divided into active processes, which involve patients, or passive processes, which are done to patients or separate to patients. The patient, their experience and their feelings are at the centre of the theory.

The active processes contributing to *patients' safety* are illustrated on the right of the diagram in Figure 4.12. Two types of active process were identified: performed and shared. 'Performed' refers to actions or processes undertaken by patients themselves, which then lead to feelings of safety (for example, reporting concerns or taking responsibility for myself). 'Shared' refers to actions or processes that are undertaken by patients together with one of the identified actors in their care, leading to feelings of safety (for example, monitoring and checking my care, or supporting me in speaking up).

The passive processes contributing to *patients' safety* are illustrated on the left of the diagram in Figure 4.12. Two types of passive process were identified: observed and received. 'Observed' refers to actions or processes that do not involve the patient directly; these are things patients observe or witness in their care, undertaken by one of the other identified actors in their care, which lead to feelings of safety (for example, cleaning or the presence of protocols). 'Received' refers to actions or processes done directly to the patient by one of the other actors in their care (for example administering medications and treatment, or looking after me).

Importantly, it is not just the process or action itself that is important in the patient experience of feeling safe, but also the nature and quality of processes. For shared and received processes, the quality of interactions and the relational components of the process (for example, quality of communication, the attitudes and characteristics of staff) additionally contribute to patients' feelings of safety.

In summary, TPST explains *patients' safety*, or the patient conceptualisation of patient safety, as a subjective experiential phenomenon or a feeling of safety that arises from the patient experience of active and passive processes undertaken by actors within their care.

4.6 Discussion

This study sought to understand how patients conceptualise patient safety. It aimed to explore perceptions of what patient safety is, to explain how patient safety is conceptualised, and to consider the impact of clinical setting upon conceptualisations of patient safety. Patient safety was conceptualised by patients both objectively and subjectively. The objective components of safety paralleled academic definitions of patient safety; however, these ideas about patient safety were not forefront in the minds of the participants and were elicited predominantly through prompting and direct questioning. Participants predominantly referred to patient safety as a subjective state. Patient safety was regarded as a feeling, and feelings of safety were invoked by experiences in their care. This was consistent with the findings of the meta-study in Chapter 3, where it was found that patients discussed the concept of patient safety through what made them feel safe (Rathert et al., 2011a; Vaismoradi et al., 2011b; Scott et al., 2012; Stenhouse, 2013a; Hernan et al., 2014; Lyndon et al., 2014; Lovink et al., 2015; Collier et al., 2016; Rhodes et al., 2016a).

The study therefore focussed on exploring this subjective conceptualisation by seeking to understand the experiences that led to feelings of safety. Using constructivist grounded theory, I have identified, categorised and presented the experiences in care that give rise to patients' feelings of safety. More specifically, feelings of safety arose from experiences involving specific actors within a patient's care; these actors are: the organisation, staff, the patient and their friends, family or carers. Through characterising the relationship between these actors and the types of experiences that lead to feelings of safety, I developed The Patients' Safety Theory (TPST). This theory explains the patient conceptualisation of patient safety, or *patients' safety*, as a subjective experiential phenomenon or a feeling of safety that arises from the patient experience of active and passive processes undertaken by or with the actors within their care.

In the subsequent sections I will consider the relationship between the findings of this study and the concept of patient experience. I will also compare the findings with the findings in Chapter 3. I will then go on to consider how TPST compares to existing patient safety models or theories, and thus demonstrate its original contribution to the existing literature about conceptualisations of patient safety. Finally, I will consider the steps required to apply these findings to patient safety policy and practice.

4.6.1 The patient conceptualisation of patient safety and patient experience

In this study, it was evident that patient safety and the concept of patient experience are fundamentally related: the patient conceptualisation of patient safety is mediated by the experiences they have in their care. This relationship will be considered in more detail.

The Institute of Medicine (2001) defines quality care as being comprised of the following key outcomes: safety, effectiveness, timeliness, efficiency, equity and patient-centredness. Similarly, within the NHS, the government White Paper *'High Quality Care for All: NHS Next Stage Review'* places quality at the centre of everything that we do. It suggests that quality should be understood from the perspective of the patient, through patient experience (Darzi, 2008; Department of Health, 2008), defined as the quality of caring, how personal care is, and patient satisfaction. Patient experience is therefore recognised as a pillar of quality, and improving experience and the use of experience measures have been a significant focus for the Department of Health, the National Institute for Clinical Evidence and the NHS.

Patient experience as a pillar of quality is often justified on the grounds of its intrinsic value (Doyle et al., 2013); however, it is also justified as a means of improving patient safety and effectiveness (Berwick, 2009; Street et al., 2009), and healthcare providers are increasingly using patient experience data for quality improvement (Flott et al., 2017). There can be a tendency, though, towards rejecting patient experience as too subjective and unrelated to *"'real' clinical work of measuring and delivering patient safety and clinical effectiveness"* (Doyle et al., 2013). However, there is practical evidence that a patient's experience may give us new information about or improve patient safety and clinical effectiveness (Berwick, 2009; Street et al., 2009; Doyle et al., 2013). It has been recommended that patient perceptions are a *"good first indicator of deeper systems issues"* (Rathert et al., 2012). Key reports from Francis, Keogh and Berwick also support the view of patients as 'smoke detectors' for safety, and there is evidence that the patient perspective can provide valuable contributions to patient safety (Weissman et al., 2008; Zhu et al., 2011; Ward and Armitage, 2012).

A systematic review of the evidence on the links between patient experience, and clinical safety and effectiveness, found associations between patient experience across a range of measures and the other two domains; this was consistent across different diseases, study designs and clinical settings (Doyle et al., 2013). The authors warned that whilst association does not entail causality (meaning improving patient experience not will necessarily improve safety and effectiveness), the weight of evidence suggests that patient experience is clinically important (Doyle et al., 2013). Such evidence affirms a link between patient experience and patient safety; as such, where once *"silos"* existed encasing the three domains of quality, these are beginning to be broken down (Flott et al., 2017).

The relationship between patient experience and patient safety discussed above relates to an objective conceptualisation of patient safety, to patient experience being associated with clinically defined patient safety outcomes or being safe. This study, however, has shown a new relationship between patient safety and patient experience, which has not yet been articulated. It has shown that patients conceptualise patient safety as a subjective experiential phenomenon, a feeling arising from certain patient experiences. This undoubtedly means that patient experience and *patients' safety* or feeling safe are intrinsically linked.

Accepting a conclusion that patient safety is comprised of both an objective and subjective component (both being and feeling safe), a relationship between two of the dimensions of quality can be postulated, (illustrated in Figure 4.13), with *patients' safety* existing at the intersection between patient safety and patient experience.

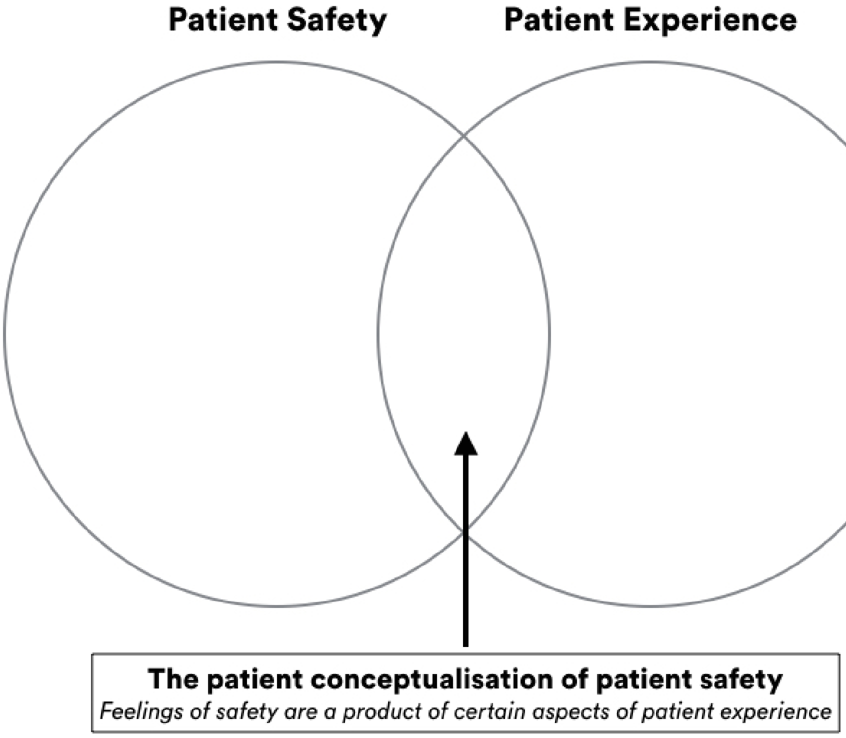

Figure 4.13: The relationship between patient safety and patient experience

4.6.2 Relationship to the findings of Chapter 3

In Chapter 3, I developed a theoretical framework for the conceptualisation of patient safety, describing thematically organised factors perceived by patients and healthcare professionals as contributing to their conceptualisation of patient safety. I importantly identified that it was difficult to draw significant conclusions about any relationship between individual factors without further research. These are presented again in Table 4.8, along with their explanations; I have additionally indicated whether these factors were represented within the common categories of experience, which have been described in the main results (Section 4.5.4) of this chapter.

Table 4.8: Comparison to theoretical factors developed in Chapter 3

Theme	Factor	Explanation	Patients or HCP?	Present in this study?
SYSTEM	**Atmosphere**	The hospital as a 'safe place' with a welcoming atmosphere, noise control, privacy and normalcy.	Patient	Yes
	Organisational functions	Gatekeeping functions, access to appointments, and finance.	Patient	No
	Resources	Adequate equipment, materials, Information Technology and electronic health record integration	HCP	-
	Safety culture	Existence of governance structures, with associated activities, events and atmosphere at ward level.	HCP	-
	Workload	Determined by staffing levels, volume and acuity of patients, working hours. Impacts tiredness, motivation, safety and quality of care.	HCP	-
	Environment	Quality, design and cleanliness of built environment.	Both	Yes
	Protocols and Procedures	Procedures have inherent risks; protocols exist for safety in everyday work and emergencies (e.g. medication administration). However, patients believe they can limit discretion and undermine safety.	Both	Yes
STAFF	**Professional qualities and competence**	Demonstration of consistent technical competence and possession of core attributes (including mannerisms, attitudes, clinical skills and knowledge).	Patient	Yes
	Acquisition of skills/training	Acquisition or maintenance of skills through training, appropriate supervision and accumulation of experience/knowledge	HCP	-
	Responsibility	The legal, ethical and individual responsibilities of healthcare professionals e.g. Human Rights law, mental health law, duty of care	Both	No
PATIENTS	**Impact of self and others**	Control over or input into care and its safety, with support from significant others/fellow patients, without threat from others.	Patient	Partly
PROCESSES OF CARE	**Responsiveness**	Presence and proximity of nursing staff providing timely management of basic care needs/symptoms, and frequent contact/checks.	Patient	Yes
	Care Planning	Quick determination of a care plan, including investigation, referral and diagnosis. Includes having and being informed of a care plan.	Patient	Yes

	Individualised care	Holistic personalised care plan, including in mental health.	Both	No
RELATIONAL ASPECTS OF CARE	**Patient-staff relationship**	Foundation of inherent trust; recognition and alleviation of power imbalances.	Patient	Yes
	Psychosocial	The feeling of safety and the minimisation of emotional harm; this includes the social elements of interaction, the expectation and experience of interaction, and what people think/feel	Patient	Yes
	Teamwork and interprofessional working	Working and cooperation within teams, including multiprofessional teams	Patient	Partly
	Communication	Communication to the patient, family, within the care team, and outside of care team. It should be professional, respectful, unprejudiced, timely, accurate, open, and patient centred. It includes listening, establishing ideas/concerns/expectations, and information transfer at transitions of care or between team members/other teams.	Both	Yes

The majority of factors from Chapter 3 arose within this study and have been discussed as categories of experience associated with patients' feelings of safety. Whilst 'Organisational functions' was not included in the common conceptual map, both the maternity and elective surgery cohort reported management of systems pressures (e.g. finances, workload) and of appointments as contributing to their feelings of safety. Some participants discussed 'Responsibility' in relation to safety as a duty. 'Impact of self and others' was discussed by participants in the surgery and elderly cohort, however, this was in relation to the organisation ensuring the safety and security of patients and protecting them from others; the elderly and maternity cohort, though, also recognised the patient role in ensuring safety and security. 'Teamwork and inter-professional working' was mentioned in relation to inter-professional communication making patients feel safe in the elderly and surgery cohorts. 'Individualised care' is the only factor that was not elicited in some way, although maternity and surgery patients did discuss the role of having a treatment plan in their feelings of safety.

Chapter 3 provided evidence, through identifying and synthesising definitions of patient safety and factors perceived as contributing to patient safety, that patients and healthcare professionals conceptualise patient safety differently. Limitations to this study were identified, requiring further qualitative work to fully understand conceptualisations of patient safety in the NHS and thus strengthen the conclusions drawn in Chapter 3. Having conducted this qualitative study presented here, there are clear similarities between the meta-synthesis findings and the theoretical categories emerging in this study. This therefore supports the conclusions drawn in Chapter 3.

However, importantly, this study has gone beyond the work in Chapter 3, which simply provided a description of thematically organised factors perceived as contributing to patient safety. Whilst the themes (System, Staff, Patients, Processes of care, Relational aspects of care) usefully organised the broad factors that contributed to conceptualisations of patient safety, it was not possible to determine relationships between themes and factors in order to explain how patients perceive patient safety. This explanation was achieved in this study, where I have developed an explanatory theory that shows the patient conceptualisation of patient safety is a product of the processes and actions of actors in their care (the system, staff and patient, as similarly seen in Chapter 3, as well as their friends, family or carers).

This study has therefore extended the conclusions Chapter 3 by postulating relationships between theoretical categories, to not only describe but also explain the patient conceptualisation of patient safety as a subjective phenomenon arising from their experiences with actors in their care. In this way, this study responds to the need, identified in Chapter 3, to definitively understand how patients conceptualise patient safety in the NHS, as the first step in developing a patient safety paradigm for the NHS that values different perspectives.

4.6.3 The Patients' Safety Theory and other patient models of patient safety

The meta-study in Chapter 3 identified existing studies that sought to understand patient perceptions of patient safety. The included studies were heterogeneous in their aims and settings, which made it difficult to generalise their findings to the NHS or broader patient populations, therefore necessitating this study. Nonetheless, two of the included studies developed patient safety models, which should be considered and compared to TPST.

Collier et al. (2016) explored safety and harm in the context of end of life care. They described six harm themes and three safety themes (which underpinned their articulation of safety as interpersonal safety); these were seen as heuristic devices for simplistically explaining participant's more complex experience of safety and harm. They too found that some of the participants' articulations of safety and harm were consistent with clinical or organisational definitions; however, they also found a broader articulation of harm. They concluded that harm, and therefore safety, emerges from how clinical tasks, interpersonal communication, the environment and socio-cultural context are intertwined. This was explicated in a patient safety model, shown in Figure 4.14.

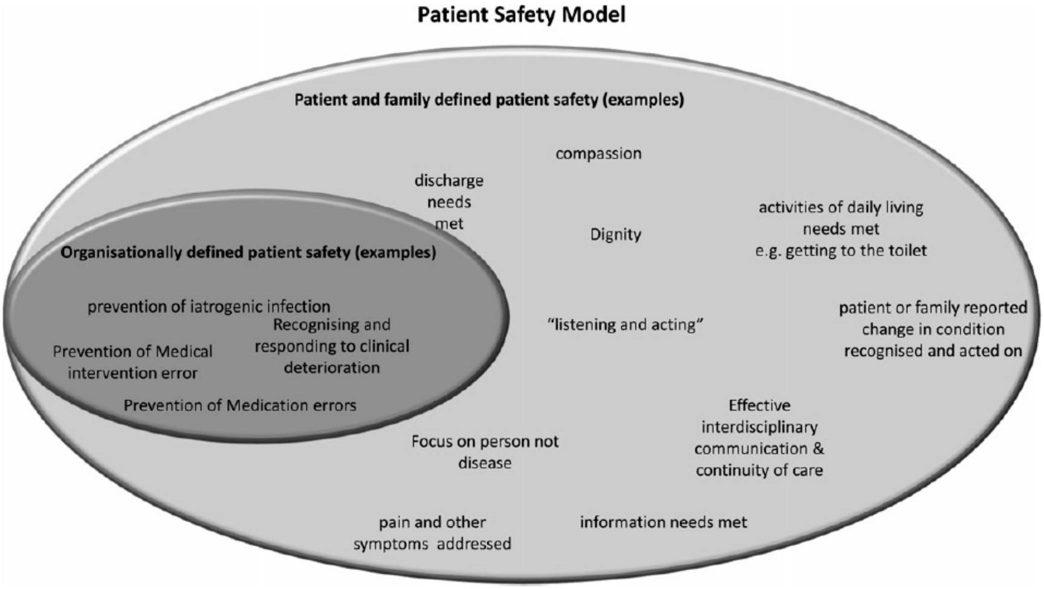

Figure 4.14: Patient safety model
From Collier et al. (2016)

This model has some consistency with the results in Section 4.5.2, which showed a distinction between an objective and subjective conceptualisation of patient safety; Collier's model makes reference to the concept of organisationally defined (objective) and patient/family defined (subjective) patient safety. Collier's model attempts to show how harm and safety framed from the patient perspective is the product of how clinical tasks, interpersonal communication, the built environment and socio-cultural context are intertwined. It attempts to illustrate a broader concept of patient safety that crucially highlights the importance of meaningful and significant interaction to patient defined patient safety. However, the model stops short of actually explaining the relationship between people, processes and their experience of safety; the model is ultimately descriptive, illustrating a difference between the patient and organisational perspective of patient safety, but not truly explaining how the patient perspective arises. In contrast, the qualitative study presented in this chapter not only identifies that patients conceptualise patient safety in a different way to our academic/professional definitions, but also explains how they conceptualise patient safety, focussing on how people and processes give rise to their subjective experience of feeling safe.

Lyndon et al. (2014) explored patient safety from the perspective of parents with a baby in the Neonatal Intensive Care Unit (NICU). They developed a model, shown in Figure 4.15, which showed that parents view patient safety as a combination of clinical team actions and patient contributions across physical, emotional and developmental safety dimensions.

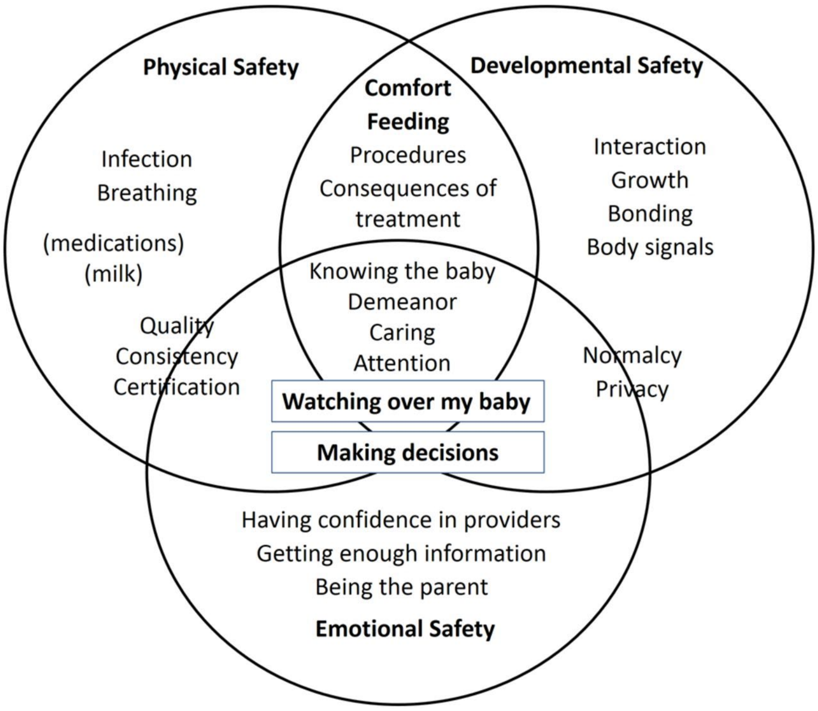

Figure 4.15: Parents perceptions of patient safety in the Neonatal Intensive Care Unit
From Lyndon et al. (2014)

The model indicates that parents think about safety in ways beyond the traditional definitions, with a particular emphasis upon the concept of emotional safety. Parent-defined patient safety is therefore more complex. This model attempts to show the relationships between the types of safety, and similar to the theory developed in the current study, Lyndon et al. (2014) emphasise the importance of interaction between staff and parents, and the roles parents could play.

In summary, the theory I have developed has similarities to other patient-defined patient safety models, despite these existing models developing from very specific clinical settings. This may tentatively suggest that my theory has applications beyond the three clinical specialities within which it was developed. However, importantly, my theory goes beyond these existing models, moving from simply describing patient safety from the patient perspective, to explaining the patient conceptualisation of patient safety as a subjective experiential phenomenon, as a feeling arising from the patient experience of actors in and processes within their care.

4.6.4 The Patients' Safety Theory and theories of feeling safe

From Chapter 3, there was some evidence that patients understand patient safety with reference to feelings of safety or feeling safe; in the discussion I considered theories of feeling safe, which exist in broader healthcare literature. In this section, I briefly re-visit these models/theories to consider how the theory I have developed compares to these.

There are similarities between TPST and the theories developed by Hupcey (2000), Lasiter (2011), Lasiter and Duffy (2013), and, most recently, the theory developed by Mollon (2014) in a concept analysis which includes all three of these studies. Mollon defined 'feeling safe' in a way that is similar to how patient safety is conceptualised by patients in this study. Critically, in these studies, experiences in care were key to patients feeling safe in hospital and similar types of experiences led to these feelings. The experiences that contribute to this (the actions, interactions and relational aspects of care) are similarly reflected in the passive and active processes in care reflected in TPST.

The theory developed in this chapter, TPST, significantly extends and improves upon the theory presented by Mollon (2014) and other researchers. A key strength of the study presented in this chapter is that, whilst Mollon's definition of feeling safe was developed a priori (independent of experience and deduced from pure reason), I have reached the definition of '*patients' safety*' a posteriori (from experience and evidence). Mollon recognised the lack of theoretical foundation to much of the existing work contributing to the concept analysis; in contrast, this study has developed TPST from empirical evidence with a transparent method for analysing and theorising.

TPST addresses some key limitations to the concept analysis presented by Mollon (2014). A key limitation of Mollon's concept analysis is the limited number of empirical referents with which to measure and quantify the concept of feeling safe. This means the theory of feeling safe developed in the concept analysis, whilst supporting the existence of a unique patient conceptualisation of patient safety that must be recognised in clinical practice, remains to fully develop and explain the concept of feeling safe. TPST addresses this limitation of Mollon's theory and responds to the call for further qualitative research specifically addressing the patient perception of feeling safe in order to further develop the concept. TPST is therefore an important and new contribution to understanding patient safety from the patient perspective and gives support to the need to develop models of care centred on the patient and including their conceptualisation of safety.

4.6.5 The Patients' Safety Theory and clinical theories or models of patient safety

In Chapter 1, I discussed the common definitions of 'patient safety' and the models that currently exist to explain patient safety. I also criticised the lack of patient perspective in current definitions and models, and suggested the need to understand and value the patient perspective in patient safety, forming the rationale for this thesis. This study has shown that patients could formulate explanations of patient safety similar to our academic definitions; however, ultimately the patient conceptualisation of patient safety has been shown to be different. I briefly revisit these clinical models to demonstrate how the TPST provides a new dimension to patient safety or could be used to inform modification to existing models or theories.

Donabedian's quality model, an SPO model, describes how structure and processes are linked to outcomes (Donabedian, 1966; Donabedian, 1978; Donabedian, 1980; Donabedian, 1988). The theory developed in this chapter similarly places importance on the component parts of this model, structure (e.g. environment, cleaning) and particularly on processes, upon which the theory is developed. Donabedian's SPO model, however, is criticised for its linearity and failure to acknowledge interactions and interdependencies within healthcare (Carayon et al., 2006). I support the criticism made by Carayon; I have found the patient conceptualisation of patient safety to be dynamic and not to be consistent with this linear model. Instead TPST is based upon complex active and passive processes, with the patient at the centre, interacting with a range of actors in a patient's care.

There are obvious similarities between the 'seven levels of safety' framework (Vincent et al., 1998) and the categories of experience defined in this current study (with results Section 4.5.5). However, Vincent et al. (1998) obviously focus on patient safety in the objective sense, although this could be reasonably adapted to additionally incorporate the patient's conceptualisation of safety as part of a broader definition of safety that recognises both being and feeling safe. TPST is a theory, and is therefore explanatory; this makes it more sophisticated than a framework like this, which provides the structure for a theory, but does not provide any further relationships between 'levels of safety' to more fully explain the concept of safety.

The SEIPS model, improving upon the Donabedian model, additionally considers the relationships between structure, process and outcome, and how this contributes to the work system and patient safety (Carayon et al., 2006). In this way, the SEIPS model has similarities to TPST, which shows *patients' safety* as a phenomenon arising from complex dynamic processes between patients and other actors within their care. Remembering that the term 'patient safety' includes the patient, Carayon et al. (2006) also show how the patient would fit within the model, both as a recipient of processes but also performing tasks. However, the position of the patient in this model is not central as in TPST, reflecting the dominance of the clinical perspective. Additionally, the example patient tasks are system and clinically orientated, and there is a focus on passive received processes (things done to the patient) and no reflection of the shared processes undertaken by patients evident in TPST. Therefore, some similarities exist between this model and TPST, but the patient perspective is not fully integrated. This would require an expanded view of the types of processes that are important in achieving safety (being and feeling safe), moving the patient perspective to share centre stage within the model, and an expanded view of the outcomes, incorporating feelings of safety as an accepted outcome.

Comparing TPST to the model for patient safety (Emanuel et al., 2008), TPST similarly shows interactions between components of safety; however it focuses on a different subjective outcome, focussing on the interaction between patients and others in the system, which drives the patient experience and gives to feelings of safety.

Overall, TPST has some similarities with clinical patient safety models. These similarities lie in the types of contributory experiences, and the focus on processes and interactions. These models, however, are designed with the objective conceptualisation of patient safety in mind, the concept of being safe. Current models of patient safety continue to exclude the patient and do not consider the patient defined outcome of feeling safe, although I have highlighted the potential for these models (the SEIPS model in particular) to be modified to also include this patient conceptualisation. Additionally, the models also do not take into account the range of experiences that patients implicate in their conceptualisation of patient safety by focussing solely on received actions and neglecting performed, shared and observed actions or processes also contribute to *patients' safety* or feeling safe.

4.6.6 Future work

The findings of this study raise a challenge to healthcare professionals, healthcare systems and policymakers to expand our ideas about patient safety, to consider not just being safe, but also feeling safe. Currently, the patient conceptualisation is not acknowledged, defined or addressed in governance or patient safety processes (Collier et al., 2016). I have highlighted the inadequacies of existing patient safety models, the limitations of current theories and models for feeling safe, and the failure of clinical theories and models of patient safety to consider the concept of feeling safe and to account for the range of experiences patients implicate in their conceptualisation of patient safety. This study should encourage the expansion of the definition of patient safety, to include feeling safe as well as being safe; it is necessary to incorporate TPST into clinical practice to ensure that the patient conceptualisation of patient safety is valued.

Grounded theories are particularly useful as they assist us in solving practice problems (Cutcliffe, 2005). The theory explains the types of processes (both active and passive) that healthcare professionals and healthcare systems need to be aware of and improve on in the patient experience to engender patient feelings of safety. Fundamentally, improving patient feelings of safety needs to focus on the processes that exist at the intersection between patient experience and patient safety, which are explained by TPST. Future work should include how the theory can be practically applied and implemented in order to incorporate the patient conceptualisation into everyday patient safety practice whilst enhancing patient feelings of safety - this will be the task of Chapter 6, which will seek to practically apply the findings of this study.

Before this, additional work is required, however, to empirically establish the perspective of healthcare professionals managing patient safety practically in their day to day practice, in order assess how far apart this perspective is from both the clinical models of safety and the patient conceptualisation as explained by TPST.

4.7 Strengths and limitations

The theory builds on existing models by drawing on multiple clinical specialties, enhancing its generalisability, and by understanding the underlying abstract processes that lead to patient feelings of safety. Importantly, the study demonstrates a distinction between academic and healthcare professional conceptualisations of patient safety and the patient conceptualisation. This difference poses an important challenge to how we define and discuss patient safety moving forward.

The study included participants who were older and many whom did not speak English as their first language; these patients are often most risk, but frequently excluded from patient safety research (O'Hara and Lawton, 2016).

This study took place at a single site, which may limit the generalisation of its outcomes to other hospitals. Many of the patients, however, had experience of care at other hospitals and drew on those experiences when describing their conceptualisation of patient safety; this may therefore assist generalisation of the resultant theory. The study excludes the most vulnerable (i.e. those lacking capacity or those who were clinically too unwell to participate) and they may have reported different care experiences as affecting their feelings of safety; future work could include friends, relatives or carers to represent their views.

The use of abbreviated grounded theory is a limitation. Ideally, data collection and analysis should continue until theoretical saturation, meaning no new categories or variation within categories are found (Willig, 2001). It is recognised though, that even with this aim, modifications and changes in perspective are always possibly, so that grounded theory is always provisional (Glaser and Strauss, 1967).

In conducting the study, the principles of rigour discussed in Chapter 2 and earlier in this chapter were maintained. In relation particularly to truth value (ensuring representativeness of findings and preventing bias), I found it particularly challenging to put aside my personal biases around understanding and defining patient safety; I was mindful to ensure this did not influence my questioning or interpretation of the data through engaging in reflexivity, self-reflection and discussion with my supervision team through all stages.

In making the comparison between different clinical specialities, there were differences between and notable absences in, the types of experience reported to give rise to feelings of safety. Some of these experiences could feasibly be expected to arise in any clinical specialty (e.g. ‘Providing staff’ or ‘Ensuring security of me and my belongings’), yet did not. Categories that were not represented by all three participant cohorts were not included for the purposes of theory development, for example ‘Interprofessional communication,’ which was only discussed in the elderly and surgical cohort. These absences have the potential to impact the richness of the theory. Without further qualitative exploration, it is not possible to determine the impact of this or why this occurred. These aspects could be tested in future work through theoretical sampling, which serves to obtain data in order to explicate conceptual and theoretical categories (Charmaz, 2006).

Finally, there were some types of experience that were clearly specialty specific including 'Planning my discharge,' 'Preventing falls' and 'Mobility' within the elderly cohort. Within the conceptual mapping, these experiences lie beneath the theoretical and conceptual category level and, as a result, would not change the overall theory on a theoretical level. However, they do have implications within conceptual categories, which represent the specific processes that lead to feelings of safety. This would have an impact for the practical application of TPST (i.e. knowing which processes were important for feeling safe) within different clinical contexts.

4.8 Reflection

This study was my first experience of conducting qualitative research. It has therefore been useful to reflect upon my experience and how my practice developed.

Patient recruitment was a challenge in this study; whilst I did not formally log how many patients I approached during recruitment, I estimate I approached twice the number of patients as participated in this study. The main barrier to participation was the patient perception that they did not have anything relevant to contribute to research. By reframing the way I discussed the study, with an emphasis on the interview being a discussion about their experiences during their hospital admission, I found more patients were willing to participate. I also avoided telling patients I was a clinician and researcher, to prevent this impacting recruitment, their answers or their interaction with me.

I initially found interviewing challenging. Firstly, I felt an imposition to patients; however, I quickly found that patients were willing and enthusiastic to share their thoughts and experiences. Secondly, I found myself frustrated by patients' answers to questions about their understanding of patient safety; what they were describing to me was not 'patient safety.' Reflecting upon these feelings, I realised that I was listening to their perspectives with my clinical lens; I learnt to undertake interviews with an open mind, giving value their accounts and recognising their conceptualisations of patient safety were different to mine.

In the analysis, I initially felt similarly frustrated as during interviewing. This was overcome through careful reflection, discussion with my supervision team and discussion with patients in my clinical work, which served to confirm to me that what I was uncovering and presenting in my analysis was indeed a unique patient conceptualisation of patient safety. I have had to work hard to ensure I did not impose my clinical conceptualisation onto the coding and subsequent theory development; this has required me to return to original transcripts and *in vivo* codes at times to ensure the language used reflected that used by the patient participants.

4.9 Conclusion

This chapter has shown that patients understand patient safety both objectively and subjectively. I have clearly shown that patients have their own unique conceptualisation of patient safety, which exists at an intersection between the concepts of patient safety and patient experience. Predominantly, patients have a subjective conceptualisation of patient safety, describing feeling safe or feelings of safety, arising from experiences in their care. Using constructivist grounded theory, I have developed The Patients' Safety Theory (TPST); this is a broad theory, derived from three clinical specialities within the NHS. It is patient centric and dynamic, with multiple interactions. TPST explains the patient conceptualisation of patient safety, or *patients' safety*, as a subjective experiential phenomenon, with feelings of safety arising from specific experiences with specific actors in their care.

The development of TPST is fundamentally important for expanding how we conceptualise patient safety moving forward. Current models of patient safety continue to exclude the patient and focus on objective outcomes, not the patient defined outcome of feeling safe. There is predominant focus on objective measures, rather than subjective measures or patient experience. I have shown that *patients' safety* is different to patient safety as explained by existing models, theories and frameworks. I have additionally shown that TPST extends and improves upon other existing theories of feeling safe, which do not reflect the complex and dynamic patient perspective. This theory has therefore begun the process of moving away from clinically derived definitions and the concept of merely being safe, by inviting patients to contribute in establishing what patient safety is, its boundaries and exactly how it is comprised.

Recalling the conclusions of Chapter 3, I identified that further work is required to understand conceptualisations of patient safety in order to provide further evidence, within the context of the NHS, of differences between the patient and healthcare professional conceptualisation of patient safety. Having explored and explained the patient conceptualisation, it is now necessary to consider the healthcare professional perspective. This will allow an assessment of how far apart the healthcare professional conceptualisation of patient safety is from both the clinical models of safety and the patient conceptualisation as explained by TPST. This will provide the extensive evidence required to support the need for and then develop a patient safety paradigm that values different perspectives and is relevant for the NHS.

Chapter 5: How do healthcare professionals conceptualise patient safety?

5.1 Introduction

This thesis has presented growing evidence of a difference between the patient and healthcare professional perspective of patient safety. This was evident in Chapter 3, which used meta-study to synthesise qualitative evidence of both patient and healthcare professional definitions and perceptions of patient safety; there were limitations to the findings of this study, particularly that the conclusions reached were simply descriptive and generated from a heterogeneous body of literature.

Chapter 4 addressed these limitations, extending the findings of the meta-study by empirically deriving the patient conceptualisation of patient safety across elective surgery, acute medicine for the elderly and maternity in the NHS using constructivist grounded theory. This showed that patients have a unique conceptualisation of patient safety, referred to as *'patients' safety'*, which is a subjective experiential phenomenon, or the feeling of safety, arising from different experiences in their care. This was explained by The Patients' Safety Theory (TPST), a dynamic patient centric theory, in which patients experience active and passive processes, involving specific actors within their care. The theory expresses the types of processes that should be focussed upon in order to engender patients' feelings of safety.

It was shown how TPST differs to existing models, theories and frameworks for patient safety (Donabedian, 1966; Vincent et al., 1998; Hupcey, 2000; Carayon et al., 2006; Emanuel et al., 2008; Lasiter, 2011; Lasiter and Duffy, 2013; Lyndon et al., 2014; Mollon, 2014; Collier et al., 2016), which do not adequately acknowledge the patient perspective (Collier et al., 2016). TPST adds to the evidence that the patient perspective of safety differs to academic, policy and clinical perspectives of safety. The findings of Chapter 4 therefore assert the need to expand current definitions of patient safety to incorporate the patient perspective and translate this into patient safety policy and practice.

However, this assertion of a difference is based upon comparison of TPST to existing policy definitions, models, theories and frameworks, and the findings of Chapter 3, which are subject to limitations. It still remains unclear as to what extent existing definitions and models of patient safety accurately reflect the patient safety definitions and perceptions held by healthcare professionals actually working within the NHS.

In order to provide a true comparison of the patient and healthcare professional perspectives of patient safety, it is necessary to firstly empirically establish the perspective of healthcare professionals managing patient safety in their day to day practice. This will then allow a comparison of existing policy definitions and models of patient safety, with an empirically derived healthcare professional theory of patient safety. Finally, it will be possible to compare TPST and an empirically derived healthcare professional theory of patient safety.

If differences are found between a healthcare professional theory of patient safety and both existing definitions/models of patient safety and TPST, this will strengthen the call to expand the current patient safety paradigm as a necessity. Additionally, the comparisons will allow an assessment of how much of a paradigm shift is necessary in order to incorporate the patient perspective into both policy and clinical practice.

5.2 Research question

As in Chapter 4 (Section 4.2 Defining the research question), broad and exploratory research questions are defined, with a central research question and associate sub-questions. The central research question for this study was:

How do healthcare professionals conceptualise patient safety?

This was supported by sub-research questions:

1. How do healthcare professionals define patient safety?

2. What are healthcare professionals perceptions of patient safety, including their knowledge, understanding, and experience of patient safety in their day-to-day practice?
3. How do these definitions and perceptions contribute to the healthcare professional conceptualisation of patient safety?
4. What is the impact of clinical setting upon the conceptualisation of patient safety?
5. What is the impact of professional role upon the conceptualisation of patient safety?
6. How does the healthcare professional conceptualisation compare to the patient conceptualisation of patient safety?

5.3 Methodology

As in Chapter 4, constructivist grounded theory, as defined by Charmaz (2006), was used. The explanation of and justification for using this methodology are discussed in 'Section 4.3 Methodology' and are therefore not repeated.

5.4 Methods

In this section, I discuss the methods used in this study. The methods were broadly the same as those used in Chapter 4; as such, these are not repeated in full, and instead any differences are highlighted and explained.

5.4.1 Design

In depth, semi-structured, individual interviews were used to collect data, using pre-set open-ended questions from a topic guide. The topic guide was developed from general literature review and through reflection upon the outcomes of Chapter 3. It was adapted for each of the clinical settings. It consisted of core open questions and subsequent prompts, to be used if the participant could not answer the initial questions or to develop a more comprehensive response. The topic guide was flexible and revised as interviews took place; this reflected my developing understanding of their conceptualisations of patient safety. The topic guides broadly covered:

- Demographic details
- Knowledge and understanding of patient safety, including the definition of patient safety
- Their role as a healthcare professional in patient safety
- Responsibility for patient safety
- Experience of patient safety
- The patient role in patient safety, including patient involvement
- Discussions with patients about patient safety.

The full topic guide can be found in Appendix 9.

5.4.2 Setting and participants

The study took place at St Mary's Hospital, a large central London teaching hospital. Doctors and nurses or midwives were recruited to the study; this was because these staff members were predominantly identified in Chapter 4 as contributing to the patient conceptualisation of patient safety. In order to directly compare the conceptualisation of patient safety, participants were recruited from the specialties of acute medicine for the elderly, elective surgery and maternity (postnatal), to match the specialties in Chapter 4.

Participants were eligible if they were:

- A doctor, nurse or midwife
- Working in acute medicine for the elderly, elective surgery and maternity (postnatal ward).

5.4.3 Sample size

As in Chapter 4, the desirable sample size for each group was 6-8 participants. Because of the potential differences in perspective between doctors and nurses/midwives, they were treated as distinct participant groups for each of the clinical specialities; six participant groups were therefore defined.

5.4.4 Ethics

Ethical approval was granted for this study by the Health Research Authority (Reference 16/HRA/5779). As in ‘Section 4.4.4 Ethics,’ the main ethical issues related to informed consent, risks of the study, confidentiality and data management; the same principles discussed there also apply to this study.

Importantly, it was ensured that participation in the study did not impact patient care. Healthcare professionals were not taken away from their clinical duties unless adequate cover was in place to ensure safe care of their patients; the shift manager was therefore consulted to ensure an appropriate time was organised. Where possible staff were identified before/after work or during breaks.

Participants were advised that their responses would be confidential, except in the circumstance where serious unreported patient safety events, on-going safety issues or clinical concerns were identified which could present on-going risk to the participant or others; in this situation it was advised that confidentiality would be broken, although anonymity could still be preserved.

5.4.5 Recruitment

Participants were recruited via two methods. Firstly posters were displayed in clinical areas to advertise the study; these provided the contact details of the researcher to allow potential participants to express an interest and seek further information. On enquiry, a copy of the participant information sheet (Appendix 10) was sent by email, after which the individual could decide if they wished to participate; an interview date and time was then agreed. Secondly, the interviewer approached members of staff in the clinical environment (on wards, at/after handover or clinical meetings) to explain the study and distribute participant information sheets; staff were asked to contact the researcher if they wished to participate.

5.4.6 Data collection

The researcher (EB) sought written informed consent (Appendix 11) from all study participants for participation in the interviews. The informed consent discussion and interview took place at a convenient location. At the beginning of each interview, participants were given an explanation of the interview and overall study. They were reminded that the content of the interview was confidential and anonymous. An audio recording was made of the interview. The interviewer took field notes reflecting verbal responses and reflections to be used to adapt the topic guide/study direction. The audio recordings were professionally transcribed and the transcripts were reviewed for accuracy.

5.4.7 Data analysis

As in Chapter 4, abbreviated grounded theory, using constructivist grounded theory, was used for data analysis. The same processes used in Chapter 4 for data analysis (constant comparison, memo-writing, initial coding, focussed coding, theoretical coding, theory development and theoretical sorting – described in Section 4.4.7 Data Analysis) were used in this chapter and are therefore not repeated in full here; the pertinent steps, however, that differ to Chapter 4 are described.

In analysing the data, the transcripts for each participant cohort were initially analysed in their separate groups; this therefore allowed comparison within groups and between groups at each coding stage.

5.4.7.1 Initial coding

Initial coding, as per Charmaz (2006) is described in full in Chapter 4 (Section 4.4.7.3 Initial coding) and was applied in the same way in this study. A second researcher (AM), a healthcare professional with experience in qualitative data analysis but no background in patient safety research, initial coded 25 percent of the transcripts. There was evident concordance between the two researchers; furthermore the process served to clarify, expand and refine developing codes by providing new insights.

5.4.7.2 Focussed coding

Focussed coding, as per Charmaz (2006) is described in full in Chapter 4 (Section 4.4.7.4 Focussed coding) and was applied in the same way in this study.

5.4.7.3 Theoretical coding

Theoretical coding, as per Charmaz (2006), is described in full in Chapter 4 (Section 4.4.7.5 Theoretical coding) and was applied in the same way in this study. Conceptual maps showing the theoretical categories, conceptual categories and their sub-categories were developed for the pooled data, clearly identifying the clinical specialty origin for the categories.

5.4.7.4 Theory development and theoretical sorting

Theory development and theoretical sorting, as per Charmaz (2006), is described in full in Chapter 4 (Section 4.4.7.6) and was applied in the same way in this study. In this stage, I sought to uncover the processes underlying the conceptualisation of patient safety; this was done through theoretical sorting, considering the possible relationships between categories and how they could be integrated into theory (Glaser, 1978; Charmaz, 2006; Walker and Myrick, 2006). Relationships were postulated between theoretical categories and a theory was developed.

5.4.8 Maintaining rigour

This was addressed in Chapter 2 (Section 2.6 Rigour in qualitative research) and Chapter 4 (Section 4.4.8 Maintaining rigour) and was similarly applied in this study.

5.4.9 Transcription quotes

This was explained in Table 4.2; the same notation for illustrative quotes was applied in this study.

5.5 Results

This results sections is divided into the following sub-sections: demographic details, definitions of patient safety, perceptions of patient safety in day to day practice, and The Clinical Patient Safety Theory.

5.5.1 Results 1: Demographic details

A total of 42 healthcare professionals were interviewed between 23rd February 2017 and 30th June 2017. The demographic details of each participant group are presented here.

Seven surgical doctors were recruited from three surgical wards. Five male and two female doctors were interviewed with an average clinical experience of 9.3 years (range 1 to 22 years). The interviews lasted an average of 28 minutes (range 18 to 42 minutes). The full demographic details are given in Table 5.1.

No.	Gender	Ethnicity	Role	Clinical experience (years)
1	M	White British	Registrar	5
2	M	Other White	Senior house officer	7
3	F	White British	Senior house officer	7
4	M	Asian British	House officer	1
5	F	Other White	Registrar	8
6	M	Asian British	Consultant	22
7	M	White British	Consultant	15

Table 5.1: Demographic details - elective surgery doctor participants.

Nine surgical nurses were recruited from four surgical wards. Two male and seven female nurses were interviewed with an average clinical experience of 9.2 years (range 1.5 to 27 years). The interviews lasted an average of 22.4 minutes (range 17 to 30 minutes). The full demographic details are given in Table 5.2.

No.	Gender	Ethnicity	Role	Clinical experience (years)
1	M	Asian	Charge nurse	11
2	F	White British	Sister	15
3	F	Asian	Sister	27
4	F	Black British	Staff nurse	2
5	F	Black African	Sister	8
6	F	Other White	Staff nurse	10
7	F	White British	Staff nurse	2
8	F	White British	Staff nurse	1.5

9	F	White British	Staff nurse	6

Table 5.2: Demographic details - elective surgery nurse participants

Six acute medicine for the elderly doctors were recruited from two wards. Four male and 2 female doctors were interviewed with an average clinical experience of 10.1 years (range 1 to 29 years). The interviews lasted an average of 25 minutes (range 15 to 42 minutes). The full demographic details are given in Table 5.3.

No.	Gender	Ethnicity	Role	Clinical experience (years)
1	F	White British	Senior house officer	1.5
2	M	White British	Consultant	29
3	F	White British	House officer	1
4	M	White British	Registrar	6
5	M	White British	Registrar	8
6	M	White British	Consultant	15

Table 5.3: Demographic details - acute medicine for the elderly doctor participants.

Six acute medicine for the elderly nurses were recruited from two wards. Five female and one male nurse were interviewed with an average clinical experience of 9.2 years (range 0 to 17 years). The interviews lasted an average of 20.8 minutes (range 16 to 30 minutes. The full demographic details are given in Table 5.4.

No.	Gender	Ethnicity	Role	Clinical experience (years)
1	F	White British	Band 7 Nurse	10
2	F	White British	Band 7 nurse	15
3	F	Black African	Band 5 nurse	2
4	M	Black British	Band 5 nurse	11
5	F	White British	Student nurse	0
6	F	Black African	Band 6 nurse	17

Table 5.4: Demographic details - acute medicine for the elderly nurse participants

Eight obstetrics and gynaecology doctors were recruited from the maternity department. Two male and six female doctors were interviewed with an average clinical experience of 13.9 years (range 3 to 36 years). The interviews lasted an average of 31.1 minutes (range 24 to 40 minutes). The full demographic details are given in Table 5.5.

No.	Gender	Ethnicity	Role	Clinical experience (years)
1	M	White Irish	Consultant	36
2	F	British Asian	Consultant	14
3	F	Other White	Registrar	12
4	F	White British	Senior house officer	6
5	F	White British	Senior house officer	3
6	F	White British	Registrar	7
7	M	British Asian	Consultant	30
8	F	White British	Senior house officer	3

Table 5.5: Demographic details - maternity doctor participants.

Six midwives were recruited from the maternity department. One male and five female midwives were interviewed with an average clinical experience of 15.3 years (range 7 to 30 years). The interviews lasted an average of 19.8 minutes (range 16 to 25 minutes). The full demographic details are given in Table 5.6.

No.	Gender	Ethnicity	Role	Clinical Experience (years)
1	F	Black British	Band 6 midwife	23
2	F	White Irish	Band 5 midwife	7
3	M	Other White	Band 6 midwife	7
4	F	White British	Band 5 midwife	30
5	F	Asian	Band 5 midwife	8
6	F	White British	Band 5 midwife	17

Table 5.6: Demographic details - maternity midwife participants

5.5.2 Results 2: Definitions of patient safety

Participants were first asked to define or explain what they thought patient safety was. Frequently occurring initial codes relating to the definition of patient safety (participant statements of meaning) were brought together into focussed codes. Subsequently, three main conceptual categories were identified, illustrated in Figure 5.1. The healthcare professional definition of patient safety is therefore comprised of: ‘Doing no harm,’ ‘Optimising’ and ‘Realising the patients’ perspective.’

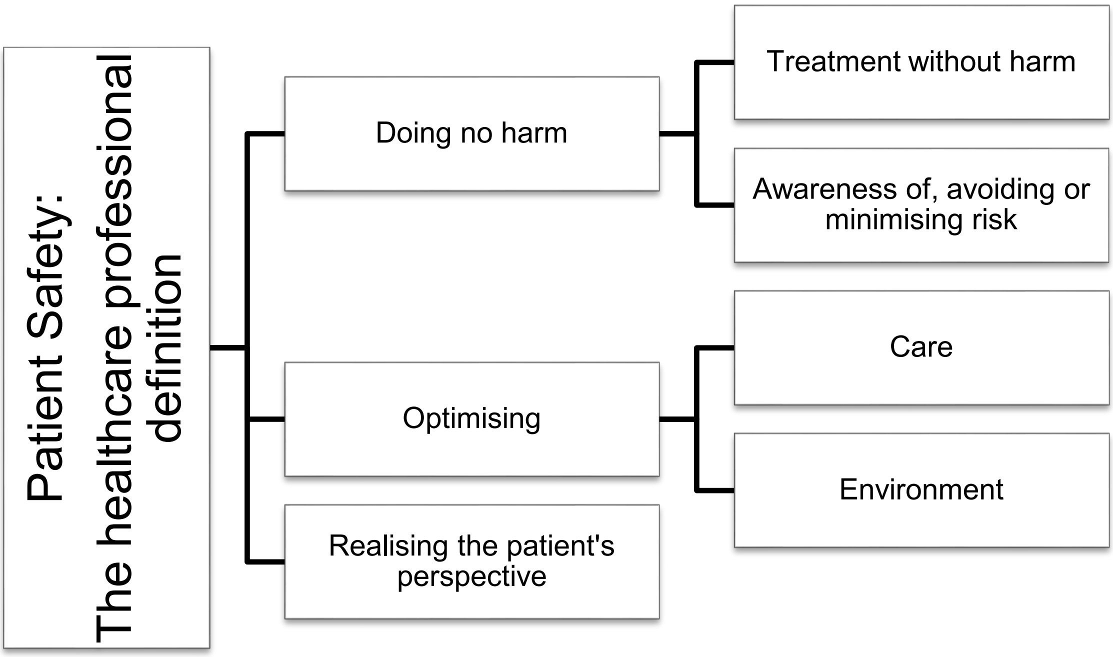

Figure 5.1: The healthcare professional definition of patient safety

5.5.2.1 Doing no harm

Doing no harm was comprised of two main facets: treatment without harm, and awareness of, avoiding or minimising risk.

It was widely recognised that things can go wrong in healthcare and that when this happens, patients could experience harm; a spectrum of harm that could be endured by patients was described, including clinical deterioration, injury, psychological harm, or even death. Patient safety was commonly defined as the concept of doing no harm; one consultant commented that the mere existence of the concept of patient safety implies *"that there's some understanding that something could go wrong"* (Maternity Doctor 7).

Doing no harm specifically meant avoiding patients coming to harm as a result of their admission, and care and treatment for a condition:

> *"Well it is, patient safety I think, is ensuring that patients will not suffer any harm due to our actions, any sort of actions, and that is what I consider, so doing no harm, from a doctor's point of view." (Surgery Doctor 2)*

A range of terms was used for the causes of harm; this included accidents, medical misconduct, injuries, incidents, adverse events, never events, errors and complications. Participants discussed a range of types of error that could lead to harm including medication errors, human fallibility, blood transfusion, wrong site surgery and retained swabs/instruments.

The concept of risk was also discussed in relation to patient safety. Participants identified various risks of hospitalisation that could lead to harm: infection (hospital acquired, multi-drug resistant), falls, risks to self or from other patients, risks from staff, the physical environment, treatment, and (particularly in the elderly) deconditioning, delirium and pressure sores. Some risks, for example treatment risks and procedural risks, are expected and accepted risks; these are explained to patients during discussions about treatment or, in the context of surgery, during the consent process for surgery:

> *"But then I think there are other risks like risks that we might accept, so you might have someone who's very, very sick but they need a toxic drug, but we would accept the potential risks to them, kidney injury, for example." (Surgery Doctor 5)*

Patient safety and the concept of doing no harm, was therefore recognised as being specifically related to *"avoidable and non-acceptable risks"* (Surgery Doctor 5) or to unintended and unanticipated harms:

> *"But in patient safety I think it's mainly unintended harm. Something that could be prevented potentially in the future, and has an adverse impact on their care that was not either anticipated or intended, is what I think patient safety is related to." (Surgery Doctor 1)*

There was awareness that avoidable harms are preventable, or that those unintended/unanticipated harms could be learnt from in order to prevent future risk:

> *"--that opens out a whole number of reasons why errors and harm might come to patients and what we can do to reduce the risk." (Elderly Medicine Doctor 2)*

Doing no harm therefore included understanding the risks and errors that may cause harm, why they happen and working to avoid or minimise them and their impact. Participants described *"mechanisms and protocols"* (Surgery Doctor 7), *"beliefs--guidelines and understandings"* (Surgery Doctor 5), *"processes"* (Elderly Medicine Doctor 6), ways of doing things, systems, procedures, checklists and care plans as the means through which risks were managed, and error and harm were avoided. Participants discussed processes (their own and others' roles and responsibilities) that were implicated in doing no harm.

5.5.2.2 Optimising

Participants also identified a positive side to safety; rather than focussing on avoiding risk, harm and things going wrong; this focused on ensuring things going right. Within this aspect of safety, processes and systems are designed to optimise and promote good outcomes:

> *"To me, patient safety is more focusing on the positive side of the safety not the negative side, not preventing accidents, but looking at ways to optimise how we do things for patients…" (Maternity Doctor 1)*

This had a broad scope and included optimising care processes, *"being able to give the care that you would deem as safe"* (Maternity Midwife 1), and the physical environment, ensuring the patient was in *"safe surroundings"* (Elderly Medicine Doctor 3).

As with doing no harm, participants discussed processes (their own and others' roles and responsibilities) that were implicated in optimising care and the environment.

5.5.2.3 Realising the patient's perspective

Participants demonstrated an awareness of the patient perspective of patient safety. Healthcare professional participants acknowledged that they predominantly focussed upon clinical or physical aspects of patient safety; however, they also recognised that patient safety may be comprised of more than just physical safety, and that appreciation of a potentially wider definition of patient safety was lacking:

> *"I think that actually it's a lot wider than you first think right safety, safety is like a physical safety, put your seatbelt on, that's my safety belt. But I think it is wider and I think that*

> *it's so important that a huge aspect of it is lacking…" (Maternity Doctor 6).*

The wider definition of patient safety pertained to the idea that the concept of patient safety is different to different people, with its components and definition varying between individuals:

> *"I think, because patient safety encompasses so many things at so many different levels, it will, by definition, mean different things to different people, depending on their lens," (Maternity Doctor 3).*

Participants reflected that definitions and subsequently attainment of patient safety reflected achieving clinical outcomes and avoiding harms. This therefore failed to recognise the patient perspective, which included their experience of care and patient outcomes:

> *"I think sometimes we think, "Well pneumonia treated, no major hazards, major hazards along the way avoided, they've gone home, job done" without really maybe giving too much thought to the actual experience as well. So, I think we may be still a bit too much concerned with the medical outcomes rather than the patient outcomes." (Elderly Medicine Doctor 2)*

Therefore, despite the one-sided policy definitions of patient safety, participants actually had their own more expansive concept of patient safety, recognising the importance of different lenses and the patient perspective. Patient safety was therefore seen as a holistic concept, also encompassing a mental or psychological component experienced by patients:

> *"And it's also about, not only the physical side of the patient's journey, I would suggest it's psychological as well and for patients to feel safe in our care." (Elderly Medicine Nurse 2).*

Reference was made to the concept of patients feeling safe and there was appreciation of how feelings of safety may arise. This included softer aspects of care, for example caring, communication and interpersonal qualities. A third component of patient safety, the patient perspective, therefore formed part of the definition of patient safety.

5.5.2.4 Summary

Through coding, participant definitions or statements of meaning for the term 'patient safety' were identified. Three main conceptual categories were identified: Doing no harm, Optimising, and Patients' perspective. 'Doing no harm' meant avoiding harm in treatment of patients, as well being aware of and avoiding/minimising risk. 'Optimising' reflected a positive side to patient safety, where healthcare professionals focus on ensuring things go right or achieving good outcomes in a patient's care; processes and the physical environment are designed and maintained to promote and support this. 'Realising the patients' perspective' reflected awareness by healthcare professionals that patient safety may have a different meaning depending upon your lens or perspective; the patient perspective, though seen as lacking in traditional definitions of patient safety, focussed on outcomes beyond physical clinical outcomes, including experience of care, patient defined outcomes, psychological outcomes and feelings of safety arising from the softer aspects of care.

5.5.3 Results 3: Perceptions of patient safety in day to day practice

Participants elaborated on their relatively abstract definitions of patient safety by describing what they perceived in their day-to-day practice as contributing to patient safety. Specifically, they talked about their own and others' responsibilities and roles in relation to practically achieving patient safety, reflecting upon their own practical experience and knowledge upon which to base these perceptions. This compliments the concept of the patient experience of patient safety identified in Chapter 4; importantly, whilst healthcare professionals 'do' patient safety everyday as part of their clinical practice, it is also part of their lived experience of clinical practice or being a healthcare professional.

Patient safety was deemed to be a responsibility of those involved in patient care, directly (i.e. looking after the patient or in contact with the patient), or indirectly:

> *"I think a fair answer for that is anyone involved in patient care directly or indirectly, and that means that anyone has a responsibility, whether you are the consultant, the registrar, the junior doctor, the nurse looking after the patient, the secretary taking a phone call." (Surgery Doctor 1)*

> *"It's everyone. So, patients, relatives, healthcare professionals, be it HCAs, nurses, students, doctors, big up*

> *managers that don't ever turn up on the wards. Anyone really." (Elderly Medicine Doctor 4)*

More precisely, everyone had their own individual part to play in patient safety, specific to their professional position:

> *"I think everyone has a role in maintaining the safety in the bits that they are doing..." (Surgery Doctor 7)*

It was deemed impracticable for one person to be responsible for every single aspect of patient safety and individual people within the system had to be relied upon to perform their specific role that contributed to patient safety. Many examples were given of the different professional positions in the hospital and their various roles in patient safety; for example, the occupational therapist was deemed responsible for the safety of discharge (including the safety of the home environment and necessary modifications). Responsibility varied with seniority and experience; for example a surgical consultant, had responsibility for overseeing all parts of the system and care, but delegated responsibility of task completion to others depending on their role and skills. Auxiliary staff, including administrative staff, cleaners and kitchen staff, also had their own specific roles that contributed to patient safety.

This section therefore expands upon the healthcare professional definition of patient safety by identifying their perceptions of patient safety in their day-to-day practice. Initial codes that described roles or responsibilities for achieving patient safety were identified, and examined and compared in focussed coding. From these, categories were developed: the categories organised the different type of patient safety role, responsibility or process undertaken to accomplish patient safety; where possible categories were named using gerunds to preserve action. These categories were organised and conceptual categories were formed (with associated sub-categories) by considering how they were related, through memo-writing and clustering. Conceptual categories defined the type of role or responsibility undertaken in order to achieve patient safety. Examples of conceptual categories included: 'Risk management,' and 'Managing my skills and training.'

Through theoretical coding, the conceptual categories were examined and relationships developed between them. As in theoretical coding in Chapter 4, theoretical codes were applied that defined the main actor implicated in the role or responsibility defined within the conceptual categories; this organised the conceptual categories. The identified actors were the patient, their friends, family or carers, staff, and the system; these formed theoretical categories. The theoretical categories therefore explained patient safety as being accomplished through the various types of roles and responsibilities of specific actors within healthcare. Each of these groups and their roles will be discussed in turn in the subsequent sections.

As discussed in the method section, through the stages of coding, conceptual maps were developed to help describe and explain the data. Overall, these maps explain patients' feelings of safety as being accomplished through the roles and responsibilities of specific actors within healthcare. The relationship between theoretical categories, conceptual categories and sub-categories is shown in an illustrative example conceptual map in Figure 5.2.

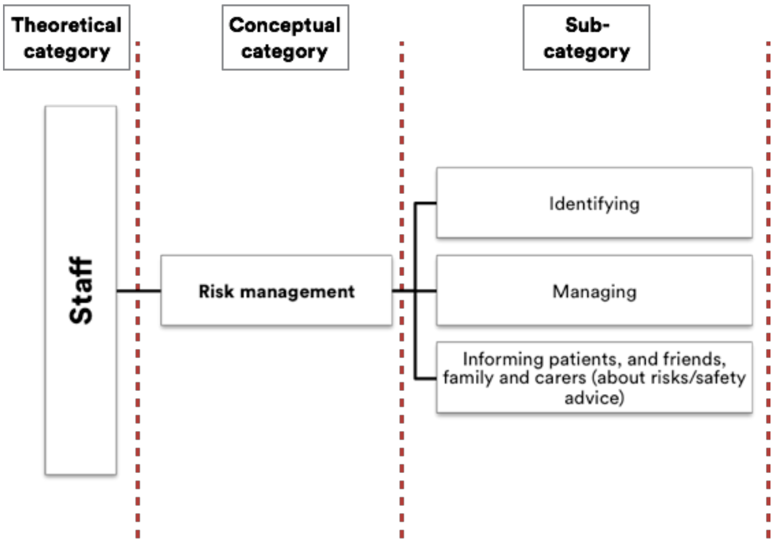

Figure 5.2: Example of conceptual map demonstrating categories

As in Chapter 4, the maps are colour coded to reflect which clinical specialty group a category was derived from (Orange = acute medicine for the elderly; Blue = maternity; Green = Elective surgery), with the majority of categories saturated.

5.5.3.1 System

Participants described the roles of the System in achieving patient safety; this is illustrated in Figure 5.3.

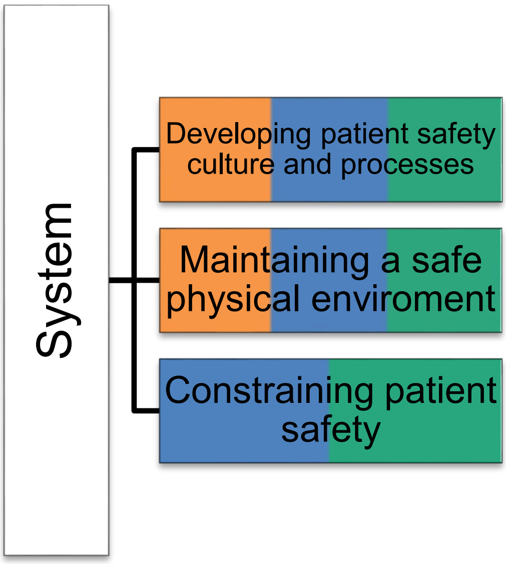

Figure 5.3: System roles in achieving patient safety

(Key: Orange = Elderly, Blue = Maternity, Green = Surgery)

The system refers to both an NHS Trust and the wider NHS. The system has been identified as having two main roles in achieving patient safety: developing patient safety culture and processes, and maintaining a safe physical environment. The system was also seen as constraining patient safety, meaning various system pressures were a threat to achieving patient safety.

5.5.3.1.1 Developing patient safety culture and processes

Participants discussed patient safety as a *"pervasive culture"* (Elderly Medicine Doctor 6), a series of intrinsic processes and ways of doing things to ensure and optimise safety in an organisation. Culture and systems for maintaining safety were *"institutional"* (Surgery Doctor 7) and derived at the level of the organisation. Responsibility lay with the Trust to ensure staff worked within an organisational environment that promoted patient safety; culture therefore provided the framework for this. Institutional messages around care, innovation and patient safety were reported to be publicly displayed for patients and staff in the organisation; these provided guidance for staff to practice in a way that acknowledged patient safety:

> *"I believe that with the trust values, as a nurse, you work in line with that to accommodate or to…identify with this patient safety." (Surgery Nurse 9)*

The organisation was responsible for staff training, staff motivation and systems necessary for ensuring patient safety. This included setting standards, guidelines and *"clinical governance"* (Elderly Medicine Doctor 5), which if followed would lead to patient safety.

Patient safety culture was seen as important for supporting a *"safe and effective environment"* (Surgery Doctor 1). This was evidenced by the outcome of investigations into failing hospitals or patient safety incidents; it was recognised that failures in patient safety culture within an organisation were often identified as causes.

5.5.3.1.2 Maintaining a safe physical environment

The system was considered responsible for maintaining a safe physical environment:

> *"The hospital management has a responsibility for making the environment safe, like the thing with the environment like the electricity, the wires, the lifts, that sort of thing" (Maternity Doctor 6).*

This extended to managing potential hazards and physical risks to patients, which could lead to harm (including slips, trips and falls); staff received training on this from the Trust.

5.5.3.1.3 Constraining patient safety

The system was seen to constrain patient safety standards. Maternity and surgery participants were very aware that the ability of the system to maintain patient safety was threatened by various pressures on the NHS. Staffing was a particular concern, with recognition of the prevalence of understaffing, rota gaps and increased patient to doctor/nurse ratios. Staff commented they are stretched, trying to manage more than they are safely able to do, but that the limits of the system mean they have no choice but to try and care for and treat patients in these circumstances:

> *"There are so many levels of issues in patient safety, from, you know, staff management, rota gaps. That's a problem at the moment… it becomes very difficult when we're having, out of necessity, to cover more things than is safe to do so. And it's a real ethical dilemma because you have to look after the patients, and you know it's not safe to do what you're doing, but you can't not do it." (Maternity Doctor 6)*

These pressures impact patient safety and delivery of care. Additionally, pressures on resources (e.g. beds), increasing workloads and budget cuts were identified as systemic patient safety risks:

> *"I think that we have to appreciate that the NHS pressures that we are suffering do inherently, if you ask me, put pressures on safety." (Surgery Doctor 7)*

In response to system pressures, the expectation from organisations was that clinical practice be changed; this included discharging people, who you may not have discharged that day to ease bed pressures, looking after an increased number of patients, putting patients on outlier wards, and cancelling operations. In changing their clinical practice, staff felt that patients and their care were subsequently less safe. Staff viewed patient safety as a concept that should be *"immovable,"* meaning that the standard for patient safety is set and should not change. Participants felt, however, that through encouraging staff to engage in practices they would not normally follow or practices that they deemed to be less safe for patients, the encourages *"changing the bar"* (Surgery Doctor 7) for patient safety, changing the limits of and accepting different lower standards for patient safety that becomes the new normal.

Overall, patient safety culture and governing processes are defined intrinsically by the system. However, these are subject to extrinsic pressures, meaning the system also changes and constrains the limits of and standards for patient safety to react to the ever-changing landscape of healthcare.

5.5.3.2 Staff

Participants described the roles staff had for achieving patient safety; these are illustrated in Figure 5.4.

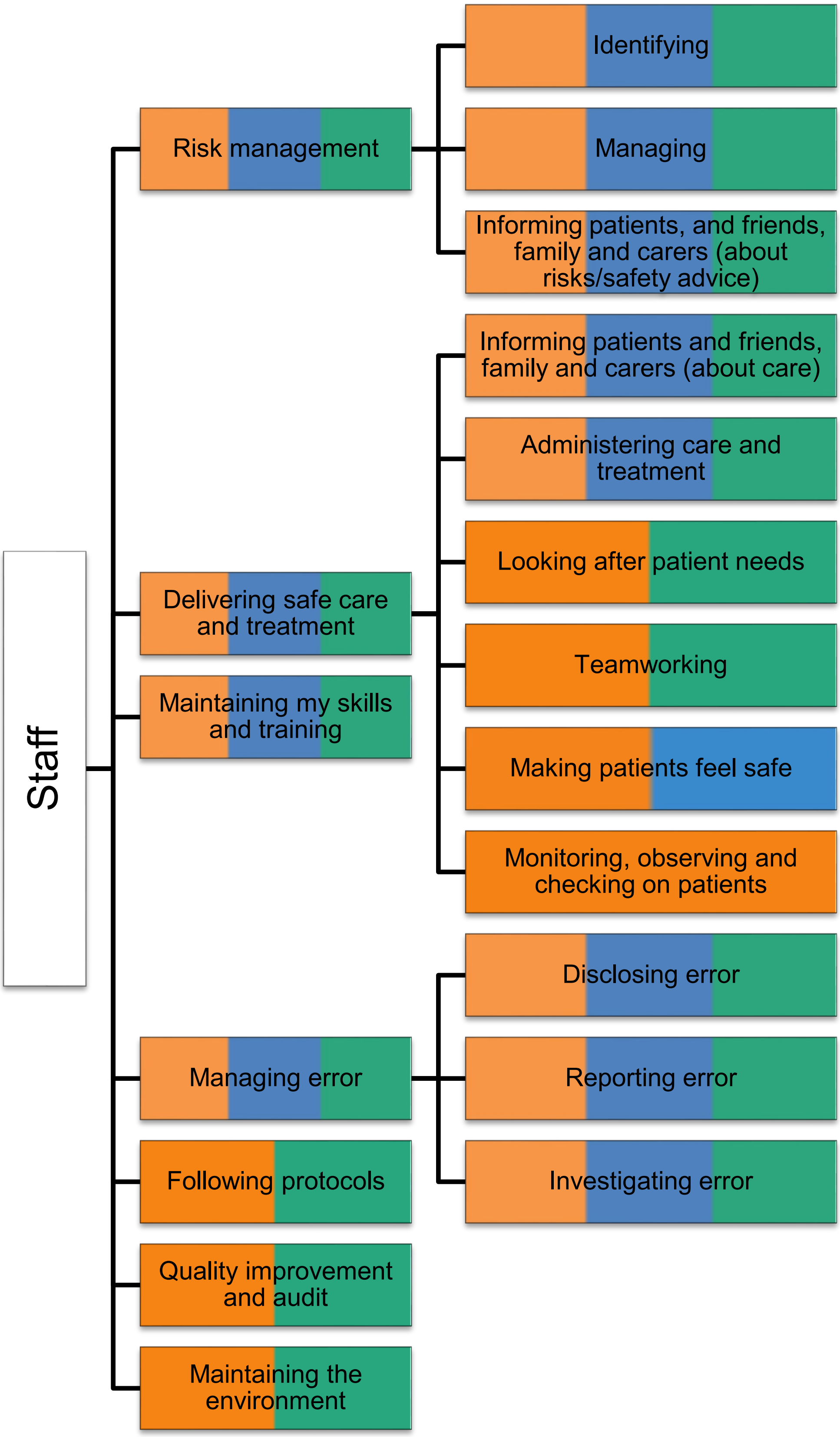

Figure 5.4: Staff roles

(Key: Orange = Elderly, Blue = Maternity, Green = Surgery)

5.5.3.2.1 Risk management

Participants identified that staff had roles in managing risk; this included identifying risk, managing or minimising risk, and informing patients and their relatives about risk and offering related safety advice.

Participants identified a responsibility to identify risk and address problems. Identifying risk involved being *"observant to potential risks"* (Elderly Medicine Doctor 1), using screening, risk assessments and care plans to identify risks (e.g. falls, pressure area care, nutrition) and using available tools and observations to identify risks (e.g. clinical observations, cardiotocograph (CTG) and fetal scalp blood gas). In maternity, CTG interpretation was particularly important:

> *"The key issue, like the most important issue regarding midwifery is recognise [sic] when the heart rate is not reassuring." (Maternity Midwife 3)*

Through this, midwives could identify 'at risk' pregnancies/labours and escalate their concerns to the doctors. Once risks of any type had been identified, staff had a role in minimising or managing those risks:

> *"My specific role is to detect where there might be a risk, through the nursing care plans and through general observations then put action plans in place to rectify, to reduce that risk as much as possible." (Surgery Nurse 9)*

Minimising and managing risks meant actioning risk assessments and escalating concerns to prevent harm to patients. In elderly care, there was a particular awareness that there would always be issues of concern or harm to elderly patients, which may not be possible to remove, but it was important to ensure people were aware of these and did what was possible to minimise associated risks:

> *"So, [my role] is to try and minimise the risk medically as a junior doctor, so spotting things early, on this ward, constipation, urinary retention, to try and ensure that everything I do, I minimise the risk associated with it." (Elderly Medicine Doctor 1)*

As well as constipation and urinary retention, other important named risks to elderly patients included medication, catheters and confusion

Staff also had a role in informing patients and their relatives about risk and offering safety advice to try and mitigate these. Risk was discussed in the context of consent for procedures (e.g. blood tests, induction of labour, administration of drugs) and surgery:

> *"You know, when I'm consenting patients for an operation it is all patient safety, so with a patient safety focus, it's talking about the consent process, talking about the checks that we'll do, going through the operation including the risks of the operation, so that itself has lots of areas where patient safety could be a problem." (Maternity Doctor 8)*

Staff would discuss with patients specific safety issues related to the procedure or surgery, risks of infection, medication and venous thromboembolism, site marking and mobility. Some surgical staff members discussed the risks of wrong site surgery, and reported that they discussed this with patients and involved them in site marking:

> *"I think I have a conversation every time I mark someone's leg when I get an unusual response and a look of quite serious concern. I say this is standard and this is what we do. This is where you're involved and you agree with us that we're operating on the correct side. I've marked it. You agree with me and it agrees with the paper. And to try and have a conversation about that." (Surgery Doctor 5)*

In addition to discussing site marking as a check for patient safety and to mitigate against risks, staff also discussed other checks they undertook; in maternity this included *"bringing people in for the 'fresh eyes' check,"* (Maternity Doctor 2) a mechanism for ensuring CTG interpretation is checked.

Staff additionally talked to patients about things they do within the hospital environment that put them at risk (e.g. mobilising alone) and advised patients what they should or should not to do to avoid these risks. They reported giving patients safety advice about such risks:

> *"I would discuss with the patient patient safety things that they can do from their perspective." (Maternity Doctor 3)*

5.5.3.2.2 Delivering safe care and treatment

The delivery of *"care of the highest standard"* (Surgery Doctor 6) was a crucial patient safety role of frontline staff. Staff had roles in patient safety through various aspects of delivering safe care and treatment. The sub-categories are shown in Figure 5.3 (above) and will be discussed in turn.

Administering medical care and treatment and doing so safely, accurately and to a high standard, was an important role for staff in patient safety. This related to a range of aspects of medical care and treatment including *"to try and get to appropriate investigations, to diagnose appropriately"* (Maternity Doctor 4), medications and other medical or surgical management, looking after women in labour, and care during the post-operative period. In relation to medication, nurses described their role to *"dispense their medication to them, and we make sure that we dispense the medication in a safe way"* (Elderly Medicine Nurse 3); this included understanding the patient's medication, giving them the right medication and being aware if allergies. For the doctors, this involved safe prescribing, rationalising medications and ensuring medication compliance and reconciliation. Doctors reported responsibility for ensuring *"medical or surgical management is right for them [the patient]"*, whilst nurses were then responsible for delivery:

> *"…whatever treatment they're having, as far as I'm involved in it, making sure that it's done you know accurately and in the proper way. And yeah, safely done, you know?" (Surgery Nurse 8)*

In addition to delivering care and treatment, participants identified that in the accomplishment of patient safety, staff had a role in informing patients about their care:

> *"Also, I think, giving patients information, what's going on with them, is very important and so they're aware of what's happening, and also that they're aware, or able to contribute to their care plan is very important…" (Elderly Medicine Nurse 1)*

This meant informing patients about their condition, what was happening and their care plan; subsequently, through being informed about their condition and treatment, patients would be able to contribute to their care, which was implicated in enhancing their safety.

Participants from the elderly and surgery cohorts reported that the staff role of looking after patient needs was important for patient safety:

> *"I have to ensure that my…the needs of my patient is being looked after." (Surgery Nurse 2)*

This included *"getting fed and watered properly"* (Elderly Medicine Doctor 5), having their pain managed, having their care and comfort needs met, and having access to their call bell. Additionally, staff also discussed the attitudes and characteristics required from a healthcare professional in a caring role.

Team working was identified as a staff role for achieving patient safety in the surgery and elderly cohorts:

> *"--and also the way I work with my colleagues, make sure the environment is safe, make sure I communicate with my colleagues clearly and communication obviously with all the team knows what is happening to the patient, the risk of safety or harming patients might be slightly reduced." (Surgery Nurse 5)*

Through staff working together and communicating between each other, staff could ensure patient safety and reduce harm. Everyone in the multidisciplinary team had a role to play and could *"contribute to improve patient safety by being a team player"* (Surgery Nurse 1). Communication within and between teams was also vital.

Participants from the elderly and maternity cohorts reported that one of their care and treatment roles included attending to patients' feelings of safety: *"making sure my patients feel safe"* (Maternity Doctor 6). This involved asking patients if they felt safe or what they needed in order to feel safe, and putting this in place.

Finally, in acute medicine for the elderly, participants reported a staff role in monitoring, observing and checking on patients to ensure their safety:

> *"I think they come here with confusion or dementia, so that is why you will see us, we don't leave the ward, we keep an eye on them 24/7, because none of them is, they are not aware of*

> *any safety or whatever." (Elderly Medicine Nurse 3)*

This was essential for these particularly vulnerable patients who were at greater risk (e.g. of falls). Staff would ask for additional observation and monitoring of patients if they were deemed to be high risk; this included one to one nursing if they felt a patient's safety was particularly compromised.

5.5.3.2.3 Maintaining my skills and training

Staff had a role in patient safety through ensuring they possess clinical and professional skills, knowledge, competence and experience, and that these were maintained through training. It was recognised that ***"****if people don't have knowledge of what they are doing, safety can be compromised"* (Surgery Nurse 5). This included having clinical knowledge, competence with practical skills, and awareness of Trust specific policies; this was affected by the level of experience of staff (e.g. newly qualified) and the duration of time they had been working on a specific ward or within the trust. It was deemed important that the *"right level of experience is applied to a particular clinical problem to reduce the likelihood that things may go wrong"* (Maternity Doctor 1). Where staff lacked competence, they were expected to seek senior help or supervision in order to ensure safety of the patient.

To ensure safety, participants reported that staff needed to have up to date training, including *"all the competencies and what have you, you know, by Trust protocols"* (Elderly Medicine Nurse 1). Participants in more senior staff roles recognised they had a role in not only their own training, but also the training of others:

> *"But also in terms of teaching and training, because I can't be there all the time and I've got trainees on the ground and I've got midwives on the ground, so I've got a responsibility to make sure that the people I interact with learn from example and also keeping up to date with their skills." (Maternity Doctor 2)*

5.5.3.2.4 Managing error

Staff had a role in informing patients and their relatives when errors occurred; this was seen as a mandatory part of patient safety and the majority of participants made reference to the duty of candour:

> *"So, I think the duty of candour is morally correct and also now enshrined in policy, and I think it is vital that you are honest and open with the patient and the family about when an error happened, and what happened and why it happened, what you are going to do about it, and I think often patients want to know how you are going to stop it happening again." (Surgery Doctor 7)*

Participants identified that staff had a duty to tell patients about error and be honest and transparent about what had happened, why it had happened and what would done to remedy it and prevent it happening again. Participants thought that error reporting occurred within professional groups (i.e. a nurse would report a nursing error, and a doctor would report a doctor-related error); if a serious error had been made or identified, this would cross the lines of professional working roles and would generally be escalated to a senior staff member and may necessitate the assessment of the patient by a doctor.

Staff identified a responsibility to report errors, using Datix. Submitting incident reports through Datix would lead to an investigation of the incident using root cause analysis; in some circumstances, a Datix would lead to a serious incident investigation. Reporting was seen as important:

> *"--make sure that we improve on errors, so that it doesn't repeat itself, just to make sure that there are improvements, to guard against the reason why the errors occurred, so that it doesn't repeat itself next time." (Elderly Medicine Nurse 3)*

It would identify the causes of error and potential improvement to prevent future errors, and was considered crucial for team learning. In maternity in particular, women were offered the opportunity to debrief after serious incidents, signposted to services like PALS, informed about the process of investigation and even potentially involved in the investigation if appropriate.

5.5.3.2.5 Following protocols

Staff had a role in patient safety through following patient safety protocols put in place by the organisation:

> *“And, as part of an employee within the organisation that should promote patient safety, and I’m sure it does, I need to subscribe to all the protocols and all the regulations in place, that the organisation has stipulated. (Surgery Doctor 6)*

This included following the correct protocols or processes around medication administration, procedures, adhering to identity checking procedures and infection control measures like hand washing. Midwives also discussed specific safety checks like the ‘fresh eyes’ CTG check and equipment checks. Participants were aware of the existence of proformas and checklists used by staff to improve the safety of procedures. However, one participant commented that the existence of so many checklists meant that they were at risk of becoming a tick-box exercise, so that *“people lose sight of why they’re actually doing these new checklists”* (Maternity Doctor 8).

5.5.3.2.6 Quality improvement and audit

Staff had a role in patient safety through engaging with quality improvement and audit. Nursing participants reported that nursing staff engage in the completion audits and harm care reports. For doctors, audit and quality improvement were seen as an expected training requirement for doctors, an important element of Trust clinical governance and a professional requirement as mandated by regulatory and governance bodies:

> *“So, as an individual I think my role in patient safety is part of my GMC requirement training and governance bodies that I should be always thinking about patient safety, doing audits-” (Surgery Doctor 1)*

5.5.3.2.7 Maintaining the environment

Staff had a role in maintaining the environment to ensure patient safety. Whilst doctor participants noted that patient safety was related to the hospital environment, it was the nursing participants that predominantly discussed *“mak[ing] sure the environment is safe”* (Surgery Nurse 5) as a staff role, and specifically a nursing role. This included ensuring facilities were functional, the absence of obstacles or hazards, and the cleanliness of the ward. These roles were particularly important in elderly care, where the environment was deemed to pose a greater risk to patients. Additionally, for elderly patients, adaptations to the ward environment for managing frailty was considered important for patient safety:

> *"I think it's about having those people managed in an environment where everybody…understands the nature of frailty and actually what they can do to – well enhance the patient experience but also to reduce the risk of harm to patients." (Elderly Medicine Doctor 2)*

It was necessary to ensure the ward facilities were appropriately adapted to meet the needs of these patients. This extended beyond physical adaptation to include developing a ward culture with a shared understanding of frailty and its clinical management, which may include altering one's clinical practice.

Maintaining the environment related not only to the physical environment but also the ward atmosphere:

> *"--physically go round and have a look at all the environments, chat to the patients, chat to the relatives, get a feel for how a ward environment was. You can get a feel as soon as you walk into a ward environment as to how frenetic, how chaotic it is. You can have chaos, but feel safe, chaos and feel unsafe. And so there's a lot of those sort of subliminal, quite hard to explain, sort of, instincts." (Elderly Medicine Nurse 2)*

Participants, particularly those with a senior staff position, reported a role in ensuring the ward felt safe and this was evident from the atmosphere of the ward.

5.5.3.3 Patients

The patient was seen to be responsible for achieving patient safety and patient roles were described; these are illustrated in Figure 5.5. In addition to discussing the role of patients in safety, participants also discussed the value of patient involvement in patient safety more broadly. This is addressed before the identified patient roles are discussed.

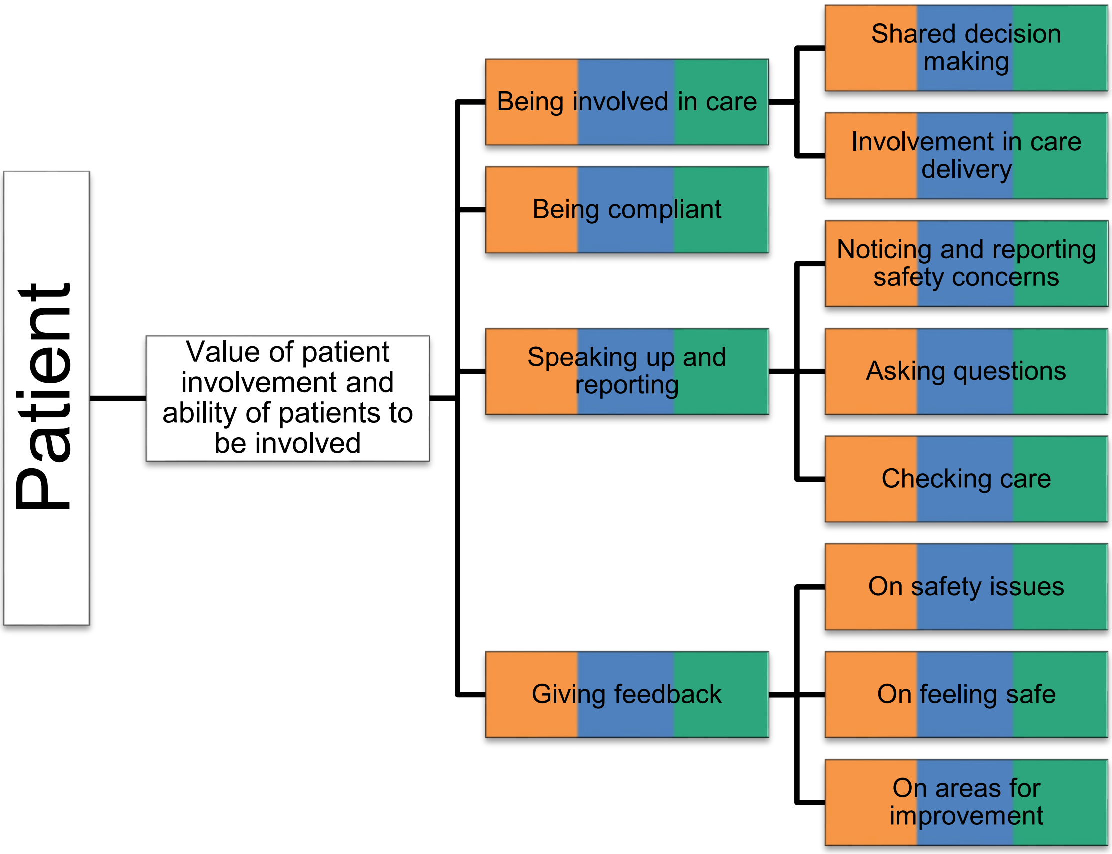

Figure 5.5: Patient roles

(Key: Orange = Elderly, Blue = Maternity, Green = Surgery)

5.5.3.3.1 Value of patient involvement and the ability of patients to be involved in patient safety

Patient involvement in safety was considered to be of value for a number of reasons:

> *"I think your safety levels will be higher, they'll be improved, the patients will be happier, they'll be more satisfied and you'll get better outcomes which in turn I think will get people out of hospital faster because they won't be falling so much, they won't have all the additional risk factors that are keeping them in… And then there'll be a quicker turnover of beds and*

> *that in turn will have a positive impact on the NHS." (Maternity Doctor 6)*

The reported benefits to patients included better outcomes, greater levels of safety, faster discharge, greater levels of satisfaction, fewer complications and a reduction in risks and harms (e.g. falls, infection). There were also benefits named for the system including quicker turnover of beds, improved patient safety culture and safer environment.

However, participants thought a patient's ability to be responsible for patient safety or be involved in the safety of their care was variable. Staff believed that patients should *"be aware of their safety and also, [be] responsible"* (Maternity Midwife 5), provided they had *"mental capacity"* (Elderly Medicine Nurse 3) or were competent to do so. The onus of responsibility, though, was not placed on the patient and there was perceived to be a joint responsibility or *"partnership"* (Surgery Doctor 7) in achieving patient safety, with the balance of responsibility on the side of the healthcare professional. This reflected the vulnerability of the patient in hospital. It was deemed that patients, therefore, could not be responsible for or involved in patient safety if they lacked capacity, had severe cognitive impairment or dementia, or were subject to section under the Mental Health Act:

> *"I mean you can't expect someone with advanced dementia to be responsible for their own safety." (Surgery Nurse 6)*

This affected both their awareness of risk and the concept of patient safety, and their ability to be involved in roles or functions that minimised risk or promoted their safety.

For patients who did have capacity and therefore could assume some responsibility for patient safety, engagement with the subsequently discussed roles and functions of patients in patient safety was also affected by other factors. Some patients were identified as assuming a passive role, reverting to paternalism. Participants felt that patients assumed that staff have the right skills and knowledge and therefore:

> *"--some patients will sit back and assume that because we're the ones telling them this that we know what we're on about." (Maternity Midwife 2)*

In doing so and not engaging with care, it was thought that patients would be at risk of things going wrong without them even realising. Some patients reportedly demonstrated *"diffidence"* (Surgery Doctor 6) and simply would not be interested in their own care. The involvement of other patients was limited by the lack of processes or interventions to enable their involvement:

> *"And so I think that although there is some responsibility put on them, we don't really enable… Although I think some responsibility could be and should be probably put on patients, I think we're particularly bad at acknowledging the value that patients have by having their own autonomy in a hospital." (Surgery Doctor 5)*

Participants acknowledged that being in hospital removes power and autonomy from patients and as such patients may not feel able to speak up or feel they have the ability to change the direction of something that might be going wrong. The failure to enable patients to be involved can compound the idea that it is not the patient's role and it is somebody else's job.

A lack of knowledge was also noted to impact patients' ability to be involved in or take responsibility for patient safety. In Maternity particularly, participants noted that patients did not necessarily understand the risks involved when making decisions and that differences in the perception of what is safe or not could lead to decisions that the medical professional may not deem safe:

> *"--she was advised to have a caesarean section for the safety of the baby, but in her opinion that is not the safest option, but she doesn't have that background – that medical background – and she doesn't understand, which is unfortunate because we have tried to explain that to her." (Maternity Doctor 2)*

Participants felt that when patients did not necessarily understand the risks involved, their ability to make a safe decision was limited.

Having discussed factors that influence patient responsibility for and involvement in safety, the next sections will discuss the roles and functions of patients in patient safety identified by the participants.

5.5.3.3.2 Being involved in care

Participants reported a patient role in patient safety by being involved in their care; this included engaging in shared decision-making and being involved in their care and care delivery. Decisions about treatment were considered to be a partnership through which patients and staff discussed the problem, the treatment options, and the risks, and the decision was reached with the patient, not for the patient:

> *"I've watched and observed that the consultant explains this and this, and then the patients will take a long time on each item. They will discuss. The patient will ask, "Why can you not do this instead?" So, at least, there's a matter of involvement from the patient. They have the right to vent whatever they want to, you know, and then, obviously, at the end of the day, they will come to a decision which is beneficial for both." (Surgery Nurse 2)*

In the context of elderly care, where patients were frail, vulnerable or lacking capacity, decision-making also included the family.

By being involved in the delivery of their care, patients could also be involved in the safety of their care. This had a range of meanings across the clinical contexts and included attending appointments and investigations, taking and managing medications, engaging with physiotherapy, taking care of their lines and drains, engaging in pre-operative site marking, being involved in checks (e.g. identity, transfusion, WHO surgical safety checklist) and engaging in discharge planning. It also included educating themselves about their condition or procedure, looking after themselves and engaging with lifestyle behaviours. These roles ultimately represented patients *"taking some ownership over their care and health"* (Maternity Doctor 6); all of these were ways patients were involved in their own safety.

5.5.3.3.3 Being compliant

Participants reported that patients have a role in patient safety through being compliant. This involved being compliant both with their care and with other safety processes within the hospital setting:

> *"First of all, they need to be compliant with care, yes, and they need to be compliant with the house rules, or what you call it, yeah." (Surgery Nurse 1)*

Participants reported that patients are given advice or instructions relating to their care, which should be complied with; failure to do so would compromise the safety of the patient. One surgical participant described the risks to patients who defy nil by mouth orders:

> *"I've seen patients aspirated because they ate, which they are not allowed to. I've seen anastomosis that were suffered really because they ate, and they shouldn't be eating. I think non-compliance is a major health factor, I think, in patient safety." (Surgery Nurse 1)*

This also extended to discharge advice including taking medications like low molecular weight heparin for venous thromboembolism prophylaxis after surgery or iron tablets to treat anaemia; failure to comply with such instructions had associated risks and would compromise the safety of the patient. Patients are therefore involved by complying with safety advice and instruction relating to their care and treatment.

Additionally, participants reported they give patients safety advice and instructions related to keeping themselves safe in hospital:

> *"So, regular prompting. If they are doing something that is unsafe, explaining to them the risks that are associated with that..." (Elderly Medicine Doctor 1)*

> *"So actually if you involve them in those discussions, about how they can do things safely, they are more likely to do those things." (Surgery Doctor 7)*

This advice included mobilising safely, wearing grip socks, calling for help when it is needed, and complying with infection control guidance. Participants felt that as well as improving the safety of patients, having these discussions actually improved their engagement with these activities. In the elderly care context, though, patients were recognised as not being able to follow instructions and therefore needed closer observation and regular prompting.

5.5.3.3.4 Speaking up and reporting

Participants reported that patients have a role in patient safety by asking questions, checking aspects of their care, and noticing and reporting issues. By asking questions about their care, patients could be involved in decision-making, understand more about their care and enhance their safety:

> *"You need to ask questions. You need to get involved. You need to know what's going on." (Surgery Nurse 9)*

This included asking about care, treatment risks, the safety of the baby, or any other safety issues they wanted to know more about.

Patients could enhance their safety by checking on aspects of their care and therefore *"be another line of defence for bedside error"* (Maternity Doctor 1). Patients could check the plan was being implemented as expected, *"'Actually, I thought we were doing this, or we should be doing that today'"* (Maternity Midwife 2), which was deemed particularly helpful as staff could be looking after more than one patient and at times errors may occur which could be identified or prevented by patients.

Additionally, patients could check their medications and assess the ability of the nurse (e.g. whether the nurse knew about their medications or knew how to use certain equipment). This behaviour was heightened when an agency nurse was caring for patients:

> *"Some of the agency nurses, they're not familiar with the equipment, so they do question the ability of the nurses. 'Am I safe to be looked after by this nurse?'" (Surgery Nurse 3)*

Finally, patients could observe and notice safety concerns; patients watch what is happening around them and may draw attention to things that have been overlooked. They were deemed responsible for reporting problems that they had noticed:

> *"Yeah, they have responsibility for their own safety, so the patients on the wards, and if they're concerned about the safety, then it's their responsibility to highlight the problem as well. I think it's important for the patient to be able to recognise something that they feel compromised." (Elderly Medicine Doctor 3)*

If they could see they were not safe (e.g. they had concerns about a staff member), it was recognised that patients would report not feeling safe:

> *"--they have said, "Matron, I don't feel safe with the nurse. I don't think she knows what she's doing." (Surgery Nurse 2)*

Other examples of things that patients noticed and reported included issues with care overnight, medication not being given, cleaning, issues with facilities, safety hazards, problems or errors in their care, problems relating to their condition, issues relating to the safety of self, the baby or others, and concerns about fire safety.

5.5.3.3.5 Giving feedback

Participants reported that patients have a role in patient safety through giving feedback. There were recognised formal processes for this: the friends and family test, qualitative feedback surveys completed at the end of a hospital stay, patient liaison groups, and the opportunity to act as a patient representative at board level.

Participants discussed the perceived value of obtaining patient feedback on patient safety. Firstly, there was intrinsic value in knowing the perspectives of patients; all patients, regardless of their capacity were recognised as human beings with *"feelings and wants and what have you"* (Elderly Medicine Nurse 4) to understand and respond to. Secondly, patients were seen as experts, both of their own condition (and therefore seen as best placed to recognise a patient safety issue in their care, compared to a staff member looking after multiple patients) and of their own experience of all aspects of healthcare (including safety, areas for improvement and the success of service changes). As "*the ones the harm is done to"* (Elderly Medicine Doctor 2), *"the receiver of care"* (Maternity Midwife 4) and *"the only one that has that whole view of the pathway from beginning to end"* (Elderly Medicine Nurse 2), the patient experience was seen as fundamental to gaining insight into patient safety. One participant particularly reflected upon the relationship between patient experience and patient safety as a key focus of patient safety work at the Virginia Mason Hospital in the United States, but suggested this is not particularly emphasised in the NHS Trust:

> *" –their cultural emphasis on safety, patient experience, and patient care is very different from what we deliver here in that, I think due to the difficulties the NHS –if you go to an institution like Virginia Mason you can see that there are people actively attempting to improve patient safety and experience, and I think safety and experience are two different things, but they come together to a certain extent –they've*

> *gone beyond the slogans of it and they're really committed to delivering it and this reflects in their results, outcomes, as well as their standing in the world as an institution of safety and experience." (Surgery Doctor 1)*

Feedback, however, was noted to be constrained to the clinical patient safety paradigm, and as such it was suggested that patients should be asked to feedback on their own experiences and perceptions of patients safety, particularly *"on what makes them feel safe, where they think safety is an issue"* (Surgery Doctor 3).

Further to this, patients were seen to provide a different viewpoint on patient safety. Patients saw things that may have been missed by healthcare professionals or, furthermore, that healthcare professionals may be blinkered to or fail to perceive owing to their clinical lens on patient safety. The difference between the patient and healthcare professional perspective of patient safety was again alluded to, and the patient role was vital to ensuring the accomplishment of patient safety in a broader sense:

> *"--healthcare professionals often get blinkered because they only see things from one point of view and their priority is often different from the patients... So, patient safety may mean something different to healthcare professionals, so patients will probably need to know what they think, because if we think we're dealing with patient safety but actually patient safety to patients is different then we're not really going to solve anything or improve anything." (Maternity Doctor 5)*

Given this, a *"one-way process"* (Surgery Doctor 1) in which professionals decide what is safe and what is unsafe, and expecting patients to give feedback in this paradigm, was insufficient. Therefore, in addition to educating patients about the clinical perspective of patient safety, the patient perspective needed to be recognised, valued and brought together with the healthcare professional perspective.

5.5.3.4 Friends, family and carers

Participants reported that friends, family and carers of patients had roles in achieving patient safety; these are illustrated in Figure 5.6.

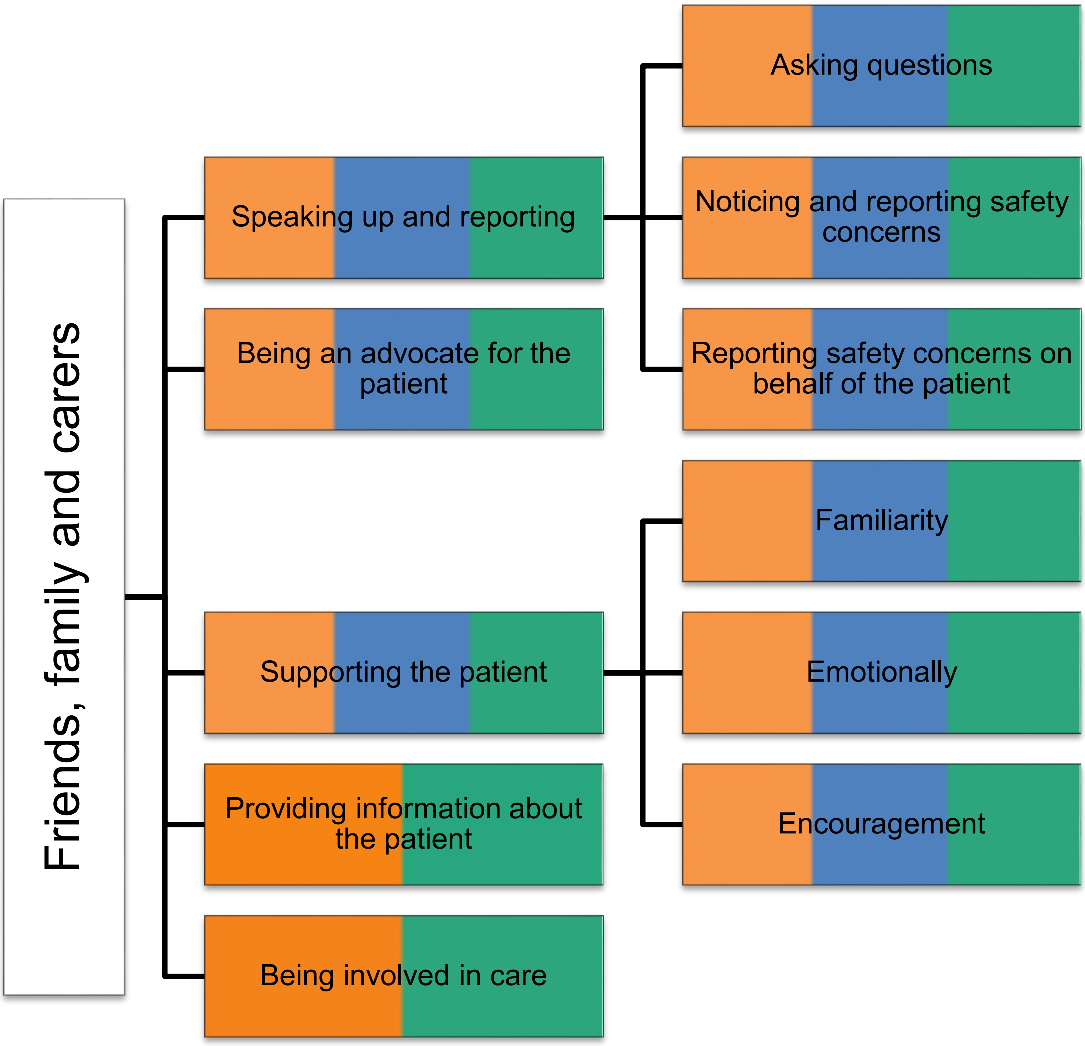

Figure 5.6: Friends, family and carers roles

(Key: Orange = Elderly, Blue = Maternity, Green = Surgery)

Friends, family and carers were particularly valuable, *"especially if you're dealing with patients who might be confused or not quite their normal selves and feel vulnerable"* (Surgery Doctor 5). However, those without friends, family and carers to support the accomplishment of patient safety were at increased risk, especially if they were deemed a vulnerable patient (e.g. due to lack of capacity, age, illness):

> *"So if you've no relatives and you've got a vulnerable patient, you probably have an increased risk of miscommunication, accidental error, etc." (Maternity Doctor 1)*

Therefore, it was recognised that that you could not rely on the role of friends, family and carers (especially as they are not continually present) for ensuring safety.

However, participants described a range of roles and functions they could fulfil in patient safety.

5.5.3.4.1 Speaking up and reporting

Friends, family and carers were considered to have a role in patient safety through a range of speaking up and reporting behaviours. Firstly, they could ask questions; this included about care, safety, specific risks (e.g. delirium and falls), and risk management. For example:

> *"Yes, they ask ... especially for patients who need supervision, who is admitted because of a fall, they normally ask if the one to one, for example if the patient keeps on standing throughout the night, they will ask if it is possible that we can get another person to look after her 24 hours." (Elderly Medicine Nurse 4)*

Friends, family and carers were reported to have a role in observing care, noticing issues or when things go wrong, and reporting them. Because of their separation from the care experience, they could often see things more clearly:

> *"I guess because they're the ones that are in the background more so, and they can see what goes on maybe a little bit more clearer than the actual woman who is actually going through labour at the time." (Maternity Midwife 1)*

They were seen as fresh eyes on a situation and could see things staff had become *"blinded to"* or that staff *"subconsciously ignore"* (Surgery Doctor 1). Relatives were sometimes noted to be watching how the patient and other patients were being cared for and spoken to and making judgements.

Additionally, friends, family and carers could report on the behalf of the patient. This would particularly happen when patients lacked capacity, were confused or vulnerable or scared, or feared disturbing staff or the implications of complaining.

> *"And the visitors, because they're not here, I think sometimes, you know, they can come talk to us and they, you know - I don't think patients feel scared about coming to talk to us about things, but I think they sometimes don't want to disturb us or something like that, you know, they don't want to be the complaining patient." (Surgery Nurse 7)*

5.5.3.4.2 Being an advocate for the patient

Friends, family and carers had a role in patient safety by being an advocate for the patient:

> *"I think they are often the patient's advocate when the patient is too unwell or not able to bring things up themselves, especially in things like elderly care or in mental health." (Maternity Doctor 4)*

This included prompting and reminding patients of their wishes or about aspects of their care, being their voice when they were unable (e.g. because they were unwell, in labour, lacked capacity, dependent or not engaging), representing their wishes and being there for the patient as a confidant.

5.5.3.4.3 Supporting the patient

Friends, family and carers had a role in patient safety through the role of supporting the patient; this constituted a predominantly psychological/emotional supportive role:

> *"They obviously have a very important role by making the patient feel safe within their environment because they're a familiar entity." (Maternity Doctor 6)*
>
> *"Specifically for geris[sic], I would probably say that they have a massive role because of the cognitive impairment, having someone that you know, a friendly face rather than my ugly mug probably means it's a better environment. You can be calmer. They're less likely to become agitated, try to get up, fall over, hurt themselves, etc." (Elderly Medicine Doctor 4)*

The presence of friends, family and carers, as a familiar entity, would make patients feel safe; in the context of elderly care this additionally helped to calm patients and reduce agitation, which in turn would reduce their risk of them coming to harm. Additionally, friends, family and carers were seen to contribute to patient safety through giving emotional support and reassurance, giving encouragement (e.g. to engage with mobilising), providing comfort, listening, and normalising and maintaining normal routines.

5.5.3.4.4 Providing information about the patient

Friends, family and carers had a role in providing information to healthcare professionals about the patient; this was particularly relevant in the context of elderly care, for confused patients or for more vulnerable patients who may not be able to provide information about themselves:

> *"I think they know the patients very well. They live with them. And a lot of the time, the relatives is the main carers of the patients. They can communicate things that are important to us, to the healthcare professionals, to make them more comfortable and find out what things might put them at risk. They'll be very good at highlighting those for us.' (Surgery Doctor 4)*

Relatives could provide background medical information about patients, as well as detailed information about their routines, likes and dislikes, and their behaviours, as well as external factors that might put them at risk. Additionally, they were considered to know the patient well and be able to read their reactions/expressions and communicate with them in ways those less familiar with the patient may not be able to. In relation to discharge from hospital, they could provide *"accurate information about their home environment, whether it's safe or not"* (Elderly Medicine Nurse 6). Relatives, family and carers can therefore provide an important link between different care settings and enhance safety during care transitions.

5.5.3.4.5 Being involved in care

Friends, family and carers had a role in being involved in care; this was also particularly relevant in the context of elderly care, where relatives tended to be more present. Their roles included working in partnership with the patient and the multidisciplinary team to make decisions about care and discharge planning:

> *"Often relatives tend to be around a lot more with the older patients than the younger patients, so they will be involved in decisions that we make on ward rounds. And if they are big decisions, then we will contact the relatives and let them know in advance." (Elderly Medicine Doctor 5)*

They could also get involved in care whilst being present on the ward; this included knowing the care plan, reminding their relative about their care and treatment, and helping to prompt their relative about behaviours and measures to prevent harm.

> *"But I think they should be more supportive of the care regime, yeah, and they should be reminding their relatives, their patient, that this is what you need to do, and that you have a … I don't want to use the word "duty," but if you can help, then that would be great, because it's for their welfare in the first place." (Surgery Nurse 1)*

5.5.4 The Clinical Patient Safety Theory

The final stage of this study was to develop an explanatory theory for the healthcare professional conceptualisation of patient safety. In discussing patient safety, participants gave abstract definitions or statements of meaning of the term 'patient safety'; in Section 5.5.6, patient safety was defined by three conceptual categories: 'Doing no harm,' 'Optimising' and 'Patients' perspective.' Participants then elaborated upon their definitions, identifying their perceptions of patient safety in their day-to-day practice and describing the roles and responsibilities about how they practically accomplish patient safety. Specifically, participants reflected upon their practical clinical experience and knowledge to describe their own and others' roles and responsibilities that practically accomplish patient safety.

In order to develop an explanatory theory, I postulated relationships between the roles and responsibilities of actors categorised in Section 5.5.7 and the three conceptual categories defining patient safety identified in Section 5.5.6; this is shown in Table 5.7. For each role, I considered if it was implicated in each conceptual category of patient safety (Green = Yes; Red = No).

Actor	**Role/Responsibility**	**Conceptual component of the healthcare professional definition of patient safety**		
		Doing no harm *= Avoiding harm in the treatment of patients; awareness of and avoiding/minimising risk*	**Optimising (care and the physical environment)** *= Processes and the environment promote and support good outcomes/things going right*	**Patients' perspective** *= The patient perspective of patient safety including experience of care, patient defined outcomes, psychological outcomes and feeling safe*
System	Developing patient safety culture and processes	🟩	🟩	🟥
	Maintaining a safe physical environment	🟩	🟩	🟥
	Constraining patient safety	🟩	🟩	🟥
Staff	Risk management	🟩	🟥	🟥
	Delivering safe care and treatment	🟩	🟩	🟩
	Maintaining my skills and training	🟩	🟩	🟥
	Managing error	🟩	🟩	🟥
	Following protocols	🟩	🟩	🟥
	Quality improvement and audit	🟩	🟩	🟥
	Maintaining the environment	🟩	🟩	🟥
Patient	Being involved in care	🟥	🟩	🟥
	Being compliant	🟩	🟩	🟥
	Speaking up and reporting	🟩	🟩	🟩
	Giving feedback	🟩	🟩	🟩
Friends, family and carers	Speaking up and reporting	🟩	🟩	🟥
	Being an advocate for the patient	🟥	🟩	🟥
	Supporting the patient	🟥	🟩	🟩
	Providing information about the patient	🟩	🟩	🟥
	Being involved in care	🟩	🟩	🟥

Table 5.7: Relationship between the roles/responsibilities of actors and the conceptual categories defining patient safety

Key: Green = Yes; Red = No

Consistent with constructivist grounded theory and rejecting a focus on a ‘single basic process,’ through exploring relationships between the defined conceptual categories of patient safety and the actors and their specific roles in Table 5.6, a number of processes were identified that accomplish patient safety (as defined from the healthcare professional perspective). I have subsequently developed a theory, The Clinical Patient Safety Theory (TCPST), which explains how healthcare professionals conceptualise patient safety. This is illustrated in Figure 5.7.

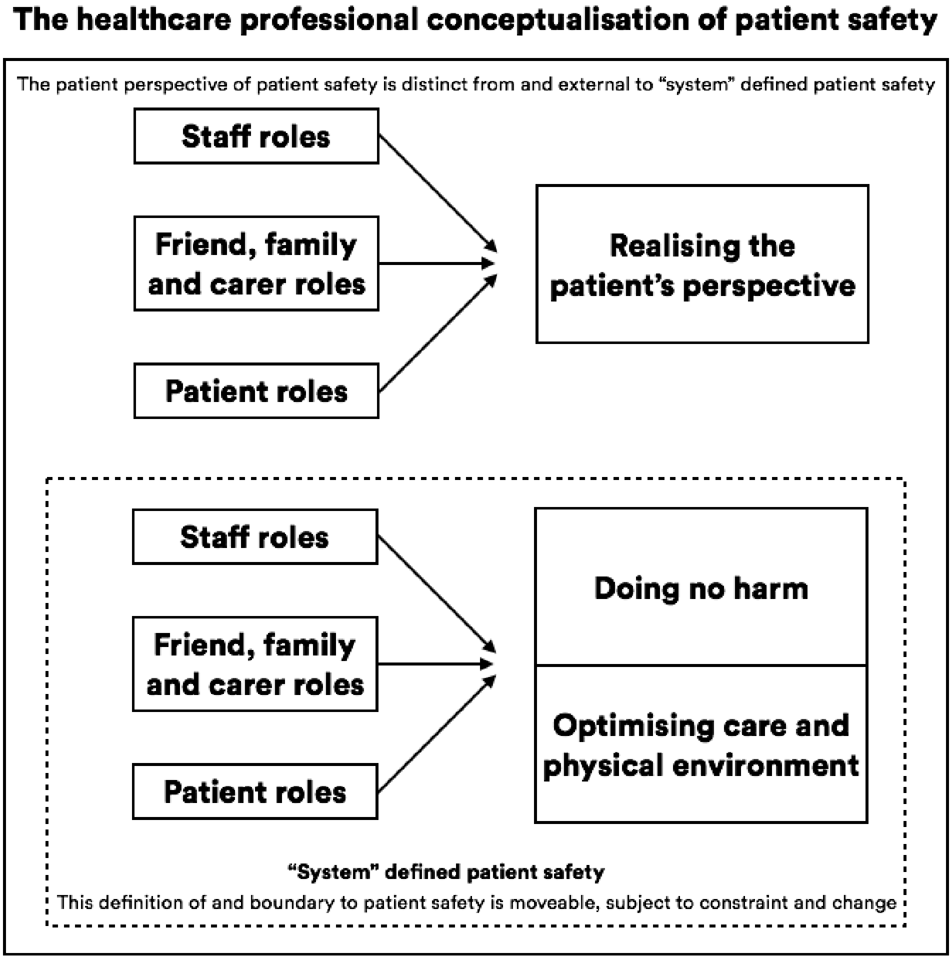

Figure 5.7: The Clinical Patient Safety Theory

The Clinical Patient Safety Theory explains the healthcare professional conceptualisation of patient safety as doing no harm, optimising care and the physical environment, and realising the patient's perspective, through the practical accomplishment of the system (an NHS Trust or the NHS more broadly), staff, patients and friends, family and carers. Importantly, however, the healthcare professional conceptualisation of patient safety arises from processes which take place both within and distinct to the system.

Firstly, the system constrains the healthcare professional conceptualisation of patient safety; it is responsible for defining patient safety by developing patient safety culture and processes, focussed upon the concepts of 'Doing no harm' and 'Optimising care and the physical environment.' The system therefore provides a structure or framework for patient safety and influences the actions of those within it (i.e. defining the roles of staff, patients and friends, family and carers); this is represented graphically within the theory by showing staff, patients and friends, family and carers undertaking their roles within the system to achieve system-defined patient safety. Threats upon and within the system, however, mean that the definition and boundary to patient safety are subject to constraint and to change to respond to the ever-changing landscape of healthcare; this is represented graphically in the theory with a broken line, illustrating how the definition and boundary to patient safety are moveable.

The healthcare professional conceptualisation of patient safety is not limited to the practical accomplishment of patient safety as defined by the system; it is also concerned with 'Realising the patient perspective.' TCPST explains the healthcare professional conceptualisation of patient safety as also realising the patient's perspective of patient safety (experience of care, psychological outcomes, feeling safe), through the practical accomplishment of staff, patients, and friends, family and carers. Importantly, the patient perspective of patient safety is not a component of system defined patient safety; the patient perspective lies outside of policy definitions of patient safety upon which the system models its culture and processes. This perspective is, as yet, unrecognised by the system and therefore represented graphically within the theory as distinct from and external to system defined patient safety.

5.5.5 The impact of different clinical settings and different clinical roles

There was significant concordance evident between the different specialties and between different clinical roles. This is evident from the conceptual maps, with the majority of categories saturated (coloured green, blue and orange). There was agreement across all six participant groups about the definitions of patient safety; differences arose in how participants discussed their perceptions of patient safety in their day-to-day practice, and particularly the types of roles and responsibilities that varied between speciality and professional roles in achieving patient safety.

Patient safety was suggested to have some differences in different clinical contexts, in particular in the elderly care context: *"But I'd say in an elderly setting, it's a little bit different"* (Elderly Medicine Nurse 2). Unique aspects to the patients and their care, including a perception that their patients were more *"challenging"* (Elderly Medicine Doctor 4), meant that patient safety was considered more complex. Aspects of these patients that increased their risk of harm included their frailty, lack of capacity, and different physiology:

> *"The potential to do harm in frail patients is actually considerably greater than in non-frail patients… It's all about understanding the nature of frailty and how that translates in to different physiology, different responses to medication, different responses to disease, the dangers of putting frail patients to bed because of the risk of deconditioning." (Elderly Medicine Doctor 2)*

In practical terms, this meant that in different clinical settings, participants were preoccupied with different risks and harms, and thus the specific roles and responsibilities within these clinical settings would vary. For example, in the maternity setting, participants focussed upon the CTG as an important patient safety tool in risk management and prevention of harm in labour. In elective surgery, raising awareness of the risk of procedures and the potential harms of surgery was important.

In discussing roles and responsibilities in the practical accomplishment of patient safety, doctors and nurses/midwives generally volunteered roles that were more specific to their own profession; for example, nurses would discuss their role in medication administration whilst doctors would discuss their role in prescribing.

These differences would not change the developed theory at a theoretical level; however, in practically applying the theory, it would be important to be aware that the different roles and responsibilities of those within the system would vary between clinical specialty and professional identity.

5.6 Discussion

This study sought to understand how healthcare professionals conceptualise patient safety. Whilst the thesis had thus far presented growing evidence of a difference between the patient and healthcare professional perspective of patient safety and a subsequent need to expanded the current patient safety paradigm, the assessment of this difference had been based upon existing commentary in the literature, policy definitions, models and frameworks for patient safety, and the findings of the meta-study in Chapter 3, which are all subject to limitations that have been discussed. This study therefore sought to empirically establish the perspective of healthcare professionals managing patient safety in their clinical practice, in order to provide a definitive comparison of the healthcare professional perspective to existing definitions/models of patient safety and the patient perspective as explained by TPST. Confirmation of a difference between patient and healthcare professional perspectives would then strengthen the call for a more expansive patient safety paradigm that includes the patient perspective. It therefore aimed to explore how healthcare professionals define patient safety, to explore their perceptions of patient safety in their day-to-day practice, to consider variations between clinical setting and professional role, and finally to show how patient safety is conceptualised with an explanatory theory.

In this study, the healthcare professional definition of patient safety is comprised of 3 conceptual components: ‘Doing no harm’ (treatment without harm, awareness of/avoiding/minimising risk), ‘Optimising’ (promoting good outcomes and ensuring things go right), and ‘Realising the patient perspective’ (recognising the patient lens of patient safety and promoting feeling safe). Healthcare professionals therefore have a more expansive definition of patient safety than is defined within policy or accepted by the system, recognising different lenses, including the patient lens, which focuses on experiences of care and feelings of safety. They elaborated on their abstract definitions of patient safety to describe the roles and responsibilities that practically accomplish patient safety in their day-to-day clinical practice. The Clinical Patient Safety Theory (TCPST) brings this together into an explanatory theory of the healthcare professional conceptualisation of patient safety. It explains the healthcare professional conceptualisation of patient safety as doing no harm, optimising care and the physical environment, and realising the patient's perspective, through the practical accomplishment of the system (an NHS Trust or the NHS more broadly), staff, patients and friends, family and carers. Importantly, however, the healthcare professional conceptualisation of patient safety includes processes, which take place both within, and distinct from the system, thus recognising their more expansive conceptualisation of patient safety than that defined by the system.

Having established a theory that explains how healthcare professionals conceptualise patient safety, it is therefore necessary to consider how this compares to the existing definitions, models and frameworks for patient safety.

5.6.1 The Clinical Patient Safety Theory and clinical theories/models of patient safety

In Chapter 1, I discussed the common definitions of 'patient safety' and the models that currently exist to explain patient safety. I briefly revisit these to demonstrate how TCPST provides an expanded understanding of the healthcare professional conceptualisation of patient safety.

Donabedian's quality model, an SPO model, describes how structure and processes are linked to outcomes (Donabedian, 1966; Donabedian, 1978; Donabedian, 1980; Donabedian, 1988). The theory developed in this chapter similarly follows an SPO model and places importance upon the component parts of Donabedian's model. Donabedian was criticised for the linearity of the models and its failure to acknowledge interactions and interdependencies within healthcare (Carayon et al., 2006). Unlike Donabedian's models, TCPST is more complex, with multiple processes and multiple outcomes; additionally, the theory illustrates that healthcare professionals identify that there are patient safety processes and outcomes that occur independent to the organisation/system and its definitions of patient safety.

There are obvious similarities between the ‘seven levels of safety’ framework (Vincent et al., 1998) and the categories of roles and responsibilities described here for achieving patient safety (e.g. institutional context/organisation factors, patient factors, staff factors). TCPST is a theory, and is therefore explanatory; this makes it more sophisticated than Vincent’s framework, which is descriptive and therefore does not provide further relationships between ‘levels of safety’ to more fully explain the concept of safety.

The SEIPS model, improving upon the Donabedian model, additionally considers the relationships between structure, process and outcome, and how this contributes to the work system and patient safety (Carayon et al., 2006). In this way, the SEIPS model has similarities to TCPST, which shows the healthcare professional conceptualisation of patient safety as complex processes within a work system leading to outcomes; importantly, thought, TCPST diversifies patient safety outcomes to additionally recognise different perspectives or lenses in patient safety.

Comparing TCPST to the model for patient safety (Emanuel et al., 2008), TCPST similarly shows interactions between components of patient safety; however, it also recognises a patient orientated patient safety outcome, which Emanuel’s model does not account for.

Overall, TCPST has some similarities to existing clinical patient safety models, both in terms of structure (e.g. SPO models) and contributory processes. However, TCPST shows greater complexity in the processes contributing to patient safety and demonstrates broader outcomes for patient safety due to the broader conceptual definition given. Therefore, overall, existing patient safety models are not sufficient to represent the healthcare professional conceptualisation of patient safety; TCPST explains the healthcare professional conceptualisation of patient safety to be both more complex and broader than is currently defined in policy, given the healthcare professional recognition of different lenses in patient safety.

5.6.2 Relationship to the findings of Chapter 3

It is also necessary to consider how TCPST compares to the findings of the meta-study in Chapter 3. In Section 3.6.1.1, line of argument synthesis brought together six qualitative studies (Vaismoradi et al., 2011a; Dias et al., 2014; Jones, 2014; Valiee et al., 2014; Aveling et al., 2015; Kanerva et al., 2016) focussing upon healthcare professional definitions of patient safety. In the synthesised definition, as an overarching abstract concept, patient safety was considered to be complex and multifaceted, with the main focus on doing no harm. There was awareness of several difference types of safety (e.g. physical safety and emotional/psychological safety). Embedded within the definitions were factors contributing to establishing patient safety: adherence to standards of care, maintaining competence, upholding professional duty) plus environmental and organisational infrastructure. Similarly, in this study, healthcare professionals identified patient safety as comprising different conceptual categories. This included the concept of doing no harm, as well the realisation of the patient perspective, a phenomenon grounded in experiences and feelings of safety (akin to emotional/psychological safety).

In Chapter 3, I developed a theoretical framework of factors perceived by patients and healthcare professionals as contributing to patient safety, in an attempt to explain how patient safety is conceptualised more broadly; these were grouped thematically (system, staff, patient, processes of care, relational aspects of care), though I identified that it was difficult to draw significant conclusions about any relationship between themes or factors without further research. These are presented again Table 5.8, along with their explanations; I have additionally indicated whether the factors were represented within this study in Chapter 5.

Table 5.8: Comparison to theoretical factors developed in Chapter 3

Theme	**Factor**	**Explanation**	**Patients or HCP?**	**Present in this study?**
SYSTEM	**Atmosphere**	The hospital as a 'safe place' with a welcoming atmosphere, noise control, privacy and normalcy.	Patient	Yes
	Organisational functions	Gatekeeping functions, access to appointments, and finance.	Patient	Yes
	Resources	Adequate equipment, materials, Information Technology and electronic health record integration	HCP	Yes
	Safety culture	Existence of governance structures, with associated activities, events and atmosphere at ward level.	HCP	Yes
	Workload	Determined by staffing levels, volume and acuity of patients, working hours. Impacts tiredness, motivation, safety and quality of care.	HCP	Yes
	Environment	Quality, design and cleanliness of built environment.	Both	Yes
	Protocols and Procedures	Procedures have inherent risks; protocols exist for safety in everyday work and emergencies (e.g. medication administration). However, patients believe they can limit discretion and undermine safety.	Both	Yes
STAFF	**Professional qualities and competence**	Demonstration of consistent technical competence and possession of core attributes (including mannerisms, attitudes, clinical skills and knowledge).	Patient	Yes
	Acquisition of skills/training	Acquisition or maintenance of skills through training, appropriate supervision and accumulation of experience/knowledge	HCP	Yes
	Responsibility	The legal, ethical and individual responsibilities of healthcare professionals e.g. Human Rights law, mental health law, duty of care	Both	No
PATIENTS	**Impact of self and others**	Control over or input into care and its safety, with support from significant others/fellow patients, without threat from others.	Patient	Yes

PROCESSES OF CARE	**Responsiveness**	Presence and proximity of nursing staff providing timely management of basic care needs/symptoms, and frequent contact/checks.	Patient	Yes
	Care Planning	Quick determination of a care plan, including investigation, referral and diagnosis. Includes having and being informed of a care plan.	Patient	Yes
	Individualised care	Holistic personalised care plan, including in mental health.	Both	Yes
RELATIONAL ASPECTS OF CARE	**Patient-staff relationship**	Foundation of inherent trust; recognition and alleviation of power imbalances.	Patient	Yes
	Psychosocial	The feeling of safety and the minimisation of emotional harm; this includes the social elements of interaction, the expectation and experience of interaction, and what people think/feel	Patient	Yes
	Teamwork and interprofessional working	Working and cooperation within teams, including multiprofessional teams	Patient	Yes
	Communication	Communication to the patient, family, within the care team, and outside of care team. It should be professional, respectful, unprejudiced, timely, accurate, open, and patient centred. It includes listening, establishing ideas/concerns/expectations, and information transfer at transitions of care or between team members/other teams.	Both	Yes

As can be seen from Table 5.7, the themes in this study are similar to the factors defined within the framework resulting from the meta-study. Of the factors derived from the healthcare professional understanding of patient safety within the meta-study (indicated in Table 5.8), all but the factor ‘Responsibility’ (including the moral, ethical and legal components of patient safety) were identified within the themes of this study in Chapter 5. This demonstrates concordance between the findings of the meta-study and the findings of this qualitative study.

However, this study goes further in conceptualising the healthcare professional perspective. Extending the results of the meta-study, this qualitative study identified additional categories of role/responsibility implicated in patient safety, as defined from the healthcare professional perspective. Many of the factors identified as ‘patient’ factors within the meta-study theoretical framework were represented within the healthcare professional conceptualisation of patient safety in this study: for example, atmosphere, organisational functions, professional qualities and competence, impact of self and others, responsiveness, care planning, teamwork and interprofessional working, patient- staff relationship, and psychosocial. It is therefore clear that the healthcare professional conceptualisation of patient safety explained here by TCPST is broader than that which was described by the meta-study in Chapter 3. This difference may be explained by the earlier described limitations of the meta-study. Alternatively, the broader definitions found in this study may be a reflection of the broader clinical settings and clinical roles included within the study, or an evolution over time of how patient safety is conceptualised.

Thus far, the reviewed literature had demonstrated the healthcare professional perspective as being constrained within academic and health policy views and definitions of patient safety; here, however, the healthcare professional conceptualisation of patient safety appears to be different to the perspective defined within health policy. For healthcare professionals in this study, patient safety focussed on optimising care and doing no harm, but also upon realising the patient perspective. In this way, by recognising different lenses with which patient safety can be viewed, particularly the patient lens, healthcare professionals have a more expansive definition of patient safety than is defined within policy or by the system. The definition given by participants is broader and more complex, elaborated upon through descriptions and perceptions of the key processes fundamental to the practical accomplishment of this conceptualisation of patient safety.

5.6.3 Comparing patient and healthcare professional conceptualisations of patient safety

Having empirically derived separate healthcare professional and patient theories in Chapter 5 and Chapter 4, it is now possible to make a true comparison of the patient and healthcare professional conceptualisation of patient safety in the NHS. This comparison allows an assessment of how much of a paradigm shift is necessary in order to incorporate the patient perspective into patient safety practice.

In Chapter 4, patients predominantly focus upon patient safety as a subjective experiential phenomenon, the feeling of safety arising from specific experiences in their care. In Chapter 5, healthcare professionals have a predominantly objective view of patient safety, and the roles and responsibilities they describe relate to being safe and achieving patient safety as defined within policy and by the system. However, importantly, healthcare professionals are able to recognise that patient safety may be viewed through different lenses, recognising that patients have a different conceptualisation of patient safety.

In order to assess how much of the patient conceptualisation of patient safety healthcare professionals are aware of, in Table 5.9, I have mapped the processes described by patients in Chapter 4 to the roles and responsibilities described by healthcare professionals in this chapter.

Conceptual category	Processes experienced by patients (From Chapter 4)	Present as a role or responsibility? (In Chapter 5)
Organisation	Maintaining the environment	Yes – Maintaining the physical environment
	Cleaning	Yes – Maintaining the physical environment
	Having protocols and plans for safety	Yes – Developing patient safety culture and processes
Staff	Demonstrating their qualities and skills (Attitudes/characteristics, knowledge/practical skills, communication skills)	Yes – Maintaining my skills and training; specific roles not discussed but caring, communication and interpersonal qualities discussed in relation to patient perspective
	Performing clinical tasks and procedures (Being present, looking after/caring for me, checking on/watching me, responding to my needs, administering treatments and procedures)	Yes – Delivering safe care and treatment
Patients	Monitoring and checking my care	Yes – Speaking up and reporting; giving feedback
	Reporting my concerns	Yes – Speaking up and reporting
	Taking responsibility for myself	Yes – Being involved in care
	Being compliant	Yes – Being compliant
Friends, family and carers	Being my advocate (Speaking up/reporting, supporting me in speaking up/reporting)	Yes – Being an advocate for the patient
	Supporting me	Yes – Speaking up and reporting

Table 5.9: Comparison of processes described by patients in Chapter 4 to the roles/responsibilities of healthcare professionals in Chapter 5

From this table it is clear that all of the experiences named by patients as contributing to their conceptualisation of patient safety or engendering feelings of safety, are also identified by healthcare professionals as a role/responsibility for achieving patient safety. Therefore, it appears at first glance that the patient and healthcare professional perspectives of patient safety are not as different as was initially thought. Healthcare professionals, however, did not have awareness that these roles were important for patients to feel safe. Healthcare professionals lack awareness that tasks that they perform to in order to fulfil system-defined patient safety also contribute to achieving the patient conceptualisation of patient safety and make patients feel safe. Additionally, healthcare professionals lack a full awareness of the importance of the psychosocial/relational aspects of care to the patient conceptualisation of patient safety, although this is alluded to in their discussion of the concept of 'Realising the patient perspective.' Therefore whilst healthcare professionals recognised that patients have their own conceptualisation of patient safety, they had limited understanding of what actually contributes to it.

It is important that healthcare professionals can already see, to an extent, what safety looks like through the eyes of a patient, as this facilitates expanding our current patient safety paradigms to include the patient perspective and enhances its acceptability. However, it is clear that this perspective is not forefront in the minds of healthcare professionals and that their perceptions of safety still predominantly focus on roles and responsibilities aimed at the practical accomplishment of system defined safety; whilst many of these roles are also fundamental for achieving the patient conceptualisation of patient safety, this is perhaps unknowingly so. In developing a new paradigm, it is necessary to create awareness by healthcare professionals about the roles and responsibilities they undertake which are fundamental to the patient conceptualisation of patient safety and enhance awareness of what makes patients feel safe.

5.6.4 Summary

This study has clearly established how healthcare professionals across three clinical specialities in the NHS conceptualise patient safety. The development of TCPST has been fundamentally important for comparing patient and healthcare professional conceptualisations of patient safety. The theory developed in Chapter 5 shows that healthcare professionals conceptualisations are strongly influenced by system, academic and health policy definitions of patient safety, with the tasks they discuss in relation to patient safety rooted in the concept of system defined patient safety.

It was also evident that healthcare professionals recognise and have empathy for the patient perspective of patient safety, and that part of their work in day-to-day clinical practice is to realise this perspective; this sets the healthcare professional conceptualisation of patient safety apart from academic and policy definitions. The study in this chapter has therefore demonstrated that healthcare professionals have a wider understanding of patient safety than how it is defined by the system and in academia and policy. This is reinforced by similar conclusions in other recent studies (van Gaal et al., 2009; De Wet et al., 2018). This has implications for implementing patient safety, as the way researchers and policy makers define patient safety and its associated clinical practices may not have practical meaning for frontline staff (De Wet et al., 2018) and may not reflect their lived experience of patient safety in clinical practice. These recent studies, and TCPST, therefore demonstrate that there is a need for developing a broader paradigm for patient safety that is valid and relevant to healthcare professionals.

Overall, the findings of Chapter 4 and 5 provide clear evidence to support assertions that the patient safety paradigm must be broadened and serve to raise a challenge to healthcare professionals, healthcare systems and policymakers to expand our ideas about patient safety, to consider not just being safe, but also feeling safe. Firstly, the patient conceptualisation is not acknowledged, defined or addressed in governance or patient safety processes (Collier et al., 2016). This study has shown that healthcare professionals do recognise the patient perspective, and, as is suggested by De Wet et al. (2018), it is now necessary to align and reconcile the understandings of all stakeholders. Secondly, the healthcare professional conceptualisation of patient safety, by virtue of having empathy for the patient conceptualisation, does not fit within the boundaries of the definitions made by the system or given within policy. Considering these two points, overall this suggests that the current patient safety paradigm is inadequate. Future work must therefore focus on broadening the current patient safety paradigm to create a working view of patient safety that is valid and representative of those experiencing it and doing it; particularly it must broaden the current patient safety paradigm to include the perspective of the patient and the concept of feeling safe.

5.7 Strengths and limitations

This study significantly extends our current understanding of the healthcare professional perspective of patient safety. It builds on existing models and theories for patient safety and offers a more complex understanding of patient safety from a clinical perspective. It has successfully demonstrated the similarities and differences between the patient and healthcare professional conceptualisation of patient safety and, in doing so, provided clear evidence to support previous assertions for the need to expand the current patient safety paradigm.

This study took place at a single site, which may limit the generalisation of its outcomes to other hospitals. However, the participants had a broad range of experience (across other hospitals, countries and specialities) and drew on those experiences when describing their conceptualisations of patient safety; this may assist the generalisation of the resulting theory. The study does not include the 'system' perspective (e.g. management, executives, board members), whose conceptualisation of patient safety may also be different. Understanding these differences will be important for the implementation of the findings of this body of work, although existing theory, models, frameworks and policy are essentially used as a proxy for this perspective.

There was agreement across all six participant groups about the definitions of patient safety; differences arose in how participants discussed their perceptions of patient safety in their day-to-day practice, and particularly the types of roles and responsibilities that varied between speciality and professional roles for the practical accomplishment of patient safety. Some categories (Constraining patient safety, Following protocols, Quality improvement and audit, Maintaining the environment, Providing information about the patient, Being involved in care) were evidently not saturated across all the specialities, from assessment of the conceptual maps (Figures 5.2-5.5). However, these categories arguably could represent generic roles/responsibilities, which could feasibly arise in any clinical specialty and this could be tested through theoretical sampling, which serves to obtain data in order to explicate conceptual and theoretical categories (Charmaz, 2006). These differences would not change the developed theory at a theoretical level; however, in practically applying the theory, it would be important to be aware that the different roles and responsibilities of those within the system would vary between clinical specialty and professional identity.

The limitations of the use of abbreviated grounded theory and issues around the principles of rigour were discussed in Chapter 4 (Section 4.7 – Strengths and limitations), and apply similarly here; therefore, they will not be repeated.

5.8 Reflection

In comparison to the patient qualitative study in Chapter 4, the healthcare professional qualitative interview study was easier to conduct. Recruitment was quicker and easier, with all healthcare professionals approached in recruitment agreeing to be interviewed. Additionally, as the concept of patient safety was familiar to participants, the interviews were easier to conduct. I did not encounter the same initial frustrations as I experienced during the patient study as, broadly, the healthcare professional participant accounts of their conceptualisation of patient safety reflected my own.

5.9 Conclusion

This chapter sought to empirically establish the perspective of healthcare professionals managing patient safety practically in their day to day practice, in order assess how far apart this perspective is from both the clinical models of safety and the patient conceptualisation as explained by TPST. Using abbreviated grounded theory, I have developed The Clinical Patient Safety Theory (TCPST). It explains the healthcare professional conceptualisation of patient safety as doing no harm, optimising care and the physical environment, and realising the patient's perspective, through the practical accomplishment of the system (an NHS Trust or the NHS more broadly), staff, patients and friends, family and carers. Importantly, the healthcare professional conceptualisation is broader than existing definitions, models, theories and frameworks that exist in academia and health policy; this is because healthcare professionals also recognise different perspectives of patient safety, including the patient perspective, which focuses on experiences of care and feelings of safety, and are aware of a limited number of roles important in achieving this.

This study has shown it is necessary to encourage awareness by healthcare professionals about the roles and responsibilities they undertake which are fundamental to the patient conceptualisation of patient safety, enhance awareness of what makes patients feel safe and broaden the systemic definitions of patient safety within academia and health policy.

Chapter 6: Co-designing patient safety in surgery

6.1 Introduction

Attempts to involve patients in patient safety have focussed upon the clinical patient safety paradigm; this poses a fundamental challenge for patients for whom clinically orientated interventions may not be meaningful or accessible. This thesis has concerned itself with understanding patient and healthcare professional conceptualisations of patient safety in order to broaden the current patient safety paradigm by valuing and including the patient perspective.

In Chapter 4 and Chapter 5, qualitative theories (The Patients' Safety Theory and The Clinical Patient Safety Theory) have been derived using constructivist grounded theory, which conceptualise patient safety from the patient and healthcare professional perspectives. Importantly, for patients, patient safety is a subjective experiential phenomenon, with feelings of safety arising from lived experiences with specific actors in their care; the patient perspective of patient safety exists at an intersection between patient safety, as defined within health policy and the clinical perspective, and patient experience. This builds upon existing research around patients feeling safe (Lasiter, 2011; Mollon, 2014).

Currently, patient safety policy focuses on the concept of being safe and not necessarily on feeling safe, placing more value on the physical, objective and measurable (Mollon, 2014). Additionally, the patient conceptualisation is not acknowledged, defined or addressed in governance or patient safety processes (Collier et al., 2016); this is evident in the theory and evidence discussed in Chapters 1 and 3. Chapter 4 therefore raised a challenge to healthcare professionals, healthcare systems and policymakers to expand our ideas about patient safety, to consider not just being safe, but also feeling safe.

The theory developed in Chapter 5 showed that healthcare professionals conceptualisations are strongly influenced by system, academic and health policy definitions of patient safety, with the tasks they discuss in relation to patient safety rooted in the concept of system-defined patient safety. It was also evident that the healthcare professional conceptualisation of patient safety extends beyond the boundaries of system-defined safety. Healthcare professionals recognise and have empathy for the patient perspective of patient safety, and part of their work in day-to-day clinical practice is to realise this. It was clear though that this perspective is not forefront in the minds of healthcare professionals and that their perceptions of safety still predominantly focus on roles and responsibilities aimed at the practical accomplishment of system defined safety.

Overall, the conclusions of Chapter 4 and 5 highlight the need to broaden the current patient safety paradigm to ensure that it is valid and representative of those experiencing and doing it. In particular, it must recognise the concepts of being safe and feeling safe. The evidence built through this thesis shows that if genuine patient involvement is desired in patient safety, the patient conceptualisation of patient safety centred on subjective experiences and feeling safe, must be honoured. At present, system design and safety improvement focuses only upon the concept of being safe and not feeling safe. Mollon (2014) highlights the importance of developing patient centred models of care and the creation of environments that make patients feel safe. In terms of improving clinical practice, it is necessary to encourage awareness by healthcare professionals about the roles and responsibilities they undertake which make patients feel safe. Developing this more expansive view of safety requires creativity and co-design to generate true partnership and opportunities for patients to define what patient safety is to them (O'Hara and Lawton, 2016).

Currently, what is known about the patient conceptualisation of patient safety remains abstract and theoretical, bound within The Patient Safety Theory (TPST). This abstract and theoretical knowledge needs to be incorporated into current clinical practice. This chapter will therefore focus upon how TPST can be practically applied, using experience-based co-design, and implemented in the surgical setting.[12]

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[12] Here it is important to note that only The Patient Safety Theory (and not The Clinical Patient Safety Theory), the healthcare professional derived theory) will be focussed upon in this study. This acknowledges that many aspects of the clinical conceptualisation of patient safety are already common practice and therefore focuses

The next sections will address the methods that will be used to translate and implement TPST. Firstly, I will explore the use of qualitative theory in practice, how theory has been applied and how these techniques may be applied to TPST.

6.2 Using qualitative theory in practice

This chapter seeks to translate theory explaining the patient conceptualisation of patient safety into practice in order to broaden the existing patient safety paradigm. Davidoff et al. (2015) recognises that initiatives to improve quality and safety often result in limited meaningful changes; however, he articulates the role and value of theory in improvement work in healthcare, which can reduce the duration of development of interventions, optimise design, identify the conditions for success and enhance learning. Programme theories, or small theories for intervention, are practical and accessible; they generally specify the components of an intervention intended to solve a particular problem, as well offer a narrative around the various structures, behaviours, process and context required to achieve its aim (Davidoff et al., 2015). TPST may be considered a programme theory for the improvement of patient safety.

There are, however, barriers to the incorporation of qualitative findings into everyday clinical practice; a primary criticism is that qualitative research does not produce *"practical, applied, outcome-oriented research"* (Morse, 1991). Applications of research in clinical settings typically favour knowledge of the objective and particular (Hunter, 1989; White, 1997; Colyer and Kamath, 1999; Sandelowski, 2004); the importance, however, of subjective patient values and preferences in treatment is being increasingly recognised (Sandelowski, 2004). Nonetheless, such qualitative research findings are frequently excluded from evidence-based practice processes because subjective knowledge is criticised for being developed from irreproducible interactions between healthcare professionals and patients (Sandelowski, 2004). Lack of reproducibility (i.e. the concept that research is so personal to the researcher that another may not come to the same conclusions (Mays and Pope, 1995)), is a common

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changes in the patient safety paradigm and everyday practices upon the unique subjective components of the patient conceptualisation of patient safety.

criticism of qualitative research; however, transparency of methods and attention to the principles of rigour (as discussed in Chapter 2) aim to counter this.

To enhance the utility of qualitative research in the healthcare, it is necessary for qualitative researchers to produce results that are immediately or potentially translatable into practice, or that are accessible for others to be able to do so (Sandelowski, 2004). It can be unclear how theories that have been developed through qualitative research may be translated into practice. Estabrooks classifies three means of research utilisation: instrumental, conceptual or symbolic (Estabrooks, 1999; Estabrooks, 2001; Kearney, 2001; Sandelowski, 2004). Instrumental utilisation involves clear application to practice (e.g. clinical guidelines, standards, protocols, policies, assessment tools), which are visible and measurable. Symbolic utilisation uses qualitative research findings as a persuasive tool, for defending a particular point of view, and can indirectly lead to changes in practice. Conceptual utilisation is even less visible, as it serves to change the way a user thinks about a particular issue, or enlightens them on something they did not already know about (e.g. by reading qualitative findings, a healthcare professional may gain access to the experiences of patients, enhancing their understanding and revealing new approaches to care).

Whilst qualitative findings lend themselves more to symbolic or conceptual utilisation, there are examples of instrumental utilisation of qualitative findings (Morse et al., 1998; Ononeze et al., 2006) and commentary on the means through which theory may be applied to clinical practice (Kearney, 2001; Cohen et al., 2002). In these examples, qualitative findings are valued for their independent contribution to the development of practical solutions that can be moved directly into practice and then evaluated, meaning that the qualitative findings have *"face utility"* (Sandelowski, 2004). Examples of instrumental utilisation are briefly considered in the next section to understand how TPST may be applied.

6.2.1 Examples of applying qualitative theory in clinical practice

Kearney (2001) considers how qualitative findings with different levels of complexity may be applied. Five categories of qualitative findings are discussed: findings restricted by a priori frameworks, descriptive categories, shared pathway or meaning, depiction of experiential variation and dense explanatory description. The greater the complexity of findings, the stronger their potential for clinical application is considered to be. Related to this Kearney describes four modes of clinical application: insight or empathy (with the findings teaching others what is like to be in a given situation), assessment of status or progress (with findings suggesting trajectory of illness), anticipatory guidance (with findings shared with patients, illustrating what they may themselves experience), and coaching (whereby findings are shared and use to advise).

Morse et al. (1998) published their approach to developing a patient clinical assessment guide for illness experience from qualitative theory derived from patient interviews. By using this method for the development of a nursing intervention, the intervention is rooted in the patient perspective and context. Theory is recognised as representing *"a refined and tightened view of real world experience"*; it is unravelled into its component theoretical and conceptual parts (i.e. components that subsequently reflect patient goals, nursing assessment questions and behavioural signs/symptoms within the assessment guide) and nursing interventions are developed through extrapolation, theoretical deduction and nursing knowledge. In this way, the assessment guide is developed collaboratively between patient, clinician and researcher, and theory is integrated into an assessment guide in a patient centred way.

6.2.2 Translating and applying The Patient Safety Theory into clinical practice

It is necessary to consider how these approaches to applying qualitative theory, discussed in Section 6.2.1, can be used to apply TPST into day-to-day clinical practice. Importantly, for grounded theory to be considered useful, the theory must fit the problem (a need to incorporate and value the patient perspective of patient safety in clinical practice), be understandable and general enough to be applied to similar problems or adapted (Glaser and Strauss, 1967).

TPST has symbolic utilisation; it has served as a tool to demonstrate the need for patient safety paradigm change to value and include the patient perspective. It also has conceptual utilisation as it serves to enlighten and explain the patient conceptualisation of patient safety, which to date had been poorly understood. It also has potential instrumental utilisation through the development of a practical product or intervention which, when put in place, would raise awareness of the patient conceptualisation of patient safety and lead to patients feeling safe in hospital (Estabrooks, 1999; Estabrooks, 2001).

TPST provides a dense explanatory description of the patient conceptualisation of patient safety. Therefore it has strong potential for clinical application via anticipatory guidance for healthcare professionals or coaching, through sharing learning and advising on how to enhance patient experience and feelings of safety (Kearney, 2001). Morse et al. (1998) gives clear guidance that can be applied to TPST; like the theory they describe, TPST is rooted in patient experience and context, and represents the patient real world experience of *patients' safety.* Key to TPST is the fundamental relationship between patient safety and patient experience; it shows that patients conceptualise patient safety as a subjective experiential phenomenon, a feeling arising from certain patient experiences with actors in their care, which have been categorised within Chapter 4 and TPST. TPST can be deconstructed into its theoretical and conceptual component parts in order to understand the experiences of patients (the specific actions and processes, involving actors in their care) which healthcare professionals and healthcare systems need to be aware of, enact and improve to engender patients' feelings of safety. Researcher, healthcare professional and patient input (via theoretical deduction, knowledge and experience) can be used to collaboratively derive interventions for the implementation or improvement of these experiences (Morse et al., 1998), and theory is thus integrated into a practical product which is patient centred.

6.3 Methodological approaches for translating theory into clinical practice

Having considered how the theory may be practically applied, it is necessary to consider the methodological approach to achieve this. There are three fundamental concepts that must be considered. Firstly, in the practical application of TPST, a methodology that focuses upon interventions for implementing or improving specific patient experiences, as patient experience is the central tenet of the theory, is vital. Secondly, it is fundamental to include patients in the process of TPST's practical application. In contrast to other existing patient safety interventions discussed in Chapter 1, the practical product of TPST needs to be meaningful and accessible to patients. The theory is, of course, intrinsically patient centred and grounded in their experience; however, involving patients ensures meaning is preserved and accessibility of the final product. Involving patients in their care is a priority for the NHS (NHS England, 2016) and is highlighted in both the NHS constitution and NHS Five Year Forward View; this extends to involvement in patient safety, where patients are seen as fundamental for improvement (Illingworth, 2015). Thirdly, the patient experiences described within TPST are dependent upon others in the healthcare system; as such, these parties should be involved. In their recent report on the state of patient experience, The Beryl Institute asserts this idea (Wolf, 2017):

> *"A commitment to patient experience must include a commitment to the people delivering it. The experience of those who healthcare serves is directly dependent on the engagement of those who serve; therefore, the two ideas cannot be operated as disjointed or distinct efforts. Rather they must be linked for maximum results."*

As such, developing a patient experience product for clinical practice, designed around the patient conceptualisation of patient safety, should involve those who will be delivering it, as well as the patients who will be experiencing it. This ensures it is practical and acceptable. In addition, the opportunity for healthcare professionals to work directly with patients enhances empathy, distils a sense of importance through hearing directly from patients about what matters (Robert et al., 2015), and fulfils the need for education and raising awareness of the patient conceptualisation (as identified in Chapter 5).

Therefore, overall, the methodological approach for practically applying TPST needs to encompass partnership working between patients and other actors in healthcare and focus on the experiences of patients. Berwick (2016) recognises the importance of partnership working in medicine and healthcare, and has called for a third era in medicine which embraces co-production and co-design:

> *"…(T)he more patients and families become empowered, shaping their care, the better that care becomes, and the*

> *lower the costs. Clinicians, and those who train them, should learn how to ask less, 'What is the matter with you?' and more, 'What matters to you?' 'Co-production', 'co-design' and person-centred care are among the new watchwords, and professionals and those who train them, should master those ideas and embrace the transfer of control over people's lives to the people."*

Co-production and co-design, components of the so-called *"participatory Zeitgeist"* (Palmer et al., 2018), acknowledge the concept that those with lived experience should be central in decision-making. Therefore, co-production and co-design, particularly experienced-based co-design, have been identified as important methodological approaches for the practical application of TPST as they are collaborative in nature and focus upon patient experience. These approaches will be explored in more depth in the next section.

6.3.1 Co-production

Co-production in health is described as a way of working together to improve health and create user-led, people-centred health care services (Kickbusch and Gleicher, 2012). The term is becoming common discourse in government (Needham, 2008), in policy (Carr, 2016) and even in mainstream media (Malby, 2012). A conceptual model (Figure 6.1) developed by Batalden et al. (2016) shows how patients and healthcare professionals interact within a healthcare system, and within society (which serves to support, constrain and influence), to produce healthcare that contributes to good health for all.

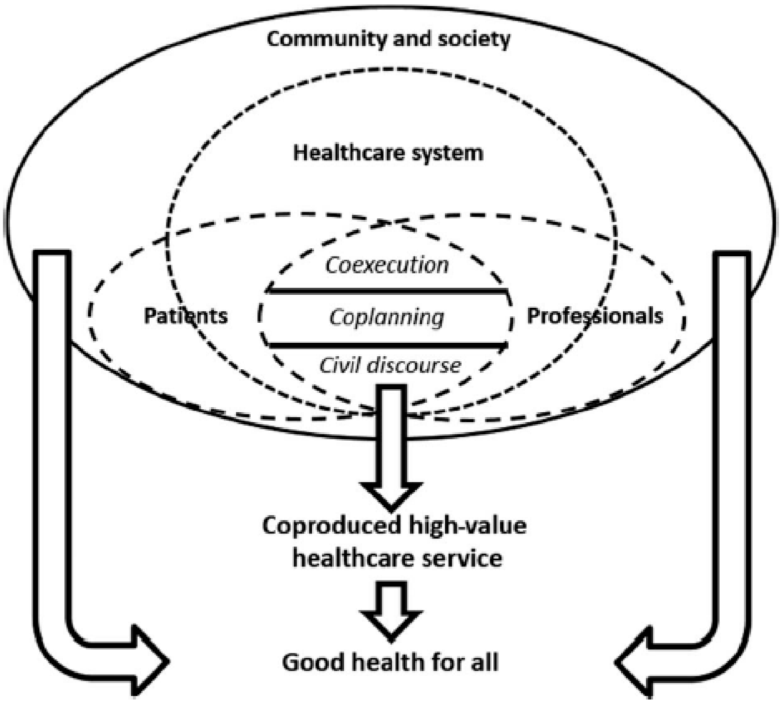

Figure 6.1: A conceptual model for co-production
From Batalden et al. (2016)

Co-production is far-reaching and can involve partnership at many levels (e.g. co-commissioning, co-design of services, co-delivery, co-assessment of services) (Loeffler et al., 2013). Involving patients in service improvement has played a key part in the redesign of healthcare services (Bate and Robert, 2006), although efforts to involve patients have rarely extended beyond asking patients what is good or bad about something, or seeking their attitudes or opinions, and very little time has been spent addressing their experience (what something was like, or should be like) (Bate and Robert, 2006). Whilst current approaches to improving patient experience focus on metrics and view patients as passive (Robert et al., 2015), co-production seeks to incorporate perspectives and expertise more meaningfully, engaging the patient in an active role rather than as a passive receiver of care (Filipe et al., 2017).

6.3.2 Design sciences in healthcare improvement

Increasingly, in the pursuit of improvement of healthcare, design sciences are being applied. Design sciences seek to make things better for the user, just as we are seeking in healthcare to make things better for patients; in design this done by making users integral to the design process (Bate and Robert, 2006). Similarly to design, healthcare focuses on performance (evidence-based practice) and engineering (clinical governance, standards and safeguards); however, healthcare rarely focuses upon the aesthetic or human experience or how something feels (Berkun, 2004; Bate and Robert, 2006). Designing for experience in healthcare places patient experience goals at the centre of service design (what matters for patients), giving it the same value as process and clinical goals. This includes many aspects of subjective experience (e.g. physical, sensual, cognitive, emotional, kinetic, aesthetic) and using them to design experience that is better (Bate and Robert, 2006).

Applying these design principles to patient safety, the current patient safety paradigm is predominantly concerned with 'being safe' or the performance and engineering aspects of design. However, the patient conceptualisation of patient safety is concerned with 'feeling safe,' a subjective experiential phenomenon akin to the aesthetics of design. Designing for experience in patient safety would place patient experience goals at the centre, giving what matters to patients to feel safe the same value as what matters for patients to be safe.

One way of achieving this is through experience-based design; this is a user-focused design process in which the designer accesses experiences to allow the design of experiences rather than services. This is possible by identifying from 'touch points' from narratives, key moments where people come into contact with the service and their experience is shaped, and working with the people involved in those touch points to design experience (Bate and Robert, 2006). This can be usefully applied in the practical application of TPST, where the aim would be to design the experiences that lead to *patients' safety* or feeling safe.

6.3.3 Experience-based co-design

Specific to healthcare, a new approach to designing services has been developed. Experience-based co-design (EBCD) is a co-design framework which focuses on lived experiences and collaboration for service-redesign (The King's Fund.; Bate and Robert, 2006; Bate and Robert, 2007; Robert et al., 2015); in this, the patient is no longer passive, but crucial to the improvement process. It is a joint venture; patients do not just provide feedback, but bring their experiences to the process, which tell us where the service needs to improve. The process focuses on the subjective pathway; the end product has been described as *"science and the objective sitting alongside the aesthetics and the subjective"* (Bate and Robert, 2006), as is the aim of this study.

EBCD is a multi-stage process that usually takes six to nine months to complete; the stages of EBCD are seen in Figure 6.2.

- Setting up the project.
- Observation of clinical areas.
- Gathering staff experiences through observation and in-depth interview.
- Gathering patient and carer experiences through narrative interviews.
- Edit interviews into a film.
- Hold a staff event to highlight their priorities for improvement.
- Hold a patient event to watch the film, agree any edits and discuss their priorities for improvement.
- Bringing staff, patients and carers together to watch a "trigger" film of patient narratives, share their experiences and identify priorities for improvement.
- Small groups of staff and patients work on the identified priorities.
- Celebration and review event.

Figure 6.2: The stages of Experience-based co-design
(The King's Fund.; Bate and Robert, 2007)

EBCD has been used for improvement in various forms and in many clinical settings (Palmer et al., 2018); examples include improving patient experience in breast and lung cancer services (Tsianakas et al., 2012b), identifying priorities for quality improvement in breast cancer care (Tsianakas et al., 2012a), improving experience of mental health inpatient services at Oxleas Mental Health Trust (Point of Care Foundation) and improving the experience of hip and knee replacements at Bolton NHS Foundation Trust (Point of Care Foundation). Co-design has also been applied to patient safety, where co-design was used to develop a feedback mechanism based on safety experiences in organisational care transfers and perceptions of safety (Scott et al., 2016).

Accelerated EBCD is an alternative approach which removes the lengthy 'discovery phase,' often using pre-collected and analysed audio and video interviews for triggers and to identify priorities (Locock et al., 2014). In a review of EBCD, Donetto et al. (2014) identified the range of ways the method has been developed and adapted including eliminating the observation phase, eliminating the review event, adapting the use of trigger films and other material, and changing the small group co-design work, including holding a single co-design meeting/workshop.

6.3.4 Choosing a methodological approach

This chapter seeks to instrumentally utilise TPST, to create a practical product or intervention which, when put in place, would raise awareness of the patient conceptualisation of patient safety and lead to patients feeling safe in hospital. Considering the relevance of co-production, co-design and experience-based co-design, I opted to use an adaptation of accelerated experienced-based co-design in order to practically apply TPST.

6.4 Developing a practical product for patients' safety

Researcher, healthcare professional and patient input through co-design was used to collaboratively design interventions for the experiences that lead to *patients' safety* or feeling safe. The Macmillan Values Based Approach is an example of a practical tool that has been developed through co-design for improving patient experience. This will be considered as a case study and model. Additionally, I will consider the application of organisational values and behaviours standards.

6.4.1 Case Study: Macmillan Values Based Approach[13]

In 2009, Macmillan Cancer Support commissioned work to research and develop a standard for cancer care services. The Macmillan Values Based Standard (Macmillan Cancer Support., 2013), now known as the Values Based Approach, was developed through co-design and is an approach for achieving Quality Together, the Macmillan quality standard for professionals and services. It aims to improve the experience of

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healthcare for patients and healthcare professionals by understanding their views and aspirations and developing day-to-day behaviours to ensure people's rights are protected. It focuses on what matters to patients and changes the nature of the relationship between patients and healthcare professionals.

The approach describes 'behaviours' or the 'moments that matter' to patients and staff for improved patient-staff relationships and care experiences. The focus upon behaviours recognises that patients are aware of the types of behaviours that are necessary to fulfil abstract concepts (e.g. dignity), but that these are otherwise difficult for patients to define. The approach is patient, carer and staff led; the behaviours do not represent imposed benchmarks but are co-produced, seeking to create more equitable relationships and serving to move towards using patient experience to judge quality. Importantly the associated vocational nudges provide practical everyday reminders to staff of how to improve a patient's experience. An example of one of the behaviours is given in Figure 6.3.

NAMING:
'I AM THE EXPERT ON ME.'

Leadership behaviour + **Vocational 'nudge' examples** + **Behavioural standard for improving cancer care**

Leadership behaviour

Leaders create a personable and approachable environment across the staff structure. They want ideas and innovation to emerge from the frontline, reinforcing the importance of all roles in the organisation.

Leaders 'role model' behaviours that emphasise the importance of relationship-building because they want to encourage professionals to develop better relationships with all patients.

Vocational 'nudge' examples

'I want to know who patients really are.'

'I recognise the need to understand what is important to patients and that this information can be of assistance to me in understanding how to care for patients.'

Behavioural standard for improving cancer care

Professionals ensure that patients are asked how they want to be addressed in every new professional/patient interaction and act on this information.

Professionals ensure that this initial introduction supports the gathering of essential information such as language, support requirements, disability issues, and religious and dietary needs.

Patients help professionals understand what is factual and what is presumed and take greater responsibility for the information they provide.

Professionals are open to correcting incorrect patient information.

= **Outcome:** Patients can disclose information which will help professionals to understand them and act on their needs.

Figure 6.3: Excerpt from The Macmillan Values Based Approach
From Macmillan Cancer Support. (2013)

The Macmillan Values Based Approach (Macmillan Cancer Support., 2013) has proven to be a valuable tool in improving experience of cancer care and has been endorsed by the government (Department of Health., 2011). Whilst developed with people living with and beyond cancer, its application is broader than just cancer services and has been implemented in a wider range health and social care settings.

6.4.2 Organisational values and behaviours standards

Exploring the concept of values and behaviours standards more broadly, guidance has been developed for NHS Wales on developing organisational values and behaviour standards (Workforce Education and Development Services., 2014). Values transform an organisation’s vision and mission into reality; they help people to work as effectively together as possible by creating a shared purpose and agreement on “*how we do things round here”* (Workforce Education and Development Services., 2014). Additionally, values can also facilitate organisational change (Branson, 2008). There are several ways of developing values, including a ‘Values and Criterial Equivalents’ approach, through which values (the states that are important to us/states that matter to you) and their associated behaviours (sensory evidence that lets you know your values are being fulfilled) are designed (Workforce Education and Development Services., 2014); this approach will be applied in this study.

6.4.3 Summary

In summary, this chapter seeks to instrumentally utilise TPST, to create a practical product or intervention which, when put in place, would raise awareness of the patient conceptualisation of patient safety, *patients' safety*, and lead to patients feeling safe in hospital. The Macmillan Values Based Approach, which has used co-design to improve experiences in cancer care, along with the commentary on organisational values and behaviours, have provided a useful framework and inspiration for translating TPST.

Deconstructing TPST, the component parts of the theory describe the experiences that matter to patients to feel safe, or their values for *patients' safety*. These values could be brought to life through designing associated practical actions or behaviours. Researcher, healthcare professional and patient input through experience-based co-design will be used to determine the experiences that matter for patients to feel safe and to collaboratively design interventions for these specific experiences. These will be expressed within a practical product which, when implemented, will raise awareness of the patient conceptualisation of patient safety and lead to patients feeling safe in hospital.

6.5 Aims and objectives

The aim of this study was to create a practical product that could be implemented by Imperial College Healthcare NHS Trust to introduce and apply the patient conceptualisation of patient safety or *patients' safety*, as explained by The Patients' Safety Theory (TPST), into clinical practice.

To achieve this aim, the objectives were:

1. To identify values describing what matters to patients to feel safe in hospital.
2. To identify behaviours to bring the values to life.
3. To consider how the product may be defined, used and implemented.

6.6 Methods

These sections detail the practical methods for the study. This includes describing the participant population, recruitment, ethics and consent, and the planning and running of an accelerated EBCD workshop to practically translate and apply TPST in clinical practice.

6.6.1 Participant population

This study aimed to create a practical product that could be implemented to introduce and apply the patient conceptualisation of patient safety or *patients' safety*, as explained by The Patients' Safety Theory (TPST), into clinical practice. This theory, developed in Chapter 4, was derived from qualitative data from three clinical specialty settings: acute medicine for the elderly, maternity and elective surgery. Therefore, in seeking to translate the theory into clinical practice, one of these groups was chosen as the participant population for this study. Each clinical specialty setting was carefully considered as the potential participant population by assessing their advantages and disadvantages. These are outlined in Table 6.1.

Clinical Specialty Setting	Advantages	Disadvantages
Acute Medicine for the Elderly	• Older adults, as a vulnerable group, are often excluded from research (O'Hara and Lawton, 2016). • Support from supervisor, SL, as a Consultant in Medicine for the Elderly • Likely to have more time available to attend	• Long sessions may be physically demanding on frailer patients • Greater physical needs • May require the attendance of a carer to support • No existing groups to facilitate recruitment
Elective surgery	• Have strong links to the surgical department due to association with Academic Surgical Unit, therefore increased investment in the project • Existing patient groups e.g. patients who are involved in university examinations • A broad range of age groups will be possible • Patients may be fitter	• More heterogeneous group
Maternity	• Young, fit and well participants • Likely to have more time to attend if on maternity leave	• No existing groups to facilitate recruitment • No investment in the department • Long sessions may not be feasible with a young baby or child

Table 6.1: The advantages and disadvantages of different workshop participant groups

As the event was a pilot of a new concept, it was felt to be important to select a group who would not be significantly burdened by participation. Based upon this, it was decided to run the event with participants from the elective surgery setting.

Consistent with the principles of co-design and the rationale given earlier in the chapter, the participants in the workshop were patients and healthcare professionals. Patient participants were required to have had experience of surgical treatment within any surgical specialty. It was preferable for their experience to have been at Imperial College Healthcare NHS Trust for two reasons. Firstly, the original interviews and subsequent theory was developed from the experiences of patients at this Trust and it is currently unknown to what extent these experiences may be generalisable to other Trusts. Secondly, the aim of the workshop was to develop a product that could be used by this specific NHS trust.

Healthcare professionals were required to have had experience in surgery. This included performing surgery, or caring for patients in the perioperative period. Only doctors and nurses were included; this was a reflection of the outcomes from Chapter 4, where patients expressed that they believed doctors and nurses to be predominantly responsible for their safety. A range of levels of experience was sought.

6.6.2 Recruitment

Patient participants were recruited through three routes simultaneously. Firstly, an advertisement was placed on the website ‘People in Research’. Secondly patients were recruited via an existing pool of surgical patients who are invited to participate in Imperial College London surgical examinations; these patients are former or current surgical patients of Imperial College Healthcare NHS Trust, with experience of involvement in education, but no prior experience in research or quality improvement. Thirdly, advertisements were disseminated via social media, through personal and Imperial Patient Safety Translational Research Centre Twitter channels. Patients were recognised for their contribution as per the NIHR Imperial Patient Safety Translational Research Centre policy, which is based on the INVOLVE guidelines. As patients were involved in collaborative co-design activities they were paid £20/hour, their travel was reimbursed, and they were provided with refreshments and lunch.

Healthcare professional participants were recruited through four routes simultaneously. Firstly, an invitation to participate was circulated within the surgical department. Secondly, to seek junior doctors, an invitation to participate was circulated to foundation year trainees. Thirdly, an advertisement was placed in the weekly staff news email ‘In Brief,’ which is sent to all staff across Imperial College Healthcare NHS Trust and visible on the Trust intranet page, ‘The Source’. Finally, the snowball method was used, by which recruited participants were asked to suggest other colleagues or to refer the advertisement on to others. Healthcare professionals were released from clinical activities in order to attend and participate; they were therefore not offered any financial remuneration. However, staff were offered acknowledgement of their involvement in patient safety quality improvement activities as evidence for their training portfolios, appraisals and continuing professional development. In addition, they were provided with refreshments and lunch.

6.6.3 Ethics

Ethical review is required when a project is considered to be research. The Health Research Authority has published clear guidance to determine whether a project is research, or whether it is another activity such as audit, service evaluation or quality improvement, or public health surveillance. The key discriminants relate to intent, treatment, allocation and randomisation. This study used existing data, from previous studies, and established quality improvements methods (co-design) to develop a practical product to introduce and apply a qualitative derived theory of *patients' safety*. This study was therefore classified as quality improvement.

Quality improvement is considered to involve minimal risk, burden or intrusion, is regulated as part of standard clinical practice (Health Research Authority., 2016), and is not subject to ethical review. This study therefore did not require formal ethical approval by a Research Ethics Committee. Additionally, it was discussed with the local Quality Improvement Team who did not require a formal proposal or registration.

Whilst formal ethical approval was not sought, discussion about the potential for ethical oversight in quality improvement initiatives, and the current lack of approval and governance mechanisms for participatory and co-design approaches, exists (Taylor et al., 2010; Goodyear-Smith et al., 2015; Healthcare Quality Improvement Partnership., 2017). For example, the editors of British Medical Journal Quality and Safety recognise that requirement for ethics review of quality improvement work poses a challenge, especially as widely accepted principles have yet to emerge and guidelines may vary internationally (BMJ Quality and Safety., 2014). As such, they have adopted a policy of requiring authors to make statements justifying that reported work is exempt from ethical review on the basis of it meeting the criteria as an improvement activity according to local standards. The NHS Institute for Innovation and Improvement defined The Principles of Good Practice for an experience-based design (EBD) approach (NHS Institute for Innovation and Improvement., 2007); this was developed with advice from the National Ethics Service who stated that EBD studies should be conducted in accordance with basic ethical principles, including informed consent and respect for confidentiality (National Research Ethics Service., 2007); this is the standard that has been applied in this study.

Therefore, various ethical considerations were attended to, with reference to guidance from the Healthcare Quality Improvement Partnership (Healthcare Quality Improvement Partnership., 2017) and the former NHS Institute for Innovation and Improvement (NHS Institute for Innovation and Improvement., 2007), as well as applying knowledge and learning from earlier research ethics applications; these are shown in Table 6.2.

Ethical consideration	How these were addressed
Integrity and quality of the study	The study design was reviewed with a supervisor (SA).
Informed consent	Participants were fully informed about what they were doing, why they were doing it and given freedom to independently decide if they wished to participate. Participants consented to being filmed, photographed and audio-recorded, and were consented for the use of the resulting media (including for research and promotional purposes) and use of anonymous direct quotations.
Privacy and confidentiality	These principles were respected, and this was discussed during the development of ground rules at the start of the event.
Risks and burden of study	As patient safety could be an emotive topic, participants were encouraged to report if any topics were sensitive in nature and support offered where required; however, this was not deemed to be of significant risk to participants or likely to cause significant harm. Importantly, the study did not infringe on patient rights to make choices about their care, did not involve departure from existing treatment, did not involve untested treatments or clinical systems, and did not create any conflict of obligation to patients. Some additional burden was placed on patient participants by travelling to the workshop; however, their expenses were reimbursed, and their contribution recognised financially.
Data protection	Personal information (name, contact email and telephone number) was collected on the consent forms, as well as additional address details on the Non Payroll Fee Forms. These were kept securely in a locker.

Table 6.2: Ethical considerations for the experience-based co-design workshop

6.6.4 Co-design event structure

An accelerated format for EBCD was used (Donetto et al., 2014); rather than conducting observation of clinical areas, and gathering experience data through interviews, the data on patient experiences of feeling safe, gathered from the patient interview study in Chapter 4 was used as the basis of the event. A single joint event was run, during which co-designed values and behaviours were generated.

The agenda, ‘Introduction Planner’ and ‘Discussion Planner’ can be found in

Appendix 12 and 13; however, Figure 6.4 shows an overview of the structure of the event. The workshop was facilitated with support from colleagues within the department.

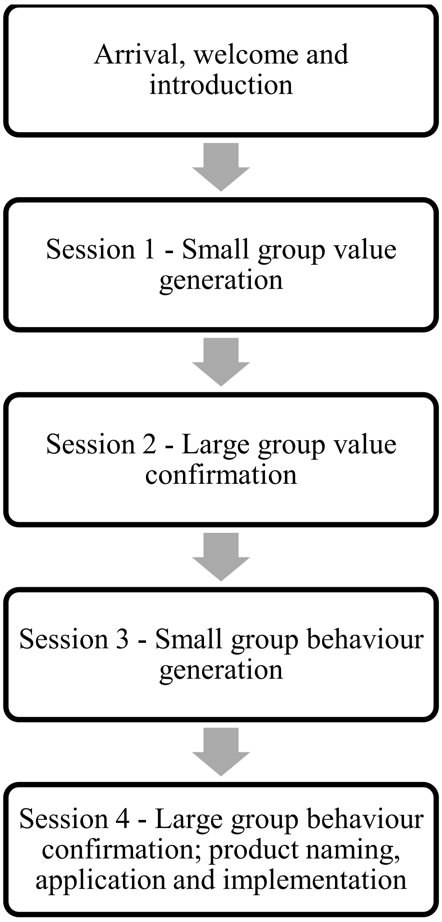


Figure 6.4: Overview of the structure of the event

6.6.4.1 Introduction

The session began with introduction of the facilitators and participants. The introduction included: an overview of the topic in lay terms, practical housekeeping arrangements, consent for photography, filming and audio-recording, an icebreaker activity, and establishing a list of principles or ground rules to guide discussion and allow the inclusion for a variety of views, involvement of all participants, and open and honest sharing of experiences.

6.6.4.2 Session 1 – Small group value generation

Patients and healthcare professionals were divided into three mixed groups. The aim of this session was to identify values describing what matters to patients to feel safe in hospital. The groups were facilitated and notes were made by the facilitator to record the discussions and provide context to the decisions they made in generating their list of values.

A modification of the Nominal Group Technique (NGT), a consensus method that aims to achieve general agreement around a topic, was used (Delbecq et al., 1975; McMillan et al., 2016). It was chosen as it is particularly useful where the aim is problem-solving, idea-generation or determination of priorities (Delbecq et al., 1975) and also has the benefits of being a highly structured group technique which allows for balanced participation of all groups members, including those who may not otherwise have their opinions heard (Tully and Cantrill, 1997; McMillan et al., 2016). It is comprised of the following stages (Delbecq et al., 1975):

- <u>Silent generation:</u> participants come up with ideas or responses to a given question.
- <u>Round robin:</u> participant share their ideas or responses in turn
- <u>Clarification:</u> ideas are discussed to ensure participant understanding and ideas may be grouped.
- <u>Voting, ranking or rating:</u> participants are asked to select their top preferences.

NGT is recognised to be a highly adaptable method; adaptations are influenced by available research, time and the level of consensus required (McMillan et al., 2016). The variations can be seen in Figure 6.5, which shows where the adaptations may be made.

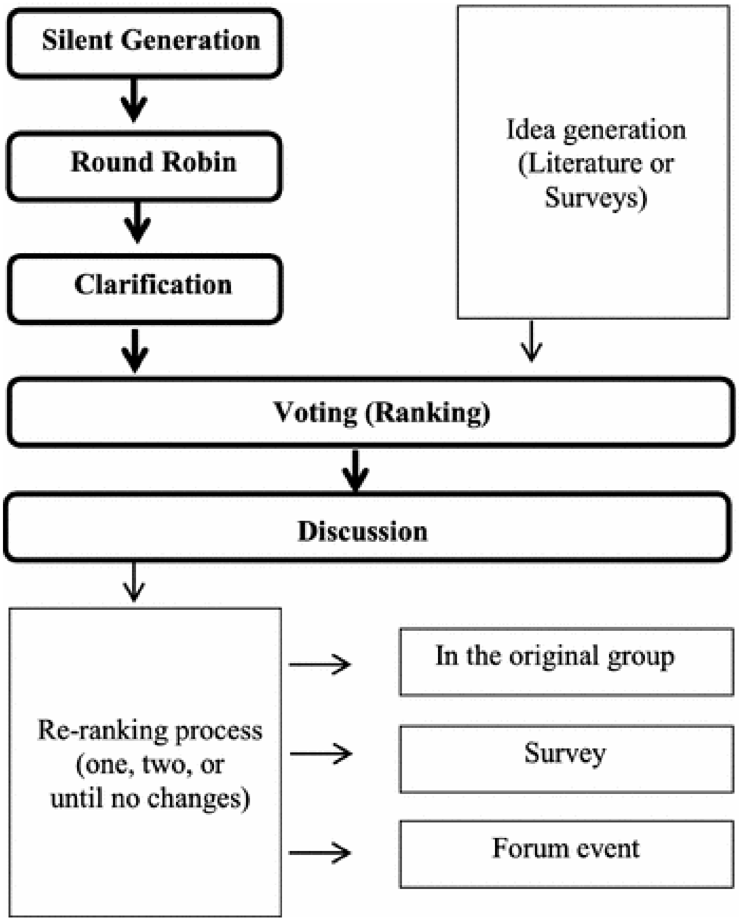


Figure 6.5: Nominal group technique and its possible adaptations
From McMillan et al. (2016).

The greatest variations are seen in the idea generation and consensus phases and include omitting the silent generation and round robin in favour of using ideas generated from literature review (Hiligsmann et al., 2013) or exploratory surveys (Vella et al., 2000). As an example, Vella et al. (2000) used NGT as a consensus method to establish national research priorities in critical care; a survey of intensive care unit leads was used to generate topics that were taken forward to the nominal group process.

Within this study, the silent generation, round robin and clarification phases were omitted. ‘Ideas’ were generated from the experience data from patient qualitative interviews in Chapter 4. A total of 30 ‘ideas’ were generated from concepts, categories and sub-categories generated by the grounded theory analysis; these can be seen in Figure 6.6.

- Being able to trust staff
- Having confidence in the staff
- Staff communication skills
- Staff knowledge and practical skills
- Level of experience of staff
- The attitude and characteristics of staff
- Being checked on by staff
- Being reviewed by a doctor
- Staff responding to patient needs and symptoms
- Staffing on the ward
- Being able to ask questions about your care
- Getting your diagnosis
- Getting your treatment
- Procedures and treatments being done correctly
- Appointments being on time
- The finances of the trust
- Being moved around the hospital
- Mobilisation
- Security of self and belongings
- Cleaning
- Infection control
- The impact of other patients
- Having friends, family or carers to provide care and comfort
- Being able to monitor the staff and your treatment
- Being able to report your concerns
- Having discussions with friends, family or carers about safety
- Having friends, family or carers who can identify and report concerns
- Taking responsibility for yourself as a patient
- Patient being compliant with the rules and regulations
- The type of healthcare professional: any/all staff, nurse, doctor

Figure 6.6: 'Ideas' for the nominal group exercise, derived from the theory in Chapter 4

Using the modified NGT method, participants were asked to read the ideas and consider them in relation to their own views about what makes them feel safe or unsafe in hospital; they were asked to vote use coloured sticky dots to indicate whether they agreed (green), disagreed (red) or were surprised (yellow) by each idea (Figure 6.7). Participants did not have to rate each idea and could signify the relative importance of an idea with more than one sticker (i.e. if it was a concept that they felt strongly about) Participants were also encouraged to write additional ideas on the sheets of paper or to use post-it notes to add additional ideas or comments.

This activity and its outcomes then provided the prompts for a facilitated small group discussion about what mattered or what was important to make them feel safe in hospital (Figure 6.8). Participants were asked to discuss within their groups why they agreed or disagreed with various ideas, to group together ideas they felt to be related, and to add ideas they felt to be missing. Each small group was asked to reach a consensus and write their list of values. For clarity, participants were offered a definition of a 'value,' consistent with the Workforce Education and Development Services definition discussed earlier.

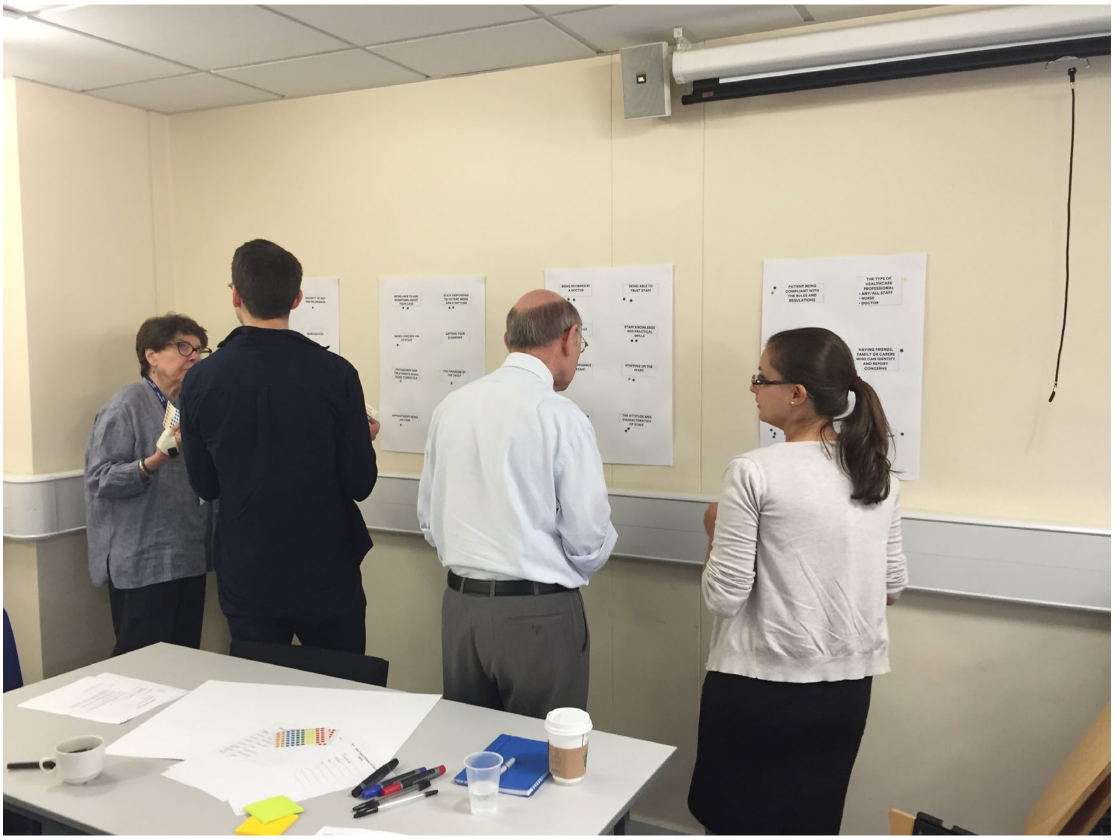


Figure 6.7: Photograph of nominal group exercise

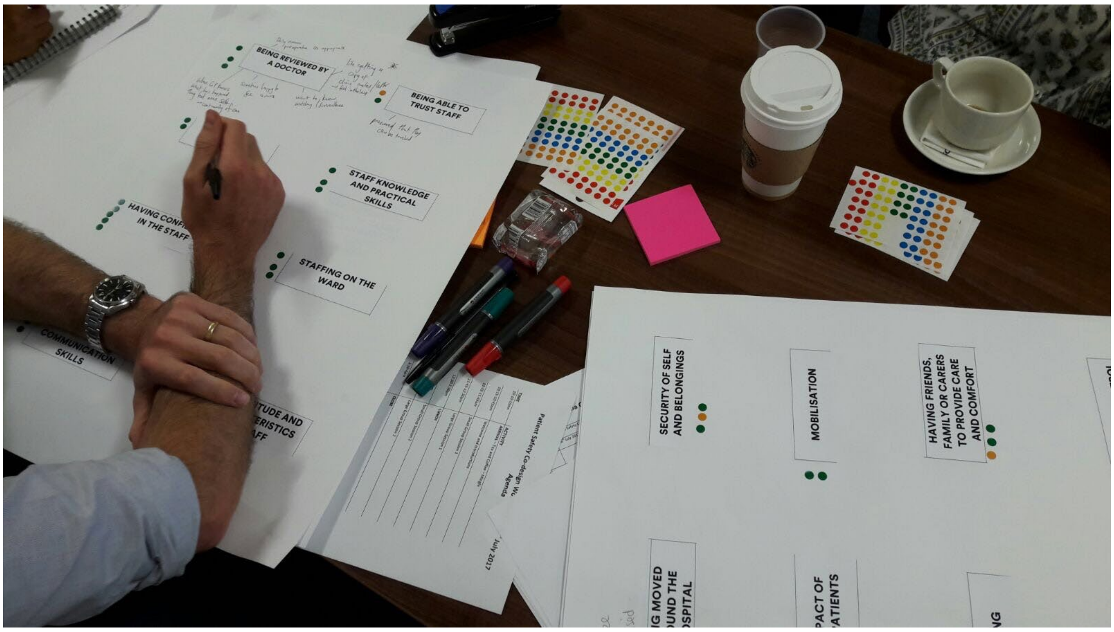


Figure 6.8: Photograph of facilitated small group discussion

6.6.4.3 Session 2 – Large group value confirmation

Each group was asked to present their list of values and share with the wider group why they had chosen each value. The wider group was asked to discuss any similarities and differences, and consider where values could be combined or subsumed by higher-order concepts. The aim was to agree a common list of values to work on in the afternoon sessions. This was audio-recorded to ensure all details of the discussion were captured.

6.6.4.4 Session 3 – Small group behaviour generation

This aim of this session was to identify behaviours that would bring the values, defined in Session 2, to life. Participants were asked to consider the behaviours of the key parties involved in healthcare: the patient, staff and the NHS Trust. For clarity, a definition of 'behaviour,' consistent with the Workforce Education and Development Services definition discussed earlier was given.

A modified World Café Approach was adopted. World Cafés are a participatory method to support conversations in a variety of different contexts, including corporate, government and communing settings (The World Cafe Community

Foundation., 2015; MacFarlane et al., 2017). It has been used for research priority setting with patients and members of the public (MacFarlane et al., 2017) and has been advocated by NHS Wales as a tool for developing organisational values (Workforce Education and Development Services., 2014). Participants are recognised as having their own experiences and experiential knowledge, which results in a diverse range of perspectives (MacFarlane et al., 2017). The method creates *"a living network of collaborative dialogue around questions that matter"*; this is achieved by participants moving between different conversations happening at different tables within the 'Cafe.' As participants move around they carry with them ever-enriching ideas, which helps to develop and link other ideas (The World Cafe Community Foundation., 2015). It has a flexible format, which serves to generate *"collaborative dialogue, active engagement, and constructive possibilities for action"* (The World Cafe Community Foundation., 2015). The key concepts of collaboration, engagement and constructive possibilities for action with the World café approach therefore suited the aims of the session.

The participants were again divided into 3 mixed (patient and healthcare professional) groups; three tables were set up with 4-5 participants at each. The values identified in session 2 were divided between the 3 groups; the participants were asked to develop the patient, staff and NHS Trust behaviours that would let you know any given value is being fulfilled. To do this, participants were prompted to consider for each value:

- What do patients need to do? What do staff and the trust need to see, hear or feel from patients?
- What do staff need to do? What do patients and the trust need to see, hear or feel from the staff?
- What does the NHS Trust need to do? What do patients and staff need to see, hear or feel from the Trust?

They were given a sheet a paper, with the value as the heading; this was divided into three columns, for the behaviours of patients, staff and the NHS Trust. They were encouraged to write or draw their ideas on this (Figure 6.9).

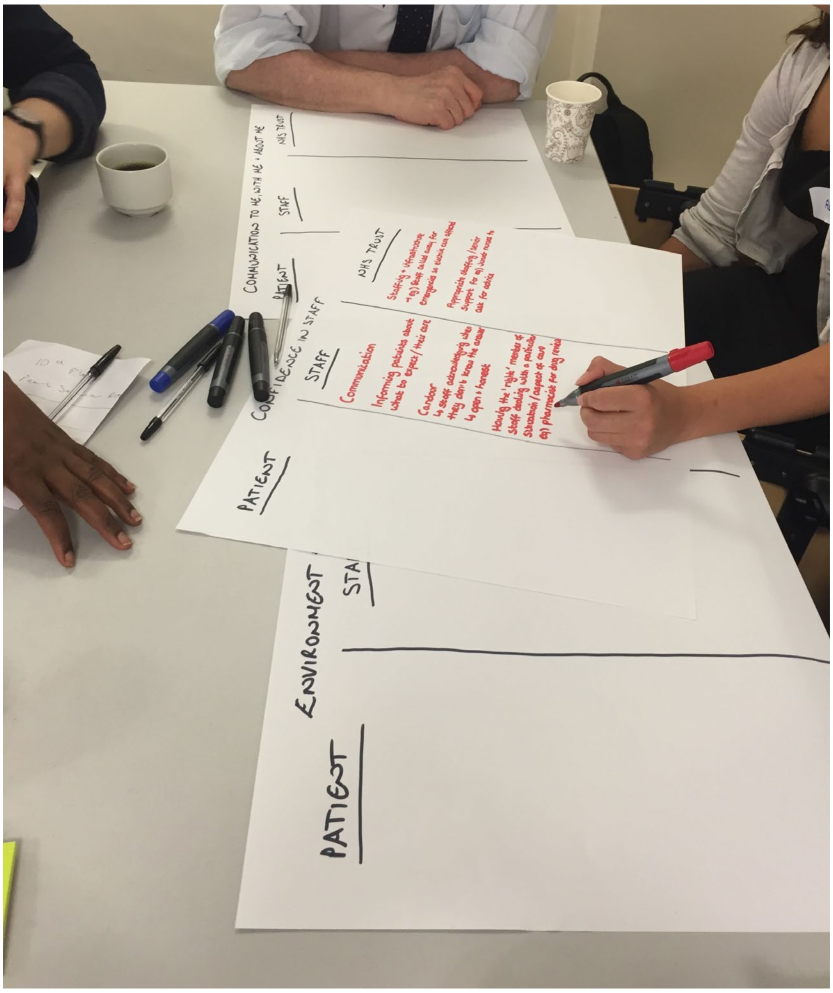


Figure 6.9: Photograph of values and behaviours sheets

Three rounds of conversation were held, lasting 15-20 minutes. Upon completing a round of conversation, participants moved onto the next table, with one person remaining as a *"table host,"* to introduce to the new guests the topics that had previously been discussed and to enhance collaboration between the groups (Figure 6.10 and 6.11). In each successive conversation, participants were encouraged to add to or amend the ideas of previous conversations.

Figure 6.10: Photograph of World Café

Figure 6.11: Photograph of World Café

6.6.4.5 Session 4 – Large group behaviour confirmation and product naming, application and implementation

Session 4 was the second large group session and final session of the day; it was audio recorded to ensure all detail of the discussion was captured. As recommended by the World Café Approach (The World Cafe Community Foundation., 2015), this session took the format of a *"town meeting-style conversation"*; these allow sharing of ideas in a whole group conversation, identifying patterns, building collective knowledge and identification of the possibilities for action. A representative from each group presented the behaviours they had developed for each value. This aimed to give the group opportunity to comment and make any changes, to seek clarifications, and to discuss how the resulting product could be named, applied/used and implemented.

The session ended with thanking the participants for their involvement in the workshop and an explanation of the next steps. Participants were asked to complete an evaluation form.

6.7 Results

The workshop took place on Wednesday 26th July 2017 from 10am to 4pm. It was held in a seminar room in the Academic Surgical Unit of the Queen Elizabeth the Queen Mother Building of St Mary's Hospital, London.

6.7.1 Participants

Fourteen participants were recruited to participate in the workshop. The characteristics of the participants are reported in Table 6.3.

Of the patient participants, three were recruited via the 'People in Research' advertisement (patients 5-7) and four via the pool of surgical examination patients (patients 1-4). Those recruited via 'People in Research' had some level of previous experience in patient/public involvement/engagement work. Patient 2 had experience as an expert patient within a patient-led condition-specific support group. All patients were treated at Imperial College Healthcare NHS Trust, with the exception of one patient (Patient 6) who was treated at Kings College London. This patient was only included after no further local patient participants could be found to ensure balance between patient and healthcare professionals participants. A broad age range is included (range 23-83 years, mean 62.1 years) and the group had some ethnic diversity.

The healthcare professional participants were recruited via departmental emails (5 participants) and via The Source advertisement/snowball referral (2 participants). The participants had a range of levels of experience; the doctors represented the range of 'grades' seen within a team, including Foundation Year One (House Officer), Senior House Officer, Specialty Registrar and Consultant. Of the nursing participants, one was a Staff Nurse and one a Sister with greater management/leadership responsibilities.

Participant	Age	Level of experience	Gender	Ethnicity	Specialty
Patient 1	79		M	White British	Vascular
Patient 2	83		F	Other White	Orthopaedics
Patient 3	67		F	White British	Urology
Patient 4	71		M	White British	Vascular
Patient 5	73		F	Other White	Cardiothoracic
Patient 6	39		F	British Asian - Indian	Orthopaedics
Patient 7	23		M	British Asian – Bangladeshi	General Surgery
Doctor 1		FY1	F	White British	General Surgery and Orthopaedics
Doctor 2		SHO	F	White British	Vascular
Doctor 3		Registrar	M	Other White	General Surgery
Doctor 4		Registrar	M	White British	General Surgery
Doctor 5		Consultant	M	White British	Upper GI Surgery
Nurse 1		Band 5	F	Black African	General surgery
Nurse 2		Band 6	F	White British	Gynaecology Oncology Surgery

Table 6.3: Characteristics of the participants

6.7.2 Session 1 and 2 – Value generation

Session 1 lasted one hour and session 2 lasted 45 minutes. Table 6.4 presents a basic summary of the results of the nominal group exercise. It shows a basic count of the number times an idea was agreed with, disagreed with or considered surprising. The items are listed in order of most agreed with to least agreed with.

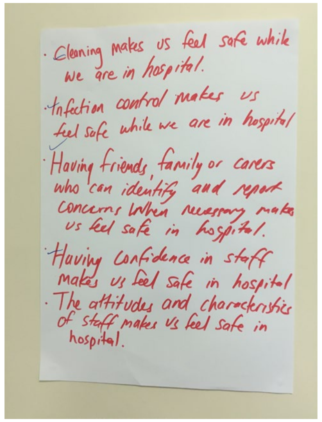
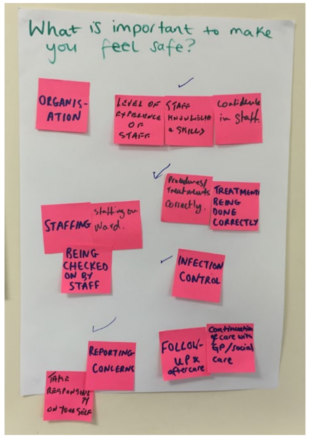
Item	**Agreed**	**Disagreed**	**Surprised**
Infection control	16	0	3
Being able to ask questions about your care	13	0	0
Cleaning	12	0	1
Having confidence in the staff	11	0	0
Getting your treatment	11	0	0
Being able to report your concerns	11	0	0
Staff communication skills	10	0	2
The attitude and characteristics of staff	10	0	2
Procedures and treatments being done correctly	10	0	1
Having friends, family or carers to provide care and comfort	10	2	1
Staff knowledge and practical skills	9	0	0
Being checked on by staff	9	0	0
Staff responding to patient needs and symptoms	9	0	0
Staffing on the ward	9	0	2
Security of self and belongings	8	0	1
The impact of other patients	8	0	1
Getting your diagnosis	8	0	2
Taking responsibility for yourself as a patient	8	2	0
Patient being compliant with the rules and regulations	7	0	3
Being able to trust staff	6	0	1
Being reviewed by a doctor	6	0	4
Having friends, family or carers who can identify and report concerns	6	1	0
Mobilisation	5	0	0
Being able to monitor the staff and your treatment	5	0	4
Having discussions with friends, family or carers about safety	4	0	2
Level of experience of staff	4	1	2
Appointments being on time	4	4	2
The type of healthcare professional: any/all staff, nurse, doctor	3	1	3
The finances of the trust	3	3	4
Being moved around the hospital	2	0	4

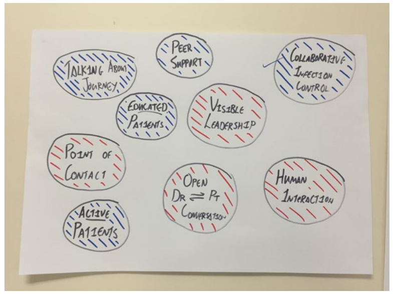
Table 6.4: Nominal group exercise ideas count

This provided the basis for the facilitated small group discussion. Participants discussed why they had voted for the items in the way that they had. Following this, participants considered the items with a majority agreement, and defined a list of values that expressed what was important for them to feel safe in hospital. Each group worked in varying ways. Group 1 discussed each idea within the nominal group exercise before creating a list of values that prioritised their top five issues. Group 2 discussed ideas from the nominal group exercise that were important to them, before having a more general discussion about what made them feel safe in hospital. To create their list of values each participant chose ideas from the exercise that were important to them; these were shared amongst the group and then grouped together where there was overlap. Group 3 agreed with many of the ideas and showed congruence in their thoughts. The group discussed the ideas they felt to be most important, and these formed a basis for more general discussion around what made them feel safe. Rather than using the nominal group exercise ideas directly as a basis for their values, this group came up with nine values for feeling safe in hospital that subsumed several of the rated ideas, as well as incorporating from their own experience.

The values defined by each group and their corresponding explanation and justification are displayed in Table 6.5. The values are reported verbatim (as written by each group to preserve their meaning); their justifications for inclusion were synthesised from various sources including notes the group made during the NGT task, notes written by designated note-takers during the discussion and from the audio-recorded presentation each group gave of their values to the group.

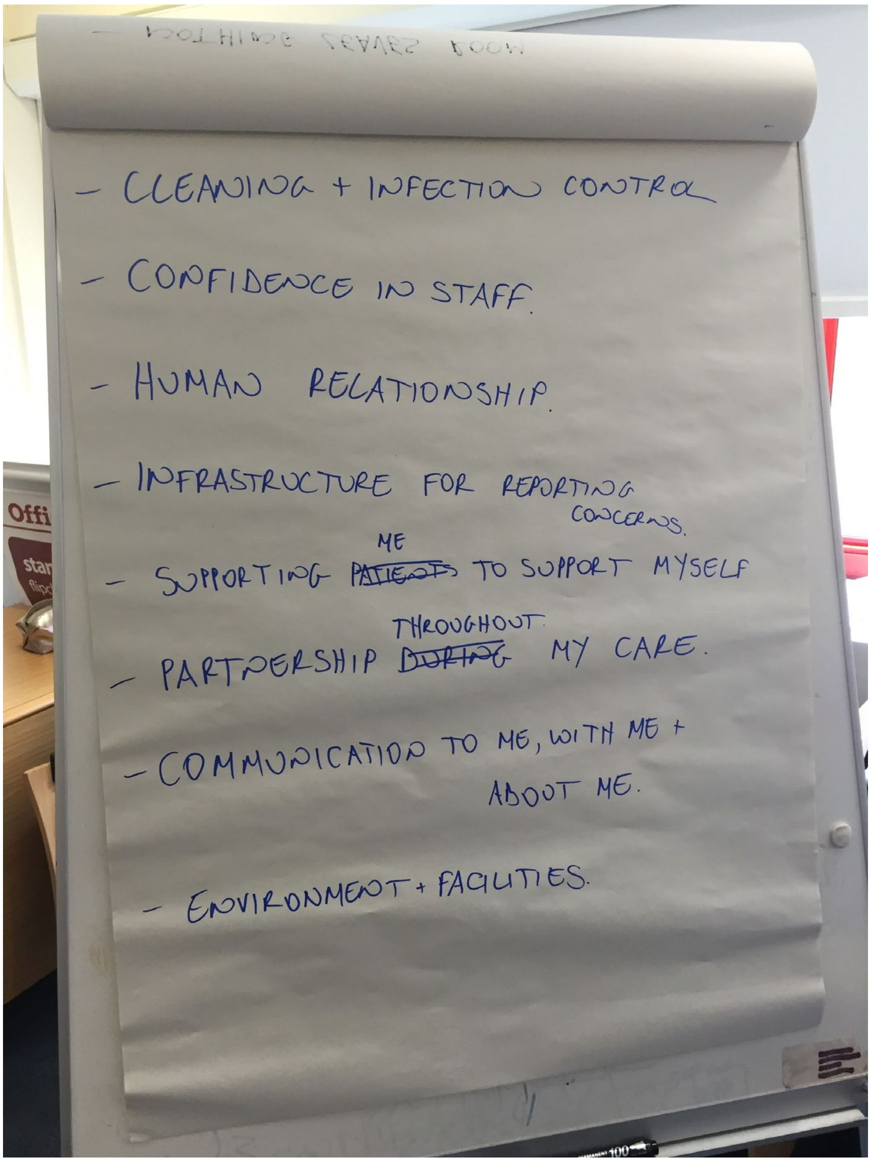
Table 6.5: Values and their corresponding explanation/justification

Group	Value	Explanation/Justification
1.  · Cleaning makes us feel safe while we are in hospital. · Infection control makes us feel safe while we are in hospital · Having friends, family or carers who can identify and report concerns when necessary makes us feel safe in hospital. · Having confidence in staff makes us feel safe in hospital · The attitudes and characteristics of staff makes us feel safe in hospital.	**Cleaning makes us feel safe while we are in hospital.** **Infection control makes us feel safe when we are in hospital.**	Perceived as *"constant worry"* cleaning and infection control were identified as priority value.
	Having friends, family or carers who can identify and report concerns when necessary makes us feel safe in hospital.	Having friends, family or relatives who could advocate for them by identifying and reporting concerns made them feel safe, but they stressed that they only wanted their involvement if it were necessary (i.e. they couldn't do it themselves).
	Having confidence in staff makes us feel safe in hospital. **The attitudes and characteristics of staff make us feel safe in hospital.**	It was important to have confidence in the staff; this was related to the final value, that the attitudes and characteristics (e.g. empathetic, friendly) of staff made them feel safe.
2.  	**Organisation.**	This referred to how activities and tasks were completed in the hospital (i.e. ensuring things are not missed, that they are done the *"way they should be"* and that they run smoothly). For example, blood tests being done in the morning and appropriately followed up.
	Staff: level of experience, knowledge and skills, and confidence in.	The levels of experience of staff, their knowledge and skills, and have confidence in the staff were seen as linked concepts. Observing that members of staff have sufficient knowledge, experience and are appropriate to the task/procedure, made the patient feel confident and therefore safe. Additionally being looked after by the same staff and having continuity of care was important to feel safe.
	Procedures and treatments done correctly.	This referred to receiving the correct procedure *("getting what you are told you are going to get")* and it being done safely.
	Staffing on the ward and being checked on by staff.	Being checked on made participants feel safe, as this was perceived as being important to ensure there were no oversights in their care. This was contingent

		upon there being sufficient staffing levels.
	Infection control.	All participants reported this as an important process for making them feel safe.
	Taking responsibility for yourself/reporting concerns.	Being able to report concerns that they had seen and had not been picked up on by doctors or nurses made participants feel safe. Additionally, being able to take responsibility for self was also important; this meant being a partner in care, being empowered and taking ownership. This was more evident in the outpatient context, where patients are expected to engage in self-management; as an inpatient, this was harder as control was taken away from them. This might not be important or, indeed, appropriate for all patients (personal choice or for reasons of mental capacity/competence e.g. children or psychiatry).
	Follow up and aftercare/continuation of care with GP and social care.	Having investigations and follow up arranged and completed after discharge made participants feel safe. This recognised inpatient care as one part on a patient's care journey. This was a new concept generated by the group, which did not originate from the items within the nominal group exercise.
3.  NB. The nine values were split into two categories: blue and red. Blue represented values relating to patient empowerment and activation. Red represented values relating to the nature of	**Active patients.**	Being an active participant (and not simply a passive receiver of care) throughout the entire care journey was important to feel safe.
	Talking about the journey.	Being informed, able to talk about the care journey and having it reiterated to them made participants feel safe. This commenced in the outpatient setting, to inpatient surgery, and continues back into the community setting.
	Educated patients.	Having an understanding of what is happening in their care made participants feel safe; this required staff taking the time to educate the patient and explain processes (e.g. explaining small interactions such as venepuncture or the cleaning of a central line). This would give patients would be given an understanding of procedures that may seem abstract; this would be learning that they could *"hold on to"* and refer to in subsequent healthcare interactions.
	Collaborative infection control.	Infection control was important for patients to feel safe. This was seen as a collaborative effort, involving everyone in the healthcare setting including the patient. This included raising concerns and following protocols. Patients needed to be educated and empowered to facilitate their involvement.
	Peer support.	Having contact with peers undertaking a similar journey and learning from each other was important to feel safe. This could include expert patient, shared

the interactions patients have with the health system.		medical appointments and developing ward based ‘communities.’ This enhanced feeling safe because patients following a similar journey were deemed likely to have similar questions but may have different willingness to ask/share, and different opportunities to ask and receive answers. Through this, it was assumed that healthcare professionals would be able to provide better care to patients as a product of them having a better understanding of it.
	Point of contact.	Having a single point of contact (someone that could be contacted or reached out to at any time to answer questions or to help them get *“back on track”* if things go wrong) was important for patient to feel safe; this was a concept that was repeatedly revisited.
	Visible leadership.	Observing the presence of visible leadership made participants feel safe. This meant observing a healthcare professional (nurse, doctors or healthcare assistant) assuming a *“calm presence”* in a busy environment, displaying leadership and control over the environment. They perceived an environment to feel safe if there was *“someone existing calmly in that space.”* This was the role ‘Matron’ was once seen to fill.
	Human interaction.	Having *“human”* interactions with staff made them feel safe; this meant having a *“chat,”* rather than procedural, formulaic or robotic communication. Through this, participants felt they would be involved in their care, rather than being told what to do, and would have their concerns and questions addressed. The concept of a *“bus stop chat”* was raised, an informal conversation that could set the scene for the interactions going forward.
	Open doctor-patient conversations.	Having open conversations between doctors and patients made participants feel safe. This was characterised by equal, balanced, two-way communication, with information flowing in both directions, equal and balanced.

In session two, the whole group generated and agreed upon a single list of values. The photograph in Figure 6.12 shows the final list of values synthesised by the group.



- CLEANING + INFECTION CONTROL
- CONFIDENCE IN STAFF.
- HUMAN RELATIONSHIP.
- INFRASTRUCTURE FOR REPORTING CONCERNS.
- SUPPORTING ~~PATIENTS~~ ME TO SUPPORT MYSELF
- PARTNERSHIP ~~DURING~~ THROUGHOUT MY CARE.
- COMMUNICATION TO ME, WITH ME + ABOUT ME.
- ENVIRONMENT + FACILITIES.

Figure 6.12: Photograph of final list of values

This was accomplished by exploring the relationships between the individual groups' values; to achieve this, the similarities and differences between values were discussed. Many of the values were deemed similar or related and just expressed in different ways; it was also possible to combine some values or subsume them within values that were considered higher order. The definitions of each of the final values, synthesised from the audio-recorded discussion, are reported in Table 6.6.

Table 6.6: Values and their definitions

Value	Meaning
Cleaning and infection control	The hospital being cleaned and the existence of and adherence to infection control protocols were important for participants to feel safe. This value was identified by all three groups and unanimously agreed upon.
Confidence in staff	Participants needed to have confidence in staff to feel safe. Having confidence in the staff meant feeling that the staff knew what they were doing and tasks/procedures were completed properly. This value was recognised as a high-order concept that encompassed several of the values defined by the individual groups including: • Attitudes and characteristics of staff • Visible leadership • Staff knowledge and skills • Level of experience It was agreed that these were aspects of care that must be seen, heard and felt in order for participants to have confidence in them, and hence represented associated behaviours that were translated into the afternoon sessions.
Human relationships	Establishing human relationships with staff and other patients was important for participants to feel safe. This meant experiencing genuine interactions, free from distractions, between patients and staff, as well as other patients, and acknowledgment of the patient as a person. Staff interactions could be with any and all staff, including cleaners. Establishing human relationships was seen as an important way for staff to acknowledge and value the patient as a person who they are trying to get better, and not simply a clinical problem or interesting condition.
Infrastructure for reporting concerns	Having an infrastructure in place for anyone to be able to report concerns, both those specific to the patient and more generally, was important for participants to feel safe. Patients needed to know how to report and needed to feel supported to do so, feeling wary of the consequences of reporting upon their care. The role of friends, families and carers in reporting concerns was discussed at length. One group had prioritised this as a value, saying having friends, family or carers being able to report concerns when necessary made them feel safe. Some agreed with this, saying if the concern was urgent or they needed an advocate, they would like friends and family to be able report on their behalf. Others preferred to maintain independence and responsibility; they were also concerned by how staff may react at their interference and consider them a nuisance for their lack of professional expertise. It was therefore agreed that infrastructure and procedures should allow anyone, including friends, family or carers, to be able to report concerns.
Supporting me to support myself	Being supported in taking a role in their own care was important for participants to feel safe. This meant staff developing patients' independence, confidence and self-esteem, and engaging and activating them, so that they could have autonomy, ownership and

	responsibility in their care. In practical terms this meant patients being able to take a role in their care in hospital (e.g. self administration of medications), take responsibility for the postoperative recovery *("I have done the operation, it is your job to get better")* and be prepared to care for themselves at home.
Partnership throughout my care	Being a partner in their care, throughout all stages, was important for participants to feel safe. This meant being involved in care processes, knowing what to expect and understanding what was going to happen to them. This encompassed the spectrum of care, from start to finish, including aftercare. Continuity of care was important to this. The support and partnership values were considered closely associated, and were linked via the communication value.
Communication to me, with me and about me	Communication of a variety of different methods was important for participants to feel safe. This encompassed dialogue within the system, within the therapeutic relationship and between teams. Continuity in communication to the patient (i.e. speaking to the same person) was important; patients particularly identified the importance of having a single point of contact or knowing whom to contact if things are not happening that should be happening. Communication of information about the patient (to the patient and others), including letters and other administration, was necessary for joined up communication across settings of care and different teams, and not being lost within/remembered by 'the system.'
Environment and facilities	The building and its facilities (including infrastructure for accessibility) were important to participants to feel safe. This also included health and safety procedures (e.g. fire safety). This concept was not identified during the nominal group exercise. Instead, this concept featured within the group discussion; it was agreed that this was an important concept that was yet to have been mentioned and was therefore included as a value at this stage.

6.7.3 Session 3 and 4 – Behaviour Generation

For each value, participants defined behaviours or the specific actions that would need to seen, heard or felt from patients, staff and the NHS Trust for the value to be fulfilled. Each value and the associated behaviours are presented in the subsequent tables and discussed in turn. The behaviours were synthesised from the written ideas in the World Café and from the audio-recorded presentation and discussion of the behaviours in the large group session. Any discussion, disagreement or clarifications around the behaviours for each value are reported. Those behaviours that were subject to discussion or disagreement are marked by an asterisk (*) and a brief overview of these points is given below each table.

6.7.3.1 'Value: Cleaning and infection control'

Patient	**Staff**	**NHS Trust**
Patients need to: • Ensure family and friends visiting are aware of and follow the hygiene recommendations. • Be respectful of the space you are living in in hospital (e.g. leaving toilets and other facilities in a clean condition). • Not be afraid to encourage staff to perform hand hygiene or wear gloves appropriately*. • Understand the infection control procedures around their medical devices (e.g. central line, cannula); what should the patient and staff be doing with it, and what should they look out for. • Maintain their own personal hygiene, where able.	Staff need to: • Encourage patients to maintain their own personal hygiene. • Be responsible for disposing their own clinical waste. • Engage in hand hygiene. • Ensure there is visible evidence of the ward being cleaned. • Clean mattresses between patient, • Monitor the cleanliness of toilets between patient uses. • Offer patients the ability to clean their hands, particularly before mealtimes, especially if you are being cared for in bed. • Healthcare staff to interact with cleaners and porters to augment their prominence and role in team, to enhance their morale and standards. • Show who has responsibility for	The trust needs to: • Provide facilities for patients to main their own personal hygiene. • Make who has responsibility for cleaning and infection control publicly visible. • Ensure the availability of soap and alcohol hand gel. • Ensure cleaning is visible and cleaners are seen regularly on the ward. • Encourage staff to have pride over their clinical areas and make cleaning more than *"just a service"* *. • Encourage respect for cleaners, porters and other staff who monitor and manage cleaning and infection control*. • Audit cleaning standards.

	cleaning and infection control. - Inspect and monitor cleaning and infection control standards.	

Table 6.7: 'Cleaning and infection control' behaviours

6.7.3.1.1 Behaviour: Not be afraid to encourage staff to perform hand hygiene or wear gloves appropriately.*

Patients encouraging staff to perform hand hygiene or wear gloves created some debate amongst the group. One doctor had experience of working in a trust where staff wore badges that said, *"Ask me if I have washed my hands."* The patient expressed that they would never want to do that. Other methods were discussed which may be more acceptable; this included staff *"calling each other out"* in order to create a visible culture where this kind of checking behaviour is deemed acceptable. One of the nurses reported doing this on the ward, as well as reminding staff to roll up sleeves and remove watches; she reflected that doctors did not like being challenged in this way. Nonetheless, the nurse tries to facilitate good hygiene practice amongst staff, and also visitors to the ward. In another trust, a member of staff was given a bottle of alcohol hand gel to carry on the ward round and it was their job to ensure the hand hygiene of the team in between each patient; this worked well and was not confrontational. Individual staff also develop their own practices like using the alcohol hand gel at the end of the patient's bed whilst saying hello to them; this created routine for the doctor but also allowed the patient to witness the doctor being compliant.

6.7.3.1.2 Behaviour: Encourage staff to have pride over their clinical areas and make cleaning more than "just a service"/Encourage respect for cleaners, porters and other staff who monitor and manage cleaning and infection control.*

Patients and staff reflected that 'back in the day' ward cleaners were part of the ward staff. There was clear ownership of the ward throughout the nursing hierarchy and cleaners, and ownership over the cleanliness of the environment. This was compared to a phenomenon a patient was familiar with from The Royal Navy, known as 'esprit de corps'; this was a sense of pride and mutual loyalty generated by personnel being on a small ship, living and working together, that they carried forward as an entity. In outsourcing the cleaners, it was suggested that ownership is lost and it becomes *"just a service."*

6.7.3.2 'Value: Confidence in staff'

Patient	**Staff**	**NHS Trust**
	Staff need to: • Look professional • Be knowledgeable points of contact, regardless of your role. • Have good communication skills, including listening skills. • Inform patients about what to expect with their care. • Honour the duty of candour: acknowledge when they do not know the answer, and be open and honest (including when things go wrong). • Ensure the right member of staff manages a particular situation or aspect of care (e.g. a pharmacist does the drug review). • Display appropriate demeanour and confidence. • Be professional. • Look professional (appearance)*. • Use good non-verbal communication (e.g. eye contact, body language, facial expression, smiling, eyes). • Possess with right skills, experience and expertise.	The trust needs to: • Provide adequate staffing infrastructure (e.g. to ensure the quality of elective care is not affect in the event of emergencies). • Provide appropriate staffing (in relation to expertise) and sufficient senior support for juniors to seek advice.

Table 6.8: 'Confidence in staff' behaviours

6.7.3.2.1 Behaviour: Look professional (appearance).*

The consultant surgeon initiated a conversation around how staff dress and the impact this has upon perception of professionalism. Reflecting that two of the patients had attended the co-design workshop wearing ties, he asked how they thought a doctor should dress; the patients were divided. Some of the older patients wanted to see the doctor *"clean, neat, tidy, shaven, not smell of sweat or alcohol, clean shoes, prefer with a tie."* The lack of a tie was seen as a sign of the world *"dumbing down."* They also preferred to see a nurse in a uniform; *"pyjama suits"* or scrubs were confusing to patients, as whilst they are good for hygiene, it was deemed difficult to determine who is who. They wanted a nurse to look recognisable and be wearing a uniform; of note, the colour of the uniform (denoting role and seniority) contributed to feelings of safety. Younger patients felt that appearance was not important; they would not mind seeing a doctor in jeans, provided they were clean. It was knowledge and quality of interaction that was more important in their assessment of professionalism; outfits were not of importance if the staff member introduced themselves and their role. Another older patient also agreed with this perspective and said that it was the human relationship (interaction, facial expression, eyes) that was most important. In the end, consensus was reached that a healthcare professional's interaction, confidence and demeanour were likely to be more important in the assessment of professionalism.

6.7.3.3 'Value: Human relationship'

Patient	**Staff**	**NHS Trust**
Patients need to: • Speak up and notify staff if they think something has been missed or gone wrong, • Be honest with doctors and nurses if you think something is wrong (without fear of care being affected). • Encourage patient-patient relationships as sources of support and humanity. • Be aware that healthcare professionals are humans too*.	Staff need to: • Have telephone contact with patients to notify patients about appointments and investigations; consistency between staff is appreciated. • Notifying patients of results of procedures or investigations as soon as they are available. • Encourage patient interactions. • See the patient as a person or human. • Address the patient's personal concerns and not just order tests/tick the boxes. • Encourage patients to be involved in their own handover*.	The trust needs to: • Provide a regular point of contact and continuity in that relationship (e.g. specialist nurse). • Fund systems that encourage patient communications e.g. patient self-help groups*. • Provide adequate staffing and time in clinics to address concerns and questions. • Provide for patients to interact e.g. dining areas. • Facilitate peer-to-peer interactions*.

Table 6.9: 'Human relationship' behaviours

6.7.3.3.1 Behaviour: Be aware that healthcare professionals are humans too.*

To have a human relationship, patients needed to recognise that healthcare professionals are not robots, that they are also human and have their own problems and concerns. It was important though that staff be mindful of the extent to which you are having a bad day should be declared; this may have implications of patient confidence in staff and professionalism.

6.7.3.3.2 Behaviour: Encourage patients to be involved in their own handover.*

It was suggested that patient can and should be involved in their own clinical handover, if they are competent to do so. The patient becomes more than just a name, number or condition, handover is patient centred, it would encourage communication and team spirit, and could be fun. Additionally, it would involve patients in their care so that they may identify and learn things they do not know. One patient had experience of this, and it is a concept that is often used in the maternity setting.

6.7.3.3.3 Behaviour: Fund systems that encourage patient communication e.g. patient self help groups/Facilitate peer-to-peer interactions.*

Patients discussed the value of interaction and relationships with other patients through self-help groups. The information gained through these interactions helped in managing long-term conditions and the relationships made them feel safe; it was comforting, for example, to know that others had had similar experiences to you.

6.7.3.4 'Value: Infrastructure for reporting concerns'

Patient	**Staff**	**NHS Trust**
Patients need to: • Complete feedback forms where appropriate. • Ensure they know who to talk to in order to raise concerns.	Staff need to: • Ensure feedback forms are available. • Inform patients who they can talk to in order to raise concerns. • Report concerns, including whistle blowing. • Seek support from unions to deal with concerns. • Keep the patient informed so that they understand care and can identify concerns. This includes checking the accuracy of clinic letters. • Encourage communication between ward manager, staff and patients to ensure direct resolution of concerns and avoid escalation. The ward manager needs to: • Introduce themselves directly to the patient every morning, identifying themselves as the person who is responsible and the main point of contact. • Be visible on the ward.	The trust needs to: • Ensure feedback forms are more readily available. • Raise awareness of the Patient Advice Liaison Service (PALS). • Provide a point of contact within the administration team. • Provide a patient with the means to report back when information in letters is incorrect, or if concerns about care or condition as an outpatient (e.g. Virtual clinic email and telephone number)*. • Provide patients with a helpline to contact if there are concerns about safety. • Provide a response to feedback or complaints raised by patients. • Create multiple pathways to raise concerns (e.g. forms, managers, phone apps).

Table 6.10: 'Infrastructure for reporting concerns' behaviours

6.7.3.4.1 Behaviour: Provide a patient with the means to report back when information in letters is incorrect, or if concerns about care or condition as an outpatient (e.g. Virtual clinic email and telephone number).*

Patients wanted a means to deal with errors or concerns that arose in the outpatient setting. This included errors in information in clinic letters, incorrect discharge from outpatient care, failure to have investigations/appointments amended, or concerns about their condition or care more generally. Errors in clinic letters included wrong account of the discussion, wrong factual information (e.g. right instead of left foot) or wrong instructions to primary care (where a patient reported a GP was more likely to believe the letter than listen to the account of the patient). There was no apparent mechanism for amending this or seeking clarification; it was possible to speak to a secretary, but this was often useless. One patient had experience of using PALS to successfully amend an incorrect discharge from outpatient follow up.

Virtual clinic was described by the surgical consultant as a way that could solve this issue. This currently exists as a way to follow up test results with patients if they do not need to be seen in person. In addition, there is a virtual clinic telephone number and email address, which are responded to within four days. This was deemed to work well for addressing errors, updating your healthcare professional or getting back in touch, or reporting new concerns developed at a later date.

6.7.3.5 'Value: Supporting me to support myself'

Patient	**Staff**	**NHS Trust**
Patients need to: • Vocalise their concerns and expectations. • Engage with the staff that are caring for them. • Engage in peer-to-peer support, where offered. • Take initiative with their own care e.g. notifying staff if they want to self administer medications. • Be part of the *"bridge"* from hospital to home. • Look after themselves if they are able (e.g. washing, tidying up)*. • Educate themselves by asking for advice (e.g. from GP, who could provide printouts from online). • Educate themselves by seeking information online.	Staff need to: • Encourage patients to vocalise their concerns and expectations. • Explain what is happening to the patient and use it as an opportunity to teach them about their diagnosis and required care. • Explain to patients, in every clinical encounter, what is being done and why. • Develop a rapport with patients and treat them like human beings, • Create opportunities for patients to care themselves (e.g. facilitating self administration). • Advertise the services of charitable sector that can provide support to patients.	The trust needs to: • Provide an environment that enables patients to vocalise their concerns and expectations. • Be flexible to allow care to be more patient-centred (i.e. less regimented around how patients can loom after themselves, self administer medications). • Create peer support networks, particularly for preoperative patients. • Define the roles of patients and staff during an inpatient say, so that staff are empowered to encourage patients to look after themselves *("No, you can brush your teeth, this is something you can do for yourself")*.

	- Use the admission as a window of opportunity to change lifestyle habits and make change.	

Table 6.11: 'Supporting me to support myself' behaviours

6.7.3.5.1 Behaviour: Look after themselves if they are able (e.g. washing, tidying up)/ Define the roles of patients and staff during an inpatient say, so that staff are empowered to encourage patients to look after themselves

Staff noted that some patients *"take advantage"* of being in hospital; they are able to look after themselves but choose not to because there are staff that are able to help. Staff wanted a way to be able strongly encourage patients to take care of themselves and feel empowered to tell them they can and should complete a task themselves, without fear of being complained about or reprimanded.

6.7.3.6 'Value: Partnership throughout my care'

Patient	**Staff**	**NHS Trust**
Patients need to: • Take an active role in their care, including being honest about how they are feeling. • Invite family members to participate as 'carers' on the ward*. • Ask questions about their care. • Use specialist nurses, points of contacts and hotlines to discuss your care. • Take responsibility for their care e.g. knowing when to get their prescriptions. • Use their autonomy to have an equal relationship with staff.	Staff need to: • Encourage patients to be honest about how they are feeling and enquire about their ideas, concerns and expectations. • Involve patients in their decisions. • Explain treatment and diagnosis. • Give patients enough information so that they are properly informed. • Give patients clear considerate discharge summaries and clinic letters; allow patients to define how they are named*. • Try to ensure continuity of staff caring for the patient. • Give a good handover of the patient where	The trust need to: • Provide specialist nurses, points of contact and hotlines (and not just for cancer). • Create a better relationship and communication between patient, secondary care, primary care and social care. • Develop shared health records; these must be secure and confidential.

	continuity of staffing is not possible. - Be accessible (e.g. having a specialist nurse available by phone). - Assigning roles and responsibilities for tasks to different members of the team and informing the patient. - Ensure the multidisciplinary team know who is doing what.	

Table 6.12: 'Partnership throughout my care' behaviours

6.7.3.6.1 Behaviour: Invite family members to participate as 'carers' on the ward.*

It was recognised that the charity in the Trust is implementing a role for carers on the ward. If patients have a family member who normally cares for them at home, they can come out of visiting hours, are identified as a carer and they provide for the patient. This creates partnerships between staff and a patient's extended support network, creates continuity in their care, and also allows the nurses to provide care to those who need it.

6.7.3.6.2 Behaviour: Give patients clear considerate discharge summaries and clinic letters; allow patients to define how they are named.*

Patients wanted the opportunity to choose how they are named or addressed in clinical correspondence. They particularly disliked 'flowery' language *("this pleasant lady"* or *"this nice gentleman"*).

6.7.3.7 'Value: Communication to me, with me and about me'

Patient	**Staff**	**NHS Trust**
Patients need to: • Provide an up to date contact number • Keep contact details (e.g. address) up to date so that letters are received correctly. • Inform the hospital of their individual communication needs including translation (e.g. bring a friend or family member to translate, or inform the hospital that they need one). • Feel able to ask who someone is*.	Staff need to: • Liaise with patient's social support networks. • Engage in active communication (e.g. eye contact, active listening, acknowledging, nodding head, turning away from computer in clinic consultations)*. • Give respect to patients and their colleagues. • Maintain the patient's privacy and dignity (e.g. remembering that bedside curtains are not doors, considering location of private conversations). • Clarify whom patients want information shared with before speaking in front of others. • Introduce themselves when they see a patient and wear a name badge*.	The trust needs to: • Provide patients with a point of contact. • Ensure patients have access to right telephone numbers. • Use functional and streamlined administration systems. Ideally this would include linking electronic health records to primary care, district nurses, other hospitals and social care services. • Make links with social support and other external facilities/services. • Send outpatient letters with the correct information (date, time and place). • Provide information in other language. • Adopt a 'Hub and Spoke' model for clinics to enhance communication with the patient*.

Table 6.13: 'Communication to me, with me and about me' behaviours

6.7.3.7.1 Behaviour: Engage in active communication (e.g. eye contact, active listening, acknowledging, nodding head, turning away from computer in clinic consultations)/Adopt a 'Hub and Spoke' model for clinics to enhance communication with the patient.*

Patients spoke at length about their experiences in clinics; doctors were described as sat at a computer and not looking away from it when talking to the patient. This was a surprise to some of the General Surgery doctors who operate a 'Hub and Spoke' model in their clinics. In this, the doctors work out of a central room, where they look at notes and investigation results, before going to see the patient who is already in a room. Patients were mostly used to a more traditional model where patients were called to a room where doctor is already sat at desk and behind a computer; they described rarely being looked at, except during a physical examination. The surgical doctors preferred the Hub and Spoke model as it allows teams to discuss cases between them, and junior staff to seek advice from their seniors; they were unaware that this model, which is not a universal model throughout the Trust, may be preferable for patients in terms of improving communication.

6.7.3.7.3 Behaviour: Feel able to ask who someone is/Introduce themselves when they see a patient and wear a name badge.*

Patients found that staff often forgot to introduce themselves; they also did not always feel able, or know when or how they could interrupt to ask. Name badges facilitated this to an extent but not everyone has them or they are not easy to read or visible. Patients needed to feel able to ask and staff needed to make sure they introduce themselves on every interaction.

6.7.3.8 'Value: Environment and facilities'

Patient	**Staff**	**NHS Trust**
Patients need to: • Help look after facilities and keep the environment clean. • Take responsibility for their own cleanliness.	Staff need to: • Encourage patients to look after themselves (e.g. personal hygiene). • Identify team members who have responsibility for providing patients with facilities (e.g. toothbrush). • See the environment through the patient's eyes (e.g. Is the water jug within the patient's reach?) • Make patients feel comfortable in the environment.	The trust needs to: • Provide water fountains in all public-waiting areas. • Ensure the hospital is clean. • Provide seats for visitors. • Provide facilities like toothbrush/toothpaste for emergency admissions. • Ensure adequate staffing levels to maintain the quality of the environment. • Display signage and maps that are clear and up to date. • Ensure there is adequate lighting for security at night. • Ensure maintenance of facilities. • Provide the ability for patients, visitor and staff to

		report maintenance issues. - Provide common rooms, dining rooms and tea/coffee facilities for patients and visitors*.

Table 6.14: 'Environment and facilities' behaviours

6.7.3.8.1 Behaviour: Provide common rooms, dining rooms and tea/coffee facilities for patients and visitors.*

Some patients felt that facilities like a common room or dining room were a nice extra but not a patient safety issue. Staff felt that this might be relevant to patient safety, as it encourages socialisation with others (important if you have no visitors) and sharing of experiences. It could enhance openness and discussion about issues of concern and encourage group reporting or speaking up behaviours. Additionally it could be seen as an intervention for enhanced recovery, encouraging patients to mobilise and thereby reducing risks related to low mood, venous thromboembolism, chest infections and gastro-intestinal dysfunction (particularly constipation).

6.7.4 Naming of the co-designed product

Participants were asked to consider how the end product, the final list of values and behaviours, could be named. Words like *"foundation," "compendium"* and *"blueprint"* were proffered in summarising the values and behaviours, reflecting that these were considered to be fundamental underlying principles for delivering safe healthcare. The behaviours were focussed upon different aspects of care to make you feel safe (e.g. communication, cleanliness, infrastructure). This ultimately led to agreement upon, *"The Foundations of Safe Care."*

6.7.5 Application of the co-designed product

"The Foundations of Safe Care" was thought to be a useful product for patients, staff and the Trust, in a range of circumstances. The potential applications are summarised in Table 6.15.

Application	**Explanation**
Improvement	The concepts covered within the values and behaviours were considered to be common sense, basic ideas that may already be known, but needed prompting. Whilst it does not necessarily *"reinvent the wheel,"* as one participant said, the 'product' offers a *"practical quality improvement"* opportunity for improvement in areas where gaps lie, by providing reminders to staff about things to do or things to tell patients. Emphasis was placed on the fact that it responds to what patients want and what the trust can do: "*You say, we do"* or *"what you want, what we can do, and what have we done to show".* This was compared to Costa Coffee which reports, "You said, we did" style feedback.
Information or raising awareness	It would be possible to "*distil all of this into one compact little package"* and *"The Foundations of Safe Care"* could take the form of a booklet or leaflet for staff and patients, which could be left at the bedside, to raise awareness of what matters to patients to feel safe and act as a reminder of the behaviours and commitments of patient, staff and the Trust in achieving this. Other suggestions for its application included as an introductory film, the basis of a "chat" with the ward manager, information to be displayed on TVs in waiting areas, or welcome information you are given on arrival to show what the trust does or is striving for.
Staff training	Other suggestions for its application included as a training tool for staff. It would be used to educate staff about what matters to patients to feel safe and the expectations of the behaviours and commitments of patient, staff and the Trust in achieving this.

Table 6.15: Applications for "The Foundations of Safe Care"

Importantly it was deemed to have potential for application to many clinical disciplines and to sites beyond Imperial College Healthcare NHS trust:

> *"It needn't just be this trust either… the general principles are going to apply to everybody… its like a coverall."*

One participant raised the important issue of planning for implementation, determining the success of implementation, and monitoring of adherence and impact. This will be considered in the discussion.

6.7.6 The Foundations of Safe Care

The following figures demonstrate the final product, *"The Foundations of Safe Care."* Figure 6.13 presents *"The Foundations of Safe Care"* in an accessible one-page format, outlining the key values that define what matters to patients to feel safe in hospital.

NHS
National Institute for Health Research

The Foundations of Safe Care

For patients, by patients

The Foundations of Safe Care are essential values that define what matters to patients to feel safe when they are in hospital

Cleaning and infection control
I feel safe when the hospital is clean and infection control procedures are followed

Environment and facilities
I feel safe when the environment and facilities are accessible and maintained

Infrastructure for reporting concerns
I feel safe when there are processes for everyone to be able to report concerns

Having confidence in staff
I feel safe when I am looked after by staff I have confidence in

Establishing human relationships
I feel safe when I am acknowledged as a person in all my interactions

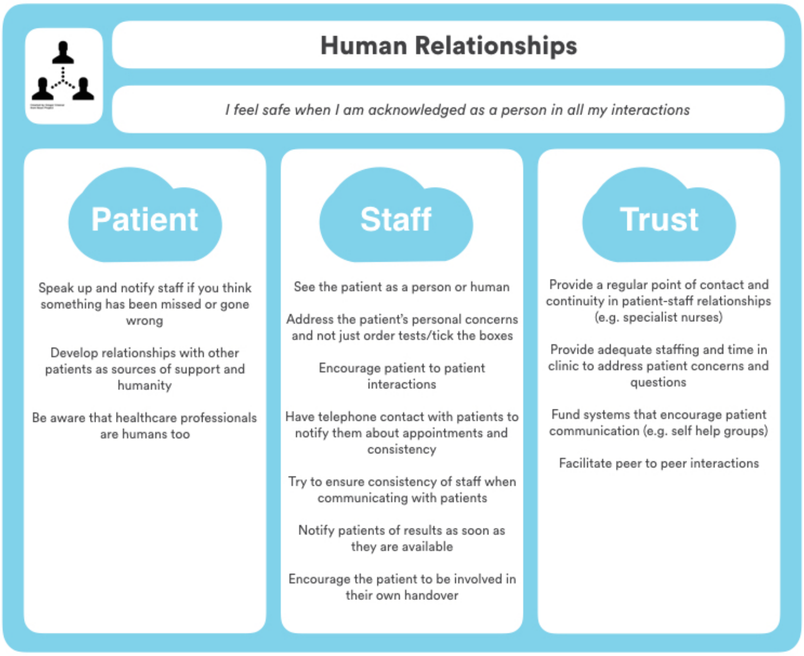
Supporting me to support myself
I feel safe when I am supported to take ownership and responsibility for my care

Partnership throughout my care
I feel safe when I am involved in my care throughout all stages

Communication to me, with me, about me
I feel safe if you communicate information to me, with me about my care and to others

Figure 6.13: "The Foundations of Safe Care"

Figure 6.14, as an illustrative example, expands this one-page format, to also show the associated behaviours, illustrating what patients, staff and the trust need to do in order for patients to feel safe in hospital.



Human Relationships

I feel safe when I am acknowledged as a person in all my interactions

Patient

Speak up and notify staff if you think something has been missed or gone wrong

Develop relationships with other patients as sources of support and humanity

Be aware that healthcare professionals are humans too

Staff

See the patient as a person or human

Address the patient's personal concerns and not just order tests/tick the boxes

Encourage patient to patient interactions

Have telephone contact with patients to notify them about appointments and consistency

Try to ensure consistency of staff when communicating with patients

Notify patients of results as soon as they are available

Encourage the patient to be involved in their own handover

Trust

Provide a regular point of contact and continuity in patient-staff relationships (e.g. specialist nurses)

Provide adequate staffing and time in clinic to address patient concerns and questions

Fund systems that encourage patient communication (e.g. self help groups)

Facilitate peer to peer interactions

Figure 6.14: Values and Behaviours example

These are presented for each in value in Appendix 14.

6.7.7 Evaluation of the co-design workshop

At the end of the workshop, the participants offered verbal and written feedback. This is summarised in Table 6.16.

Theme	**Comments**
Organisation and running	Participants were positive about the organisation and running of the workshop. Some improvements were suggested including involving patients in co-designing the workshop and the agenda, and involving managers as participants in the workshop. Practical suggestions included smaller group sizes for the large group sessions and running the workshop over two days to allow more time for the World Café behaviours exercise of session 3.
Participant discussions	Participants enjoyed listening to each other, open and honest discussion around a difficult topic, interesting conversations and the opportunity to hear conflicting views. Through the discussions, some participants gained new knowledge about patient safety.
Co-design	Co-design was felt to be an appropriate way to approach patient safety. The exercises made it *"easier"* for the patient participants to be involved. The format and the use of different group technique and findings of previous research with patients were praised. Patients and healthcare professionals enjoyed the opportunity to interact with one another about their experiences and insights about safety and good care, particularly from the patient perspective. The range of staff members, the presence of a consultant, and range of ages contributed positively to the outcome.
Patient involvement	Importantly, patients felt they had been given a *"platform to raise issues and be listened to,"* air their views and to contribute to *"a valuable piece of work."* It was regarded as *"real PPI (patient public involvement),"* unlike the usual *"talking shops with tick box agenda[s]."* the workshop was considered to reach a rich and productive outcome.
Perceived clinical impact	Staff commented on the *"clear clinical applicability"* and felt that it had the *"scope to make a huge difference in clinical practice."* Immediate desire to apply the outcomes of the workshop was reported. For one member of staff, hearing the patient perspective was eye opening and motivating: *"This was very though thought provoking. This has empowered me to make changes to my ward environment and disseminate what I have learnt."*

Table 6.16: Summary of co-design workshop feedback

6.8 Discussion

This study aimed to create a practical product that could be used by Imperial College NHS Trust to introduce and apply the patient conceptualisation of patient safety or *patients' safety*, as explained in Chapter 4 by The Patients' Safety Theory. I have identified that the patient conceptualisation of patient safety is not acknowledged within current patient safety processes (Collier et al., 2016) and demonstrated that healthcare professional conceptualisations are rooted in systemic, academic and health policy definitions of patient safety, with some limited understanding of and empathy for the patient perspective of patient safety. I therefore recognised the need to practically apply TPST and translate the patient conceptualisation into everyday patient safety practice. In doing so, this aims to broaden the current patient safety paradigm to consider the concept of feeling safe as well as being safe, and raise awareness amongst healthcare professionals about the patient conceptualisation of patient safety and the roles and responsibilities fundamental to this. Experience based co-design (EBCD) was used as a methodology, and The Macmillan Values Based Approach, which has used co-design to improve experiences in cancer care, along with commentary on organisational values and behaviours, provided a useful framework and inspiration for translating TPST.

Through the EBCD process *"The Foundations of Safe Care"* has been developed for the surgical setting; it translates the patient conceptualisation of patient safety into a practical product for implementation in the NHS. From the patient perspective, it describes their values for *patients' safety* or what matters to patients to feel safe. It defines eight values: Cleaning and infection control, environment and facilities, infrastructure for reporting concerns, having confidence in staff, establishing human relationships, supporting me to support myself, partnership through my care, and communication to me, with me, about me.

Bringing these values to life are co-designed practical actions or behaviours; these state the particular experiences required for patients to feel safe. The values and behaviours have been presented within a practical product, which presents a broader conceptualisation of patient safety; this should be implemented in clinical practice in order to raise awareness of the patient conceptualisation of patient safety and the roles and responsibilities fundamental to this, and thus lead to patients feeling safe in hospital.

Beyond this, *"The Foundations of Safe Care"* has applications to quality improvement, education and awareness, and staff training. Whilst this has been developed for Imperial College NHS Trust, *"The Foundations of Safe Care"* could be implemented more broadly across the NHS to introduce the broader definition of patient safety, developed through this thesis, that values and incorporates the patient perspective system wide.

6.8.1 The Foundations of Safe Care: A new patient safety paradigm

To this point in time, patient safety practice has remained firmly rooted in the *"clinical risk paradigm"* (O'Hara and Isden, 2013). This has two main implications. Firstly, patient safety processes focus on the concept of being safe (and not necessarily on feeling safe), thus placing more value on the physical, objective and measurable aspects of patient safety (Mollon, 2014), rather than the patient experience of patient safety. Secondly, any existing emphasis on the patient experience has related to measurement using tools such as the Picker Survey and the Friends and Family Test in the UK, the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) in the USA, and the Australian Patient Experience Survey. These tools, however, do not specifically focus on patient experiences of patient safety.

The Patient Measure of Safety (PMOS), goes some way to addressing this criticism of these tools by allowing patients to feedback on their experience of safety of their care (Giles et al., 2013; McEachan et al., 2014). However, PMOS is subject to limitations as it is based upon the Yorkshire Contributory Factors Framework (YCFF), which describes factors that contribute to patient safety incidents (Lawton et al., 2012); these in turn are derived from reviews of studies conducted with healthcare professionals. It therefore proffers the patient perspective, but somewhat limited within the clinical paradigm. This means that PMOS may not truly reflect the views or experiences of *patients' safety* and is therefore limited in its ability to truly represent the patient perspective of patient safety.

The Health Foundation (O'Hara and Isden, 2013) has advocated for a *"new risk 'paradigm'"* that identifies, uses and understands the perspectives of patients and the public. This includes recognising and embracing more expansive views of safety, including both the presence of safety (feeling safe) and harm, as well as involving patients in the design of services to ensure they feel safe physically and psychologically (Illingworth, 2013). The Beryl Institute, a global community of practice for improving patient experience, also advocates this:

> *"In a commitment to shift how healthcare works, we must dedicate ourselves to the broader human experience, honouring both the patient experience at its core and the experiences of all driving and supporting healthcare's efforts every day"* (Wolf, 2017).

The experiences of patients and the power of their stories should and are starting to be harnessed for improvements in their care (Flott et al., 2017).

"The Foundations of Safe Care" achieves these goals by truly harnessing patient experiences and views. It achieves recognition of the patient experience of patient safety by using design science to translate TPST, an abstract theory of feeling safe, anchored in patient experience and context, into a practical product. In this way, it responds to the repeated calls for a shift in patient safety to value the perspective of the patient.

"The Foundations of Safe Care" is unique; to date, no other study or intervention has dedicated itself to the patient experience of feeling safe. This true recognition of the patient perspective would not have been achievable with continued use of existing models/theories of patient safety or tools for the measurement of safety, and would only be partially achievable through the use of PMOS.

Implementation of *"The Foundations of Safe Care"* will provide recognition of the patient perspective of patient safety and improve the patient experience of feeling safe in hospital. More significantly, by having identified, understood and used the perspective of the patient within a tool for clinical practice, *"The Foundations of Safe Care"* represents the beginning of a new and more expansive paradigm for patient safety in the NHS which values both patient and healthcare professionals perspectives.

6.8.2 The Foundations of Safe Care: Implementation

Having developed a tool for a new patient safety paradigm that will value the patient perspective of patient safety, I briefly consider methods that could be used for implementation in clinical practice, particularly focussing upon the discipline of implementation science.

6.8.2.1 Implementation science

Implementation science developed to address the need for research to more directly impact public health (Bauer et al., 2015) and to bridge the gap between science and practice (Meyers et al., 2012); it is the study of methods to promote the uptake of research findings, evidence-based practices or interventions into clinical policy and practice to improve quality, safety and effectiveness (Gray-Burrows et al., 2018). Adoption of research findings, practices and interventions often requires behaviour change within organisations and amongst healthcare professionals (Bauer et al., 2015; Gray-Burrows et al., 2018). As the product of research findings and a potential intervention for the improvement of patient safety and patient experience, which will require system and behaviour change, implementation science is therefore relevant for the application of *"The Foundations of Safe Care"* in clinical practice.

6.8.2.2 Barriers and facilitators to improvement and implementation

There are various barriers and facilitators that must be addressed for successful implementation of new interventions; these have been widely discussed in the literature (Dixon-Woods et al., 2012; Allcock et al., 2015; The Health Foundation, 2015). Barriers include intervention, individual, organisational, and system wide factors (The Health Foundation, 2015). In addressing how to accelerate change, The Health Foundation specifically identify the key behavioural barriers to successful action (Allcock et al., 2015); these map to existing work on behaviour change, the COM-B model for behaviour change, which describes the role of capability, opportunity and motivation in behaviour change (Michie et al., 2011).

Allcock et al. (2015) additionally identify seven success factors for changes in the NHS, which broadly address the barriers described in The Health Foundation (2015) and Dixon-Woods et al. (2012). Importantly, implementation science can provide systematic approaches to identifying and addressing barriers and facilitators to system change (Bauer et al., 2015).

6.8.2.3 Tools for improvement and implementation

The Sustainable Improvement Team[14] offers evidence-based quality improvement support, with a range of tools for improvement and change. The Change Model provides a framework to enable effective and sustainable change (Sustainable Improvement Team, 2018); it has eight components that should be considered when planning and implementing change, including ‘Improvement tools’ (Boaden et al., 2008). They recommend The Model for Improvements (Langley et al., 1996) as an example of a model for developing, testing and implementing changes that lead to improvement. This is based upon the Plan-Do-Study-Act (PDSA) cycle (NHS Improvement, 2018), which allows testing of changes on a small scale, before building on learning to inform wider implementation.

Another example is The Quality Implementation Framework (QIF), derived from 25 implementation frameworks, which focuses on specific actions or the ‘how to’ of high quality implementation (Meyers et al., 2012). QIF highlights 14 critical steps within four phases, seen in Figure 6.15; it demonstrates that implementation can be viewed as a temporal series of linked steps to be addressed to enhance the likelihood of implementation.

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[14] https://www.england.nhs.uk/sustainableimprovement/

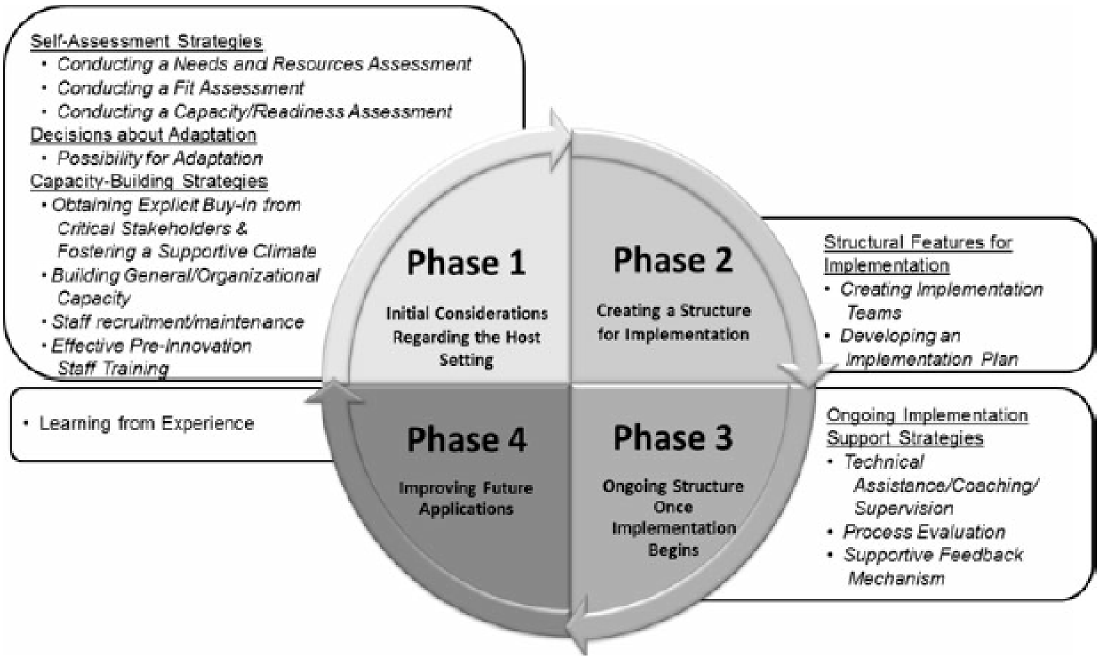

Figure 6.15: The Quality Implementation Framework
Taken from Meyers et al. (2012)

6.8.2.4 Application of implementation science to "The Foundations of Safe Care"

Overall, considering the implementation approaches discussed, QIF addresses barriers and incorporates facilitators to change in a systematic and practical way. *"The Foundations of Safe Care"* could be implemented in clinical practice guided by the tools recommended by The Sustainable Improvement Team (The Model for Improvement, PDSA cycles) or using the Quality Implementation Framework (Meyers et al., 2012). These tools should therefore guide future implementation.

Patient and public involvement (PPI) in implementation, like patient involvement in research, should also be considered. Unlike patient involvement in research, there is little guidance on PPI roles in implementation and it remains relatively novel. Gray-Burrows et al. (2018) sought to generate and define the potential roles for PPI in implementation research and proposed that patients could be involved in planning, implementing, sharing and using research knowledge. As a product that is for patients and fundamental to the patient experience of patient safety, it would be necessary to involve patients in the implementation of *"The Foundations of Safe Care."*

6.9 Strengths and limitations

The strength of this study is the co-design approach. Co-design enables collaborative working on patient safety by bringing their perspectives together. Too often, patient and public involvement happens by involving patients separately in a group, analysing the data, and then feeding back to staff who design the interventions and solutions. This means patients do not interact in this process and cannot give their viewpoint. This EBCD approach supports the creation of practical co-designed solutions, the opportunity for staff to learn about changes they can make to their practice, as well as the opportunity to educate patients (e.g. informing patients that some of the things they need in order to feel safe are already happening). Whilst the product is aimed at the patient perspective of patient safety and focuses on their experiences of feeling safe, by also including healthcare professionals it prevents the notion of 'them and us.' By healthcare professionals hearing from patients first hand about their experiences and what matters to them to feel safe, the process increases empathy. This in turns increases the likelihood of the acceptance of the product and its subsequent success in improving the patient experience.

There were limitations to the organisation and duration of the workshop. Firstly, a full day workshop was a significant commitment for patients and staff to make; however, achieving attendance over more than one day or multiple days could be challenging. Secondly, due to the number of values identified, the volume of work in the afternoon to define the associated behaviours was significant. The participants had a lot of opinions, and as such it felt hurried. Nonetheless, a meaningful product was created; however, in the future, the workshop would benefit from being run over a minimum of two days.

The study result is limited to the clinical setting of surgery; however, it could be tested for its relevance to other clinical settings, or the same method applied to other settings, to compare the results. The product could have been strengthened by the inclusion of managers within the co-design workshop. To further improve the co-production aspect, patients could have been involved earlier in the design of the workshop and, in the future, could be involved in the delivery of the workshop, the development of the product external to the workshop, and subsequent implementation and evaluation.

A significant challenge to the organisation of the workshop was getting healthcare professionals to attend. It relied on them having time off or being released from clinical time; this required buy in from senior managers. For future work, it will be important to have the support of the NHS Trust to encourage staff attendance by endorsing the event and putting in place the infrastructure to allow people to be released from clinical time.

6.10 Reflection

I recognise that my use of experience-based co-design departs from the processes and stages described by the Point of Care Foundation (i.e. not undertaking observation, no use of a trigger film, no use of healthcare professional experiences). However, there are there are many examples of the EBCD process being adapted (Donetto et al., 2014); I am aware, though, that this is a potential criticism of this study. I, importantly, learned the value of co-production and co-design in ensuring the patient perspective is meaningfully and actively engaged; its application to the patient conceptualisation of patient safety, which is currently not valued or represented in patient safety policy, was therefore fundamental to translating the findings of this body of research into practice.

6.11 Conclusion

This study has used experience-based co-design to translate TPST into clinical practice. *“The Foundations of Safe Care”* is a practical product that applies the patient conceptualisation of patient safety to clinical practice by translating an abstract theory of feeling safe into values, that remind us what matters to patients to feel safe, and behaviours, that prompt us to consider the actions necessary to bring those values to life. This work addresses calls to embrace more expansive views of patient safety; it has taken theoretical understanding of the patient conceptualisation of patient safety and, through experience based co-design, delivered a practical product for the NHS to support the expansion of our existing patient safety paradigm to value the perspective of the patient.

Chapter 7: Discussion and conclusion

In this concluding chapter, I revisit the thesis research questions. The key findings of the studies are summarised; this is followed by a discussion of the limitations of this body of work overall, the relative strengths and limitations of each study having been discussed in the relevant chapter. I propose the implications of this work for future research, clinical practice and NHS policy, and finally offer some concluding remarks on this doctoral research.

7.1 Thesis aims

This thesis recognised that, despite extensive calls to develop a more expansive and inclusive patient safety paradigm that values the patient voice, the patient safety movement continues to situate the patient in the clinical patient safety paradigm. Strategies that have been employed to involve patients may not be meaningful or accessible to the patient, and fail to acknowledge the patient conceptualisation of patient safety. Chapter 1 explored the background to patient safety, patient involvement in patient safety and the barriers to patient involvement. In doing so, it set out an argument for establishing a stronger narrative around patient safety that accepts the perspectives of different stakeholders. Given the lack of understanding about different stakeholder conceptualisations of patient safety, this thesis therefore aimed to understand and acknowledge different conceptualisations of patient safety in order to define a new paradigm in patient safety that identifies, understands and uses the perspective of the patient, thereby truly putting the patient in patient safety.

This thesis used qualitative methods (justified in Section 1.9 and Chapter 2) to achieve the thesis aim. As in qualitative research, the thesis aims were further delimited by two main research questions:

1. How is patient safety conceptualised?
2. How can patient and healthcare professional conceptualisations of patient safety be reconciled in a new paradigm?

These main research questions were supported by the following sub-questions:

1. What is the patient conceptualisation of patient safety?
2. What is the healthcare professional conceptualisation of patient safety?
3. How are the patient and healthcare professional conceptualisations of patient safety similar or different?
4. How do patient and healthcare professional conceptualisations of patient safety vary between different clinical specialties in secondary care?

The use of the term paradigm denoted the aim to develop new theory in relation to conceptualisations of patient safety and subsequently an approach to patient safety that would value both the patient and healthcare professional perspective. The thesis was structured to answer these research questions in turn.

In Chapter 3, a systematic review, using meta-study methodology, synthesised the current qualitative evidence exploring patient and healthcare professional perspectives of patient safety, and began to compare patient and healthcare professionals conceptualisations of patient safety. Expanding upon the findings of Chapter 3, Chapters 4 and 5 used constructivist grounded theory to explore patient and healthcare professional conceptualisations of patient safety in acute medicine for the elderly, elective surgery and maternity, and developed explanatory theories for their conceptualisations of patient safety. The newly developed theories were compared to each other, as well as to existing patient safety theories and models, and the findings of Chapter 3. Finally, in order to translate the findings of Chapter 4 into clinical practice, Chapter 6 used experience-based co-design to create a practical product that could be introduced and applied in clinical practice in order to expand the current patient safety paradigm and thereby truly value the patient perspective of patient safety.

7.2 Summary of findings

The key findings will be discussed as they relate to each research question and its associated sub-questions.

7.2.1 How is patient safety conceptualised?

Chapters 3, 4 and 5 were designed to address this research question. The thesis addressed both healthcare professional and patient conceptualisations of patient safety. ‘Patient safety’ was an unfamiliar term for patients and they struggled to offer a definition of it (Chapter 3, Chapter 4); they named types of safety including physical, emotional or psychological safety (Chapter 3). Patients were able to discuss patient safety more broadly when asked to describe their own experiences, to reflect upon safe or unsafe care, or to explain what made them feel safe or unsafe (Chapter 3, Chapter 4); they were also able to discuss factors that contributed to patient safety from their perspective.

In the meta-study (Chapter 3), eighteen factors contributing to the conceptualisation of patient safety were defined and organised into a theoretical framework for the conceptualisation of patient safety. Nine of the factors were unique to patients, with predominance towards those related to communication, relationships and professional qualities, and a particular focus upon the psychological feeling of safety.

The theoretical framework created through meta-synthesis thematically grouped factors named by patients and healthcare professionals as contributing to their conceptualisation of patient safety. Whilst this provides a useful summary of how patient safety is conceptualised more broadly, and where there are differences between the patient and healthcare professional perspective, the framework has limitations. Firstly, the themes are purely descriptive; from this it was not possible to draw conclusions about the relationship between themes and factors and develop an explanatory theory of the conceptualisation of patient safety. Secondly, the framework is based upon heterogeneous studies, both geographically and in terms of clinical context. Six out of thirteen studies were based in primary care, with the remainder focussing upon disparate aspects of secondary care. The meta-study is therefore significantly based within primary care. Overall, these limitations pose restrictions upon the potential generalisation and application of the meta-study framework to the NHS, and the extent to which it is applicable to primary care, secondary care and other care settings remains unclear.

The purpose of the meta-study was as a broad exploration of the current evidence on conceptualisations of patient safety; importantly, it was a starting point to identify areas that warrant further study. As such the findings do not heavily influence the subsequent studies and their findings, and the focus upon primary care does not limit the meta-study in guiding the subsequent research within this thesis. Therefore, despite the limitations, this study has provided an important broad understanding of perceptions of patient safety and subsequently a focus for the following qualitative studies, by highlighting the psychosocial aspect of patient safety as necessary to explore. Given the inclusion of broad clinical settings in Chapter 3, at this stage, I recognised it was necessary to develop in-depth context specific information about conceptualisations of patient safety. I therefore decided to focus the subsequent studies upon secondary care in order to be able to understand and then apply conceptualisations of patient safety in a specific context.

The importance of the concept of feeling safe in the patient conceptualisation of patient safety was confirmed by the qualitative study in Chapter 4, where patients (within aucte medicine for the elderly, elective surgery and maternity) referred to patient safety as a subjective state, feeling safe or feelings of safety, invoked by experiences in their care.

The Patients' Safety Theory (TPST) was developed and describes *patients' safety*, or the patient conceptualisation of patient safety, as a subjective experiential phenomenon or a feeling that arises from the patient experience of active and passive processes undertaken by or with actors within their care. Importantly, *patients' safety* was argued as existing at the intersection between patient safety and patient experience, as two facets of quality. Overall, TPST is an empirically bound theory, developed using perspectives from a range of clinical specialities; it provides an important new contribution to understanding the patient conceptualisation of patient safety and gives support to the need to develop more expansive models and patient safety practices that include the patient conceptualisation.

In the meta-study (Chapter 3), healthcare professionals defined patient safety objectively, commonly adhering to definitions seen in academia and health policy. In the theoretical framework developed in the meta-synthesis, four factors were unique to staff, with a predominance towards factors that were tangible and measure (e.g. skills, training, workload, resources). The Clinical Patient Safety Theory (TCPST) developed in Chapter 5 explains the healthcare professional conceptualisation of patient safety as doing no harm, optimising care and the physical environment, and realising the patient's perspective of patient safety, through the practical accomplishment of the system (an NHS Trust or the NHS more broadly), staff, patients, and friends, family and carers. Healthcare professionals elaborated on their definitions of patient safety by describing the key processes fundamental to the practical accomplishment of their conceptualisation of patient safety.

Discordant to the findings of Chapter 3, TCPST explains the healthcare professional conceptualisation of patient safety to be broader and more complex than is currently defined in policy; healthcare professionals appreciate different lenses in patient safety, including the patient lens, which they recognise as focussing on experiences of care and feelings of safety. Therefore, whilst the healthcare professional conceptualisation of patient safety is influenced and constrained by system-defined patient safety, healthcare professionals also conceptualised a component of patient safety that is distinct to the systemic and clinical patient safety paradigms discussed in Chapter 1.

7.2.2 Comparing patient safety conceptualisations: patients and healthcare professionals

Narrative (Chapter 1) and systematic (Chapter 3) reviews of the literature suggested that patients and healthcare professionals have different conceptualisations of patient safety, although some overlap was identified between factors contributing to the conceptualisation of patient safety (Chapter 3). Factors within the theoretical framework demonstrated (Chapter 3) that healthcare professionals conceptualised patient safety objectively, whilst patients conceptualised patient safety more subjectively, with the concept of feeling safe particularly significant to their conceptualisation.

More thorough and direct comparisons of the patient and healthcare professional conceptualisation of patient safety were possible through the qualitative studies in Chapter 4 and 5. Patients had some awareness of the objective components of patient safety, paralleling academic definitions; however, these were not forefront in their minds and had to be elicited through direct questioning (Chapter 4). TPST had some similarities to existing clinical patient safety models; however, these models do not consider the patient-defined outcome of feeling safe or the range of experiences that patients implicate in their conceptualisation of patient safety.

When comparing The Patients' Safety Theory (Chapter 4) and The Clinical Patient Safety Theory (Chapter 5), the healthcare professional conceptualisation of patient safety seems more similar to the patient conceptualisation than first thought from the narrative (Chapter 1) and systematic (Chapter 3) reviews. Whilst healthcare professionals were strongly influenced by the current one-sided patient safety paradigm (with a preoccupation for objective outcomes and being safe), healthcare professionals also recognised a different patient perspective of patient safety and their role in realising this. Whilst this empathy existed, there remained a lack of awareness and understanding as to how to fully realise this aspect of patient safety. Many of the roles and responsibilities named by healthcare professionals as fundamental to the practical accomplishment of system-defined patient safety, also matched the processes named by patients, which must be experienced in order for them to feel safe. However, healthcare professionals were seemingly unaware of this and lacked understanding of what matters to patients to feel safe.

7.2.3 Comparing patient safety conceptualisations: clinical setting

TPST and TCPST are explanatory grounded theories developed from the combined lived experiences of patients and healthcare professionals respectively across three specialties. However, there was some evidence of similarities and differences in conceptualisations of patient safety between the different clinical specialty settings: acute medicine for the elderly, elective surgery and maternity.

There was recognition that patient safety may be different across different clinical settings (Chapter 5), and there were both experiences (Chapter 4) and roles/responsibilities (Chapter 5) described that were considered to be 'specialty specific' and therefore differences arose between specialties. However, many of these experiences and roles/responsibilities were considered 'generic,' meaning they could feasibly arise in any clinical specialty setting; this could be tested through theoretical sampling. There was, however, more concordance between specialties in Chapter 5, with the majority of categories of roles/responsibilities for patient safety being saturated.

Overall, conceptualisations of patient safety varied at a more granular level (within conceptual categories and their subcategories which describe specific types of experience/roles and responsibilities). Because of this, the differences did not impact the development of TPST (Chapter 4) and TCPST (Chapter 5) at a theoretical level. However, these differences are important in the practical application of the theories, where it is important understand the specific types of experience, or role/responsibility implicated in conceptualisations of patient safety.

7.2.4 Reconciling conceptualisations of patient safety

Using experience-based co-design (Chapter 6), *"The Foundations of Safe Care"* was developed for the elective surgical setting. This translated the patient conceptualisation of patient safety (as explained by TPST in Chapter 4) into clinical practice by describing what matters to patients to feel safe (their values) and the practical actions (behaviours) that patients must experience in order to feel safe. *"The Foundations of Safe Care"* has been formally presented as a practical product and tool for quality improvement, education, training, awareness and, importantly, the clinical practice of a patient safety paradigm that values and incorporates the patient perspective.

This practical application of TPST broadens the patient safety paradigm within which we currently operate, by incorporating the patient conceptualisation of patient safety into everyday patient safety practice, and expanding definitions of patient safety to consider the concept of feeling safe as well as being safe. It also raises awareness amongst healthcare professionals about the patient conceptualisation of patient safety and the roles and responsibilities fundamental to realising this.

7.3 Thesis limitations

This section offers a broad critique of the thesis; the limitations of each individual study have already been described in the relevant chapters.

7.3.1 Study participants

In the qualitative studies (Chapter 4 and 5), study participants were limited to patients, doctors, and nurses or midwives across three clinical specialties. As previously described, there was concordance, generally, across these groups in relation to the broad conceptualisations of patient safety; therefore, the addition of further clinical specialties may not have significantly changed the resulting theories. However, at a more granular level it was evident that the experiences, roles and responsibilities related to the conceptualisations of patient safety varied across setting, professional identity, and discipline. Therefore future work should include more specialities and more professional disciplines in order to fully understand conceptualisations of patient safety across the NHS.

Additionally, the perspectives of friends, family and carers may be key in specialties where patients are unable to be their own advocate (e.g. paediatrics/neonatal care, intensive care, emergency medicine, psychiatry, medicine for the elderly). In these specialties, there may be a different conceptualisation of patient safety, accounting for the lack of power and capacity of the patient.

The thesis has also not considered the perspective of higher-level managers (e.g. policymakers, organisations, NHS trust boards, clinical directors). A systematic review has considered the roles of managers in patient safety, which were classified as being strategy-centred, data-centred or culture-centred (Parand et al., 2014); however, from brief literature review, there has not been any focus upon management conceptualisations of patient safety. Future work should also consider the perspective of Trust management, as implementing change in patient safety practice ultimately requires their engagement and input, and a shift in patient safety paradigm needs to incorporate and value the perspectives of all relevant stakeholders. This could be achieved through further qualitative work; alternatively, an assessment could be made about how NHS Trusts perceive patient safety through examination of their public facing vision, mission, quality strategies, patient safety priorities and 'Sign up to Safety' commitments

7.3.2 Sample size

The samples sizes used for the qualitative studies were sufficient to achieve saturation (Guest et al., 2006). Additionally, the participants were diverse in their gender, age, ethnicity, clinical work experience, or experience as a patient. However, the studies were limited to single central London teaching hospital. It is unclear if the findings could be more broadly generalised to other specialties, type of hospital, location of hospital and ultimately to the NHS as a whole. Future work should therefore consider to what extent the theories developed are applicable to other specialities, hospitals and the NHS more broadly.

7.3.3 Use of constructivist grounded theory

The use of constructivist grounded theory as the qualitative methodology for Chapter 4 and 5 was discussed and justified in Section 4.3.3. In particular, it was used for its fundamental aim of constructing dense explanatory theory of the phenomenon under study, which could be practically applied for managing a problem (Corbin and Strauss, 2015). The knowledge created through constructivist grounded theory, with its relativist ontology, is considered an interpretation of the researcher. Furthermore, the resulting theory is considered one of many possible interpretations of the data; this means that a different researcher, with the same data, may create a different interpretation of the findings (Charmaz, 2006; Willig, 2013). This is an accepted outcome within constructivist grounded theory; however this, of course, has implications for the findings of this body of research, as the theories created are only my interpretation of patient and healthcare professional conceptualisations of patient safety.

There are mechanisms, however, within this thesis that serve to counter this concern; the principles of rigour have been applied. Firstly, the methodological and analytical decisions have been made clear to the reader (dependability). Secondly, I have acknowledged my biases and my role as the researcher, and engaged in reflexivity; additionally, a second coder was utilised to reduce bias and verbatim quotes ensure representativeness of the findings to the phenomenon under study (confirmability and credibility). In future work, participant involvement in analysis and theory development could further ensure the representativeness of findings; additionally, further testing of the theories within the clinical contexts from which they are developed, as well as other contexts, could test the accuracy of my interpretations.

Importantly, however, the co-design (in Chapter 6) serves to ratify the findings of the thesis to an extent. In applying and translating the theory developed in Chapter 4, the co-design process is akin to external audit or member checking to ensure representativeness of the findings (The Patients' Safety Theory) to the phenomenon under study (the patient conceptualisation of patient safety). The theory was representative of the experiences of the patient participants, thus providing support for TPST as my interpretation of the patient conceptualisation of patient safety.

7.3.4 Extent of patient and public involvement

Patient and public involvement (PPI) is now fundamental to the research process; it is recognised as best practice and often essential for funding, grants and ethics (Gray-Burrows et al., 2018). It is also thought to assist the production of higher quality research through guiding priorities and research design (INVOLVE, 2012; Brett et al., 2014), and ensures research is relevant and likely to have beneficial impact (Gray-Burrows et al., 2018). PPI is reported as having a positive impact upon research, although there is limited evidence for its effect (Brett et al., 2014). There are a range of ways in which patients and public can be involved in research; these include: identifying research priorities, leading and designing research, improving access to clinical trials, assessing patient experience, informing participants and applying research findings, training and information about research objectives, and as an expert patient (Sacristan et al., 2016).

Whilst patients participated in the qualitative study in Chapter 4, participation in research does not equate to involvement (as discussed in 1.2). However, patients have been involved applying the research findings of the thesis through generating its main output, *"The Foundations of Safe Care",* developed through a collaborative experience-based co-design process. This has the benefit of ensuring the output of this thesis is relevant and meaningful (Bate and Robert, 2006; Bate and Robert, 2007; Robert et al., 2015; Filipe et al., 2017).

The thesis, however, could have incorporated patient and public involvement to a greater extent, potentially through the use of a steering group or having a patient research partner. To achieve greater involvement, roles could have been identified for patients throughout, including underpinning the rationale for this body of work and the research questions, identifying relevant search terms for the systematic review, conducting and analysing qualitative interviews and theory development. By partnering with patients throughout the research process, the findings would be co-produced, potentially strengthening the theory developed for explaining the patient conceptualisation of patient safety (Chapter 4). In addition, patient involvement may have reduced the potential impact of my own personal biases as a clinical patient safety researcher (discussed in Chapter 2).

7.4 Implications for research, clinical practice and health policy

In this section I consider the implications of this thesis for future research, clinical practice and health policy.

7.4.1 Research

Some directions for future work have already been discussed, including undertaking further qualitative work within different specialties, type of hospital, location of hospital, and with a broader range of participants, in order to further develop and strengthen the generalisability of the theories developed. This would allow for the development of a more expansive definition of and paradigm for patient safety, which truly incorporates, and values the perspectives of all relevant stakeholders. Alternatively, the existing TPST and TCPST could be evaluated and tested in other settings to assess whether they are representative of conceptualisations of patient safety across the NHS more generally.

"The Foundations of Safe Care" requires evaluation and testing in other clinical

settings to assess whether the values and behaviours can be extrapolated to other specialties, care settings (e.g. primary care, institutional care) and geographical locations. This would allow assessment of whether this product could be applied to the NHS as a whole.

In their concept analysis, discussed in Chapter 4, Mollon (2014) recognised that there is a lack of empirical referents with which to measure and quantify feeling safe. Currently, there is no truly patient orientated measure of safety. Therefore, the qualitative findings of Chapter 4 could be used to develop an objective measure of patient safety from the patient perspective, particularly focussing on the concept of feeling safe. From this, alongside expanding the definition of and paradigm for patient safety, the findings of this thesis could form the basis of an integrated framework for the measuring and monitoring of safety that reconciles the patient, healthcare professional and other stakeholder conceptualisations of patient safety, to assess patient safety as per the expanded paradigm postulated in this thesis.

7.4.2 Clinical practice and health policy

7.4.2.1 The boundary between patient experience and patient safety

The findings of this body of research have implications for the boundary that currently exists between patient experience and patient safety. Patient experience and patient safety, as facets of quality, have often been considered as unrelated, separate *"silos"* (Flott et al., 2017). There is, however, growing recognition of a link between patient experience and patient safety (Doyle et al., 2013). The development of TPST, and subsequently *"The Foundations of Safe Care,"* has further implications for this relationship. The patient conceptualisation of patient safety is intrinsically related to their experiences of care; more specifically, in Chapter 4 I suggested that there is an overlap between patient experience and patient safety, with *patients' safety*, as a subjective experiential phenomenon, existing at the intersection between patient experience and patient safety.

Considering patient experience more closely, The NHS Patient Experience Framework, published in 2011 by the Department of Health, outlines the elements that are critical to the patient experience in the NHS. This is, in turn, based upon a modified version of the Picker Institute Principles of Patient-Centred Care, an evidence based definition of a good patient experience. The elements of each are shown in Table 7.1.

NHS Patient Experience Framework	**Picker Institute Principles of Patient-Centred Care**
• Respect of patient-centred values, preferences, and expressed needs • Coordination and integration of care • Information, communication and education • Physical comfort • Emotional support • Welcoming the involvement of family and friends • Transition and continuity • Access to care	• Fast access to reliable healthcare advice • Effective treatment delivered by trusted professionals • Continuity of care and smooth transitions • Involvement of, and support for, family and carers • Clear information, communication, and support for self care • Involvement in decisions and respect for patient's preferences • Emotional support, empathy and respect • Attention to physical and environmental needs

Table 7.1: Elements of the NHS Patient Experience Framework and Picker Institute Principles of Patient-Centred Care
(Picker Institute, 1987; Department of Health, 2011)

It is from these elements that surveys such as Picker Patient Experience-15 (PPE-15) (Jenkinson et al., 2002) and the NHS Inpatient Survey (NHS Inpatient Survey, 2018), both used for measuring patient experience in the NHS, are constructed. Considering the types of actions/processes described by patients as fundamental to feelings of safety in Chapter 4 and the values for feeling safe defined in "*The Foundations of Safe Care,*" some overlap exists between the patient conceptualisation of patient safety and the given elements of patient experience. By extension, these patient experience measures may also measure, to a degree, the patient conceptualisation of patient safety. This supports the suggestion that patient experience and patient safety are linked, with the patient conceptualisation of patient safety existing at their intersection.

It is therefore necessary to consider what implications this relationship between patient experience and patient safety has for their clinical practice. The issue in current patient safety practice is that it remains fixed in the *"clinical risk paradigm"* (O'Hara and Isden, 2013); this means that patient safety processes focus on the concept of being safe (and not necessarily on feeling safe), thus placing more value on the physical, objective and measurable aspects of patient safety (Mollon, 2014), rather than the patient experience of patient safety. The current emphasis on patient experience relates to measurement using tools such as the Picker Survey and the Friends and Family Test in the UK, which do not specifically focus on or measure the patient experience of patient safety. The findings of this thesis and specifically *"The Foundations of Safe Care,"* however, uniquely dedicate themselves to patients' safety or the patient experience of feeling safe, thereby eroding the boundaries between patient experience and patient safety that currently exist in policy and practice.

7.4.2.2 The need to develop and expand policy definitions of patient safety

In addition to TPST providing evidence of a need to broaden the patient safety paradigm to incorporate the patient perspective, TCPST strengthens this requirement. TCPST suggests that healthcare professionals practice patient safety in a way that is different to how patient safety is defined within "the system," with healthcare professionals recognising their role in realising the patient perspective in patient safety. Policy definitions of patient safety therefore need to develop and expand to reflect that patients and healthcare professionals have a broader conceptualisation of patient safety.

7.4.2.3 The use of "The Foundations of Safe Care" in practice

"The Foundations of Safe Care" should be seen as adding a new dimension to our patient safety paradigm or, indeed, shifting towards a new paradigm for patient safety that values the perspectives of all those involved, and particularly recognises the

association between patient experience and the patient conceptualisation of patient safety. It has three main potential uses in practice: setting the vision for patient safety that values the patient perspective, informing or training, and improvement of the patient experience. These will be considered in turn.

Firstly, more broadly, *"The Foundations of Safe Care"* can be seen as setting a vision for a patient safety culture within secondary care that truly values the patient perspective of patient safety. This could be displayed at the hospital entrance, on wards, at the bedside or online, to demonstrate a hospital's commitment to valuing and applying the patient conceptualisation of patient safety. This could take the form of banners or simple leaflets displaying the eight values. Beyond this, "The Foundations of Safe Care" has potential applications beyond Imperial Healthcare NHS Trust. The patient conceptualisation of patient safety and this tool have potential for application within different hospitals throughout the country and, with testing and development, within different clinical settings. Beyond this, it could be embedded within national patient safety policy, through adoption by the NHS or the CQC, thereby implementing a new patient safety paradigm that values the patient perspective. Additionally, the tool could be used for establishing outcome measures or benchmarks, which Trusts would be required to demonstrate, for the patient experience of patient safety.

Secondly, more practically, *"The Foundations of Safe Care"* could be used to raise awareness among staff about the patient perspective of patient safety. The values and their associated behaviours could be included in a leaflet, in a hospital induction training workshop, or within an e-learning package, to educate staff about what matters to patients to feel safe and what they can do in their work to achieve this. For patients, *"The Foundations of Safe Care"* and the associated behaviours could be presented as a bedside handbook or leaflet, which explains to patients not only what they can expect of the Trust and staff, but also what they can do themselves as patients to achieve the feeling of safety in hospital.

"The Foundations of Safe Care" should not be seen as replacing traditional patient safety efforts, including efforts to involve patients in patient safety as defined by the system, academia and health policy. However, it is necessary to consider approaches

for developing awareness and acceptance of and applications for this expanded paradigm. This includes developing acceptable methods, tools and interventions that engage and involve patients in patient safety in ways that are meaningful and accessible to them.

7.4.2.4 Applying the findings in clinical practice: Issues

The value and importance of the concept of feeling safe, key to the patient conceptualisation of patient safety, may be challenged in clinical practice. For example, there can be a tendency towards rejecting patient experience as too subjective and unrelated to *"'real' clinical work of measuring and delivering patient safety and clinical effectiveness"* (Doyle et al., 2013), supporting primacy over the physical, measurable aspects of safety, of being safe. Indeed, there is also a challenge to be resolved where the patient feels safe but is not physically, objectively safe. Despite these potential issues, there remains clear intrinsic value in understanding the patient experience and the patient perspective of patient safety and translating this into healthcare practice.

7.5 Personal reflections

In this penultimate section, I wish to offer some personal reflections on the impact the journey through this doctoral research has had upon my own clinical practice.

I wrestled, initially, with putting my healthcare professional lens to one side; I listened to patient accounts of patient safety with frustration, as their experience seemed so unrelated to patient safety as I had learnt and practiced it. As I discussed what I was learning with academic and clinical colleagues, as well as patients, the lack of acknowledgement of this alternative lens on patient safety became clearer and the importance of my work was reinforced. When I explained to patients what I thought I was learning, it was apparent I was representing their perspectives in my analysis and theorising. Through reflection and learning to expand my own conceptualisation of patient safety, I was able to gain valuable insight into the patient perspective of patient safety and of their care, and thus articulate an entirely new dimension to a concept so frequently talked about.

Throughout my PhD I continued to work clinically and have now returned to full time clinical practice. I find I am now more alert to the patient experience, particularly considering the impact my attitudes, behaviours, actions and communication with patients and those around me may have on the way patients feel. I talk about my research passionately to my clinical colleagues and patients, which is greeted with curiosity and recognition of its potential value to patient safety practice. After presenting the initial outcomes of this body of work to the Patient Safety Culture Committee within my local NHS Trust, I received positive feedback and there was enthusiasm for translating and implementing the concepts I have developed into clinical practice. I have realised the potential that this doctoral research has for improvement and I am excited to see the tangible impact this may have upon patient safety policy in the future.

7.6 Concluding remarks

Despite calls to develop a more expansive and inclusive patient safety paradigm that values the patient voice and the general shift within healthcare to consider what matters to the patient, the patient safety movement has remained preoccupied with the clinical, academic and health policy perspectives of patient safety. To my knowledge, this thesis represents the first in depth exploration of both patient and healthcare professional conceptualisations of patient safety, in an attempt to reconcile perspectives of patient safety and broaden the current patient safety paradigm. I have developed novel explanatory theories of the patient and healthcare professional conceptualisations of patient safety and demonstrated a clear difference between patient and healthcare professional conceptualisations of patient safety. This has supported my assertions of a need to expand the current clinical patient safety paradigm to include the patient perspective.

I have subsequently proffered the first attempt at expanding the patient safety paradigm to include the patient perspective by using experience-based co-design to create a practical product for introducing and applying the patient perspective of patient safety in clinical practice. Through future implementation of *"The Foundations of Safe Care"* I am hopeful that this thesis represents an opportunity to expand existing definitions of patient safety within NHS policy, and to broaden the current patient safety paradigm to incorporate and value the perspectives of all stakeholders, thereby truly putting the patient in patient safety. In this way, I hope the NHS embraces and implements changes in patient safety practices that focus attention on patients not only being safe, but also feeling safe.

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Appendix 1 – Categories of extracted data

- Author
- Year
- Title
- Clinical specialty/study setting including country
- Participant type
- Nature of sample including number and characteristics of participants
- Research method
- Major findings
- Definition of patient safety
- Factors contributing to patient safety
- Research problem statement
- Research purpose
- Research question
- Theoretical framework
- Researcher credentials including discipline
- Role of the researcher
- Sampling of participants including sample procedure, inclusion/exclusion criteria, attrition
- Data collection procedures including methods, timing and questions asked
- Data analysis procedures
- Conclusions and implications for further study
- Reflections upon the study

Appendix 2 – Timeline of research meetings

Day 1 04/07/2016	Review and discussion of included studies against inclusion/exclusion criteria
Day 2 28/07/2016	Assess accuracy of data extraction (methods, theory) Assess accuracy of data extraction and agreement with themes in primary studies by reading/discussing full texts
Day 3 19/08/2016	Identify second order constructs relevant to each study aim Undertake meta-data-analysis – write translations for each of the second order constructs for the study aims
Review/discussion of meta-method and meta-theory by electronic communication	
Day 4 29/11/2016	Meta-synthesis of each study aim

Appendix 3 – Meta-data-analysis example

Construct ➔ **Study ↓**	**Trust**
Van Vorst et al. (2007)	Violations in trust. Following event, loss of faith or trust in the integrity of medical professionals. Led to discontinued treatment or relations and seeking treatment elsewhere. Although loss of trust was often the outcome of a mistake, several described breach of confidentiality or trust that led to a person feeling harmed by the incident. For example: '...made me lose confidence in the doctor and nurse.' 'Doctor was visiting [my family member]. [My family member] had a visitor, not immediate family, Doctor proceeded to tell visitor intimate details about [family member].'
Scott et al. (2012)	Trust inherent in participants regardless of experiences of care, originating intrinsically and from the knowledge that healthcare professionals were sufficiently trained; also participants made excuses for the healthcare professionals when something went wrong. For example: 'I just put myself in their hands. I know that they'll get me there safely. I don't know why, I just trust people.' 'I think that when you're poorly you're at your lowest ebb. And the reassurance in knowing that you have trained people with you, yes that does make you feel safe.' 'Being safe as I say, it's just something that I assume. I mean, I presume I'm in capable hands, I presume they're capable people that will get me from A to B in a comfortable manner.' 'I think they do as much as they can with the resources that they have. I don't think they could do any more really.'
Holliman and Bernstein (2012)	Trust in one's surgeon is important: instils confidence, allows patients to exclude anxiety about potential error from their concerns, many patient used faith to engender confidence and trust. For example: 'it comes down to trust and the personal relationship with your medical staff',’ 'no, this should be your last worry thinking about that. You go on trusting the physicians' 'because the doctor was going to be

	looked after, a prayer for him and for God to watch all the staff, you know you leave it in their hands and you leave God to work in your heart, the doctor's heart and their knowledge.'
Lyndon et al. (2014)	Confidence in their infants' medical and nursing providers, getting enough information, having opportunities to 'be the parent'. If these were diminished, became worried about their infants care.
Hernan et al. (2014)	Spoke of characteristics of GPs that contribute to sense of trust (confidence in clinical competence, personal knowledge of patient). After experiencing harm in GP, trust compromised to varying degrees - some took action to rebuild, others sought care elsewhere. Those who had not experienced harm relied heavily on their trust in provider - some were forthcoming about their lack of knowledge or understanding of safety and their limited ability to accurately identify when risks could occur. Experience and expertise promoted trust – For example: 'The thing is...when you don't have confidence in a doctor either a) because of something they've done or b) because you don't know them, it makes like even that more difficult.' 'Well they're doctors and they're nurses and they've probably done it 100 times before, they all know. You just go with it, like that'd me and I'm one of those personalities to just say, "yep, yep OK". I trust that they know what they're doing.'
Rhodes et al. (2016a)	Trust in GP's competence to practice as a professional group, guaranteed by quality of education and ability. Stems from generalised trust in doctors. But trust in individual doctors derived from experience of good care.
Summary:	Patient's perceived trust as important to patient safety. Trust in healthcare professionals is inherent - both intrinsic and because of training. Trust is created by confidence In clinical competence, personal knowledge of the patient, experience and expertise. Having trust instils confidence and alleviates anxiety about error. Breaches of trust can be a cause of error. Error also causes loss of trust. When trust is lost, it is either rebuilt or patients seek a new therapeutic relationship. Patients rely upon trust due to their lack of knowledge or experience of patient safety.
Requirements for/factors contributing to patient safety:	Trust is inherent. Trust means confidence in clinical competence, personal knowledge of patient, experience, and expertise. Trust instils confidence and alleviates anxiety about error. Error damages trust. Patient lack of knowledge means they rely on trust.

Appendix 4 – Characteristics of included studies

Author (Year)	• **Purpose** • **Type of qualitative study** • **Theoretical framework**	• **Setting** • **Country** • **Impact of setting** • **Method of sampling** • **Who was sampled** • **Who was excluded** • **Impact of sampling** • **Number of participants (Age range)** • **Other characteristics**	• **Relationship between researcher and participants** • **Method of data collection** • **Impact of data collection** • **Data analysis**	**Key research questions**
Vaismoradi et al (2011)	• To explore nursing student perspectives of patient safety and the role of education • Not reported • None	• Nursing • Iran • Iranian culture • Purposive sampling based on maximum variation approach • Nursing students • Not reported • Aimed for maximum variation but only one group of students sampled • 7M, 10F (Mean age 22.6 years) • N/A	• Roles of researchers stated but no discussion of relationship and influences/biases • Face to face semi structured interview • Not stated • Thematic analysis/content analysis	What does the idea of patient safety mean to you?
Jones et al (2014)	• Not clearly stated (identifies lack of investigation of resident perceptions of patient safety • Not reported • None	• 3 academic medical centres and 3 community teaching hospitals; metropolitan areas • USA • Some generalizability • Not reported (specialties chosen for prevalence and interaction) • Residents: internal medicine, general surgery and diagnostic radiology • Not reported • Not reported • 33 (unknown) • N/A	• Unknown • Interactive group interview • Not stated • Thematic analysis	What constitutes patient safety? Risks to patient safety and factors contributing to

Dias et al (2014)	- To assess understanding of nurses of patient safety and medication errors - Qualitative exploratory descriptive cross-sectional study - None	- Basic health units and hospitals - Brazil - Limited generalizability - Unknown - Nurses - Unknown - Unknown - 2M, 18F (Hospital 25-40 years; Basic health units 30-50 years) - Average working time: 2 years 6 months (hospital), 6 years 5 months (basic health unit)	- Unknown - Individual semi structured interviews - Unknown - Thematic analysis	What do you understand about patient safety? What is a medication error to you?
Valice et al (2014)	- To assess nurses' perceptions about nursing error and its causes - Unknown - None	- ICU/CCU/Dialysis units - Iran - Limited generalizability - Purposive sampling - Nurses with at least on year of experience in critical care units of hospitals affiliated to Tehran and Kurdistan Universities of Medical Sciences - Not reported - Not reported - 5M, 7F (average 34.8 years) - 9 Bachelors degree, 3 Masters degree; average work experience 9.5 years, range 1-16 years; average critical care experience 6.3 years	- Not reported - Deep semi structured interviews - Not reported - Inductive content analysis	Can you explain the errors you have seen during your caretaking? What is nursing error in your views? Which causes have led to the occurrence of nursing error from your side?
Aveling et al (2015)	- To identify and explain obstacles to ensuring patient safety - Unknown - None	- Two hospitals across specialty and profession - East Africa - Limited generalizability - Purposive sampling - Works of differing grades, areas of practice and management responsibility, including surgery, obstetrics & gynaecology, clinical services, administration, management, paediatrics and cleaning staff - Not reported - Not reported - 57 (Unknown) - 31 in one hospital, 26 in other. 21 nurses, 16 physicians, 8 anaesthetic technicians, 10 clinical services, 2 administration	- Roles of researchers stated but no discussion of relationship and influences/biases - Semi structured interviews - Not reported - Thematic analysis	No specific questions given. Interviews covered perceptions of patient safety and challenges in delivering safe care

Kanerva et al (2015)	• To explore nursing staff perceptions of patient safety • Not reported • None	• Inpatient psychiatry; one open ward and five closed wards • Finland • Limited generalizability, culture specific but inpatient psychiatry has similar features and challenges worldwide • All 34 nurses working on morning shifts of a randomly chosen weekday contacted and invited to participate • Nurses • Not reported • Participants all work in same district in a small country – views may be culture specific • 10M, 16F (23-60 years, mean 39 years) • 1-30 years experience, mean 11 years	• Not reported but some discussion in limitations. Possible that issues not raised as assumed researcher would know them having worked in the area - to minimise, participants always asked to elaborate • Semi structured interviews • Not reported • Inductive content analysis	No specific questions give. Asked to freely describe patient safety as they see and understand it
Van Vorst et al (2007)	• To assess experiences to medical mistakes • Community-based participatory research • None	• Four rural and frontier communities • Northeastern Colorado, USA • Not reported • No specific method: self selected – adverts placed in newspapers one week before survey distribution • Rural community members • Not reported • Self-selected – may not be reflective of population • 386 (59 percent female, 38 percent male) • 86 percent believed they had experienced some degree of harm	• Not reported • Survey with open ended questions • Not reported • Qualitative analysis with combined template and editing approach	Not reported

Rathert et al (2011)	• To explore perceptions of safety (experiences of safety and influence on perception of care) • Grounded theory • None	• Acute care • USA • Not reported • Recruitment through random digit dialing; cash incentive • 18+ with hospital stay of at least one night within last 6 months or member of family with such a stay; adult patient with acute care visit, adult patient with chronic condition, parent of child with an acute care visit or family/caregiver of an adult with recent acute care or chronic health problem • Not reported • Limited to those with a phone; may under-represent the elderly; may be impacted by cash incentive • 29F, 10M (20-69 years, average 44 years) • Parents of children: 7F, 4M, mean 39 years, 29-57 years, 10 hospitals; 2) Family of adult patient: 8F, 2M, mean 44 years, 31-54 years, 8 hospitals; 3) Patient with chronic condition: 9F, 1M, mean 51 years, 33-69 years, 9 hospitals; 4) Patient with acute care visit: 5F, 3M, mean 44 years, 20-69 years, 7 hospitals	• Backgrounds of researchers given but research roles and relationships not discussed • Focus groups with semi-structured questions • Not reported • Grounded theory – inductive coding structure	What does patient safety mean to you? Good/bad experiences, critical patient safety issues, patient safety factors
Vaismoradi et al (2011)	• To explore understandings and feelings of safety during hospitalization • Not reported • None	• Medical and surgical wards • Iran • Not reported • Purposive sampling; maximum variation • Patients hospitalized for at least 3 days, with no medical contraindication and willingness to share understandings • Not reported • Broad • 11M, 8F (mean 49.57 years) • Mean length of stay 5.63 days. Specialties: kidney and liver transplant, cardiac surgery, diabetic complications, elective surgery	• Not reported • Individual semi structured interviews • Not reported • Thematic analysis	What is your understanding of patient safety? How safe do you feel during hospitalization?
Kooienga & Stewart (2011)	• To explore perceptions of error • Qualitative descriptive component of a large randomized experimental design mixed methods study • None	• Community • USA • Not reported • Follow up with a purposive sample of 30 community member who agreed to “tell their stories” about medical error. • Recruited from a larger sample of community members who participated in a randomized experiment • Not reported • Limited to those opting in after experiment who have a phone and are contactable • 19F, 11M (24-72 years)	• Not reported • Telephone interview using open ended questions • Limited rapport • Thematic analysis	Not reported

Scott et al (2012)	• To explore the concept, explanations and terms used when talking about safety in organizational care transfers • Appreciative inquiry – Discover and Dream process	• Community care – three community care teams spanning two NHS trusts, two city council resources centres and two private nursing and residential homes • United Kingdom • Not reported • From community care teams and snowball method • Age over 17 years, able to give informed consent, undertaken an organizational care transfer in the last 6 months or extensive experience • Under 18 years, unable to give informed consent, no experience of organizational care transfer • Broad sample • 10F, 4M (56-88 years, mean 76.8 years)	• Not reported • Semi structured interviews; some dyadic • Dyadic interviewing thought to enrich information • Thematic analysis	Topic guide including: Feeling safe during organizational car transfers, what safety means to participants, what would make participants feel safer
Holliman & Bernstein (2012)	• To explore perception of potential medical error • Not reported • Swiss cheese model	• Neurosurgery ambulatory clinic • Canada • Not reported • Not reported • Patients attending ambulatory clinic in tertiary referral hospital who have previously undergone craniotomy for brain tumour • Less than 18 years, not sufficiently cognitively intact, emotionally fragile, not able to speak English • Single centre • 20F, 15M (21-76 years, mean and median 51 years)	• MB was the patients' surgeon – participants may be influenced by knowing the surgeon running the research • Semi structured interviews • Not reported • Modified thematic analysis with open and axial coding; similar to grounded theory	Knowledge and perception of error
Stenhouse(2013)	• Reports on the theme of safety arising from a large narrative study of being a patient on an acute ward • Narrative study • None	• Inpatient psychiatry • Dundee, UK • Interviewed away from home – safe place • Not reported • Capacity to give informed consent, on ward one week or more • Risk of violence to researcher, being on a criminal section of the Mental Health Act • Single centre • 6M, 7F (18-65 years)	• Not reported • Unstructured interviews at two and six weeks post discharge • Allowed participants to construct their own narratives how they choose, producing accounts that are close representations of their experience. Rapport developed in first interview facilitated deeper exploration during second. • Narrative analysis	What is it like to be a patient on an acute inpatient psychiatric ward?

Lyndon et al (2014)	• To explore conceptualization of safety in NICU • Parallel convergent mixed methods study using questionnaire, interviews and field observations. Constructivist grounded theory. • None – theory developed	• Neonatal intensive care unit • USA • Interviews away from ward – safe setting • Not reported • English speaking parents over 18 years with infants admitted to a single NICU at least 72 hours prior to approach • None • Single centre, small sample, limited to English speaks • 35F, 11M (19-42 years, median 35 years). • 46 completed questionnaire, 14 were interviewed	• Investigators have clinical backgrounds in obstetric nursing (AL, KW), midwifery (CJ), and NICU/Paediatrics (KMF, LSF). Participants informed the data collectors (AL, CJ) were academic research nurses. Risk of social desirability bias – risk of impact of criticism on care but not observed. • Observations/field notes on ward, questionnaire with free text answers, individual semi structured interviews • Variety of means to gain information • Thematic analysis and constructivist grounded theory	Not reported
Herman et al (2014)	• To identify perceptions of patient safety • Not reported • None	• General Practice • South-west Victoria, Australia – rural • Not reported • Self selected for study through local community heath or allied health organisations. Received $50 voucher. • Frequent users of general practice – chronic condition, repeat medication, older people, mothers with children • Not reported • Varied sample • 14F, 12M (mean 59 years) • 18 repeat prescription, 11 high BP, 10 high cholesterol, 10 arthritis. Mean visits in last year: 12	• Not reported • Semi structured focus groups • May have gained more information through individual interviews • Thematic and iterative approach, Narrative analysis and constant comparative method to generate a coding structure	Nor reported
Lovink et al (2015)	• To explore feelings and experiences of safety during haemodialysis • Descriptive exploratory study • Feeling safe – monitoring and blunting model	• Outpatient haemodialysis – one academic and one clinical hospital • Netherlands • Interviews in private rooms (before, during or after) or at home – allows greater discussion • Purposive sampling. Homogenous group but maximal variation sough: academic/clinical hospital, gender, years of treatment, co-morbidities • Over 18 years, haemodialysis for more than half a year, receiving as an outpatient, adequate command of Dutch • Home haemodialysis, nocturnal haemodialysis, inpatients, low cognitive state, other life threatening condition, those who have decided to stop • Homogeneous sample • 5M, 7F (39-82 years) • Patient characteristic described in depth	• ML - dialysis nurse in a participating hospital and PhD Student. Others - Lecturers/professors in nursing. Tension of dual role. Not involved in recruitment or informed consent. Interviews outside of work hours and did not wear a uniform during interviews. Emphasised separation between roles at beginning of interview. Recruitment by direct caregivers may be coercive. • Individual semi-structured interviews • Not reported • Content analysis	How do you experience your safety during your haemodialysis treatment? Prompts: patient definition of safety, causes of (un)safe feeling, perceived risks

Rhodes et al (2016)	• To explore patients' understandings of safety in primary care • Not reported • None	• Primary care: five general practices in two primary care trusts • Northwest England, UK • Interviews at participants home • Letters of invitation sent to members of Patient Participation Group and through waiting room advertising; further recruitment by snow-balling techniques. • Not reported • Not reported • People with multi-morbidities over-sampled, as group known to be vulnerable to safety incidents. • 14M, 24F; 2 (21-30), 13 (31-50), 8 (51-60), 15 (61-80) • Patient characteristics described in depth	• Roles of researcher and relationship with participants not addressed. • Semi-structured interviews • Not reported • Constant comparison, by one person (PR)	Interviews began with broad questions. Topic guide generated from pilot interviews but as exploratory, topics mostly introduced by interviewees.
Rhodes et al (2016)	• To understand hos individuals make sense of their experiences of primary care and how that reshapes conceptualisations of patient safety • Not reported • Concept of sensemaking	• Primary care: five general practices in two primary care trusts • Northwest England, UK • Interviews at participants home • Letters of invitation sent to members of Patient Participation Group and through waiting room advertising; further recruitment by snow-balling techniques. • Not reported • Not reported • People with multi-morbidities over-sampled, as group known to be vulnerable to safety incidents. • 14M, 24F; 2 (21-30), 13 (31-50), 8 (51-60), 15 (61-80) • Patient characteristics described in depth	• Roles of researcher and relationship with participants not addressed. • Semi-structured interviews • Not reported • Constant comparison, by one person (PR)	Interviews began with broad questions. Topic guide generated from pilot interviews but as exploratory, topics mostly introduced by interviewees.
Collier et al (2016)	• To explore how patient safety and harm is defined • Video reflexive ethnography • Sociocultural perspective on patient safety inspired the underpinning theoretical approach	• End of life care • Australia • Filming in places of every day practice • Purposive and snowball sampling; recruited from specialist palliative day hospital and large Australian tertiary acute hospital • Patient living with life limiting illness, family member of patient as nominated by patient. Over 18 years, able to speak English, regarded as poor prognosis using the 'surprise question, able to give informed consent • Not reported • Designed to be as inclusive as possible • 29 (27-89 years) • 13 consented to be filmed. Respiratory, gynaecology, surgery, acute medicine, renal, orthopaedics, haematology/oncology.	• AC is an experienced community palliative care nurse. Carried out fieldwork as part of doctoral studies. As an ethnographer, AC took a reflexive approach by acknowledging how data collection and analysis might be influenced by the clinical experience of caring for dying people • Semi structured interviews, field interviews (spontaneous dialogue), ethnographic field notes, videoreflexive sessions • Filming in every day practice • Video reflexive ethnography	Can you tell me about what makes this place safe or unsafe?

Appendix 5 – Patient interview topic guide

Version 1.0 – 13th April 2015

1. Let us begin by talking a bit about you…
Prompts:

- Age
- Employment
- Education
- Experience in hospital – reason for admission, duration of stay

2. What do you know or understand about 'patient safety' in hospital?
Prompts:

- Definition
- Risks in hospital: infection, DVT, falls, incorrect medication, delay, complications, mistakes
- Publicity
- Regulation of safety e.g. CQC

3. Is 'patient safety' something that is important or unimportant to you?
Prompts:

- Healthcare as a safe thing – is it safe? Do you feel a need to worry?
- Feeling safe in hospital – do you feel safe in hospital?
- Interest
- Concern – about yours or others safety
- Primary concerns when in hospital
- Responsibility – who?
- Maternity – whose safety is of greatest value, mother or baby?

4. Do you think patients can be involved in 'patient safety' in hospitals?
Prompts:

- Ways you have seen
- Ideas of ways
- Interest in involvement
- Ability
- Responsibility – who?

5. How much are you told about patient safety?
Prompts:

- Healthcare professionals – do they discuss it with you?
- Posters – have you seen any posters?
- Media – what do you know from media?
- What was said – by healthcare professionals or others?
- Encouragement to be involved/aware

6. How much can and do you ask about safety?
Prompts:

- Asking questions
- Reporting problems
- Barriers and facilitators

7. What does your relative/informal care think about patient safety?
Prompts:

- Their opinion
- Their role
- How are they/can they be involved?
- Have they discussed safety with your or healthcare professionals?
- Have they asked questions?
- Have they reported problems?

Appendix 6 – Patient information sheet

Patient Information Sheet

Version 6 08/09/15

Qualitative exploration of patient and relative/informal carer perceptions of patient safety and patient involvement in safety

Researcher: Dr Emily Barrow
Supervisors: Professor Ara Darzi, Dr Susannah Long, Dr Stephanie Archer

About the study
Patient safety is becoming increasingly important in the NHS to healthcare professionals and patients. There is growing interest in the role that patients can play in improving patient safety.

We want to talk to the public, current inpatients, patients who have been discharged from hospital, carers/relatives of current inpatients and members of patient safety groups. We will do this by conducting individual interviews with participants.

We are interested in understanding more about your views, experiences and understanding of what patient safety is in hospitals. We also want to explore the roles that patients may be able to play in safety and how you think you could be involved.

This study forms part of a PhD research project, being undertaken by Dr Emily Barrow at Imperial College London.

Why have I been invited to take part?
You have been invited to take part because you fall into one of the following groups:

- Member of the public
- Current inpatient (acute medicine or surgery, elective surgery, maternity)
- Previous inpatient (acute medicine or surgery, elective surgery, maternity)
- Member of a patient safety group or pressure group
- Nominated relative, friend or informal carer of a current inpatient.

Do I have to take part?
No. It is completely up to you to decide whether you want to take part. If you decide not to take part, it will not affect your care in any way

What will happen if I take part?
We will arrange a time and place that suits you for the interview to take place. It can take place on hospital or university premises or by telephone. You will be asked some questions about your experiences, views and understanding of patient safety in hospital. You will also be asked how patients can be involved in safety in hospitals. We will take some notes during the discussion and this will also be audio recorded. The interview will last approximately 45 minutes. If you are an inpatient, we will ask to interview you on discharge. We will also ask you to nominate a relative, friend or informal carer important to your care to interview. You can be interviewed alone or together. We will only interview your nominated individual once.

Is taking part anonymous and confidential?
Yes. All information gathered will be treated as confidential. Paper records will be kept securely in a locker in a locked office. Electronic data will be stored on a password protected computer at Imperial College and backed up regularly. No personal identifiable information will be used in any reports arising from this research; you will be using unique study ID number.

I do not speak English. Can I still take part?
Yes. You can have an interpreter to help you.

What are the possible benefits of taking part in this study?
There may not be any direct benefit of you taking part in this study. The information we get from this study will help us to understand more about peoples views on patient safety and improve the way that we involve patients in patient safety in the hospital.

What are the possible risks of taking part in this study?
There is a small chance that talking about the issues raised in this interview may make you feel a bit worried. If so, we can put you in contact with somebody who will be able to help you with your concerns. If you report serious incidents or unreported events, in the interests of safety, these may need to be reported to the appropriate clinical manager. If you have been affected by incidents that have happened at the hospital, we can put you in contact with the hospital PALS service.

What will happen after this study?
We hope that the results will allow us to understand more about different perceptions of patient safety and the ways patients can be involved in patient safety. The results will be published in journal articles. If you wish, we can send you a summary of the results of the study when they are ready.

Can everyone take part?
We may not be able to talk to everyone who wants to take part in the study.

Can I stop taking part?
You can decide to stop participating at any time without giving a reason by informing the researcher. If you would like to withdraw from the study, please contact Dr Emily Barrow.

You can stop the interview at any time; just tell the researcher.

What if there is a problem?
We do not expect that this study will cause harm or worry for anyone taking part. If you have concerns, inform the researcher.

The study has been reviewed and approved by NRES Committee North West – Greater Manchester South (REC Reference 15/NW/0694).

Who can answer my questions about this study?
You can talk to the researcher about any questions or concerns you have about this study:

Dr Emily Barrow
Email: e.barrow@imperial.ac.uk
Contact Telephone: 02033121995

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator: Dr Emily Barrow (e.barrow@imperial.ac.uk). The normal National Health Service complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial AHSC Joint Research Compliance Office.

Appendix 7 – Consent form

Consent Form
Version 4 08/09/15

Qualitative exploration of patient and relative/informal carer perceptions of patient safety and patient involvement in safety

Name of Researcher: Dr Emily Barrow
Supervisors: Professor Ara Darzi, Dr Susannah Long, Dr Stephanie Archer

Participant ID:

Instructions for the participant:

Please read each of the sections below. In the box next to each section, please write your initials to show that you agree with what the section says.

When you have written your initials, please write your name, today's date and your signature in the spaces at the bottom.

		Initials
1	I have read and understand the information sheet for the above study (Version 6)	
2	I have had the opportunity to think about the information and to ask questions about it if I want to. If I have asked questions, I am happy with the way my questions have been answered.	
3	I understand what will happen in the interview	
4	I understand that what I say to the researcher will be recorded using a digital voice recorder and saved on a computer at Imperial College London.	
5	I understand that it is my right to refuse to take part in this study or withdraw at any time without having to give a reason. I understand that I can withdraw at any time without my medical or legal rights being affected.	
6	I have been informed that anything I say during the interview will remain completely confidential; my name will not be used, nor any other information that could be used to identify me.	
7	I understand that parts of what I say may be used anonymously in in the results of this study.	
8	I would like to receive a summary of the results.	
9	I agree to take part in this study.	
10	I agree that my own words may be used anonymously in the report of this study.	

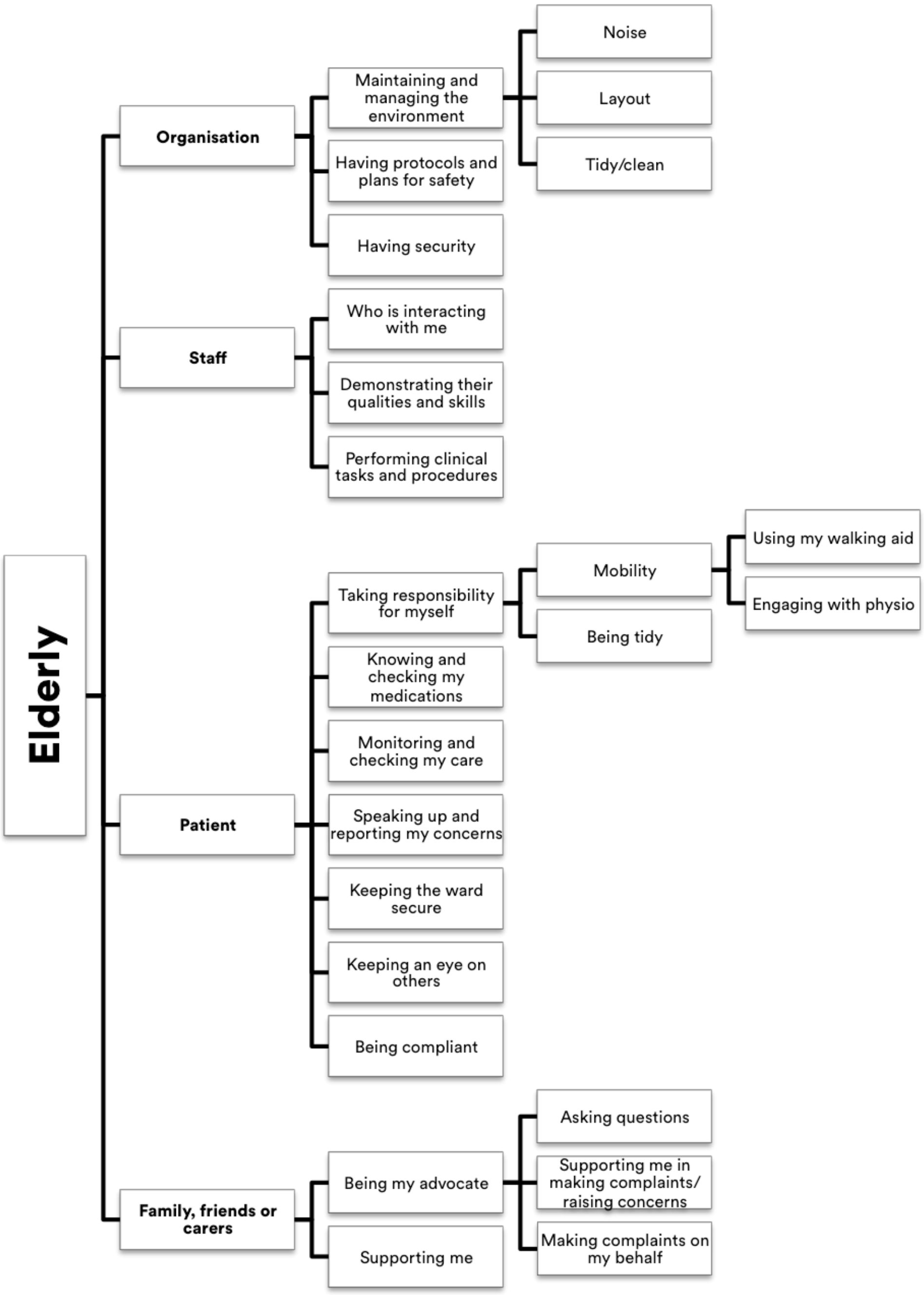
Signature of participant:

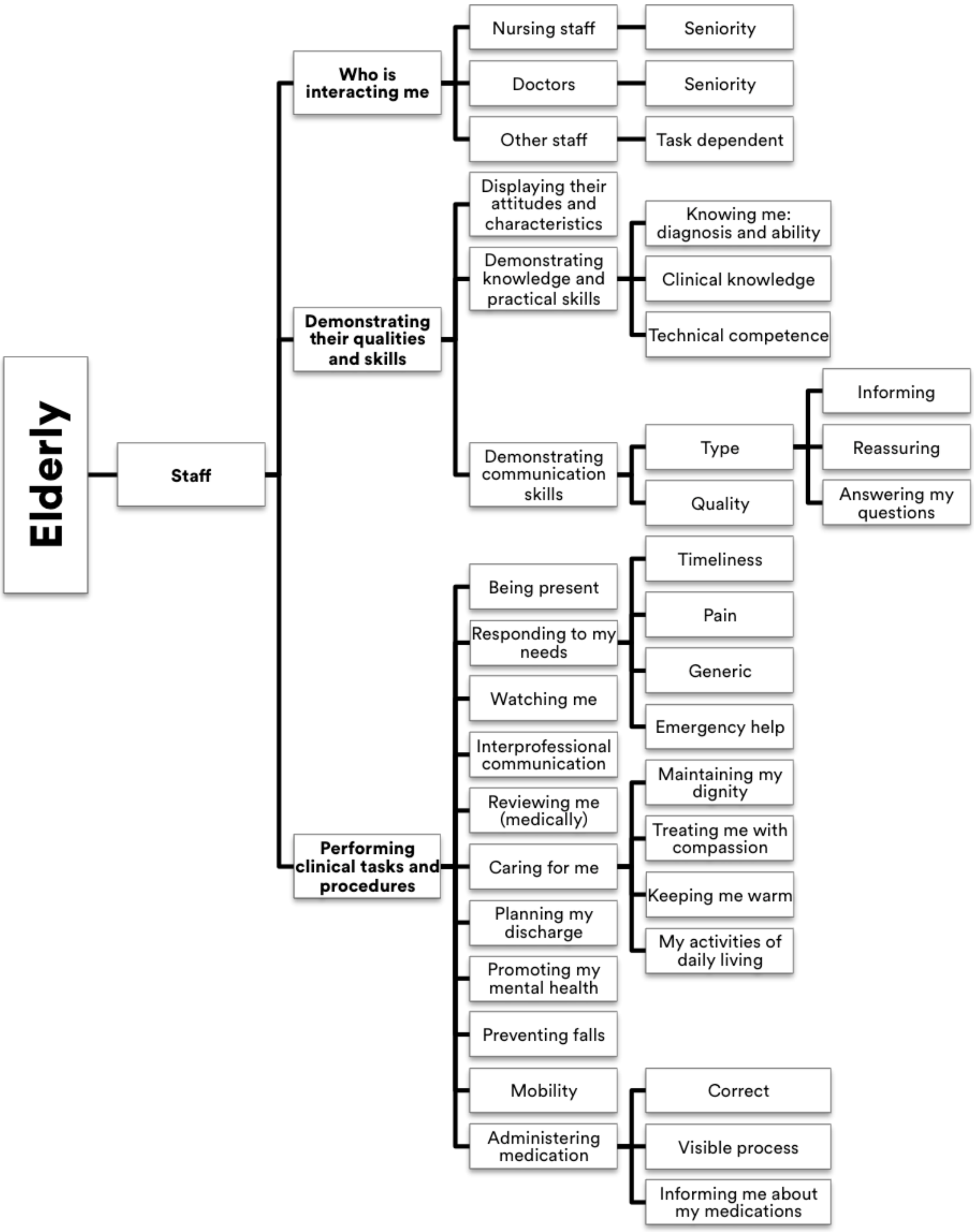
Date:

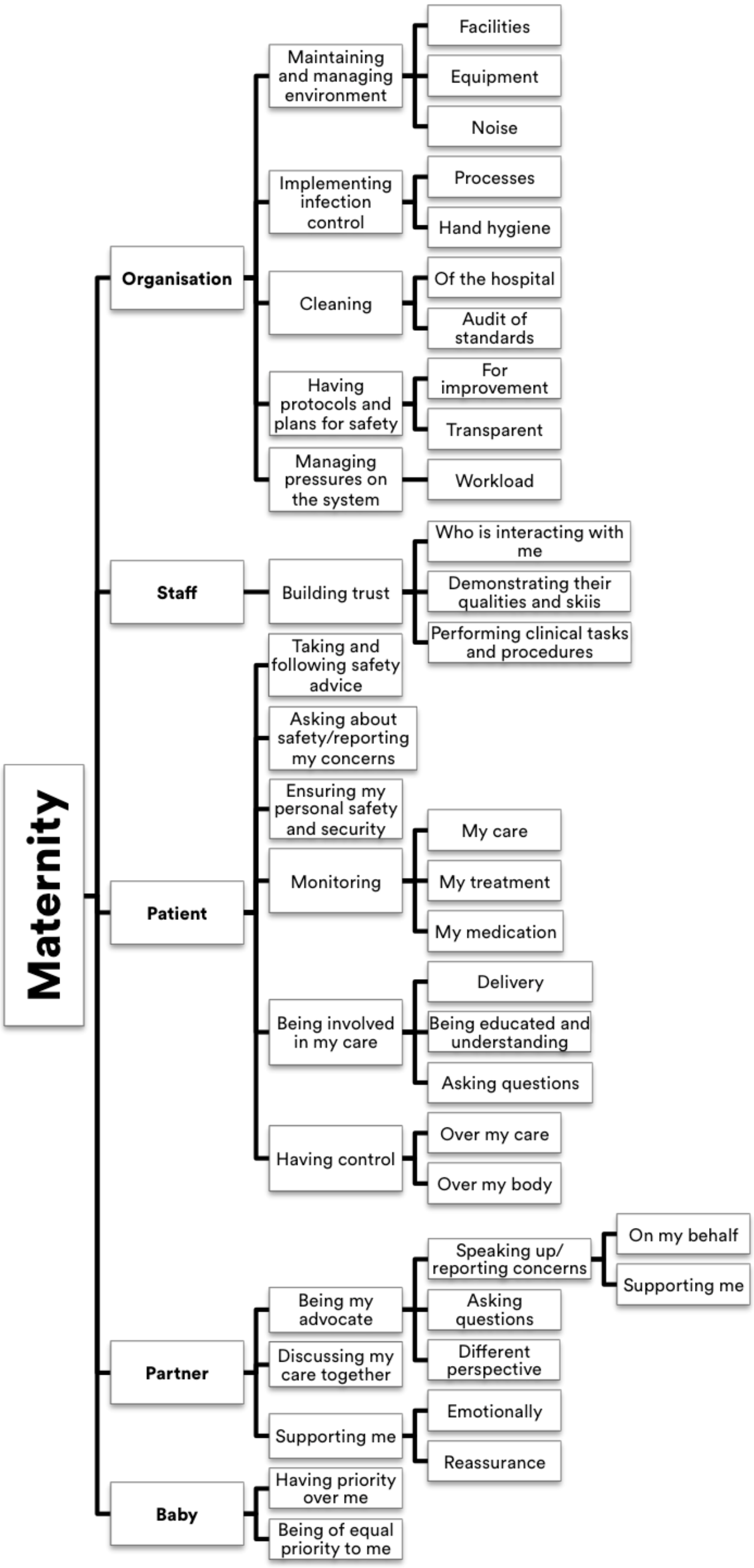
Signature of researcher:

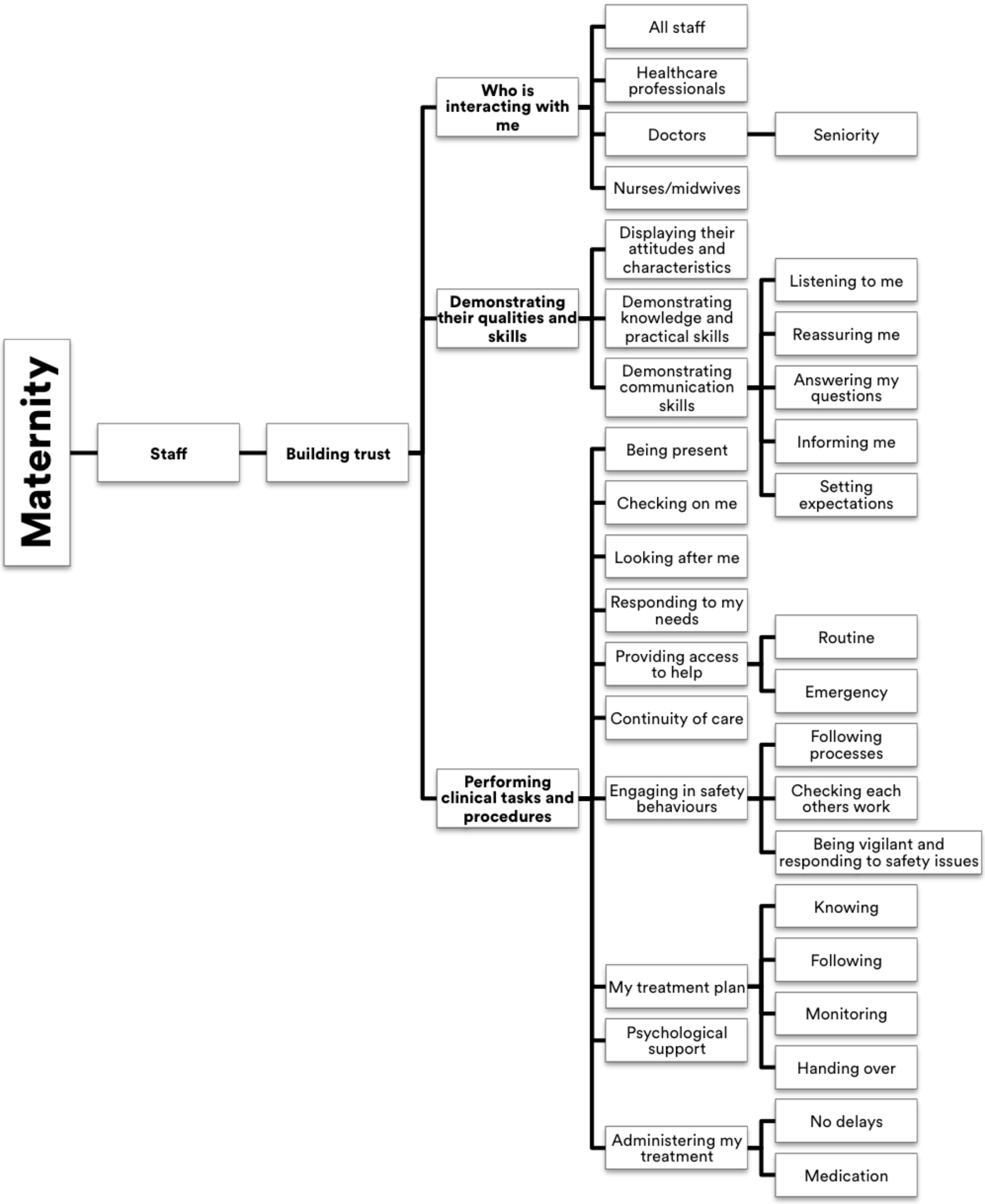
Date:

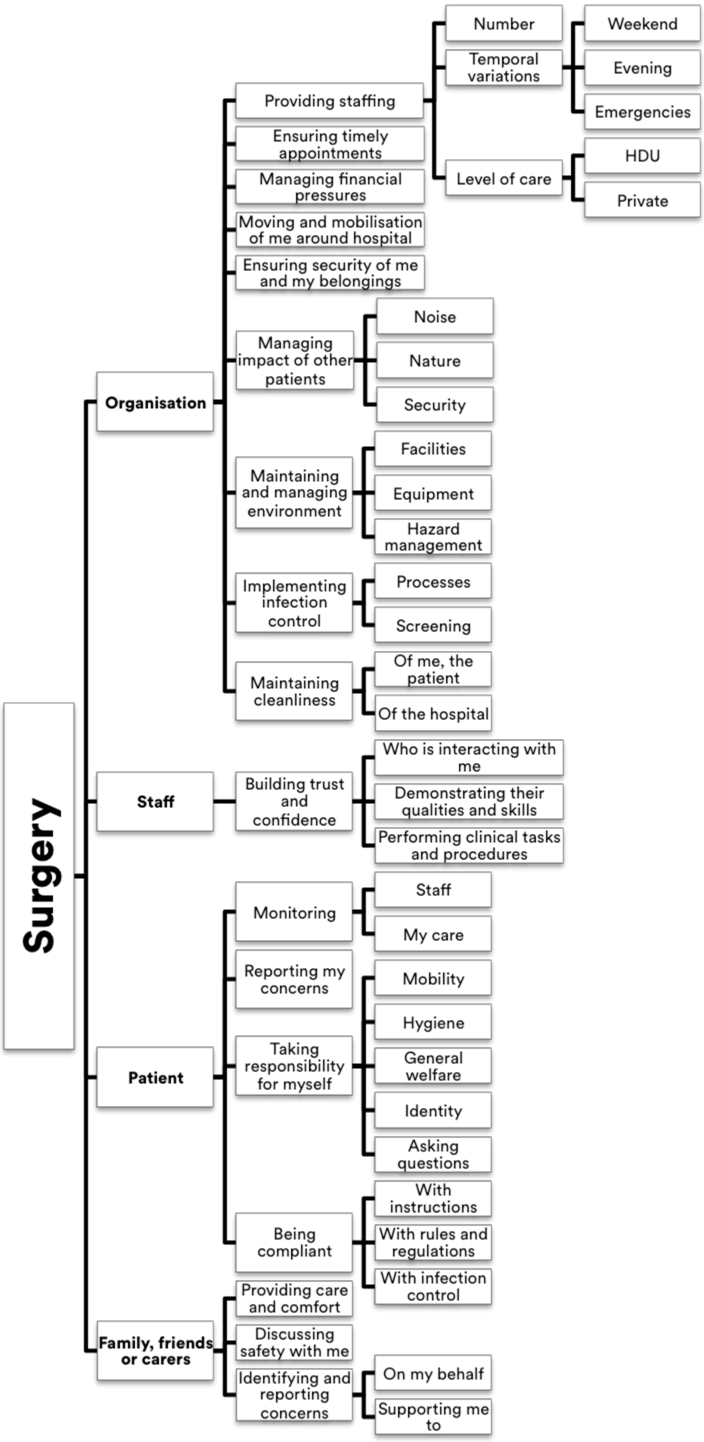
Appendix 8 – Conceptual maps

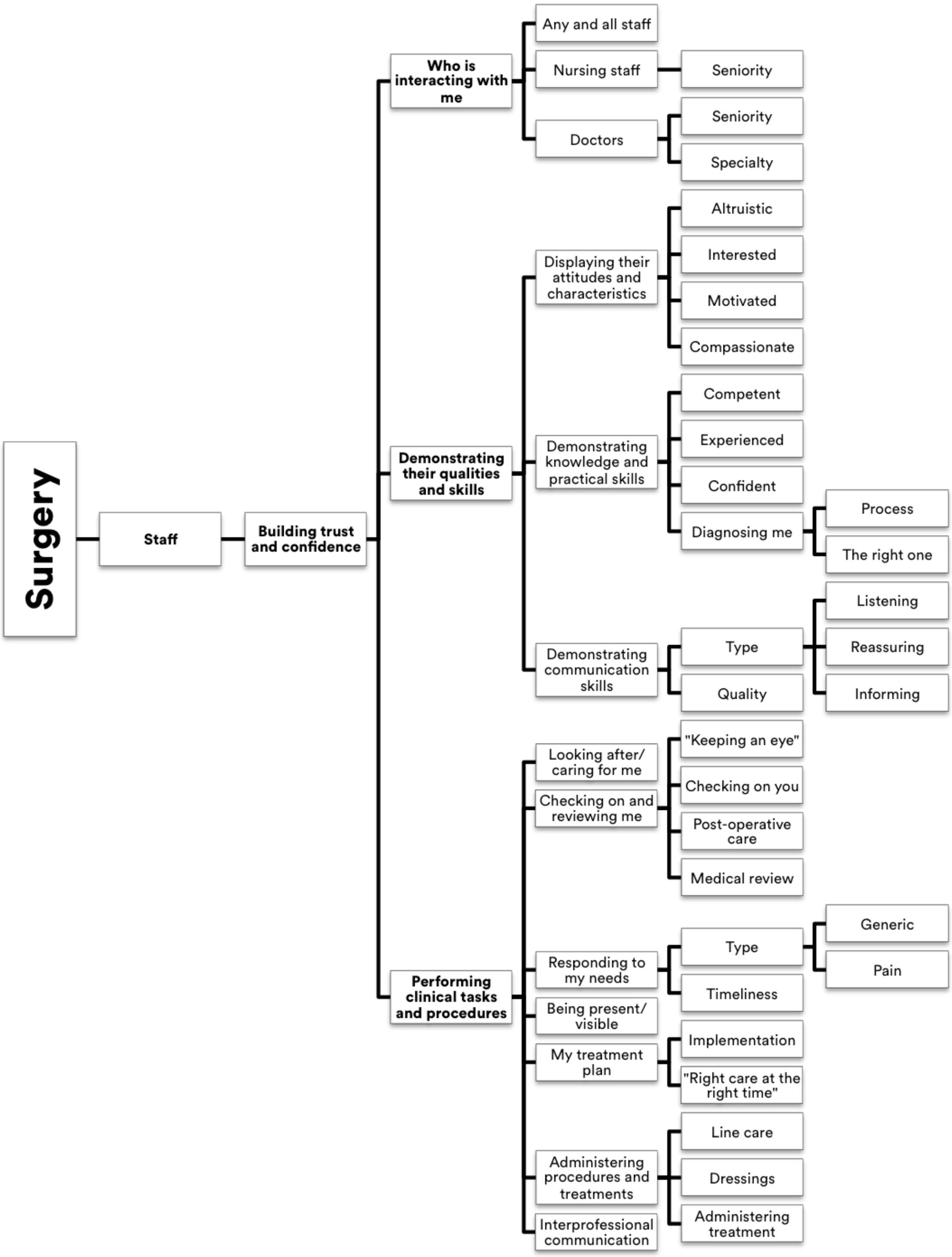



Elderly
Staff
Who is interacting me
Nursing staff
Seniority
Doctors
Seniority
Other staff
Task dependent
Demonstrating their qualities and skills
Displaying their attitudes and characteristics
Demonstrating knowledge and practical skills
Knowing me: diagnosis and ability
Clinical knowledge
Technical competence
Demonstrating communication skills
Type
Informing
Reassuring
Answering my questions
Quality
Performing clinical tasks and procedures
Being present
Responding to my needs
Timeliness
Pain
Generic
Emergency help
Watching me
Interprofessional communication
Reviewing me (medically)
Caring for me
Maintaining my dignity
Treating me with compassion
Keeping me warm
My activities of daily living
Planning my discharge
Promoting my mental health
Preventing falls
Mobility
Administering medication
Correct
Visible process
Informing me about my medications


Maternity
Organisation
Maintaining and managing environment
Facilities
Equipment
Noise
Implementing infection control
Processes
Hand hygiene
Cleaning
Of the hospital
Audit of standards
Having protocols and plans for safety
For improvement
Transparent
Managing pressures on the system
Workload
Staff
Building trust
Who is interacting with me
Demonstrating their qualities and skiis
Performing clinical tasks and procedures
Patient
Taking and following safety advice
Asking about safety/reporting my concerns
Ensuring my personal safety and security
Monitoring
My care
My treatment
My medication
Being involved in my care
Delivery
Being educated and understanding
Asking questions
Having control
Over my care
Over my body
Partner
Being my advocate
Speaking up/ reporting concerns
On my behalf
Supporting me
Asking questions
Different perspective
Discussing my care together
Supporting me
Emotionally
Reassurance
Baby
Having priority over me
Being of equal priority to me


Maternity
Staff
Building trust
Who is interacting with me
All staff
Healthcare professionals
Doctors
Seniority
Nurses/midwives
Demonstrating their qualities and skills
Displaying their attitudes and characteristics
Demonstrating knowledge and practical skills
Demonstrating communication skills
Listening to me
Reassuring me
Answering my questions
Informing me
Setting expectations
Performing clinical tasks and procedures
Being present
Checking on me
Looking after me
Responding to my needs
Providing access to help
Routine
Emergency
Continuity of care
Engaging in safety behaviours
Following processes
Checking each others work
Being vigilant and responding to safety issues
My treatment plan
Knowing
Following
Monitoring
Handing over
Psychological support
Administering my treatment
No delays
Medication


Surgery
Organisation
Providing staffing
Number
Temporal variations
Weekend
Evening
Emergencies
Level of care
HDU
Private
Ensuring timely appointments
Managing financial pressures
Moving and mobilisation of me around hospital
Ensuring security of me and my belongings
Managing impact of other patients
Noise
Nature
Security
Maintaining and managing environment
Facilities
Equipment
Hazard management
Implementing infection control
Processes
Screening
Maintaining cleanliness
Of me, the patient
Of the hospital
Staff
Building trust and confidence
Who is interacting with me
Demonstrating their qualities and skills
Performing clinical tasks and procedures
Patient
Monitoring
Staff
My care
Reporting my concerns
Taking responsibility for myself
Mobility
Hygiene
General welfare
Identity
Asking questions
Being compliant
With instructions
With rules and regulations
With infection control
Family, friends or carers
Providing care and comfort
Discussing safety with me
Identifying and reporting concerns
On my behalf
Supporting me to


Surgery
Staff
Building trust and confidence
Who is interacting with me
Any and all staff
Nursing staff
Seniority
Doctors
Seniority
Specialty
Demonstrating their qualities and skills
Displaying their attitudes and characteristics
Altruistic
Interested
Motivated
Compassionate
Demonstrating knowledge and practical skills
Competent
Experienced
Confident
Diagnosing me
Process
The right one
Demonstrating communication skills
Type
Listening
Reassuring
Informing
Quality
Performing clinical tasks and procedures
Looking after/ caring for me
Checking on and reviewing me
"Keeping an eye"
Checking on you
Post-operative care
Medical review
Responding to my needs
Type
Generic
Pain
Timeliness
Being present/ visible
My treatment plan
Implementation
"Right care at the right time"
Administering procedures and treatments
Line care
Dressings
Administering treatment
Interprofessional communication

Appendix 9 – Healthcare professional interview topic guide

Topic Guide

Version 3 – 16th October 2016

Topic Guide for Healthcare Professionals

1. Let us begin by talking a bit about you…

Prompts:

- Age
- Employment (including years of service)
- Specialty
- Role

2. Tell me what 'patient safety' in hospital means to you…

Prompts:

- Definition
- Risks in hospital
- Your role
- Who is responsible?
- Your experience of patient safety
- Healthcare as safe - is healthcare safe?
- Hospital as a safe place – are hospitals safe?
- Regulation of safety e.g. CQC
- Current or past key issues for patient safety
- Media and patient safety

3. What do patients know about 'patient safety' in hospital?

Prompts:

- Definition – how would they define it?
- Risks they are aware of
- Their beliefs about safety of healthcare and hospital – do they think it is safe?
- What makes patients feel safe or unsafe?
- Awareness of patients, including impact of the media upon patient perspective
- Comparison to professionals – Does patient safety mean the same to you as to a patient?
- Regulation – who do they think?
- Responsibility – who do they hold as responsible for safety?
- What is the role of their relative or carer?

4. Is patient safety something that is important or unimportant to patients?

Prompts:

- Are they interested?

- Are they concerned?
- What matters to patients in hospital? What are their main concerns?

5. Can patients be involved in 'patient safety'?

Prompts:

- How?
- What current roles or strategies exist? How do you currently encourage patients to be involved?
- Other potential roles/strategies – how could we involve patients?
- Do patients have any responsibility for their safety?
- Desire – do you think they want to be involved?
- Ability – do you think are they able to be involved?
- How might patients say they would like to be involved?

6. Do you discuss patient safety with patients?

Prompts:

- What? Why? When?
- What about when safety incidents or errors occur?
- Patient response to safety discussions – do they want this information?
- Barriers and facilitators to discussion
- Do patients ask you about safety? What?
- Do patients report problems or concerns to you? What? What is your reaction to this?
- What is the role of the relative/informal carer? How do you involve them?

Appendix 10 – Participant information sheet

Participant Information Sheet
Version 3 18/10/16

Healthcare professional perceptions of patient safety and patient involvement in patient safety: a qualitative exploration
(IRAS ID 217662)

Researcher: Dr Emily Barrow
Supervisors: Professor Ara Darzi, Dr Susannah Long, Dr Stephanie Archer

About the study
Patient safety is becoming increasingly important in the NHS to both healthcare professionals and patients. There is growing interest in the role that patients can play in improving patient safety.

We are interested in comparing patient and healthcare professional perceptions of patient safety. We have already spoken to patients and would now like to talk to healthcare professionals. We will do this by conducting individual interviews with participants.

We are interested in understanding more about your views, experiences and understanding of what patient safety is in hospitals. We want to explore your views on patient involvement in patient safety, the roles that you think patients may be able to play and how you could be involved in facilitating this.

This study forms part of a PhD research project, being undertaken by Dr Emily Barrow at Imperial College London.

Why have I been invited to take part?
You have been invited to take part because you are a doctor, nurse or midwife working in acute medicine for the elderly, maternity or elective surgery.

Do I have to take part?
No. It is completely up to you to decide whether you want to take part.

What will happen if I take part?
We will arrange a time and place that suits you for the interview to take place. It can take place on hospital or university premises. You will be asked some questions about your experiences, views and understanding of patient safety in hospital. You will also be asked how patients can be involved in safety in hospitals. We will take some notes during the discussion and this will also be audio recorded. The interview will last approximately 30-45 minutes.

Is taking part anonymous and confidential?
Yes. All information gathered will be treated as confidential. Paper records will be kept securely in a locker in a locked office. Electronic data will be stored on a password-protected computer at Imperial College and backed up regularly. No personal identifiable information will be used in any reports arising from this research; you will be identified using a unique study ID number. All data will be securely stored for 10 years after completion of the study.

What are the possible benefits of taking part in this study?
There will not be any direct benefit of you taking part in this study. The information we gain from this study will help us to understand more about views on patient safety and improve the way that we involve patients in patient safety in the hospital.

What are the possible risks of taking part in this study?
There is a small chance that talking about the issues raised in this interview may make you feel a bit worried. If so, we can put you in contact with somebody who will be able to help you with your concerns. If you report serious incidents or unreported events, in the interests of safety, these may need to be reported to the appropriate clinical manager.

What will happen after this study?
We hope that the results will allow us to understand more about different perceptions of patient safety and the ways patients can be involved in patient safety. The results will be published in journal articles. If you wish, we can send you a summary of the results of the study when they are ready.

Can everyone take part?
We may not be able to talk to everyone who wants to take part in the study.

Can I stop taking part?
You can decide to stop participating without giving a reason by informing the researcher within 2 weeks of the date of participation. If you would like to withdraw from the study, please contact Dr Emily Barrow.

You can stop the interview at any time; just tell the researcher.

What if there is a problem?
We do not expect that this study will cause harm or worry for anyone taking part. If you have concerns, inform the researcher.

The study has been reviewed and approved by the Health Research Authority

Who can answer my questions about this study?
You can talk to the researcher about any questions or concerns you have about this study:

Dr Emily Barrow
Email: e.barrow@imperial.ac.uk
Contact Telephone: 02033121995

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator: Dr Emily Barrow (e.barrow@imperial.ac.uk). The normal National Health Service complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial AHSC Joint Research Compliance Office.

Appendix 11 – Consent form

Consent Form
Version 3 18/10/2016

Healthcare professional perceptions of patient safety and patient involvement in patient safety: a qualitative exploration
(IRAS ID 217662)

Name of Researcher: Dr Emily Barrow
Supervisors: Professor Ara Darzi, Dr Susannah Long, Dr Stephanie Archer

Participant ID:

Instructions for the participant:

Please read each of the sections below. In the box next to each section, please write your initials to show that you agree with what the section says.

When you have written your initials, please write your name, today's date and your signature in the spaces at the bottom.

		Initials
1	I have read and understand the information sheet for the above study (Version 3)	
2	I have had the opportunity to think about the information and to ask questions about it if I want to. If I have asked questions, I am happy with the way my questions have been answered.	
3	I understand what will happen in the interview	
4	I understand that what I say to the researcher will be recorded using a digital voice recorder and saved on a computer at Imperial College London.	
5	I understand that it is my right to refuse to take part in this study or withdraw within two weeks of the date of participation without having to give a reason. I understand that I can withdraw without my legal rights being affected.	
6	I have been informed that anything I say during the interview will remain completely confidential; my name will not be used, nor any other information that could be used to identify me.	
7	I understand that parts of what I say may be used anonymously in in the results of this study.	
8	I would like to receive a summary of the results.	
9	I agree to take part in this study.	
10	I agree that my own words may be used anonymously in the report of this study.	

Signature of participant:

Date:

Signature of researcher:

Date:

Appendix 12 – Experience-based co-design workshop ‘Introduction Planner’

Patient Safety Co-design Workshop – 26th July 2017

Introduction Plan

KEY AREA TO COVER	WHAT YOU NEED TO INCLUDE
- *Thank you for coming* - *Introduce yourself & other facilitators* - *Ask people to write their names on sticky labels*	On arrival – people to write names (preferably first) on sticky labels, to indicate how they would like to be called. Tick off list. Invite to have tea/coffee and encourage people to chat. Give media consent form. Aim to start at approx. 10:15am. Introduce myself to the group Introduce facilitators: Anna and Steph
Housekeeping i.e. - *Timings of the workshop, when refreshments with be served* - *Location of bathroom, quiet room, lifts* - *Any expected fire drills and where the fire exits* - *Remind group that you can collect expense forms at the end of the session* - *Media*	Workshop is planned to finish at 4pm, with a lunch break scheduled for 12:30pm-1:30pm. Bathroom is located…. Please feel free to leave the room whenever required. We are not expecting a fire drill. The fire exits are…. Expense claim forms will be available at lunchtime for the patients/public participants. Please return them at the end of the day. Parts of the workshop will be audio recorded. This will be the larger group discussions. Photographs will be taken. You should have already received a media consent form. If you have any concerns relating to this, please let me know.
Introductions & icebreaker *Set an activity, which enables attendees to introduce each other.*	You each have 3 minutes (1.5 minutes each) to speak to the person next you about who you are and what you are looking forward to today. Then each stand-up and introduce the other person. If you know the person next to you please swap with someone.
Overview of topic and importance of their views *Provide some background info about why you are running the workshop and why the attendees views are important.*	There has been increasing interest in involving patients in patient safety. Over the years, this has been done in a way which is predominantly defined by academics, clinicians and policymakers. This means it does not consider the patient perspective. Additionally, the term ‘patient safety’ is not necessarily a familiar term to patients. This is a further barrier to involving patients and the public.

	My PhD has been focusing on understanding what patient safety is to patients, public and staff. I have done this by conducting interviews with people about what they think patient safety is. I have found that patients and the public are able to freely discuss, from their experience, what makes them feel safe or unsafe in hospital. However, what makes them feel safe or unsafe is often different to how patient safety is defined clinically or academically. Practical work to involve patients and improve safety does not consider this patient perspective. Today, we are going to start trying to change that. Everyone in this room has experience of surgery. They may have had surgery, performed surgery, or looked after patients who have had surgery. Therefore, you have an idea of what makes a safe or unsafe experience. Together we are going to design what safety looks like from the perspective of a surgical patient. We are going to decide what matters to surgical patients to make them feel safe in hospital and what this looks like in practical terms. I have already interviewed patients who have had surgery. We will be working with some of the ideas gained from those interviews, as well as the experiences of everyone in the room. The first half of the workshop will focus on deciding what matters to patients to feel safe in hospital. We will come up with a list of 'values.' The second half of the workshop will focus on describing the actions or behaviours that staff, patients and the hospital need to adopt to make the values come to life. The aim is to create a practical product that could be used by the hospital to make patients feel safer. Our final task will be to give our 'product' a name and consider how we would explain it to people and implement it in practice. You will be guided through each stage.
Principles/Ground rules *Useful to include that you are looking for:* • *Variety of views* • *Want to hear from everyone* • *Not after a consensus* • *No right or wrong answers* • *Want to know what you feel, your gut reactions, your opinions*	To suggest some and ask others for their contributions also. Remember I am looking for a variety of views, want to hear from everyone, no right or wrong answers, looking to hear what you feel from your own experiences. If you aren't sure about something, you can ask questions at any time.

Appendix 13 – Experience-based co-design workshop 'Discussion Planner'

Patient Safety Co-design Workshop – 26th July 2017

Discussion Plan

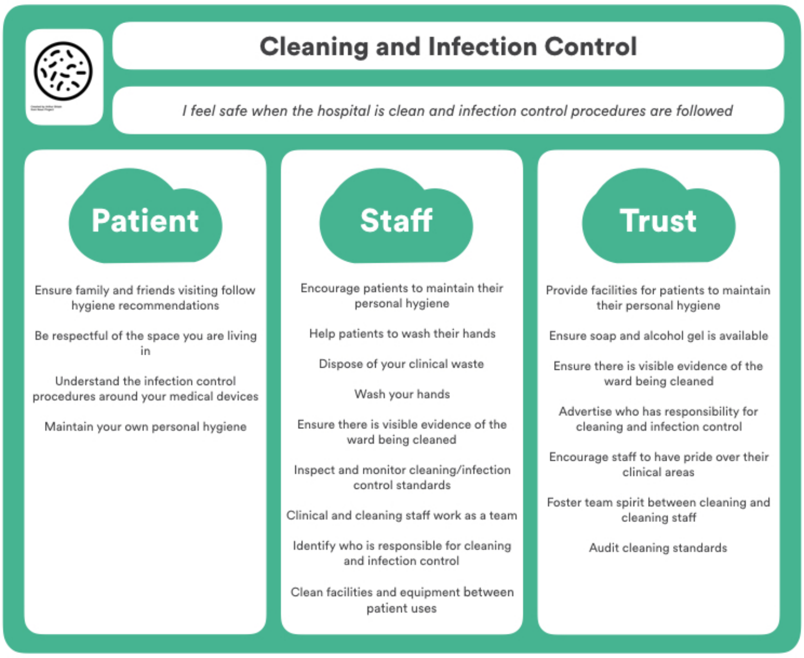
Aim	Schedule	Props	Time
	Arrival, Welcome & Introduction		**10:00-10:45**
To create an informal atmosphere & put people at ease To explain the practical aspects of the workshop To ensure people understand the purpose of the workshop	**Welcome** *Arrival* *Thanks* *Introduce self and other facilitators*	Consent forms Attendance list	15-20 minutes
	Housekeeping • *Timings* • *Location of bathroom* • *Any expected fire drills and where the fire exits are* • *Media* • *Expenses*		5 minutes
	Icebreaker		15 minutes
	Explain why we're here *Provide some background info about why you are running the workshop and why the views of patients and members of the public are important for your area of work.*		5 minutes
	Ground Rules *Suggest some ground rules*	Flip chart paper Pens	5 minutes

	The discussion		
Aim: To create a practical product that could be used by the Trust to make patients feel safe. **Objectives:** • To describe what patient safety look like from the patient perspective by describing what matters to patients to feel safe in hospital. • To use co-design to identify values that describe what matters to patients to feel safe in hospital. • To use co-design to identify behaviours that bring the values to life.	**10:45-11:45am - Small Group Session 1 – 1 hour – Facilitated by Emily, Anna and Steph** If you are able, please could you keep some notes based on the discussions that are had? Paula and Bhavita to note write. *In this part we are going to:* • *Describe what patient safety look like from the patient perspective by describing what matters to patients to feel safe in hospital.* • *Use co-design to identify values that describe what matters to patients to feel safe in hospital.* ***10:45-11am - Part 1 (10-15 minutes):*** Think about what makes you feel safe/unsafe when you're in hospital. These are things that patients in interviews said made them feel safe or unsafe. Use the coloured dots to decide whether you: agree, disagree, are surprised. ***11-11:30am - Part 2 (25-30 minutes):*** Assign a scribe to write down ideas. Based on this and your own thoughts: • Look at the themes, and how you and others agreed/disagreed. Discuss why people felt the way they felt. • Is there anything missing from this? • What does a safe experience look like? • What matters to you to feel safe? ***11:30-11:50 - Part 3 (20 minutes):*** Create a list of values. A value is a state that is important to you. When writing these, think about the following question: What is important to you to feel safe in hospital?	Flip chart paper Marker pens Coloured dots Interview theme prompts	

	11:50-12:30pm - Large Group Session 1 (45 minutes): Each group will feedback their list of values. Are there similarities? Are there differences? Can we reach some agreement? **LUNCH (12:30 to 1:30pm)** During lunch, Emily to prepare the value sheets for the afternoon activity. This will determine the timings for the afternoon session. **1:30-2:30pm approx - Small Group Session 2 (60-75 minutes depending on progress)** This will follow a world café type format. Groups will rotate around tables to identify the behaviours that bring the values to life. This will consider the behaviours of staff, patients and the hospital management. Think about what you need to see, hear, feel or do to bring these values to life. **2:30-3:30pm approx - Large Group Session 2 (45-60 minutes)** Feedback on the values and behaviours produced in the small group session. What should we call this? How should we share it? How should we implement it? How would we explain is to another colleague or patient or member of the public?		
	Summary, next steps and close		
To ensure attendees feel	Next steps		*15 mins*

valued, respected and supported. They should be clear about how their views are going to be used in your project and when they should expect to hear from you next.	Feedback • *Thank everyone for their time & reiterate the value of patients and members of the public in your work.* • *Explain how the feedback and opinions captured will be used in your work.* • *Inform attendees of the next steps.* • *Ask attendees to complete a feedback form before they leave and hand in to you.* • *Remind everyone of the process for expenses and ask attendees to give you their forms and receipts if attendees have them with them. If not, ask them to post to you using the address on the form.* • *Collect any consent forms for recording, if required.* • *Let attendees know that you will be there for 15 minutes after the session if they have any further questions.*		

Appendix 14 – "The Foundations of Safe Care" - Values and Behaviours



Cleaning and Infection Control

I feel safe when the hospital is clean and infection control procedures are followed

Patient

Ensure family and friends visiting follow hygiene recommendations

Be respectful of the space you are living in

Understand the infection control procedures around your medical devices

Maintain your own personal hygiene

Staff

Encourage patients to maintain their personal hygiene

Help patients to wash their hands

Dispose of your clinical waste

Wash your hands

Ensure there is visible evidence of the ward being cleaned

Inspect and monitor cleaning/infection control standards

Clinical and cleaning staff work as a team

Identify who is responsible for cleaning and infection control

Clean facilities and equipment between patient uses

Trust

Provide facilities for patients to maintain their personal hygiene

Ensure soap and alcohol gel is available

Ensure there is visible evidence of the ward being cleaned

Advertise who has responsibility for cleaning and infection control

Encourage staff to have pride over their clinical areas

Foster team spirit between cleaning and cleaning staff

Audit cleaning standards

Environment and Facilities

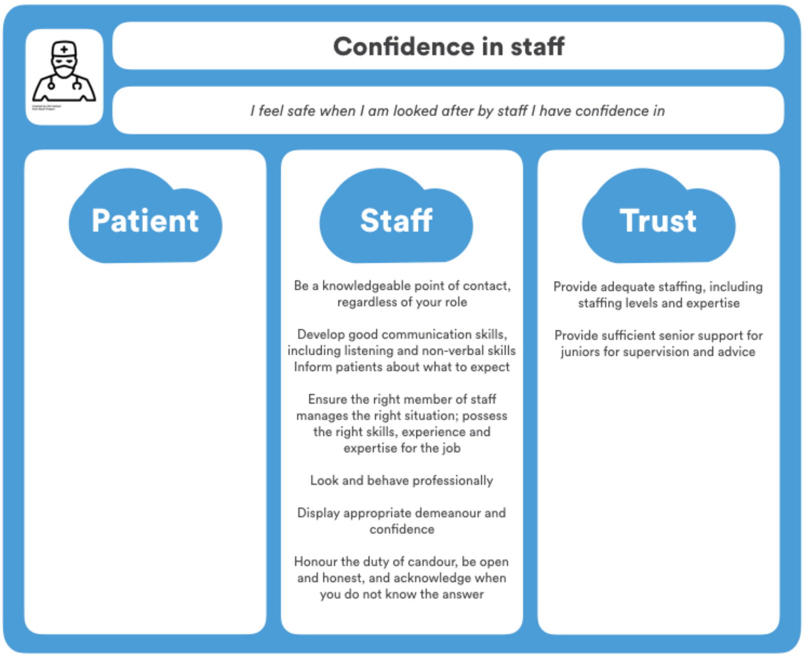
I feel safe when the environment and facilities are accessible and maintained

Patient	Staff	Trust
Help look after facilities and keep the ward clean Take responsibility for your own cleanliness	Make patients feel comfortable in the environment See the environment through the patient's eyes (e.g. Is the water jug within the patient's reach?) Encourage patients to look after themselves (e.g. personal hygiene)	Provide water fountains in all public waiting areas Provide seats for visitors Ensure the hospital is clean Ensure adequate staffing levels to maintain the quality of the environment Display signage and maps that are clear and up to date Ensure there is adequate lighting for security at night Ensure maintenance of the facilities Allow patients, visitors and staff to report maintenance issues

Infrastructure for Reporting Concerns

I feel safe when there are processes in place for everyone to be able to report concerns

Patient	Staff	Trust
Complete feedback forms Know who to talk to in order to raise concerns	Ensure feedback forms are available Inform patients who they can to talk to in order to raise concerns Keep patients informed so that understand care and can identify concerns Encourage communication between the ward manager, other staff and patients to ensure direct resolution of concerns Ward managers to introduce themselves to the patient every morning and identify themselves as the main point of contact Ward managers to be visible on the ward	Ensure feedback forms are available Raise awareness of Patient Advice Liaison Service Provide a point of contact in the administration tram Provide a patient with the means to report back about concerns in care or inaccuracies in clinical letters (e.g. Virtual clinical email and telephone number) Provide a response to feedback or complaints Create multiple pathways to raise concerns (e.g. forms, managers, phone apps, helplines)



Confidence in staff

I feel safe when I am looked after by staff I have confidence in

Patient

Staff

Be a knowledgeable point of contact, regardless of your role

Develop good communication skills, including listening and non-verbal skills
Inform patients about what to expect

Ensure the right member of staff manages the right situation; possess the right skills, experience and expertise for the job

Look and behave professionally

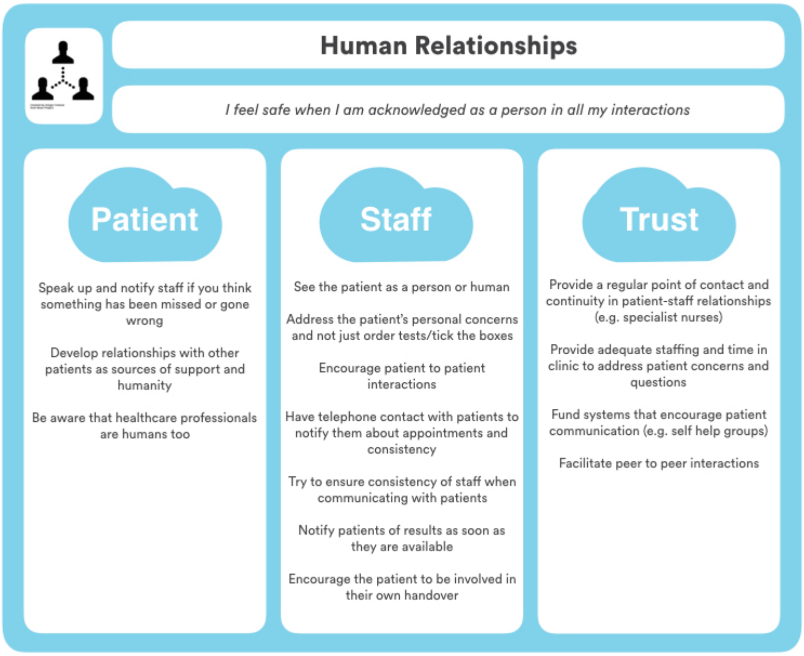
Display appropriate demeanour and confidence

Honour the duty of candour, be open and honest, and acknowledge when you do not know the answer

Trust

Provide adequate staffing, including staffing levels and expertise

Provide sufficient senior support for juniors for supervision and advice



Human Relationships

I feel safe when I am acknowledged as a person in all my interactions

Patient

Speak up and notify staff if you think something has been missed or gone wrong

Develop relationships with other patients as sources of support and humanity

Be aware that healthcare professionals are humans too

Staff

See the patient as a person or human

Address the patient's personal concerns and not just order tests/tick the boxes

Encourage patient to patient interactions

Have telephone contact with patients to notify them about appointments and consistency

Try to ensure consistency of staff when communicating with patients

Notify patients of results as soon as they are available

Encourage the patient to be involved in their own handover

Trust

Provide a regular point of contact and continuity in patient-staff relationships (e.g. specialist nurses)

Provide adequate staffing and time in clinic to address patient concerns and questions

Fund systems that encourage patient communication (e.g. self help groups)

Facilitate peer to peer interactions

Supporting me to support myself

I feel safe when I am supported to take ownership and responsibility for my care in and out of hospital

Patient

Vocalise your concerns and expectations

Engage with staff that are caring for you

Engage in peer to peer support where offered

Take initiative with your own care (e.g. notifying staff if they want to self-administer medication)

Look after yourself if you are able (e.g. washing, tidying up)

Educate yourself by asking for advice or seeking information online

Staff

Encourage patients to vocalise their concerns and expectations

Explain what is happening to patients in each clinical encounter so they can learn about their diagnosis and care.

Develop a rapport with patients and treat them like human beings

Create opportunities for patients to care for themselves (e.g. self-administration of medication)

Use admission to make lifestyle changes

Advertise services of the charitable sector that can help patients

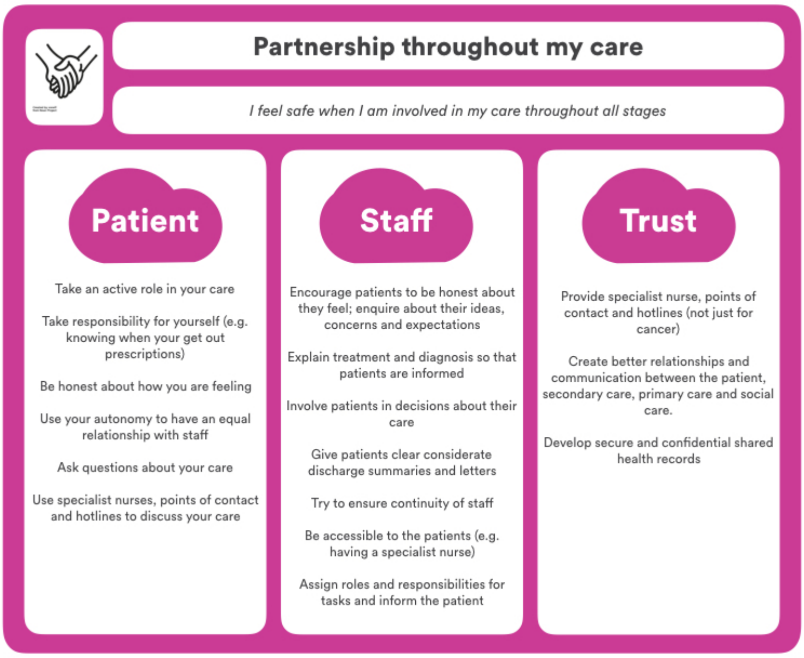
Trust

Provide an environment that enables patients to vocalise their concerns and expectations

Be flexible to allow care to be more patient centred

Create peer support networks (e.g. preoperative)

Define the roles of patients and staff so that staff are empowered to encourage patients to take care of themselves



Partnership throughout my care

I feel safe when I am involved in my care throughout all stages

Patient

Take an active role in your care

Take responsibility for yourself (e.g. knowing when your get out prescriptions)

Be honest about how you are feeling

Use your autonomy to have an equal relationship with staff

Ask questions about your care

Use specialist nurses, points of contact and hotlines to discuss your care

Staff

Encourage patients to be honest about they feel; enquire about their ideas, concerns and expectations

Explain treatment and diagnosis so that patients are informed

Involve patients in decisions about their care

Give patients clear considerate discharge summaries and letters

Try to ensure continuity of staff

Be accessible to the patients (e.g. having a specialist nurse)

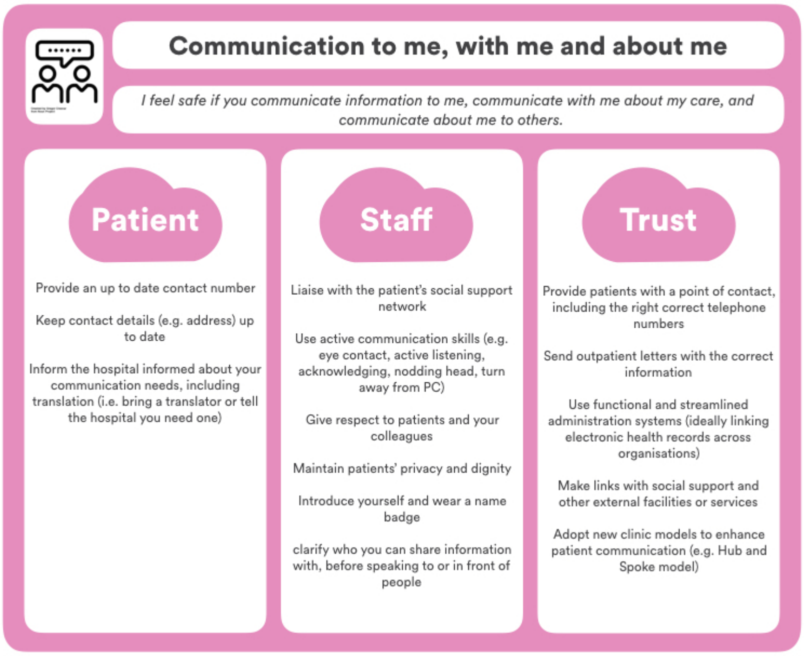
Assign roles and responsibilities for tasks and inform the patient

Trust

Provide specialist nurse, points of contact and hotlines (not just for cancer)

Create better relationships and communication between the patient, secondary care, primary care and social care.

Develop secure and confidential shared health records



Communication to me, with me and about me

I feel safe if you communicate information to me, communicate with me about my care, and communicate about me to others.

Patient

Provide an up to date contact number

Keep contact details (e.g. address) up to date

Inform the hospital informed about your communication needs, including translation (i.e. bring a translator or tell the hospital you need one)

Staff

Liaise with the patient's social support network

Use active communication skills (e.g. eye contact, active listening, acknowledging, nodding head, turn away from PC)

Give respect to patients and your colleagues

Maintain patients' privacy and dignity

Introduce yourself and wear a name badge

clarify who you can share information with, before speaking to or in front of people

Trust

Provide patients with a point of contact, including the right correct telephone numbers

Send outpatient letters with the correct information

Use functional and streamlined administration systems (ideally linking electronic health records across organisations)

Make links with social support and other external facilities or services

Adopt new clinic models to enhance patient communication (e.g. Hub and Spoke model)