A stakeholder derived framework for safety assessment in the NHS

case management programme

Sarahjane Jones

In partial fulfilment for the Degree of Doctor of Philosophy (PhD)
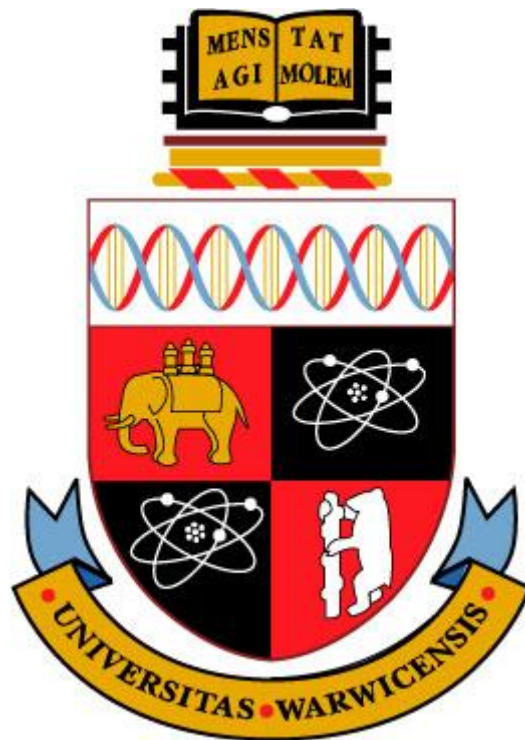
University of Warwick, WMG

March 2014

“Effective medicine could only begin when doctors began to count and to compare.”

David Wooton, Bad Medicine

Contents

Figures and Tables

Dedication

In loving memory of Jane Daniel: my mentor, my friend and my motivation. I shall forever strive to be the person you were.

Acknowledgements

The successful completion of this thesis owes itself to a number of people, without whom, I would not have traversed the turbulent journey that is the PhD process. I must thank WMG and the participating NHS organisations for granting me the opportunity to conduct my research. In addition, I must thank all the participants for allowing me access to their perspectives. Without which, there would have been no research. The stories they shared with me will be with me forever. I would also like to thank Professor Maxine Lintern and colleagues at Birmingham City University, who have supported me during the write up of the thesis.

I am especially indebted to a select few, who gave their time and effort to review and provide feedback on the progress and content of the thesis as it developed and especially towards the end. These people include my little sister, Stacie Jones and friends: Carolyn Dawson, Emma Lock, Josh Miller, Leanne Miller and Craig Nicholls. On this occasion, their red pen comments were welcome.

I owe my entire education, drive, motivation and tenacity to my parents, Margaret and Andrew Jones. They taught me the value of knowledge. Their love, support and pride has spurred me on during the difficult times.

Finally, I want to give thanks to Christopher Buckley and our girls, with whom I share my life, including the trials and tribulations experienced throughout the PhD process. They have wiped my tears, held my hand, comforted me, given me strength and sustained my motivation. This has all been for us.

Declaration

I declare that this thesis is my own work and that it has not been submitted for a degree at another university.

Abstract

Patient safety measurement methods are dominated by outcome measurement, reducing them to counts of harm or adverse events. Performance measurement recognises the limitations of the sole use of outcome indicators and proposes the use of measures throughout the system, in particular the determinants of the desired outcomes. Furthermore, it promotes stakeholder engagement in the design of measures in order to understand their expectations and how they contribute. This is particularly important in healthcare services, such as the NHS case management programme, where patient contribution is growing. This programme is a response to the ageing population and the subsequent increase in complex long term conditions, aiming to deliver care in the home to empower patients so they are able to care for themselves to a greater extent. In comparison to the institutionalised setting, the home setting is relatively unexplored. Therefore, this research has provided an opportunity to examine the concept of safety in a care service with an increasing demand from a vulnerable population. The research aimed to develop a conceptual framework for safety measurement that was: 1) reflective of key stakeholders; 2) able to incorporate the system; and 3) representative of the home-delivered healthcare of the case management programme.

An exploratory, sequential mixed method design within the critical realist philosophy, which was guided by the principles of performance measurement, was adopted. A case study utilising 13 interviews with nine patients and six carers (two interviews were held jointly) and three focus groups with 17 case management nurses was deployed. This enabled in-depth exploration of their perspectives regarding safety, including: their definitions of safety, who was involved, the contributing factors, and which outcomes were most important. Intriguing, important or contradictory findings were further examined using a survey (patient n=35, carer n=19 and case management nurse n=26), which aimed to determine the level of agreement with these qualitative findings and identify any statistically significant differences between the stakeholder groups.

Through engagement with stakeholders, this research has established a definition of safety that represents the type of care provided by the case management programme. In particular, it recognises the importance of meeting the care needs of this patient population, acknowledging that the alternative would facilitate disease progression, exposing patients to unnecessary harm. Understanding the patient perspective has proven to be particularly important because of the level of control asserted by patients on the structure, processes and outcomes of care. This level of control is an integral component of the proposed conceptual framework. Of greatest significance is the incorporation of the patients' living environments and their resources into the structure of care, as well as the involvement of their daily self-care activities in the processes of care. Consequently, the framework is inclusive of non-traditional safety outcomes, such as functional health status, because they help sustain patient controlled structures and processes, which in turn influence traditional measures of harm. The conceptual framework is a guide to the assessment of safety in case management that specifies a range of factors that facilitate the condition of safety, providing a holistic overview of the complex, nested system of care required to manage long term conditions.

Glossary

Term	Definition
A Performance Measure	A metric used to quantify the effectiveness and/or efficiency of an action
A Performance Measurement System	A set of metrics used to quantify both efficiency and effectiveness of actions
Active Failure	Errors committed at the sharp end of the service and whose effects are felt immediately
Adverse Event	1) An unintended and undesired incident directly associated with the care or services provided to the patient 2) An incident that occurs during the process of providing health care and results in patient injury or death 3) An adverse outcome for a patient, including injury or complication
Case management	A targeting intervention to support patients with complex, multiple long term conditions to empower and educate patients to better perform self-care through personalised care planning and integrated care services.
Case study	The in-depth exploration of a particular bounded entity known as a case.
Error	Failure of a planned action to be completed as intended or use of a wrong plan to achieve an aim; the accumulation of errors results in accidents
Effectiveness	The extent to which customer requirements are met
Efficiency	A measure of how economically the firms resources are utilised when providing a given level of customer satisfaction
Exploratory, sequential mixed method design	A research methodology in which a qualitative study is conducted first to explore a phenomenon, followed by a quantitative study.

Harm	Impairment of structure or function of the body and/or any deleterious effect arising there from'. Including disease, injury, suffering and disability.
Hawthorne Effect	A phenomenon whereby the observation of workers modifies their behaviour.
Latent Condition	Errors within the system, which can lie dormant for years
Outcome	The way things turn out; a consequence of an action.
Patient Safety	The reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum, as well as the use of best practice shown to lead to optimal outcomes.
Patient Safety Incident	A patient safety incident is any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving [NHS] care.
Performance Measurement	The process of quantifying efficiency and effectiveness of action
Process	The actions of care.
Stakeholders	A person with an interest or concern in something, particularly its success. This might include the patient, nursing staff, the GP, the pharmacy, carers.
Structure	The setting and environment in which care takes place.
Survey	A research methodology that uses a quantitative questionnaire across a cross section of a population to elicit data.

Abbreviations

Abbreviation	*Full term*
AHRQ	Agency for Healthcare Research Quality
CM	Case management
DoH	Department of Health
GTT	Global trigger tool
HCUP	Healthcare Cost Utilisation Project
HES	Hospital episode statistics
ICD	International classification of disease
HSMM	Holistic safety measurement model
IRS	Incident reporting system
NHS	National Health Service
ISMM	Integrated safety measurement model
NPSA	National Patient Safety Agency
NRLS	National Reporting and Learning System
OECD	Organisation for Economic Cooperation and Development
OPCS	Office of Population Consensus Surveys
PSI	Patient safety incident
QIPP	Quest for Quality and Improvement Performance
RRR	Retrospective record review
WHO	World Health Organisation

Chapter 1

Introduction

1.1: Introduction

Safety in healthcare is a priority for policy makers, healthcare organisations, patients and other service users worldwide. Methods to quantify harm have been available for over two decades (1, 2). However, these methods are subject to the limitations of isolated outcome measurements, meaning that they are incapable of predicting error, mitigating against it and defining a level of safety. This could be attributed to the level of understanding required to develop such measurement systems. In addition, the design and implementation of safety measurement systems is often done with little contribution from patients and other service users. However, the patient perspective of safety is becoming increasingly important as the care model shifts to one that not only puts patients at the centre of their own care, but also demands greater contributions from them and places the onus on them to generate better health outcomes.

This thesis presents the development of a conceptual safety assessment framework for the case management (CM) programme in the National Health Service (NHS). The conceptual framework is a guide to the assessment of safety performance that is predicated upon the structure, process and outcome model of quality care (3). It has been devised to address some of the issues of the current approach to safety measurement and contribute to the progress of safety measurement. In particular, it identifies contributory factors to safety throughout the system and incorporates the perspectives of patients, carers and CM nurses through the exploration, examination and interpretation of their perspectives using a case study approach. Furthermore, it incorporates the literature perspective. Subsequently, as part of a

sequential, exploratory mixed method design, a survey study has attempted to further enhance the reliability and validity of the findings by engaging with a larger sample size using a survey method. This chapter provides an overview of the thesis: the gap in the literature, the premise upon which the research is designed, an overview of the work and the structure in which it is presented.

1.2: Safety and safety measurement

Patient safety can be defined as *'the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum'* (4)[pg19], as well as *'the use of best practice shown to lead to optimal outcomes'* (5)[pg221]. The first large-scale studies to measure safety used retrospective record review (RRR) and highlighted the extent of medical error in America, implicating error in the deaths of as many as 98,000 people per year, 43.5% of which were perceived to be preventable (1, 2, 6). The use of this measurement method around the world, including in Britain (7), Australia (8) and Canada (9), has indicated a median overall incidence of adverse events of 9.2% (10). However, despite an awareness of the issues and high profile reports proposing recommendations to address them (6, 11), reports of lives lost still frequently appear in the media. Reports such as the Mid-Staffordshire NHS Foundation Trust Public Inquiry (12) indicate signs of long-term institutional abuse, suggesting that the needs of the organisation were put above the needs of the patients, resulting in between 400 and 1,200 more deaths than expected between January 2005 and March 2009.

The counting of harms using RRR is unreliable and unrepeatable (13-16). The subjective nature of the method means that there are issues with inter-rater reliability. Moreover, its time and resource requirements often render it single use, meaning that the RRR is unable to reliably and longitudinally measure harm. Ergo, it is unable to identify a reduction in harm over time or calculate a reduction in the risk of harm. Essentially, RRR is an epidemiological tool to study the occurrence of adverse events.

Since the application of RRR, other methods have been devised. These include: global trigger tools (GTTs) (17), incident reporting systems (IRSs) (18), patient safety incidents (PSIs) (19), safety culture assessment (20) and the NHS safety thermometer (21). However, with the exception of safety culture assessment, all remain focused on the outcome of harm and suffer the same limitations as RRR.

Systems theory (22, 23) is a recognised theory of patient safety and other high-risk industries (24). Systems theory dictates that error is caused by the alignment of multiple faults or flaws in the system (latent conditions) that enable an individual to commit an error or omit an essential action (active failures). It is accepting of human fallibility and advocates that appropriately designed systems reduce the opportunity for error and improve safety. In order for this to be achieved, the system needs to be understood, and contributing factors to error need to be identified. In this environment, errors are openly acknowledged, and efforts are made to understand the systemic cause and rectify any underlying issues. However, despite knowledge of the importance of the system and the conditions that contribute to safety, measurement is still focused at the sharp end, on outcomes (adverse events). Consequently, these methods are also unable to monitor the system upstream of the error to prevent it from occurring and reduce risk.

The field of performance measurement no longer supports the isolated use of outcome indicators (see Chapter 3.2: Lessons from other industries: the case for performance measurement). Outcomes are lagging indicators that give information only on what has been achieved in the past. Used in isolation, they are unable to promote improvement because they lack information on their determinants; consequently, they cannot predict future performance. In addressing the issues of lagging indicators, performance measurement has sought to overcome these limitations. Essentially, indicators of performance should utilise leading indicators capable of predicting outcomes, lagging indicators to ensure outcomes are being met and process indicators to control consistency. These indicators should reflect the organisation's strategy at the 'business operating system' or 'work unit' level and should be devised with stakeholder engagement, including consumer engagement, to understand demands and contributions (25-32). Conceptual frameworks, such as performance measurement frameworks (for example, the balanced

scorecard (28)), provide a comprehensive understanding of a phenomenon by identifying a network of linked concepts and relationships (33). For performance measurement, in particular, they also seek to provide guidance on the design and implementation of measurement systems. The fundamental principles of performance measurement provide an opportunity for learning and development in safety measurement. By adopting this approach, progress in safety measurement could be achieved.

1.3: Case management as a case study

Healthcare organisations worldwide, including the NHS, face a growing burden with the increasing prevalence of long term conditions (LTCs), which are strongly associated with the ageing demographic (34). This burden stretches resources and places patients at greater risk. The NHS and Social Care long term conditions model was introduced in 2005 to tackle the growing burden of LTCs, spearheaded by the implementation of the CM programme (35). The CM programme aims to reduce the burden, predominantly by reducing the number of hospital admissions experienced by the most complex and severe cases of LTCs. Using a proactive and personalised care plan, the CM programme aims to empower patients to take better care of themselves. In parallel, care is integrated by an advanced nurse practitioner, through the coordination of the multiple health and social care services required by the patient group, in order to deliver a single holistic service (35).

In comparison to institutionalised settings, little research has been conducted into safety in community services where healthcare is delivered in the home, such as the CM programme (36). The evidence base on safety in home healthcare is limited. However, studies have recently been published examining the formal carer perspective of home care in Canada (37); the types of adverse events occurring (38, 39); and the comparative perspectives of the service users, their families and healthcare professionals (40, 41). The studies concluded that there was a large contrast between safety in the hospital setting and in the home setting. This contrast was reflected most notably in the lack of control and regulation, the extended

network of caregivers and stakeholders, the isolation of the patients and the healthcare professionals and the greater role the patient plays in achieving health. A corollary to which is a need for a different approach to safety measurement in this setting. However, these studies are relatively recent and have been focused on home care in Canada. The equivalent research has yet to be conducted in the UK.

1.4: Research Problem

The initial exploration of the literature has indicated that safety measurement in healthcare is dominated by outcome measures. The methods by which these measures are calculated suffer from individual limitations. In addition, the isolated use of outcome measures is restricted to counting past performance and does not facilitate an understanding of how the performance was achieved, nor does it hold any predicative capability. The review of the performance measurement literature suggested the use of whole system measures to address the limitations of isolated outcome measurement (i.e. identifying the determinants of outcomes). Conceptual performance frameworks inform the identification of indicators that represent the components of the system responsible for contributing to the desired outcomes. This can be achieved by a comprehensive understanding of the system, including the consumer's contribution. Furthermore, the patient perspective, as a consumer of healthcare, is not well reflected in the literature but is being recognised as an area for improvement. This is particularly important as care services, like the CM programme, aim to more effectively engage patients in healthcare activities. Research to date has not yet led to a comprehensive understanding of safety in the home care setting.

1.5: Research aim and objectives

In order to address the gap in the literature, the primary aim of the research is:

To develop a framework for safety measurement for the NHS case management programme that is reflective of key stakeholder perspectives to guide the assessment of safety.

The objectives are to:

1. Create a model that identifies the key stakeholders of the case management programme and the overarching domains for measurement to inform the research design

2. Validate the model

3. Explore the concept of safety from the stakeholders' perspectives, as identified in the above model

4. Understand what it means to be safe in the home to the key stakeholders of this patient group and determine desired outcomes and influencing factors

5. Devise a safety performance assessment framework that manifests the perspectives of the key stakeholders

1.6: Research design

The aim of this research was to devise a framework to support safety measurement to be used when care is delivered in the home that was reflective of both key stakeholder perspectives and the system. To achieve this, the researcher has adopted a critical realist philosophy to facilitate the exploration of unobservable mechanisms and test their acceptability amongst a large population. Therefore, the research has explored, examined and understood the key stakeholders' perspectives of safety in the CM programme and has determined the acceptability of these perspectives. This was achieved using an exploratory, sequential mixed method design (42). The first phase of this design was a case study (study I) (43), and the second phase was a survey (study II) (44). Study I explored, through multiple methods within a case study design, the perspectives of safety, including its definition, contributing factors and desired outcomes. Methods of data collection included 13 interviews with nine patients and six carers, and three focus groups with 17 CM nurses. Study II deployed a survey that determined the level of agreement with the qualitative findings amongst a larger sample size (patient n=35, carer n=19 and CM nurse n=26).

1.7: Thesis outline

This chapter has provided the background information to the research, introduced the research problem and its subsequent aims and objectives. The following two chapters present the literature and the critical evidence and argument needed for this research. In Chapter 3, the integrated safety measurement model is presented as a prerequisite for the research design, which is discussed in Chapter 4. Chapter 4 specifically describes the research design, and the two study protocols are given in Chapter 5. The findings of each study are presented in Chapters 6 and 7. Chapter 8 discusses the findings of the preceding chapters in relation to the aims of research, which enables the conceptual framework to be devised before giving consideration to the limitations of the research. Finally, conclusions are drawn in Chapter 9, and possible future work is proposed. A diagrammatic outline of the thesis can be found in Figure 1.1: Thesis outline.

Chapter 1: Introduction

Chapter 2: Safety measurement, management and performance in healthcare

Chapter 3: The case for an alternative approach to patient safety measurement

Chapter 4: Research design

Chapter 5: Study protocols

Chapter 6: Study I - A qualitative exploration of key stakeholder perspectives of safety in healthcare delivered in the home

Chapter 7: Study II - Quantitative examination of key stakeholder perspectives of safety in healthcare delivered in the home

Chapter 8: Discussion

Chapter 9: Conclusions

Figure 1.1: Thesis outline

Chapter 2

Safety measurement, management and performance in healthcare

2.1: Introduction

Following the publication of the Institute of Medicine's (IoM) report 'To Err is Human: building a safer health system' (6), the issue of medical error became widely acknowledged. The statistics published in the IoM report equated medical error to that of the 8th leading cause of death in America, accounting for more deaths than breast cancer, and awakening the world to the extent of harm in healthcare. These statistics were derived from two large scale American studies, which, when extrapolated, indicated that between 44,000 (2) and 98,000 (1) deaths occurred as a result of medical error each year. There is no single cause of error or an individual responsible, as will be explored here, but the severity of error could be attributed to the increasingly complex and poorly understood systems within which medicine is practiced (22).

Following the revelations of harm in healthcare in the U.S.A., other healthcare organisations worldwide began to consider the extent of error experienced by their own patients and the cost implications of such error. An Australian study indicated that 16.6% of hospital admissions were associated with an adverse event, with 51% considered preventable (8). Another Australian study (45) determined that adverse events added a further $6,826 to the cost of each admission. In England, one in ten hospital admissions results in patient harm (7), costing a further £2 billion a year in increased hospital stays (11).

Furthermore, the Department of Health (DoH), in 'An Organisation with a Memory' (11), estimates that annually:

- 400 people die or are seriously injured involving medical devices

- nearly 10,000 people are reported to have experienced serious adverse drug reactions

- 15% of hospital acquired infections are avoidable and cost an estimated £1 billion

- the National Health Service (NHS) pays out about £400 million in the settlement of clinical negligence claims

Medical error is costly and patient safety presents an area of concern for policy makers worldwide. With the incidence of hospital adverse events averaging 9.2% across eight large studies from around the world (10), the evolution of patient safety has been lagging behind other components of medicine and, in particular, other industries. It is difficult to cross compare industries because of differing units of measurement however, in aerospace, during 2009 there were 685 global fatalities (46), which is considerably lower than the figures calculated in healthcare. The IoM report (6) has been seminal in the field of patient safety and subsequently, huge efforts have been made to quantify the incidence of error and harm worldwide. Through the study of adverse events, there have been developments: new methods to quantify error, improvement strategies devised and implemented, and a wealth of information generated. As indicated by the number of hospital based statistics presented, efforts have been focused in secondary care. However, there is an emerging trend towards primary care research and improvement efforts. Despite these efforts, it is still unclear as to whether healthcare is now safer in either secondary or primary care. This is because there is no longitudinal method available to validly and reliably track error, harm or safety over time.

This chapter explores safety in healthcare, its measurement and performance, and aims to identify their limitations. The chapter begins by introducing the current understanding of the concept of safety in healthcare and the systems model (22). There will be an exploration of the definition of safety and other key terms. As will be discussed, it is evident that patient safety revolves around the reduction of risk of

harm to patients through the application of evidence based processes. A critique of the current measurement methods will be presented in relation to how they achieve the goal of measuring safety. Where measurement methods fail, risk management and safety performance provide some support to fill the void. In concluding the chapter, attention is drawn to the aspects of the methods, which lead to the hypothesis that the current safety measurement methods are inappropriate for comprehensive safety measurement - where comprehensive safety measurement enables the measurement, monitoring and management of risk to promote positive outcomes.

2.2: Overview of patient safety

2.2.1: Systems approach to patient safety

According to Reason (22), there are two main approaches to error and patient safety in healthcare: the person approach and the systems approach. The person approach focuses on the individuals who commit unsafe acts or violations at the sharp end, resulting in a culture of blame. Human behaviour is perceived as being solely responsible for error as a result of things, such as forgetfulness, poor motivation, recklessness and inattention. Countermeasures are directed at reducing variability in human behaviour through disciplinary action, retraining or naming and shaming. The systems approach however, accepts human fallibility and proposes that conditions within a system (latent conditions), upstream of an action, predispose that system to error (active failures) and ultimately adverse outcomes. Ordinarily, a system will have defensive layers that tolerate error; only upon alignment of holes in the defensive layers does an error occur. This theory is presented in the Swiss cheese model, see Figure 2.1: The Swiss cheese model. Conditions in the system that are risk factors for error include inadequate training, sleep deprivation, unclear policies and poorly designed tools (23, 24, 47).
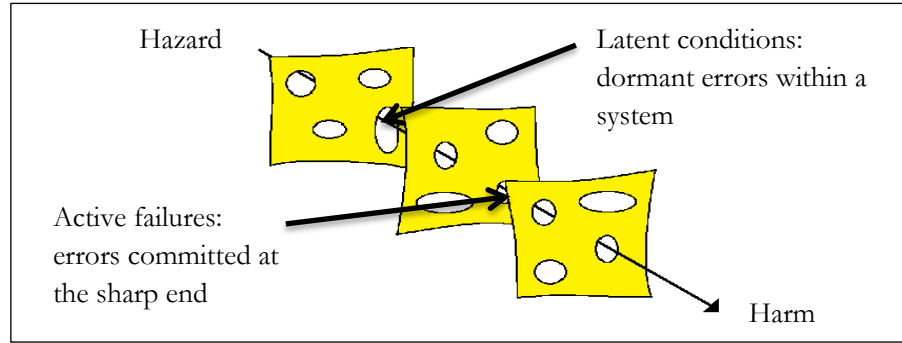
Figure 2.1: The Swiss cheese model (22)

The systems approach to safety was first implemented in other industries. Understanding the processes that were required for safe aviation, allowed the development of checklists and procedures that ensured critical steps prior to take off were commissioned (24), preventing active failures. Furthermore, understanding latent conditions, helped to inform policy and generate regulations that increased the safety of the system. For instance, the identification of pilot fatigue as a risk factor for fatal crashes and decreased performance in aviation, led to the creation of a pilot flight duty and rest proposal (24, 48). Anaesthesiology is another discipline that has successfully integrated the systems approach to safety. Previously, the risk of death was approximately one in 10,000 inductions (49), which has subsequently been reduced to one in 200,000 inductions (50, 51) following the investigation of critical incidents from the systems and human factors perspectives (47, 52). Successful implementation can be extremely rewarding, and, as indicated in anaesthesia, can result in improvements to patient safety.

The growing interest in patient safety research has resulted in multiple definitions for terms and words relating to patient safety in the literature. Inconsistency of language can hinder progress towards a better understanding and inhibit comparisons between studies. One study found 25 definitions for error in the literature (53), another study identified 17 definitions for error and 14 for adverse event. (54). The latter of these studies provided evidence for the World Health Organisation (WHO) to pursue a project to comprehensively classify patient safety (4). A patient safety glossary is required for this thesis to ensure

consistency throughout and in line with the literature. Key terms include: error, harm, adverse events, patient safety incident and patient safety. Their definitions will be discussed in the following sub-sections and conclusions drawn on the most suitable.

2.2.2: Error

Reason (55) originally defined an error as the *'the failure of planned actions to achieve their desired goal'* (55)[pg81]. The IoM report expanded on this to include: *'the failure of a planned action to be completed as intended or use of a wrong plan to achieve an aim; the accumulation of errors results in accidents'* (6)[pg4], and is the most commonly used definition in the literature (53). Thus, given its wide use, it seems appropriate to adopt this definition for the purpose of this thesis. Furthermore, there are two types of error originally described by Reason (56): latent errors, and active errors. These were also adopted by the IoM report (6) and republished by Reason (22) as latent conditions and active failures:

1. Latent conditions – errors within the system that can lie dormant for years
2. Active failures – errors committed at the sharp end of the service and whose effects are felt immediately

Understanding latent conditions provides an opportunity to proactively manage risk, potentially preventing error, or mitigating against its effects. Davies et al. (5), in the Canadian Patient Safety Dictionary, classified latent conditions under the term structure, which, was first proposed by Donabedian (3) as *'the settings in which it [care] takes place and the instrumentalities of which it is the product'* (3)[pg694]. Or, in other words, the system within which, care is delivered, such as facilities, equipment, staff and the operation of programmes. Davies et al. (5) describe structure to be *'a supporting framework or essential parts. It includes all elements of the health-care system that exist before any actions or activities take place'* (5)[pg21]. Given this, active failures are more aligned with the process of care, also described by Donabedian (3), which referred to the application and conduct of medical care. The definition of error provided above, encompasses errors of commission (failure of a planned action to be completed as intended) and errors of omission (the use of a

13

wrong plan to achieve an aim). The use of the IoM report (6) definition of error, derived from Reason (55), is supported here as it focuses on the structure and process of safety as described by Davies et al. (5), rather than on an outcome and doesn't claim that an error always results in a negative outcome or harm. Other terms are available to describe errors that result in harm. Therefore, harm, adverse events and patient safety indicators will be discussed.

2.2.3: Harm, adverse events and patient safety incidents

The WHO's (4) classification defines harm as the *'impairment of structure or function of the body and/or any deleterious effect arising there from'* (4)[pg21]. Furthermore, it describes a harmful incident as *'an incident that resulted in harm to a patient'* (4)[pg21]. However, in the literature, the term adverse event prevails in popularity and is used as the measurable indicator of the Harvard Medical Practice Study (2), which informed the IoM report (6). The Harvard Medical Practice Study defined an adverse event as an injury caused by medical mis-management that resulted in measurable disability rather than the underlying disease (2). Confusingly, the term adverse event can also be used in reference to the action that led to harm (5). Furthermore, adverse events can impose psychological trauma on patients when defined as *'an event or omission arising during clinical care and causing physical or psychological injury to a patient'* (11)[pgxii].

In the homecare setting, the definition of adverse event, as proposed by Madigan (57), describes events or occurrences, which manifest within the process of service delivery and is inclusive of additional stakeholder outcomes. This latter aspect of the definition is innovative, but it could be argued that events or occurrences may only become apparent post-service delivery, which is not considered in this definition. By omitting harm that occurs in the absence of healthcare professionals, the definition potentially excludes the proportion of care conducted by the homecare population during self-care.

The NHS utilises the term patient safety incident to describe the process of harm or potential for harm: *'any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS care'* (58). However, the use of the word incident evokes the notion of an identifiable moment in time that is

responsible for the actual or potential harmful outcome. However, as was explored previously, this is not aligned with the systems approach to safety.

2.2.4: Patient safety

The IoM report (6), defines patient safety as *'freedom from accidental injury; ensuring patient safety involves the establishment of operational systems and processes that minimize the likelihood of errors and maximizes the likelihood of intercepting them when they occur' (6)*[pg211]. Davies et al. (5) defined patient safety as *'the reduction and mitigation of unsafe acts within the health-care system, as well as through the use of best practices shown to lead to optimal patient outcomes' (5)*[pg12]. Similarly, Runciman et al. (4), who were commissioned by the WHO to classify patient safety terminology, present safety to be the *'reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum' (4)*[pg19]. Cooper et al. (59) also refers to patient safety as the process of avoiding, preventing or ameliorating adverse outcomes.

Noticeably, these definitions, although worded differently, refer to a reduction in the risk of delivering negative outcomes. These definitions successfully describe the prevention of unsafe care, but only Davies et al. (5) provide any clarity on what safe care is, by highlighting the use of best practices. Although, one might consider them symbiotic, the avoidance of negative outcomes does not guarantee optimal outcomes. The emphasis of most definitions is on the organisational practices to prevent error, rather than promote safety. This may be due, in part, to the relative infancy of patient safety research and practices in healthcare. Promotion of safety in the definition would require a level of understanding of the conditions that would need to be met i.e. standards. However, definable safety standards across healthcare have yet to materialise. Possibly because of the variability of standards required across all services, development of them would be resource intensive. Despite this, Davies et al. (5) have made some effort in recognising the use of best practices to optimise outcomes as a component of safety.

The definition proposed by Davies et al. (5) implies a focus on individuals, rather than on the systemic environment. The definition is ignorant of latent conditions; only giving attention to active failures by

using the term 'unsafe acts'. The IoM report provides an in depth definition of the systemic nature of patient safety and the development of systems that not only reduce the risk of error, but also increase the opportunity to intercept should error occur. Similarly to both the IoM report (6) and Davies et al. (5), Cooper et al. (59) express safety as a function of the removal and prevention of process which allow adverse outcomes.

Runciman et al.'s (4) definition, without being explicit, acknowledges three factors of patient safety. Firstly, it makes reference to the inherent, harmful nature of medicine through its use of the term *'unnecessary harm'.* For example, the very act of performing surgery is harmful; however, the benefits will have been considered and weighed against the consequences of not treating the medical problem surgically. Secondly, it acknowledges that healthcare, because of its inherent harmful nature and its dependency on human interaction, will never be free of error. Subsequently, what is required in order to be able to claim healthcare as safe, is to define, preferably quantifiably, what an acceptable minimum is. This raises questions as to whose responsibility and right it is to make that decision. Finally, it describes patient safety as a risk management exercise in seeking to reduce risk. This implies the on-going, active process of continuous assessment, review and prioritisation of risk. This definition offers the most comprehensive coverage of what patient safety means of the available definitions.

2.2.5: Summary

A summary of the key terms for use in this thesis relating to patient safety are reported in Table 2.1: Safety glossary.

Table 2.1: Safety glossary

Term	Definition	Source
Latent Condition	Errors within the system, which can lie dormant for years	(6, 22)
Active Failure	Errors committed at the sharp end of the service and whose effects are felt immediately	(6, 22)
Error	Failure of a planned action to be completed as intended or use of a wrong plan to achieve an aim; the accumulation of errors results in accidents	(6)
Harm	Impairment of structure or function of the body and/or any deleterious effect arising there from'. Including disease, injury, suffering and disability.	(4)
Adverse Event	4) An unintended and undesired incident directly associated with the care or services provided to the patient 5) An incident that occurs during the process of providing health care and results in patient injury or death 6) An adverse outcome for a patient, including injury or complication	(5)
Patient Safety Incident	A patient safety incident is any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving [NHS] care.	(58)
Patient Safety	The reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum, as well as the use of best practice shown to lead to optimal outcomes.	(4, 5)

2.3: Safety measurement methods

To measure is *'to ascertain the size, amount or degree (of something) by using an instrument or device marked in standard units' (60)*.

2.3.1: Retrospective record review

Since retrospective record review (RRR) was first described as a methodology (61), the process has changed very little, except to add greater validity to the findings. Originally a two stage process (1, 2, 7-9), a third phase was added to clarify records for which consensus could not been achieved (62, 63). The process of RRR has been summarised in Figure 2.2: Process of retrospective record review. In addition to calculating the number of adverse events as a rate of hospital admissions, reviewers were able to determine the impact in bed days, level of disability, likely cause and preventability.

PROCESS	OUTCOME
Phase 1	
Initial screening by trained nurse or hospital administrator against 18 criteria – progress to phase two is the identification on one or more criteria	
Phase 2	

Two trained physicians analyse positively screened records to determine presence of adverse events	Number of Adverse Events
	Impact of adverse event
	   ➢ Number of bed days
	   ➢ Level of disability
	Likely Cause
	Preventability

Phase 3	
For records for which a consensus could not be reached, a third trained physician reviews and give final judgement	

Figure 2.2: Process of retrospective record review

RRR was the first real attempt to determine the incidence of adverse events in healthcare. However, since its implementation, further investigation has uncovered some drawbacks. Neale et al. (13) report that through comparing prompted incident reporting (14) and checking risk management and litigation files (15), RRR misses up to 20% of adverse events (13). Due to the subjective nature of the process, because of its reliance on physician judgement to detect the presence of an adverse event, inaccuracies exist that generate data that seems to underreport the extent of adverse events. This is further supported by the work of Thomas et al. (16), who described a poor inter-rater reliability between physicians. In addition, an Australian study (8) demonstrated only 80% agreement on the presence of an adverse event between physicians, and only 58% on whether they were preventable or not. Furthermore, RRR is susceptible to hindsight bias i.e. knowing the severity of the outcome influences judgement (64). However, when cross comparing methods, Michel (65) found RRR to be an effective method for estimating rates of adverse events, but less effective than prospective methods for describing causes, and consequences of adverse events, as well as for evaluating risk reduction programmes.

RRR has predominantly been utilised on the records of hospitalised patients but was recently adapted by Sears et al. (38) in the Canadian home care setting, and published in mid-2013. It was recognised that the screening criteria would not be wholly applicable to the home care setting and thus, using a Delphi technique, the screening criteria used in phase 1 of the standard RRR process were modified and validated by an expert panel. Sears et al. (38) determined a 13% incidence of adverse events amongst patients receiving home healthcare with approximately one-third perceived to be preventable.

Although RRR has proven valuable in illuminating the extent of harm and error, it is not a method for measuring safety but rather, is an epidemiological tool to study the distribution, patterns and causes of adverse events. What RRR does not do, is determine a level of safety. Neither does it pursue a line of improvement activity, although its findings could help shape the direction of improvement efforts by detecting high incidence locations and/or types of events. RRR also relies on the use of outcome measures, which are subject to a time lag and the true consequence of an adverse event might not be

realised for some time. In addition, by definition, a patient must experience harm in order for it to be detected. The criteria and subsequently identified adverse events are also clinically focused, giving no consideration to outcomes that are psychological or social in nature. This is possibly related to the care setting of its origin: the hospital. The hospital care setting is heavily focused on clinical processes, which are controllable and thus cause and effect relationships have been established with respect to clinical outcomes. The time consuming and resource intensive nature of RRR reduces its use, more often than not, to one time use in any organisation. This is evidenced by the lack of repeat use in any one organisation published in the literature. Consequently, it lacks the capacity to make comparisons from baseline over time to determine evidence of improvement.

The advancement of health informatics, through the deployment of electronic medical records, has seen the development of an electronic equivalent of RRR using trigger tools, which are discussed in the next section.

2.3.2: Global trigger tools

Global trigger tools (GTTs) are available to replace the preliminary screening phase of a RRR. The use of triggers aims to facilitate a more focused and standardised review of patient records. Triggers are *'easily identifiable flags, occurrences and prompts in patient records'* (17)[pg176], which are associated with the potential presence of an adverse event. The Health Foundation in the U.K. promotes the use of trigger tools within the NHS (66). They claim that trigger tools provide an opportunity to overcome the underreporting nature of incident reporting, which is discussed in the next section. The focus of the GTT is to detect, quantify and track adverse events by scanning a small sample of patient records regularly to direct improvement efforts to where they are most needed.

The GTT has been able to identify up to 10 times more serious adverse events compared to other methods, including RRR and self-reporting (67, 68) However, conflictingly, other studies have found it to

identify fewer adverse events than prospective review and RRR (69, 70). Therefore, some authors consider that this may limit its wider use (71), whilst others argue that good inter-rater reliability between review teams and at different sites could prove useful in both individual organisations and nationally (70). In 2010, the Health Foundation published 'Evidence Scan: global trigger tools' (66), in which it highlighted that there was a *'relatively small amount of published evidence about the use and benefits of global trigger tools'* (66)[pg7]. They recognised the literature to be descriptive of how it is used and the data generated, yet the Health Foundation advocates its wide scale use throughout the U.K., arguing that a lack of evidence supporting its effectiveness is not indicative of lack of effectiveness. However, this approach is contradictory to the evidence based medicine approach adopted by the NHS.

The retrospective nature of the trigger tool approach means that the limitations of the RRR endure. When testing inter-rater reliability, Mattsson et al. (72) found only 31% of adverse events were identified by two teams and suggested limiting their use until further evaluation was conducted. However, other studies contradict this (71). The lagging outcome indicators are limited in their effectiveness to directly improve safety and rely on an adverse event (harm or potential harm to patients) occurring and thus does not intuitively reduce risk to patients. Reliance on clinical judgement post trigger tool use (phase 2 of Figure 2.2) incorporates subjectivity into the method as with RRR. Although GTTs show promise in repeatability, they are unsuitable as benchmarking tools (73). Progress is also being made in adapting the GTT to different settings, but this is yet to be achieved for the community setting.

2.3.3: Incident reporting systems

The use of incident reporting systems (IRSs) in safety management is common place in other high risk industries, such as aviation (74). Their core purpose is to support continuous process improvement (55) as well as to aid local incident management (75).This method of safety management has been embraced by healthcare organisations worldwide following recommendations by the IoM (6), which have since been endorsed by the WHO (18). IRSs were expected to identify vulnerabilities and contribute to efforts to

prevent reoccurrence (6), by learning from past failures to improve patient safety, which is aligned with the systems approach (22). The use of IRSs promotes 'quadruple loop learning', providing opportunities for learning at personal, local, national and international levels (76). The IoM (6) promoted the use of two types of reporting system: mandatory and voluntary, where mandatory systems aim to achieve accountability for more severe incidents and voluntary systems provide opportunities to learn and generate improvements from less serious incidents and near misses (prevented patient safety incidents).

The NHS is one organisation that has adopted the advice of the IoM and implemented a voluntary reporting system. Following a recommendation in the 2000 DoH white paper, 'An Organisation with a Memory' (11), the National Patient Safety Agency (NPSA) was set up in 2001. It sought to establish a National Reporting and Learning System (NRLS), which was the first of its kind in healthcare worldwide and is an example of a high level, national reporting system into which subsidiaries of the NHS are encouraged to report. It has been hailed as *"the most mature, country-level PSRS [Patient Safety Reporting System] in existence...that could be emulated in the United States"* (77) [pg5]. The NRLS is a mechanism for collecting data on patient safety incidents, inclusive of near misses across the whole of England and Wales and enables emerging trends and patterns to be detected nationwide that would otherwise be insignificant in low numbers at the local level (78).

NHS organisations are strongly encouraged to submit all patient incidents to its online database. Between July and September 2011, 77% of all organisations submitted at least one incident to the NRLS. Between October 2010 and September 2011, the care group setting: community nursing, medical and therapy service (incl. community hospital) accounted for 11% of the incidents, with the total of all other non-acute care settings, accounting for less than 1% (0.913%). Examples of the types of incidents reported are available in Table 2.2: Examples of incident reports submitted to the NRLS by incident type.

Table 2.2: Examples of incident reports submitted to the NRLS by incident type
(adapted from (73))

Incident type	Description
Patient Accident	Patient usually only mobile with assistance but walked to the toilet opposite their bed unaided. Was found behind toilet door on the floor trying to get up
Infrastructure	Temperature within dialysis unit particularly by the window reached 35c, Patient and the parents feeling unwell due to heat. Staff finding it very difficult to work in these conditions. Parent wrote complaint letter
Clinical Assessment	PT arrived for scan. The wrong form was given, as there were 2 pt with the same name for the same scan on the same day. The clinical details were similar. Images were taken on the wrong pt as a result.

There is little published evidence to support a meaningful change in the rate of improvement following the implementation of an IRS, despite large volumes of reports being published (79). However, it cannot be concluded that meaningful change isn't occurring; it could either be unmeasured or unpublished. There is limited data to support the effectiveness of reporting system, however; studies are available on their ineffectiveness. Predominantly, they relate to the under-reporting nature of systems (80), which can ultimately be attributed to the voluntary nature of many reporting systems. The disposition to report is dictated by culturally systemic factors such as: severity of the outcome, rank of staff member and lack of feedback (81-83).

The severity of the outcome can influence whether an incident is reported or not, with more serious incidents more likely to be reported (83). Furthermore, it has been determined that organisations only take action on more serious reports (84). This devalues the use of near-miss reporting or less severe but potentially more frequent events, which would otherwise offer an opportunity to prevent sharp end failures and severe outcomes. A study by Thomas et al. (75) identified incident reports as inadequate at meeting the primary objective of continuous improvement because sophisticated and effective analysis

was not achievable. This was echoed by the IoM (85). However it is recognised that some of the information collected through incident reporting would not be obtainable by other methods (84).

Research has provided evidence on factors that influence whether an incident is reported:

- lack of feedback to the reporting physician from management (83)
- excessive length of required report forms (82)
- triviality of the incident (82)
- the level of harm experienced by the patient (81)
- the clear violation of protocol and job role (82)
- rank of staff member – lower ranked members more likely to report than higher midwives/nurses most likely, then junior doctors than senior doctors (82)

Another concern of IRSs, in relation to other methods, is the inconsistencies that occur. A study (14), which examined the incidents detected in both incident reporting and medical record review identified the same number of adverse events, however, different adverse events were detected i.e. the overlap was small. This has implications on the sensitivity of both of the methods and their ability to accurately measure what they are designed to measure. The different perspectives between individuals and what each individual considers to constitute an adverse event may account for some of the insensitivity, as both methods subjectively detect adverse events. Studies have been able to conclude differences in the reporting habits between nurse and doctors, with nurses and midwives being more likely to report using IRSs (81, 83). It is conceivable that, since RRR is conducted by physicians, who are least likely to report, that RRR is merely a reflection of the physician perspective of adverse events and similarly, that incident reporting is more reflective of nurse perspectives. The voluntary nature of reporting systems renders them inappropriate for use as an index of rate or a measure of safety (82, 86).

2.3.4: Patient safety indicators

Patient safety indicators (PSIs) were first developed by the Agency for Healthcare Research and Quality (AHRQ) and were designed to take advantage of readily available hospital data, generated by the

Healthcare Cost Utilisation Project (HCUP) (87). PSIs screen for surgical complications that are a result of exposure to the healthcare system that were potentially preventable (87). The AHRQ (87) described indicators at two functional levels: provider level and area level. Provider level indicators are a measure of the adverse events experienced by patients who received their care and suffered the complication within the same hospital. Area level indicators provide an assessment across a geographical area and can be within the same hospital (as for provider indicators), but will also detect adverse events that present in one hospital but resulted from care in another. However, geographical assessment of adverse events using PSIs from the AHRQ, where data has had to be aggregated, might not be accurate. Rivard et al. (88) demonstrated the sensitivity of PSI rates to both the data file structure, and definitions and sources of data elements, when translated to a non-HCUP data source. This resulted in an inaccurate rate of PSIs. Table 2.3: AHRQ patient safety indicators, contains the most recent version of the 26 PSIs published by the AHRQ in 2007.

Two things are evident from Table 2.3:

1. All the PISs are clinical outcomes to the exclusion of psychological or social outcomes

2. There are clusters of service specific indicators – 11/26 are surgical and 4/26 are obstetrics & gynaecology and the remaining 11/26 are generic hospital indicators

An implication of PSIs being solely clinical in nature, is that outcomes that are more important to patients (89), are not measured, therefore, it cannot be determined if these outcomes are being achieved. In addition, having PSIs that place focus on particular services distracts improvement efforts away from other areas of potential risk, which remain unidentified.

Table 2.3: AHRQ Patient safety indicators
(adapted from (87))

Patient Safety Indicator Number	Definition
PROVIDER LEVEL	
1	Complication of anesthesia
2	Death in low mortality diagnosis related group (DRG)
3	Decubitus ulcer
4	Failure to rescue
5	Foreign body left during procedure
6	Iatrogenic pneumothorax
7	Selected infections due to medical care
8	Postoperative hip fracture
9	Postoperative hemorrhage or hematoma
10	Postoperative physiologic metabolic derangement
11	Postoperative respiratory failure
12	Postoperative pulmonary embolism or deep vein thrombosis
13	Postoperative sepsis
14	Postoperative wound dehiscence
15	Accidental puncture of laceration
16	Transfuaion reaction
17	Birth trauma – injury to neonate
18	Obstetric trauma – vaginal delivery with instrument
19	Obstetric trauma – vaginal delivery without instrument
20	Obstetric trauma – cesarean delivery
AREA LEVEL	
22	Iatrogenic pneumothorax
23	Selected infections due to medical care
24	Postoperative wound dehiscence
25	Accidental puncture of laceration
26	Transfusion reaction
27	Postoperative hemorrhage or hematoma

The Organisation for Economic Cooperation and Development (OECD) has also developed a set of 21 indicators (90). These were selected by an expert panel of government officials and academic experts from indicators currently in use by member states. Recommendations by the IoM (91) on indicator evaluation were followed, and indicators that were scientifically sound, potentially feasible and contained an important performance aspect, were selected. Table 2.4: Criteria and dimensions for OECD PSI selection, provides a breakdown of the selection criteria by dimension. The selection criteria could explain why the

indicators are clinically focussed and relevant to only a narrow range of services. The indicators might: be of greatest policy importance, be most susceptible to healthcare influence, represent the greatest gap between actual and potential outcomes, have demonstrated the best validity, or represent the indicators with available and comparable data.

Table 2.4: Criteria and dimensions for OECD PSI selection
(adapted from McLoughlin (90))

Criteria	Dimension	Description
Importance	Impact on health	Does it address an area in which there is a gap between actual health and potential health?
	Policy importance	Is this area of concern to policy makers?
	Susceptibility to influence by healthcare system	Can the healthcare system influence the outcomes?
Scientific Soundness	Face validity	Is the measure logical and clinically rational?
	Content validity	Does it capture meaningful aspects of care quality?
Feasibility	Data availability	Are comparable international data available?
	Reporting burden	Are the benefits of collecting data greater than the burden?

Similarly to AHRQ PSIs, the OECD PSIs are hospital specific. Furthermore, McLoughlin, et al. (90) presented several inadequacies of OECD PSIs. Their criticisms included: their inability to detect near misses, their inability to identify adherence to safe care processes, and issues relating to the under-represented adverse events associated with under-reporting of safety issues. Although these issues are presented in relation to OECD PSIs, they are applicable to the PSI procedure in general.

Despite the OECD indicators being available, research efforts in England have resulted in the translation of the AHRQ PSIs for English hospitals, utilising hospital episode statistics (HES) (92). However, the AHRQ data source differs to that used for HES, thus translation to suit the data was required. Bottle and Aylin (92) described issues in the translation relating to a range of things, including: the absence of codes in International Classification of Disease-10 (ICD) that existed in ICD-9, the conversion of ICD-9 procedure codes into Office of Population Consensus Surveys-4 (OPSC) was 'not an exact science', there was no mapping between major diagnostic categories of ICD-9 and Healthcare Resources Groups, and linkage was required of the provider code when transferring to an acute facility. The issues relating to PSI translation reduce the comparability of data from different data sources.

Despite the translation issues, evidence exists to support the use of PSIs to identify adverse events. In English hospitals, PSIs demonstrated little variation in rates over a three year period, indicating consistency in coding (93). Raleigh et al. (93), were also able to associate excess length of stay with PSIs in comparison to matched controls. Furthermore, an association has been correlated between PSIs, higher mortality and a greater rate of unplanned readmissions (92). Finally, it has been proposed that PSIs provide greater value when used in conjunction with other indicators, namely short term admissions (94) and temporal trends (95).

Whilst there is evidence to support the use of PSIs, there is further evidence to the contrary. Whilst specificity has been shown to be high (low rate of false positives), sensitivity is low (high rate of false negatives (96), i.e. it is unable to accurately detect all adverse events. The implications of this could include an inaccurate 'map' of adverse events; when, where and to whom they are occurring?

The nature of coding in electronic databases means that the accuracy of the coding for each complication or adverse event is pivotal in the representativeness of the incidence rate subsequently calculated using PSIs. A higher rate of events is not necessarily indicative of poor quality and unsafe care. In fact, it might be argued that the opposite is true; a hospital with a more positive safety culture might be more inclined

to accurately record events because of greater vigilance and attention given to patient safety (92). When NHS hospitals were invited to give their opinion on the PSIs, which had been translated from AHRQ and used to rank NHS hospitals, they raised concerns on their ability to draw valid comparisons between different organisations, questioning the sufficiency of case-mix adjustment (92). Grobman et al. (97) believed that ICD-9 was not sufficiently able to detect preventable obstetric adverse events and thus does not adequately reflect patient safety. They argue that non-hospital characteristics strongly influence the risk of obstetric trauma. This raises questions on the selection of obstetric indicators and the consideration of their susceptibility to healthcare system influence. A summary of issues can be found in Table 2.5: Summary of issues associated with patient safety indicators.

Table 2.5: Summary of issues associated with patient safety indicators

Issue

Sensitive to data aggregation when applied to non-HCOP data sources

Do not detect near misses

Do not detect adherence to safe processes

Hospital and particular services specific

Clinically oriented

Data issues because underreporting of safety issues

Not wholly susceptible to healthcare system influence

2.3.5: Prospective methods

Prospective studies observe the occurrence of outcomes as they happen during the study period, rather than examining them after they have occurred (98). Bellomo et al. (99) studied all surgical inpatients in a 4

month period who remained in hospital for 48 hours or more after surgery. They used a set of specific criteria to define postoperative serious adverse events and determined that one in six surgical patients experienced one or more, with higher risk associated with being over 75 and having unscheduled surgery. Cravero et al. (100) prospectively studied patients who were being sedated or anaesthetised. They collected multiple data in addition to adverse events including: primary illness, coexisting illnesses, procedures performed, medications used, outcomes and airway interventions. These studies involve the detection of complications as they occur and the counting of them.

Prospective observational studies such as Andrews et al.'s (101) observe the process of care as it occurs generating *'a description of the adverse event, who identified it, what was said to be the cause, what the effect on the patient was, whether any one was blamed, and whether any response to the event was mentioned'* (101)[pg310]. They calculated that 17.7% of patients experienced at least one or more serious event. Another observation study (102) had a two pronged approach. In phase 1 they collected error reports from physicians and nurses immediately after their discovery. Additionally, they conducted activity profiles over a consecutive 24 hour period by an observer. They calculated there was an average of 178 activities per patient day with an estimated 1.7 errors per patient per day, with physicians and nurses contributing equally to the number of errors (although nurses had more activities per day so not on a ratio basis). These sorts of studies have not been subjected to reliability testing, but it would seem fair to conclude that this method would be subject to bias and different reporter perspectives of error as seen in incident reporting.

Michel et al. (65) conducted a comparative study to compare the effectiveness of preventable adverse event detection between a cross sectional method (data collected on day 1), a prospective method (data collected across a 30 follow up period), and RRR (data collected after discharge). The uniqueness of this study was that it collected data from the same patient sample, in order to be truly able to compare across the three methods. The prospective method was best at identifying preventable adverse events,

which was preferred because of their pedagogical and communicative virtues with good staff involvement. However, it was also perceived to be the most expensive with the heaviest work load.

Thomas and Peterson (103) believe prospective methods offer the best opportunity for detecting active errors (active failures). They also criticise them because they have practical and methodological issues including:

- Lack of confidentially, which could lead to punitive action on staff

- Time intensive training of observers

- If observers cannot be blinded to patient outcome, then they might be subject to hindsight bias

- Focus is on sharp end and ignorant of latent conditions because they are not necessarily observable

- The Hawthorne Effect – altered behaviour because of being observed

Although these are prospective studies, the primary data being collected is that of lagging indicators: adverse events, which still require the patient to come to harm. This method still does not enable the easy detection of unsafe conditions prior to the effect of the outcome, to prevent the outcome. Because of their time intensiveness, particularly in the case of prospective observational studies, they have not been implemented on a large scale, unlike other methods.

2.3.6: Safety culture

The dominance of adverse event measurement is indicated by the multiple methods of measurement, to which, arguments have been presented for their inadequacy at generating meaningful data that is capable of determining whether something is safe (or unsafe), and able to monitor the environment, to prevent adverse outcomes. Safety culture assessment is another form of safety measurement. The importance of having a safety culture: one that admits to and learns from error, was emphasised in the IoM report (6), however, a culture of blame and secrecy still persists in healthcare. Media coverage of the Mid-Staffordshire NHS Trust unveiled details of 'gagging orders', which were used to silence whistle blowers.

In the three years up to 2011, 600 compromise agreements cost taxpayers £14.7million (104). This is not conducive to a safety culture, which supports staff to identify issues and work towards resolving and learning from them. This entrenched culture, where a fear of blame exists inhibits voluntary reporting (105), which reduces the opportunity to learn and improve. A change in culture is fundamental in the fight against poor quality and unsafe care. Despite Leape's (106) strong conviction for the need to change safety culture, Cox and Flin (107) argue that the belief in the concept has *'far out-stripped the evidence for its utility'* (107)[pg190].

Safety culture can be described as the shared beliefs, attitudes and values that contribute to patient safety changes (108, 109). Furthermore, safety culture assessments can be used as tools to identify the presence of conditions that support the identification of adverse events, and can be acted up on to prevent future adverse events (20).

Although Cox and Flin (107) argue there is greater belief in the contribution safety culture can make to improve safety, than evidence suggests, there is some evidence to support a relationship between assessment outcomes and clinical outcomes (110). In one study (111), poor hospital patient safety climate was associated with higher readmission rates for heart attacks and heart failure. Another study (112) found, that implementation of the surgical safety checklist was associated with improved safety attitudes and subsequently, improved post-operative complications. Moderate relationships between patient safety culture and fewer patient safety incidents have also been concluded (113). Despite this, Colla et al. (114), express caution at the validity of nine assessments included in a review, because of a lack of psychometric testing. Their predictive value for other safety indicators is not clear (115) i.e. it is yet to be determined conclusively, if a better safety culture results in less harm. The studies presented have all been focused on hospital care, and little research has been conducted in other settings to determine a relationship between safety culture and patient outcomes.

The Manchester Patient Safety Framework (MaPSaF) (116) is a safety culture assessment tool, supported by the NHS, to help organisations assess their progress in developing a safety culture. The MaPSaF has been made available for a variety of care settings including: acute, ambulance, primary care and mental health. Furthermore, the literature supports its use in community pharmacy as a valid tool to support the development of a mature safety culture. However, it has yet to be transferred to the community nursing setting and evidence of its effectiveness at improving patient safety outcomes is inconclusive.

The contribution of implementing safety culture assessment tools to patient safety improvements is currently conflicting. Safety culture assessment tools are not, as the measurement methods presented previously are not, comprehensive measurement systems from which a level of safety can be determined. However, they provide a new perspective and used in combination with other methods, might prove useful in the battle against healthcare error.

2.3.7: NHS safety thermometer

The NHS safety thermometer is a point of care instrument that enables organisations to collect data on four common harms: pressure ulcers, falls, urinary tract infections (in catheterised patients) and venous thromboembolism (21). In addition to surveying patient harms, it is supposed to enable analysis to measure and monitor local improvement (21). It is proposed that the safety thermometer is implemented in a range of care settings, including non-hospital settings such as the community, hospices and patients' homes. The method by which the safety thermometer collects data makes it a measure of prevalence: the measure of a factor in a given point in time, rather than incidence: the occurrence of something during a particular time period (117).

The NHS safety measurement thermometer is presented as an improvement tool, however, given its infancy, little research is available to demonstrate this. However, the pilot study conducted in 160 organisations *"showed an overall reduction in blood clots by 72%, pressure ulcers by 42% and urinary infections in patients with catheters by 33%" (118).* In the future, as more longitudinal data becomes available, its ability to

act as an improvement tool could be determined more conclusively. The Department of Health Sciences at the University of Leicester has been tasked with the following: evaluating the data collection and use; understanding how frontline staff are collecting data; and, how the definitions are being interpreted and applied (119). More time is required for more intensive analysis to be conducted, to determine its effectiveness over time.

As with the majority of measurement tools discussed previously, the NHS safety thermometer is a tool for measuring harm; not safety. Furthermore, it focuses on four clinical harms to the exclusion of other clinical harms and psychological harm. It too, is unable to determine whether care is safe; its purpose is to enable organisations to count particular harms. Targeting the four specific harms of the safety thermometer could result in improvements, but also, may result in behaviours that neglect other types of harm because they are not examined.

2.3.8: Summary

In review, the previous discussion on safety measurement methods has uncovered a fundamental flaw in their ability to measure safety. Despite patient safety being described as the reduction of risk of unnecessary harm, no method is capable of tracking risk of harm over time. Table 2.6: Comparison between the definition of safety and functionality of safety measurement methods, examines how each of the measurement methods relates to the different definitions of safety presented in 2.2.4: Patient safety.

Table 2.6: Comparison between the definition of safety and functionality of safety measurement methods

Source	Definition	Relationship with Measurement Methods
Kohn et al. (6)	Freedom from accidental injury; ensuring patient safety involves the establishment of operational systems and processes that minimize the likelihood of errors and maximises the likelihood of intercepting them when they occur.	RRR, GTTs, IRSs identify events of accidental injury. Patient Safety culture does not. RRR, GTT and IRS are unable to measure the establishment of operational systems and process, however, patient safety culture measurement is a component of the system that is hypothesised to minimise the likelihood of errors although this has not been empirically proven.
Davies et al. (5)	The reduction and mitigation of unsafe acts within the health-care system, as well as through the use of best practices shown to lead to optimal patient outcomes.	RRR, IRS safety culture are all incapable of demonstrating a reduction of unsafe acts because of their inappropriateness to be used as a benchmarking tool. GTT might be able to demonstrate reduction if used repeatedly over time. The use of measurement methods is designed to be part of a learning culture, particularly with IRS, however, there is no measurement of the feedback to evidence mitigation.
Runciman et al. (4)	Reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum.	None of the measurement methods above are capable of calculating a reduction of risk of unnecessary harm and neither is an acceptable minimum level of harm defined.
Cooper et al. (59)	The process of avoiding, preventing or ameliorating adverse outcomes.	Although measurement methods contribute to a culture of safety with the intent to learn from their data (particularly true of IRSs), none are able to quantify the process of avoiding, preventing or ameliorating adverse events.

2.4: Risk Measurement and Management

The definition of safety, as discussed on multiple occasions previously in this chapter, focuses on a reduction of risk of harm, however none of the safety measurement methods discussed thus far enable the level of risk to be measured or tracked over time, and therefore, are insufficient to meet the demands of the definition of safety. Indeed, they are insufficient to accurately track the level of harm over time.

2.4.1: Risk Measurement

When searching the literature for research on risk measurement, it is dominated by the assessment of risk of clinical disease, healthcare utilisation and cost. For instance, absolute risk (the probability of developing a disease over a given time) can be calculated for coronary heart disease (120). Goetzel et al. (121) were able to calculate that patients with high risk for poor health outcomes have a higher healthcare expenditure. Where adverse event risk has been calculated, it has been associated with specific drug therapies or interventions. Etminan et al. (122) calculated the relative risk (risk of event relevant to exposure) of adverse events with drug therapy for Parkinson's disease. The literature is absent of research that calculates the risk of adverse events during an episode of healthcare. Risk can be calculated retrospectively by examining the past occurrence and assume it to be a predictor. However, in order to calculate risk in this way, the outcome rate, in this case adverse events, is required to accurately reflect the true risk, and as discussed previously, this is currently unavailable. Alternatively, risk could be calculated prospectively, by knowing the presence of risk factors to predict outcome, however, these are not available in the field of patient safety. Currently, risk measurement for adverse events is undeveloped.

2.4.2: Risk Management

In the absence of risk calculators for adverse events, risk management is deployed. In healthcare, risk management can be described as the prevention or minimisation of harm, that is identified, analysed, treated and evaluated (123). The WHO (124), who developed an International Classification for Patient Safety, describes risk management as activities, which identify, analyse and reduce risk. In 2009, the Health Foundation commissioned a systematic review as part of its Quest for Quality and Improved Performance (QIPP) initiative, to collate the evidence on detection, mitigation and action to reduce risk in hospitals (125). They found literature that detected risk using incident reports (discussed previously) and analysis techniques such as failure mode and effect analysis (FMEA). There was no published evidence on mitigating factors to prevent harm, and actions to reduce risks focused on: medication errors; falls; diagnostic errors; adverse events and simulated survival. They concluded that evidence on safety interventions was limited, and the methodological quality of studies identified was weak. Information on their reliability and accuracy is limited and thus determining the effectiveness of safety interventions was unachievable. Subsequently, they proposed that there are three approaches to safety and risk management in healthcare:

1. Detection
2. Mitigation
3. Resilience

RRR, GTTs, IRSs and prospective methods all contribute to the detection of harm to patients. Safety culture contributes to the detection of conditions conducive or prohibitive to patient safety. Analysis techniques allow the causes of harm to be detected and potentially mitigated. Root cause analysis (RCA) is an example of a retrospective analysis technique, and failure mode and effect analysis (FMEA) is an example of a prospective analysis technique.

RCA is a retrospective technique for analysing error and can help to build a positive safety culture because of its systems approach to safety (126). It is estimated that each RCA takes between 20-90 man hours to complete (127). Evidence suggests that recommendations from conducting an RCA are at least partially acted upon with full implementation occurring in 61.4-68.1% (128), and 20% are partially implementation (129). However, RCA has flaws. RCA can direct focus upon the "*most fundamental reason*" for error and ignore smaller contributory reasons (130). The quality of the conduct of the RCA is variable (131). Similarly to other methods, there is insufficient support in peer-review literature for the effectiveness of RCA in reducing harm (127). Practitioners themselves report barriers and issues in RCA including: lack of time and resources, lack of data and feedback, difficulty with teams and uncooperativeness, compounded by unsupportive management (132).

FMEA is a proactive analysis technique to either assess the potential for process failures and their effects (process FMEA) or assess the potential failure of a product and its effects (design FMEA) (133). In healthcare, it is intended to do three things: recognise and evaluate potential failures (both process and design); identify actions to reduce or mitigate the occurrence of the potential failure; and document the process of FMEA (134). Furthermore, Woloshynowych et al. (135) suggested that all proactive analysis techniques enable priority setting, focus on the system and not the individual, and localise weak and risk areas. However, they also recognise that they can be time consuming and complex, that outcomes depend on the analyst's level of expertise and cannot guarantee comprehensiveness. Two studies have demonstrated some effectiveness in the utilisation of FMEA. Bonnabry et al. (136) conducted a before and after study reducing the number of critical incidences by 59%. Robinson et al. (137) utilised FMEA to identify risk factors in chemotherapy, which enabled them to implement improvement strategies in prescribing, dispensing and administration of drugs. Despite these studies, the majority of literature on analysis techniques is descriptive (125).

There lacks an evidence base of rigorous evaluations of quality and safety interventions (138), making their effectiveness unknown. However, the NHS does have some risk management and performance

standards for safety, which are top level standards deployed across the whole organisation (139). For example, there is a Clinical Negligence Scheme for Trusts that has risk management standards, which by adhering to, reduce the economic contributions made to the scheme that handles clinical negligence claims (140). Trusts are assessed against three levels (141), which can be seen in Figure 2.3: Clinical Negligence Scheme risk management standards. In line with the Health Foundation's interventions to risk management, the activities of detection and mitigation would be achieved in level 2 and resilience in level 3.

Level 3 – Performance

Level 1 is working across entire organisation and where deficiencies exist, are improved and risks reduced

↑

Level 2 – Practice

The process described in Level 1 is in use

↑

Level 1 – Policy

Risk management process described and documented
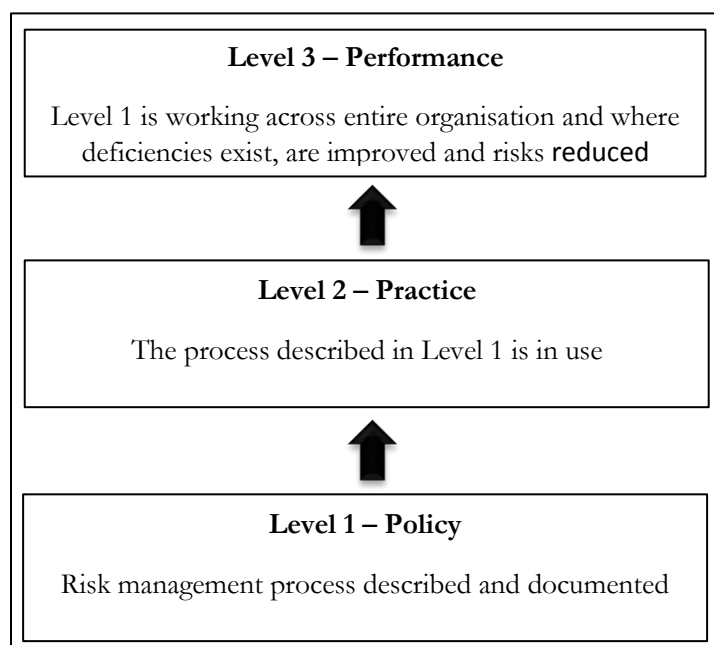
Figure 2.3: Clinical Negligence Scheme risk management standards
(adapted from (141))

In some areas of health and social care, protecting from harm is referred to as safeguarding and is considered integral to everyday activities of nurses and midwives according to the Nursing and Midwifery Council (142). Safeguarding can be described as *"a range of activities that organisations should have in place to protect people…whose circumstances make them particularly vulnerable to abuse, neglect or arm" (143)*[pg1]. The role of the Care Quality Commission in safeguarding is to ensure that organisations for which it has regulation of, have systems in place to safeguard its service users by having the organisations comply with quality and

safety standards, particularly outcomes 7 -11 (143). Despite having a regulator to oversee the compliance of health and social care organisations to have safeguarding procedures, the CQC has been criticised as being *"not fit for purpose"*, following high profile episodes of poor care including the Winterbourne View care home and the Mid-Staffordshire NHS Foundation Trust (144).

2.4.3: Summary

The measurement of adverse event risk per episode of care is not available. There are two potential reasons why. The first is that absolute risk requires that contributing factors to the outcomes be known and incorporated into the calculation. The second is that relative risk requires an accurate knowledge of the rate of outcomes, which is currently unreliable. Risk management offers an opportunity to in-still a culture, which supports the identification and mitigation of risk to prevent harm occurring. Unfortunately, the literature is lacking evidence to determine how effective risk management activities are at preventing harm to patients.

2.5: NHS Performance Measurement

Final examination will be given to NHS safety performance. The NHS Outcomes Framework supports the Coalition Government's intention to drive a focus on outcomes rather than processes (145). It has a variety of indicators covering a broad array of NHS activities categorised into five domains (146):

1. Preventing people from dying prematurely
2. Enhancing quality of life for people with long term conditions
3. Helping people to recover from episodes of ill health or following injury
4. Ensuring that people have a positive experience of care
5. Treating and caring for people in a safe environment and protecting them from avoidable harm

The purpose of the NHS Outcomes Framework is threefold: to provide a top level view of performance, provide accountability for the effective spend of £95b and to drive improvements in quality across the whole NHS. The five domains were derived from the definition of quality as outlined by Lord Darzi in the NHS Next stage review (147), which comprises effectiveness, patient experience and safety.

In the first instance, it is evident that the NHS Outcomes Framework is subject to similar limitations of the measurement methods previously discussed, namely, that the utility of outcome measures is restricted to counting past performance. The first publication of the NHS Outcome Framework in 2010 proposed that levels of ambitions (standards) were to be set, but this has since been abandoned because *"there was criticism from some that the proposals for setting levels of ambition were too reliant upon precise technical assumptions for which the evidence base is not robust"* (146). With regards to safety, this has been highlighted throughout the chapter: there lacks evidence of the effectiveness of interventions and insufficient knowledge on contributions to harm.

When examining the indicators of the 'treating and caring for people in a safe environment and protect them from avoidable harm' domain seen in Table 2.7: NHS Outcomes Framework – Domain 5, it is clear why standards would prove difficult to devise following the arguments already set out in this chapter because of the inadequacies of some of the discussed measurement methods, in particular incident reporting. Patient safety incident reports are voluntary and thus if a target was set to reduce them, implying reduction in harm, they could be susceptible to underreporting to meet targets. Similarly, if the target was to see a rise in incident reports, implying a more positive safety culture, reports could be fabricated. The same arguments apply to the reporting of safety incidents involving severe harm or death (overarching indicator 5b). Hospital deaths (overarching indictor 5c) are more traceable; however, the coding for the cause of death using ICD10 might be subject to manipulation if it were to become targeted

Table 2.7: NHS Outcomes Framework – Domain 5
(adapted from (146))

5 Treating and caring for people in a safe environment and protect them from avoidable harm
Overarching indicators
5a Patient safety incidents reported
5b Safety incidents involving severe harm or death
5c Hospital deaths attributable to problems in care
Improvement areas
Reducing the incidence of avoidable harm
5.1 Incidence of hospital-related venous thromboembolism (VTE)
5.1 Incidence of healthcare associate infection (HCA)
i. MSRA
ii. C.Difficile
5.3 Incidence of newly-acquired category 2, 3 and 4 pressure ulcers
5.4 Incidence of medication errors causing serious harm,
Improving the safety of maternity services
5.5 Admission of full-term babies to neonatal care
Delivering safe care to children in acute settings
5.6 Incidence of harm to children due to failure to monitor

2.6: A recent proposal for progress

The current limitations of safety measurement have been discussed. Since the inception of this research project, the Health Foundation commissioned a review of the academic evidence, and practical experiences, in order to form a framework for safety measurement and monitoring. The authors of 'The measurement and monitoring of safety'; Vincent et al. (148), drew conclusions aligned with those made here, which led to the development of a framework that *'provides a starting point for discussion about what 'safety' means and how it can be actively measured'* (148)[pgII]. The report acknowledges a social context to safety

measurement, because of the ambiguity of the language and the benefits of manipulating data to improve performance, which ultimately leaves safety measures, open to interpretation and adaptation.

The evidence reviewed by Vincent et al. (148) identified the need to consider safety from five perspectives, and they propose a five dimension framework of safety measurement and monitoring: past harm, reliability, sensitivity to operations, anticipation and preparedness and integration and learning. The measurement of past harm is something that healthcare has been conducting, but they acknowledge that *'past performance is not a guarantee of future safety'* (148)[pg30], which has been argued throughout this chapter. Furthermore, the methods currently available to measure safety are not reliable and accurate. Reliability refers to the *'delivery of care to agreed standards'* (148)[pg30]. This is relevant to processes of care as well as the underlying clinical systems such as correct medical equipment availability. Something that current systems are unable to do, is determine if care is safe today. Vincent et al. (148) conclude that there is a need to be able to do this, as well as incorporate the perception of stakeholders, and this relates to their dimension of sensitivity to operations. Anticipation and preparedness relate to the ability to anticipate issues and their resilience to such issues. Finally, integration and learning encompasses the ability of an organisation to respond to risk and make improvements on the basis of safety information.

The framework proposed by Vincent et al. (148) could contribute to the development of more sophisticated measurement methods but was not available at the inception of this research and thus an alternative approach has been adopted. However, Vincent et al. (148) promote learning from other safety industries. In Chapter 3, an argument is presented for learning from the discipline of performance measurement.

2.7: Conclusions

RRR provided the first large scale measurement of adverse events and was implemented around the world. In response to one of its inefficiencies, the GTT was developed and implemented to achieve RRR in a timelier and more cost effective manner. In addition to GTTs and RRR, IRSs afford healthcare staff the opportunity to report patient safety incidents, including near misses. A national reporting system in England provides top level monitoring, which is capable of detecting patterns across organisations that would seem insignificant in isolation. Its purpose: to learn from patterns of error to prevent recurrence. RRR and GTTs measure safety as a rate of adverse events (harm) against hospital admissions. IRSs count reports of patient safety incidents: *'any unintended or unexpected incident which could have or did lead to harm' (58).* PSIs are rates of outcome of interest/population at risk (88). All these methods have had greatest effect in the hospital setting, with some transference to other settings with varied success. Prospective methods seem isolated to research activity with no data collected on the scale of other methods discussed. Safety culture has been hailed as the answer to patient safety, but research is conflicted in its effectiveness, and it is yet to deliver on its promise.

Excluding safety culture assessment, all other safety measurement methods are focused on adverse events: the outcomes patients are subjected to as a result of unsafe care. These are lagging indicators, which only become apparent after an action has occurred, in this case an error. In relation to the Swiss cheese model (22) of safety (see Figure 2.1: The Swiss cheese model), to only count outcomes, is to be ignorant of the latent conditions and active failures that are present within the system, which reduces the opportunity to prevent harm to patients. The nature of the measurement methods presented above render them insensitive to the underlying latent conditions that facilitate actives failures.

Despite the literature making statements that implicate psychological and social harm as a consequence of unsafe care, the adverse events that are either detected or reported in RRR, GTTs, PSIs and IRSs are medical in nature, exclusive of psychological and social outcomes. In addition to them being medically

focused, they are also organisationally derived; they lack patient input in identifying and detecting adverse events and in the derivation of criteria. These methods do not necessarily reflect the priorities of patients in terms of outcomes, or indeed what safety means to these patients. There is little research in the field of measurement of patient perceptions and perspectives. Where some research exists, differences are apparent, highlighting gaps between what is being measured and what is perceived by patients as safety. This will be discussed in greater detail in the Chapter 3.

Finally, hospital care has been the focus of safety measurement efforts, and although some have been transferred to other care settings, their reliability and validity to accurately reflect the different environment is yet to be secured. Limited evidence exists to support the effectiveness of these efforts in improving patient safety by demonstrably reducing the risk of harm to patients. A more comprehensive approach is required that enables monitoring of contributory factors (once known) to prevent the occurrence of harm and produce a stable environment.

Risk measurement is developed in fields such as clinical risk where the risk that a patient will develop a particular disease can be calculated. This is because it is achieved using absolute risk, which requires an understanding of the contributing risk factors; these have been well researched in clinical medicine. Alternatively, risk can be calculated using relative risk which requires an accurate understanding of the past prevalence. Neither of these approaches are well understood in the field of safety thus making it difficult to calculate.

Safety and risk management are defined similarly: both refer to the process of reducing risk, but safety refers more to the conditions of the environment being one in which risk reduction is sought, risk management is the action of reducing risk. Research into risk management is fragmented; some areas are well established such as analysis techniques including RCA and FMEA. Other areas such as mitigating factors to prevent harm are unavailable in the literature, leading the Health Foundation (125) to concluded that the evidence for safety interventions is limited and insufficient.

Performance measurement in the NHS is driven by outcome measures, which are lagging indicators. The use of incident reporting numbers to determine if healthcare is safe is unhelpful because it cannot be determined from this indicator if care is safe, or if improvements are being made because they are susceptible to manipulation.

The patient safety agenda has been underway for some time; the establishment of the NPSA in the NHS marked its start in England. There are key challenges for delivering a patient safety agenda: creating an environment receptive to change, and developing an effective measurement system that goes beyond simply counting the frequency of harm, but incorporates an understanding of contributory factors to adverse events. This is fundamental in the development of preventative risk reduction strategies. Finally, a need to integrate and embed measurement, monitoring review, and improvement into everyday activities is essential (149). The design of performance measurement frameworks could contribute to the design of a comprehensive safety measurement framework, which is the aim of this research.

Chapter 3

The case for an alternative approach to patient safety measurement

3.1: Introduction

The aim of this chapter is to provide an alternative approach to safety measurement design, utilising the principles of performance measurement. This will be achieved by introducing the principles of performance measurement and applying them to the literature on patient safety in healthcare. In particular, the concept of patients as stakeholders will be explored alongside the possible role of the structure, process and outcome (SPO) model, in relation to case managed care in the NHS.

Chapter 2 provided evidence of the state of the art of safety in healthcare. The methods by which safety is measured were discussed and their limitations identified. A common limitation was the isolated use of outcome measures such as harm or adverse events, which expose the patient to harm before being detected. The current understanding of safety in healthcare is mostly derived from ultra-safe industries, such as aviation and nuclear power, who adopted the systems theory to safety (23, 24). Other industries and disciplines, such as manufacturing and performance measurement, have long recognised the inadequacy of using lagging indicators (such as outcomes) in isolation, in the improvement of performance. Performance measurement originates from the manufacturing industry, but has since evolved and is now applied to both the manufacturing industry and the service industry, across private, public and tertiary sectors. Its usefulness lies heavily in its ability to quantify the effectiveness and efficiency of action (32). In being able to do this, it can drive continuous quality improvement by

influencing behaviour to meet the organisation's objectives. Success of performance measurement is dependent on characteristics such as: being selective in what it measures; consisting of a mixture of past, present and future measures; and being relative to the organisation's strategy - which is closely related to consumer requirements. Performance measurement presents an opportunity to address the limitations of safety measurement by being inclusive of measures of the whole system that are stakeholder sensitive.

Healthcare systems are composed of complex entities, interacting with multiple stakeholders, striving to deliver on numerous aims, including: promoting public health, treating acute injury and illness, and managing long term disease. The NHS is one of the world's biggest employers, delivering a large variety of services, each with its own specific purpose and aims. Given the complexity and variety of healthcare services, it is proposed that a 'business operating system' (the activities or sequence of processes that lead to the delivery of a particular service) be selected (29). Lynch and Cross (29) argue that *'it is the day-to-day flow of work throughout an organisation until it reaches the customer that should be managed and measured'* (29)[pg45]. The case management (CM) programme targets patients with complex, multiple long term conditions for integrated care management, to prevent hospital admissions in the English National Health Service (NHS). This patient population represents a growing burden on healthcare systems worldwide, resulting in the introduction of new care models, seeking to sustain quality of life rather than to treat and cure acute illness. The use of the CM programme as a case study provides an opportunity to investigate safety in a service with growing demand.

3.2: Lessons from other industries: the case for performance measurement

Performance measurement has been a popular topic of debate in the business management field since the 1980's. Prior to this, accounting measures were common practice for determining the performance of an

organisation, but came under scrutiny and subject to heavy criticism due to their lagging nature. Lagging indicators, such as financial outcomes, are post-action measures that identify the results of previous activities, rather than current, on-going or future performance. Neither do they identify the actions, processes or behaviours that contribute to the results. Since the 1980's, efforts have been made to overcome the short-comings of financial performance measurement systems, which have resulted in a large literature database on the purpose, characteristics, design and implementation of performance measurement systems. It is important to establish terminology in relation to performance measurement. Neely et al. (32) provide succinct and relative definitions for a list of key words that can be found in Table 3.1: Performance measurement glossary.

Table 3.1: Performance measurement glossary
(Neely et al. (32))

Key Word	Definition
Performance Measurement	The process of quantifying efficiency and effectiveness of action
Efficiency	A measure of how economically the firms resources are utilised when providing a given level of customer satisfaction
Effectiveness	The extent to which customer requirements are met
A Performance Measure	A metric used to quantify the effectiveness and/or efficiency of an action
A Performance Measurement System	A set of metrics used to quantify both efficiency and effectiveness of actions

The fundamental purpose of performance measurement is to improve performance, by being able to monitor, control and reward positive performance (25), thus motivating behaviours that stimulate continuous improvement (29). Fitzgerald (30) adds that it is essential to translate the company mission statement into integrated performance measures to control, monitor and reward performance. Many authors also agree that it should be aligned with the organisation's strategy, in order to drive

performance in the direction of stakeholder satisfaction (28, 30, 31). Table 3.1 defined both efficiency and effectiveness in respect to the needs of the customer, enabling an organisation to pursue strategies that lead to the achievement of overall goals and objectives. As indicated by the NHS values laid out in the NHS Constitution (150) (see Table 3.2: NHS values), safety is an integral component of the mission and vision of the NHS and other healthcare organisations alike.

Table 3.2: NHS values
(Department of Health (150))

Values	*Description of values*
Working together for patients	Putting patients first and engaging with in in all activities
Respect and dignity	Valuing every person
Commitment to quality of care	Ensuring the basics of quality of care: safety effectiveness and patient experience
Compassion	Caring with humanity and kindness
Improving lives	Improving the health and wellbeing
Everyone counts	Access for all

Effective performance measurement provides an opportunity to make further progress in the field of patient safety by adapting of some of its key principles. Performance measurement should (25-32):

- Reflect the organisation's strategy and vision

- Be driven by the organisation's primary service users

- Consider past, present and future activities – utilise indicators that are leading (predict outcomes) and lagging (detail outcomes) but also indicators that are process oriented to manage outcomes

- Occur across the company, being implemented top down and results should be rolled up

- Represent business operating systems

3.2.1: Emergent themes in performance measurement frameworks: input, process and output

Performance measurement frameworks seek to provide guidance that can be adopted in the design and implementation of performance measurement systems. Following the criticisms of the traditional cost focused measurement systems, multidimensional frameworks that balanced financial and non-financial measures have been developed, such as: the process model (31) the performance prism (151), the performance measurement matrix (26), the balanced scorecard (28), and the results and determinants framework (30). When reviewing these frameworks, three common domains of measures were identified: input, process and output. The importance of these domains in the aforementioned frameworks is evident by their repeated presence.

Brown (31) argues that controlling inputs and processes facilitates high performance and consistency respectively. By controlling inputs such as the quality of the component parts and understanding customer requirements, outputs are more likely to meet the demands of the customer. By measuring processes, the same results can be achieved repeatedly. Brown's (31) macro process model, overtly categorises measures as: a) input; b) process; c) output and d) outcome. Process measures are of activity or behaviour, and by managing these, rather than relying on the inspection of outputs, a preventative approach is adopted.

Although Brown's (31) framework most explicitly incorporates measures of input, process and output, to some degree, other performance measurement frameworks use them too. For example, the performance prism (151) is the most recent framework and is unique in its approach to performance measurement because it considers its stakeholders at both ends of the performance delivery system: not only does it consider what stakeholders want (outputs) from the organisation, but also what they can contribute to the organisation (inputs). The remaining three facets of the prism represent strategies, processes and capabilities. Capabilities are a form of input; what is required to enter the system in order to deliver the outputs required. In an increasingly stretched healthcare system, organisations are seeking to reduce

demand by encouraging better self-care: activities which patients do to maintain or prevent ill-health. Understanding the contributions patients can make could assist in the delivery of more effective services.

The performance measurement matrix is inclusive of some input measures that are cost focused e.g. design and material costs. However, it does not establish clear relationships between the different dimensions of performance and thus the measures (26). Kaplan and Norton are more successful in achieving this in the balanced scorecard, which examined perspectives (28). The balanced scorecard is a four dimensional framework including financial, internal business processes, learning and growth and customer perspectives. It is not prescriptive, so it does not identify indicators, but it enables organisations to determine their own indicators within these four perspectives, which could include input measures, process measures and output measures. The results and determinants framework (30) was designed for use in service industries, and divides measures into two categories: results and determinants (of results). The measures of determinants, which are leading indicators, contribute to the performance of results (lagging indicators). Determinants include both inputs and processes, such as competence and communication respectively.

The input, process and output themes that emerge from the literature on performance measurement frameworks overlaps with the Swiss cheese model of safety (22). These frameworks imply that in order to be successful in meeting the organisations vision, the right inputs are required to perform processes to achieve the desired outputs, all of which can be measured in advance of failing. However, the two approaches use antonyms to one another, where performance measurement describes the requirements for success, the Swiss cheese model describes the conditions for failures, see Figure 3.1: The Swiss cheese model and its relationship with input, process and output.
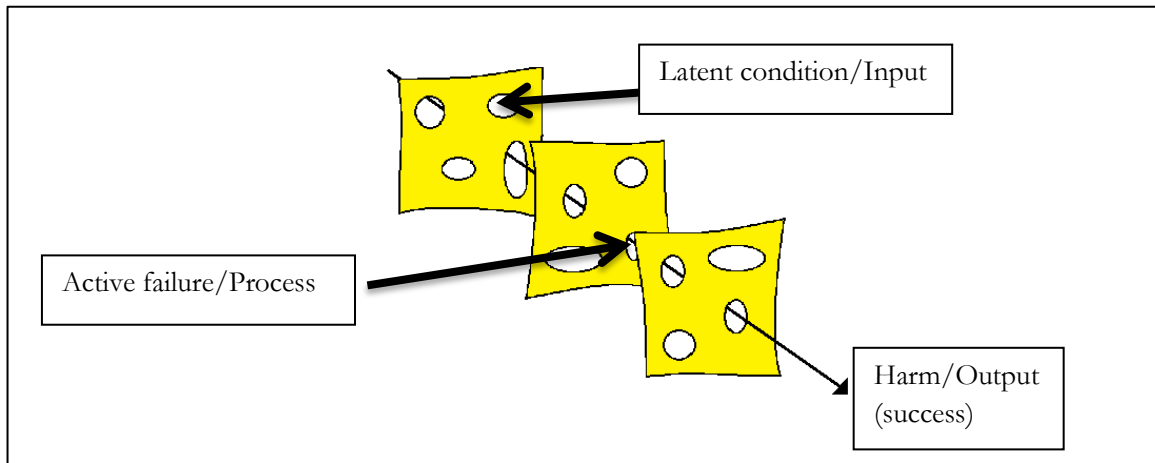
Figure 3.1: The Swiss cheese model and its relationship with input, process and output

3.2.2: Designing a measurement system

The 1980's saw the revolution of the theory of performance measurement from being output focussed to whole system considerate. Subsequently, evidence and guidance became increasingly available on the design of such systems. By 1989, Keegan et al. (26) had proposed a three step process for deciding what to measure, at a superficial level, for the performance measurement matrix. Firstly, an organisation should define their strategic objectives, secondly, populate the measurement matrix, and finally, instil a culture of performance measurement in the work force. Wisner and Fawcett (1991) expanded on this and produced a more detailed nine step process, but critically, concluded the process with periodic review. This feedback loop re-informs the strategic objectives and encourages a more dynamic system, which is more reflective of the business environment. In essence, the processes proposed by Keegan et al. (26) and Wisner and Fawcett (152) are high level objectives. They are descriptive rather prescriptive; they lack a recipe to follow that would successfully achieve a functional performance measurement system.

Kaplan and Norton (153) adopted a prescriptive approach in their measurement design process for use with the balanced scorecard. This eight step process, which can be seen in Table 3.3: Process of designing and implementing the balanced scorecard, detailed the need to identify objectives, populate the balanced scorecard and periodically review, similarly to Wisner and Fawcett (152). In addition to this, they

proposed methods for determining the objectives (step 2), selecting the measures (step 3) and reviewing the measures (step 8). Furthermore, Kaplan and Norton delivered a multiphase method that seeks consensus between stakeholders, considers issues of implementation early on and suggests the production of an implementation plan.

Table 3.3: Process of designing and implementing the balanced scorecard
(Kaplan and Norton (153))

Steps	Description
1: Preparation	Identify the business unit for which a top-level balanced scorecard is appropriate
2.Interviews – first round	identification the company's strategic objectives with senior team and possible measures
3.Executive workshop – first round	Development of draft balanced scorecard with senior management group following debate of the proposed mission and strategy statements
4. Interviews – second round	Summarise the outputs from the step 3 and discusses with each senior manager. Also identify issues involved in implementation.
5.Executive workshop – second round	Further debate the mission and strategy statements to make comments on the proposed measures, linking the various change programmes under way to the measures, and start to develop an implementation plan.
6 Executive workshop – third round	Final consensus on vision and measures develop stretch targets. Identification of action programmes to achieve the targets. Plus draft implementation strategy.
7. Implementation	New implementation team formulates a detailed implementation plan.
8. Period reviews	Each quarter or month, a book of information on the balanced scorecard measures is prepared for both top management review and discussion with managers of decentralised divisions and departments. The balanced scorecard metrics are revisited annually as part of the strategic planning, goal setting, and resource allocation processes.

Following a literature review of the performance measurement system design process, Neely et al. (154) identified characteristics of the performance measurement system design process, these can be seen in Table 3.4: Desirable characteristics of a performance measurement system design process.

Table 3.4: Desirable characteristics of a performance measurement system design process (Neely et al. (154))

Characteristics
Performance measures should be derived from the company's strategy.
The purpose of each performance measure must be made explicit.
Data collection and methods of calculating the level of performance must be made clear.
Everyone (customers, employees and managers) should be involved in the selection of the measures.
The performance measures that are selected should take account of the organisation.
The process should be easily revisable - measures should change as circumstances change.

Understanding the characteristics of designing a performance measurement system could contribute to achieving the aim of this research. Due to the infancy of safety measurement and its reliance on the measurement of harm, greater attention is required of the initial characteristics, mostly: involving stakeholders to be able to understand their needs, expectations and contributions.

3.3: Case Management: a response to the ageing demographic

The challenges faced by healthcare at the inception of the NHS differed greatly to the challenges experienced today. Life expectancy was lower and more deaths were attributed to infectious disease than today, requiring an acute care model. Today, people in the UK are living longer. In England, in the period 2007-09, life expectancy grew by 1.4 years for men and 1.1 years for women from the period 2003-05

reaching 80.9 and 82 years respectively (155). For more immediate consideration, life expectancy at age 65 grew by 1.1 years for men and 1.0 years for females during the same period (155), indicating that the elderly are increasingly living longer. This change in demographic is global; by 2050, the proportion of people aged over 60 years in the world will double, and the number will exceed the number of those aged under 15 years. In North America and Europe, 4% of the populations will comprise people aged 80 and over (156).

The ageing demographic is driving a new trend of disease: long term conditions (LTCs) (34). LTCs are:

'diseases which current medical intervention can only control not cure. The life of a person with a chronic condition is forever altered – there is no return to 'normal'.' (157)[pg3]

LTCs include, but not exhaustively: coronary heart disease (1,899,000 affected in England); heart failure (420,000 affected in England); and diabetes (1,962,000 affected in England) (158). In England, 17.5 million people report having a long standing illness, 2.75 million of whom are aged 75 and over, accounting for 66% of their population group (159). Age is considered the biggest driver of the increasing prevalence of LTCs and an estimated 42% of the English population is expected to suffer with at least one LTC by 2025 (158). The Department of Health (DoH) (158) estimates that LTCs account for 69% of the total health and social care budget in England with public spending on long term social care expected to rise by 94% to £15.9billion by 2022. Their prevalence is not just found in developed countries; *'80% of chronic disease deaths now occur in low and middle income countries...'* and approximately 60% of all global deaths are as a result of chronic disease (160).

Wagner et al. (161) suggested as early as 1996 that the ill-equipped nature of the acute-care model was insufficient to support the growing trend of chronic disease. They argued that the deficiencies in the health system at meeting the growing needs of LTCs could be attributed to the acute-care model of diagnose and treat (cure) (161). In recognition of the inadequacies of the acute care model, the DoH developed the NHS and Social Care long term conditions model (35).

The NHS and Social Care long term conditions model (see Figure 3.2: The NHS and Social Care long term conditions model), was devised to reduce the amount of emergency bed days by 5%, because 5% of inpatients accounted for 42% of acute admissions and can be attributed to patients with LTCs (35). This was to be achieved by targeting specific populations of sufferers by disease severity and complexity within four tiers of the delivery system: promoting better health, supported self-care, disease management and case management. Delivery of this care in non-acute settings, such as the community and the patient's home, was to be supported through better equipped infrastructure in these settings. In order to achieve this, there was a need for change and redesign in the structure of services, including new job roles and information systems, to deliver the three specific tiers of care for those with LTCs and a tier for supporting and promoting better general health amongst the population. All levels of care promote better health and deliver improved health outcomes by educating and empowering patients to take greater responsibility for their health. The most intense level of care is that of the CM programme.
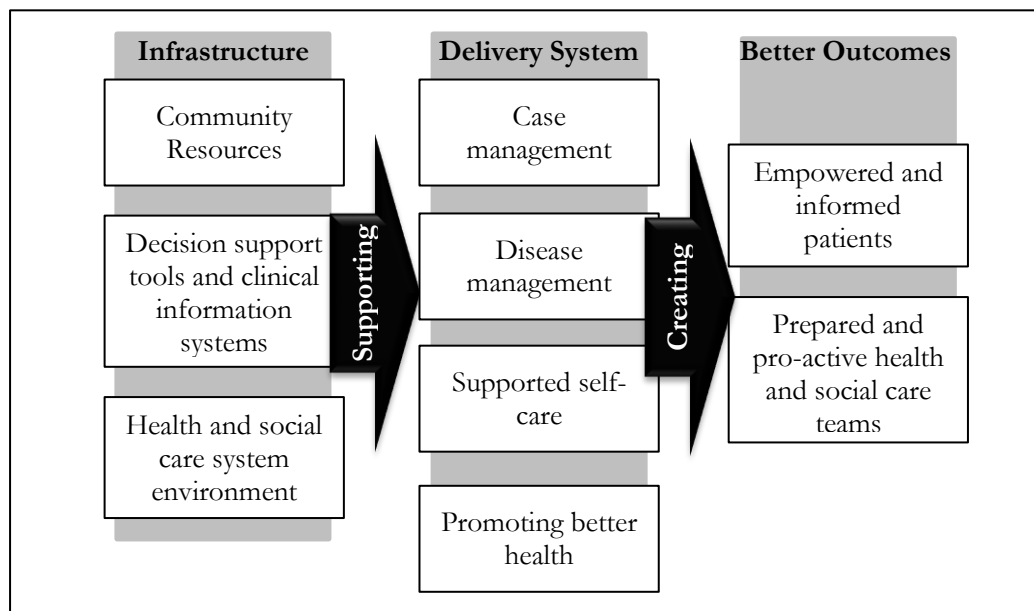
Figure 3.2: The NHS and Social Care long term conditions model
(Department of Health (35))

CM was introduced nationally in 2005 as a key component of the NHS and Social Care long term conditions model, and is a package of care, which covers a range of activities. More specifically, it identifies patients at high risk of hospitalisation with complex and multiple long term conditions. Patient

selection for CM is targeted to identify those who are frequently admitted to hospital or at risk of admission (35). It assesses treatment needs in conjunction with the patient, and devises a collaborative care plan that integrates multiple services, to provide holistic care, and the empowerment and education of patients (35). At the crux of the CM programme is care planning, which is a holistic approach to care design that focuses on the patient's needs as determined by the patient, alongside the health professional, in order to assist patients in achieving the outcomes they want (35). CM programmes are led by advanced nurse practitioners, who have greater autonomy, and the ability to make decisions about their own actions (162).

The principles of performance measurement, outlined previously, indicate that measurement should be specific to business operating systems within the organisation, such as the distinctly different care services provided within the NHS. The CM programme is a response to the increasingly demanding ageing demographic. Exploration of the concept of safety and safety measurement in the CM programme affords an opportunity to understand safety in a healthcare service, which is responsible for the outcomes of a growing number of vulnerable patients.

3.3.1: Effectiveness of case management

Following the introduction of CM in the Evercare pilot in 2003, an evaluation study was conducted to examine the rates of emergency admissions of the intervention practices against control non-intervention practices (163). There was no significant difference between the two groups for emergency admissions or mortality rate. Despite this disappointing result, success was achieved in some areas of care such as the reporting of high patient satisfaction. Patients also valued the psychological support, the rapid response to crisis, medication monitoring, communication of LTC, investigation and treatments and the patient advocacy role played by the advanced nurse practitioners. A limitation of the study was its inability to specifically evaluate case managed patients against a control group because of a poor data trail – hospital episode statistics (the database used) do not classify primary care service utilisation and therefore it was

not possible to determine the primary care utilisation of patients admitted to hospital. Gravelle et al. (163) concluded that the programme of community nurses was likely to be popular with service users but unlikely to reduce hospital admissions without radical service redesign. This is reiterated in other attempts to drive care out of the hospital. The Partnership for Older People Projects (POPPs) was implemented to relocate resources to the community and homes, away from the hospital. However, an evaluation of multiple interventions (although none were specifically CM programmes) showed no reduction in hospital admissions in comparison to matched control groups (164). Similarly to that of the Evercare pilot evaluation, patients also reported benefits in quality of life.

Although the evidence presented by the Evercare pilot suggests a lack of success of the CM programme to reduce hospital admissions, others have been able to show how CM is effective. Sutherland and Hayter (165) conducted a review of the literature that demonstrated the positive impact that nurse case managers had on five health outcomes: objective clinical measurement, quality of life and functionality, patient satisfaction, adherence to treatment and self-care and service use.

3.3.2: Scope for improvements in case management

The data on the CM programme suggests that it hasn't been successful in reducing hospital admissions, which was its primary purpose. However, it has been more successful in improving quality of life and is proving popular with patients. This does not mean that there isn't room for improvement in the quality of care. Some efforts have been made to determine the quality of the CM programme by addressing two of the three key components: effectiveness of care and patient satisfaction (147). Safety, the third component, as described by Darzi (147), has yet to be examined. With the conflicting evidence of its effectiveness and the uncertainty surrounding whether it is effective at all, questions on patient safety might be raised.

3.3.2.1: Scope for improvements to the effectiveness of care

The King's Fund (166) indicated a list of factors linked to the success of outcomes in the CM programme, which need to be overcome if community programmes, such as the CM programme are to have the effect predicted by some. These factors are:

- Assigned accountability of an individual or team
- Clarity about the case manager role and support to ensure they have the right clinical and management competencies
- Accurate case findings methods
- Appropriate case loads
- A single point of access for assessment and a joint care plan
- Continuity of care
- Self-care
- Joined up health and social services appropriately aligned to incentives
- Information systems that support communication and data that is used to proactively drive improvements

In addition, the Evercare evaluation also proposed programme improvement by providing 24/7 care with better links with out of hours services (163). In response to poor effects on hospital admissions rates, the Patients at Risk of Rehospitalisation (PARR) tool was developed as a more accurate method of identifying patients for CM (167). The tool is a case-finding algorithm that draws on patients' previous use of the hospital but no attempt has been made to assess the effectiveness of the tool.

3.3.2.2: Scope for improvements to the safety of community care

Little or no investigation has specifically been undertaken on the safety of the CM programme. However, since 2007, there have been multiple publications on the topic of safety in home healthcare that are relevant to the case management programme. Blais et al. (39) describe home care as including:

> *'the provision of healthcare intervention to clients [patients] of all ages…for the purpose of providing curative, supportive, palliative and rehabilitation care for acute and longer term illnesses and conditions'* (39) [pg1]

The definition appears to be inclusive of the care delivered under the CM programme described previously, as well as other types of care provision including district nursing and social care. In an editorial in the British Medical Journal (BMJ) Quality and Safety, Romagnoli et al. (36) highlighted some key issues in home healthcare:

> *'Patients and caregivers must struggle to absorb confusing and potentially contradictory information imparted both by multiple clinicians prior to discharge from the hospital and by home care nurses. Providers, for their part, often have incomplete understandings of home environments and patient and caregiver capabilities. Despite these difficulties, patients are largely left to themselves, expected to be engaged in their care sufficiently to own and manage their medical conditions.'* (36)[pg1]

It is apparent in the quote from Romagnoli et al. (36) that there are potential opportunities for harm, facilitated by poor healthcare professional understanding of the new environment, and patients and carers being the dominant care provider, regardless of capability or competency. This could be attributed to the relative infancy of care delivery in the home; there hasn't yet been sufficient time to understand the new care environment or fully comprehend the implications. In an effort to begin to understand home healthcare, Lang and Nancy (168) established ten common themes surrounding safety in home care that distinguishes it from hospitalised care:

1. The family is the unit of care, rather than a team of health professionals

2. Therefore, safety of the patient, family, caregivers and providers is inextricably linked

3. The setting of individual's homes is unregulated and uncontrolled

4. There are multiple dimensions of safety including the physical, emotional, social and functional

5. Patients, families and caregivers have choice and autonomy

6. Isolation is common with patients living alone and caregivers and health professionals working without supervision

7. Communication has to occur on many levels with multiple stakeholders

8. Health professionals have to develop and maintain knowledge, skill and competencies across a breadth of illnesses

9. There is a diminishing focus on prevention, health promotion and chronic care

10. Insufficient human resources is persistent in home care

Upon examination, the theme: 'diminishing focus on prevention, health promotion and chronic care' appears misaligned with the literature presented on CM. Lang and Edwards (168) suggest that rather than promoting prevention and maintenance in order to prevent institutionalisation of an elderly population, home healthcare services in Canada have become a service that treats acute care patients in the home resulting in a more reactive home care service. Where the CM programme strives to be a proactive management programme to prevent hospital admission, Lang and Edwards (168) argue that this is a diminishing focus in Canadian home healthcare. This disparity may be because the study by Lang and Edwards (168), was specific to the Canadian home healthcare system, and may not be entirely transferable to English healthcare.

The application of RRR to the medical records of patients being cared for in their homes, detected an adverse event incidence rate of 13.2% with one-third considered preventable (38) . Whilst Blais et al. (39), calculated an incidence rate of 4.2%. In addition, Blais et al. (39) considered the exposure time of patients i.e. the length of time receiving home care, to calculate a 10.1% adverse events per client (patient) year. Those who experienced adverse events appeared to be more vulnerable populations, being *'older, had more depressive symptoms and behavioural problems, and were more functionally impaired'* (57)[Pg191]. Johnson (169) determined an annual incidence in Winnipeg of 5.5%. The annual incidence rates of 10.1% (39) and 5.5% (169) fall within the ranges of 3.7% (1, 2) and 16.6% (8) calculated for hospital care. This indicates the seriousness of adverse events in the home care environment as being on par with the hospital and other healthcare settings, with falls being the most commonly occurring adverse event. This can be seen in Table 3.5: Types of adverse events in Canadian home care.

Table 3.5: Types of adverse events in Canadian home care

Adverse event type (Blais et al. (39))	%	Adverse event type (Sears et al. (38))	%
Fall injury	17.2	Falls with injury	24.6
Wound infection	14.0	Medication error	16.4
Psychosocial, behavioural, mental problems	11.8	Pressure ulcer	11.5
Medication problem	6.5	General decline	11.5
Pressure ulcer	6.5	Delayed healing	9.8
Other wound	4.3	Infection	8.2
Non-wound infection	4.3	CHF	6.6
Syncope or seizure	4.3	Catheter injury	4.9
Delayed wound healing	3.2	Bowel impaction	3.3
Skin tear or laceration	3.2	Bleed	1.6
		Dehydration	1.6
		*this study did not include psychosocial outcomes	

As healthcare organisations look to save money and deliver better care through home care and community services, there comes an intensified level of scrutiny on the safety of these services. Research in this field is increasing and adaptions to methods of measurement are enabling their transference to the homecare setting.

3.4: Patients as stakeholders in safety

The principles of performance measurement outlined in 3.2: Lessons from other industries: the case for performance measurement, implicate the customer as having a role in the design of performance measurement. However, Chapter 2 highlighted the absence of the patient in the measurement of safety, including the design of measurement and the reporting of performance. In 2002, Vincent and Coulter (170) made the following observation:

> *'The most remarkable feature in the many faceted patient safety movement is surely the lack of attention paid to the patient…lessons are sought from other industries and experts…Yet the one source of experience and expertise that remains largely ignored is that of the patient.' (170)*[pg1]

The contributions patients make are still small, but some progress is being made, as will be presented here. The current role of patients in patient safety can be broadly categorised into: their perspective of safety; their involvement in safety improvement and their contribution to poor safety, all of which will be explored here.

3.4.1: Patient perspectives of patient safety

As indicated by Vincent and Coulter (170), the patient perspective of safety largely remains an untapped source of expertise; however, some attempts have been made to address this. Following the publication of the IoM report (6), Robinson et al. (171) sought to determine the scale of the safety problem as perceived by physicians and the public. They concluded that physicians recognised the existence of a patient safety problem in healthcare, but they didn't consider it to be as significant as the public perceived it to be. The patient's perception of safety does not appear to be fixed: it alters with their experience of care. For example, when the continuity of their care is disrupted, i.e. when patients are unable to be seen by their

usual healthcare professional, patients can feel unsafe and this is more apparent in vulnerable groups, such as those with chronic conditions (172). Furthermore, Cleopas et al. (173) found that:

> *'inadequate staff responsiveness in the face of error, non-disclosure of error to the patient, and serious health consequences for the patient have a negative influence on respondents' evaluation of the incident'.* (173)[pg139]

These studies provide evidence that patient perceptions of safety are susceptible to influence by their own personal experience of care. These influential experiences might make it difficult for patients to objectively assess the safety of the whole system. Patients can, however, provide valuable insight into the factors that contribution to patient safety. A study conducted to explore older patients' perceptions of safety during organisational care transfers, identified four key themes that contribute to safety: communication, responsiveness, trust and traditional safety risks (174). Further examination of these can be found in Table 3.6: Key themes of safety in the organisational care transfer setting. It is worth examining further, the theme of trust, where participants of this study were found to be inherently trusting and even defensive of errors committed by healthcare professionals (174). Conversely, Elder et al. (175) found that patients who had experienced an adverse event, lost trust in their health professionals and Pandhi et al. (172) found that patients with high levels of trust felt more safe. In addition to the experience of having an adverse event, the severity of the event further influences the perception of safety, i.e. the more severe the adverse event, the greater the perception of the lack of safety (176).

Multiple studies, in addition to that of Scott et al. (174), have been successful in eliciting the patient perspective of safety and identifying contributing factors. When engaging with patients in a prospective hazard analysis, Dean et al. (177) conducted a study within a chronic obstructive pulmonary disease (COPD), supported discharge care pathway. They found the three highest ranked safety concerns, as perceived by the patient, to be: difficulties in accessing hospital admissions, information transfer to primary care and failure to communicate medication changes to primary care. Communication is implicated twice in this study, and previously in the study by Scott et al. (174), becoming a common

theme identified by the patient; presenting a convincing argument for its involvement in patient safety. In another study (40), when examining the patients' and caregivers' perspectives of safety, the term 'home care safety' did not resonate with them, preferring to describe concerns or challenges. Furthermore, their definitions of safety diverged from those of the paid healthcare providers. Providers were focussed on the patient and were almost exclusively physical in nature, being more aligned to that of the institutional setting (40).

Table 3.6: Key themes of safety in the organisational care transfer setting
(adapted from (174))

Theme	Description
Communication	• Being informed
	• Having a means to contact a health professional
	• Being friendly and reassuring
	• Being apologetic after an incident and listening
Responsiveness	• Responding to individual needs
	• Short waiting times
	• Making the transfer an easy process
Trust	Trust was considered inherent in the participants regardless of experience originating from the assumption that health professionals were sufficiently trained
Traditional safety risks	• Physical safety
	• Falls
	• Healthcare acquired infections
	• Receiving adequate standards of care
	• Missed diagnosis
	• Medication errors
	• Excessive painful procedures

Patients can also provide a perspective on the types of errors committed, the consequent harm experienced and their relative importance. A study examining the patient perspective of harm in the primary care setting, indicated that patients reported breakdown in access to and relationships with clinicians, as more prominent than medical errors that were technical, such as diagnostic or treatment errors (89). These relate to the communication and responsiveness themes presented by Scott et al. (174) in Table 3.6. Furthermore, patients also reported harm of a psychological nature: 119 psychological harms were reported in comparison to 39 physical harms and 12 economic harms (89). Despite the available information on the differing patient perspectives of safety, the dominance of the medical model in patient safety is still apparent in the clinical focus of safety measurement, which was critiqued in Chapter 2. Disparities between what patients would like healthcare to achieve and what healthcare is striving to achieve (indicated by what it measures), could result in healthcare systems being unsuccessful in delivering good and safe care, as perceived by the patient. In support of the need for a greater understanding of patient perspectives, Ocloo (178) argues that:

'Harmed patients' perspectives provide a unique alternative standpoint to the dominant viewpoint of the medical profession, in highlighting the broader social processes that construct harm' (178)[pg511]

Ocloo's research with a patient led safety group: Medical Harm Self-Help Network (MHSHN), revealed that the group wanted to campaign to challenge the dominant medical model, which they felt was working to their detriment. They also felt that healthcare systems adopted a paternalistic approach, which was oppressive to the patient and that their experiences had been excluded in the development of patient safety reforms. However, Ocloo concludes: *'That these experiences have acted as an important catalyst for the emergence of a patient safety movement in healthcare over the last ten years'* (178)[pg515].

More recent controversies in healthcare safety support the notion that patients and the public can catalyse movements for reform, but consideration of the patient experience in the reform process is yet to be seen.

3.4.2: Patient involvement in improving safety

Patient participation in healthcare is increasing as healthcare seeks to become more patient-centred. Patients should no longer be considered passive recipients of care, or passive victims of medical error. Vincent and Coulter (170) proposed that patients should be co-producers of care and safety, and could contribute to improving safety in multiple ways, including: helping to reach an accurate diagnosis; deciding an appropriate treatment; choosing a suitably experienced and safe provider; appropriately administering, monitoring and adhering to treatment; and identifying side effects or adverse events quickly and taking appropriate action. However, there may be difficulties with patients participating in safety. Longtin et al. (179) present the current knowledge of patient participation in patient safety efforts and provide a long list of factors that influence patient participation, including but not limited to: acceptance of the new patient role, confidence in own capabilities, stakes of the potential outcome, type of illness and co-morbidity.

One way in which patients and the public can contribute to safety and influence reform, is to voice their concerns. The problems of poor quality and unsafe care uncovered at Mid-Staffordshire NHS Foundation Trust were brought to light by a patient and relatives group: Cure the NHS. As a result of the Cure the NHS campaign, a public inquiry was undertaken at the Trust to determine the cause of excessive mortality. Consequently, three other reports have been published in light of the poor findings (12, 180, 181). The resulting reports make, in total, 308 recommendations or ambitions to improve safety in healthcare. This is evidence of the strength and power that patients and the public can have in improving safety by being involved in highlighting issues. All three reports called for greater patient and public involvement. Digital technology is another avenue that patients are using to empower themselves and voice their concerns. For example, www.patientopinion.org.uk is an independent website where patients can go and submit their opinions on the care they have received. On the 30th October 2013, 64,962 stories by patients and relatives had been submitted, there were 2125 staff listening, 56% of stories received a response and 6% led to a change. These stories can be positive or negative.

Research has investigated the opportunity for patients to report incidents, which has indicated an incidence of nearly 50% (182), substantially higher than the 9.2% incidence using retrospective record review (10). However, prospective analysis using ethnography indicated an incidence of 46% (183), providing further evidence of the under-reporting nature of methods that utilise healthcare professional reporting. Entwistle et al. (184), qualitatively explored the experiences of patients and family members who had spoken up about patient safety at the point of care. Their disposition to speak up about safety concerns was influenced by multiple factors including:

- Gravity of the threat of harm
- The relative importance of their concern given other patients' needs and staff workloads and priorities
- Their confidence about their grounds for concern, roles and responsibilities
- The likely consequences of speaking up

Entwistle et al. (184) concluded that patients that spoke up about error, were heavily influenced by the quality of the patient-professional relationship. The ability of patients to speak up might also be hindered by their perception of their role in healthcare safety. A survey by Rathert et al. (185) found that patients believed that their role in safety was to follow instructions (most common response of 23%) suggesting a passive role in safety. They also expressed the expectancy of competent care. There are two issues here: firstly, if patients believe healthcare to be inherently safe, it may not be obvious to them to criticise when it is not. Secondly, as a passive participant, they may feel they have no influence, preventing them from speaking out. Both of these issues could prevent patients from speaking out about safety.

The World Health Organisation (WHO) has recognised the increasingly active role that patients have in their healthcare provision and promote that this should be extended to safety (186). Figure 3.3: Relationships between patients' rights and empowerment in healthcare safety, demonstrates the relationship between patients' rights and patient empowerment, which support their involvement in healthcare safety. The system of care is divided into three domains; structure, process and outcome. The

structure, process and outcome (SPO) model was originally described by Donabedian (3) as a method for evaluating quality by breaking up the system of healthcare into component parts. Structure refers to the environment (physical, organisational, cultural etc.), processes are actions and outcomes are consequences.

Structure	Process	Outcomes
Macro level (Inter)national legislation and charters concerning patients' rights; requirements with respect to the education and training of professionals; (inter)national patient safety information campaigns		**Macro level** Mortality and morbidity as a result of avoidable adverse events; public trust in healthcare, reduced health expenditure through increased compliance
Meso level Providers' quality and safety management and interventions; patient participations in provider-level boards and committees; patient education programmes, etc.		**Meso level** Outcomes; incidence of avoidable adverse events; near faults and accidents, patients' experiences of safety
	Micro level Providing information about risks and benefits; obtaining informed consent; shared decision-making (SDM); patient participation in self-management; patient complains	

Figure 3.3: Relationships between patients' rights and empowerment in healthcare safety
(World Health Organisation (186))

The SPO model will be discussed further in section 3.5: Structure, process and outcome as measurement domains. The WHO also break down levels within each domain: macro (international environment), meso (organisational) and micro (patient). Figure 3.3 makes visible the links between patient contributions to safety through their compliance and participation in self-care processes, which are affected by the meso

and macro structures to influence meso and macro outcomes. It is within the mirco level that the WHO believes patients can co-produce health and actively participate in error prevention. Furthermore, it identifies patients' experiences of safety as an outcome, in addition to the incidence of adverse events.

What is absent from the micro level, are the sorts of activities that have been presented in the literature, as possible contributions to safety by patients: namely incident reporting. Instead, the WHO presents case studies of worldwide examples of patient involvement in safety, which were exploratory in nature. These case studies do not identify physical interventions in which patients contributed to safety improvement efforts. Rather, the case studies provide arguments for the need to generate a greater understanding of the patient role. This further supports the notion that the work on patient involvement in patient safety is fairly young, and further investigation is required. Examples of the case studies can be found in Table 3.7: Case studies of patient involvement in safety.

Table 3.7: Case studies of patient involvement in safety
(World Health Organisation (186))

Case Study	Description of Case Study
Patient participation in hand hygiene in Bulgarian healthcare	Understanding what patients know about healthcare acquired infections and their intentions to ask healthcare workers to perform hand hygiene
Blood transfusion safety in France: developing tools to support patients	Understanding what patients know about their rights during the blood transfusion process and how comprehensible the available information is.
Patient safety, rights and medication safety in primary care in Poland	A survey was conducted, which revealed that patient understanding of pharmacokinetics was low as a result of poor quality education and poor medical practices

As demonstrated by the WHO, patient involvement is desired; however, evidence to support the effect it has on improving outcomes is limited. In fact, a study demonstrated that patient involvement in

preventing wrong-site surgeries was unreliable (187). 200 patients were asked to mark the surgical site prior to surgery: 135 did so, 2 of who marked the wrong site (187). This suggests that patients alone could not be responsible for the prevention of error, but rather, need to be part of a multi-faceted approach. More work is needed to understand if patients can positively contribute towards improved patient safety outcomes.

3.4.3: Patient contributions to safety

So far, the perceptions of patients have been presented. Furthermore, the possibility of patients being involved in safety improvement has been discussed. In addition, patients can negatively impact on safety by contributing to the conditions that facilitate harm. The RRRs deployed by Johnson (169), Blais et al. (39) and Sear et al. (38) have been able to examine contributing factors. For example, Johnson (169) found that informal caregivers and patients contribute to 42.3% and 30.8% of adverse events, respectively. In the study by Blais et al. (39), in which an incidence rate of 4.3% was calculated, 56% were deemed preventable. More than 90% were associated with a higher utilisation of healthcare resources, 68.8% with disability and 7.5% with death. Blais et al. (39) were also able to establish that 48.4% of adverse events were as a result of patients, 20.4% informal caregiver and 46.2% healthcare professionals. These data suggest that the contributions made by patients and informal caregivers to the occurrence of adverse events are significant, and that the outcomes impact on both patients and healthcare providers.

According to Romagnoli et al. (188), home care nurses perceived the patient and informal caregiver contributions to be related to an inability to sufficiently care for wounds, follow medication regimes, manage durable medical equipment, and keep their homes free of hazards. They also considered the communication between healthcare professionals, from different care settings, to be reliant on patients and informal caregivers. Communication is an important component of safety during care transitions as perceived by the home care nurse and patients (174, 189). Particularly where healthcare professionals from the hospital have less experience of care delivery in the home, and may not have the same

understanding as home care nurses (189). This is further enhanced by Romagnoli et al. (188) who demonstrate that insufficient attention is given during care transitions to effective communication. Consequently, decisions made with inaccurate, incomplete or simply wrong information can result in adverse events, which were potentially preventable (190, 191). With between 5% and 79% of hospital readmissions deemed avoidable (192), tackling the communication issue in care transitions and between care settings might prove fruitful for both care providers and patients.

The dissonance of safety theory between the acute setting and the primary care setting has previously been explored from the staff perspective, including district nurses and home care workers. McGraw et al. (193) found that the challenges in the home setting where different to those in the bounded setting of a hospital, which restricted the applicability of models of safety derived in the hospital setting. What is absent is an evidence base on the patient and caregiver perspective.

3.4.4: Summary of patients as stakeholders in safety

The inherent trust patients place in healthcare professionals to deliver competent care to passive patients could be problematic in the pursuit of patient involvement in safety. Patients might find it difficult and be reluctant to question safety of care when they have expectations that, at the very least, care will be competent. The preoccupation with a medical dominant safety movement could conflict with the differing perceptions held by patients, who, place greater emphasis on non-medical error and harm. If this disparity remains, patient priorities will continue to be overlooked and healthcare organisations will struggle to meet the demands of the patient population.

There is some evidence to support the contributions of patients to the management of patient safety. This includes understanding their perception of safety in terms of its scale, as well as what they perceive to contribute to, and be responsible for, safety. In addition, patients can actively contribute to safety management at the point of care by speaking up, questioning, and ensuring their own contribution to

healthcare is safe and compliant. The susceptible nature of the patient perspective to influence requires a more stable environment for patients to feel safe and to feel competent to contribute to safety. Relationships and trust with healthcare professionals and organisations must be well established to ensure effective communication. Organisations need to strive to be responsive to patient needs and to understand that the outcomes of importance to them might differ to those of patients. There is value in involving patients in patient safety, as the patient grows increasingly active in their healthcare interventions, such as the CM programme.

3.5: Structure, process, and outcome as measurement domains

The discipline of performance measurement recognises the limitations of outcome measurement and promotes the use of additional measures of input and process, which contribute to the achievement of outcomes. In 1966, Donabedian argued that an *'assessment of quality must rest on a conceptual and operationalized definition of what the "quality of medical care" means.'* (194)[pg692]. This is aligned with the conceptual requirements of performance measurement outlined previously, which requires an understanding of, and alignment with, the organisations objectives, in order to inform the measures appropriately.

Donabedian (3) first proposed the structure, process and outcome (SPO) model in 1966, to provide an alternative to the commonly used outcome measures, which he argued were not necessarily the most relevant measure of quality. For example, mortality rates for care of patients with fatal disease would possibly not be appropriate in the assessment of quality. Where mortality rates appear to be more appropriate, issues still exist. The use of mortality rates might be used in conjunction with a threshold level, which needs to be breached in order to trigger an alert that something is wrong with the system: a given number of patients have to die before being made aware there is a problem. Furthermore, Donabedian (3) argued that even if the relevant outcome is measured, it is sensible to be mindful that many things influence outcomes beyond the medical care provided. This might explain why safety has

been measured in the way it has: the outcomes measured are exclusively the result of care provision and exclude disease progression. Given the issues of outcome measurement, Donabedian (3) proposed the use of process measures as an opportunity to measure where action of care is good or bad. In addition, he discussed the assessment of structure: the setting within which care is conducted. He argues that having the correct structure, such as: suitable facilities; adequately trained staff; and accessible information, enables good practice (processes) to deliver optimum outcomes.

Although the SPO model was originally described for quality measurement, it has been applied to patient safety. Patient safety and quality of care are closely related: safety is a component of quality (147). Subsequently, Davies, et al. (5) have applied the SPO model to a systems approach to patient safety. Figure 3.4: SPO applied to a systems approach to patient safety, is a diagrammatic representation of the relationships between SPO in the context of systems theory.

Figure 3.4 describes the system as component parts composed of structure, process and outcome. Latent conditions are present in the structure of care. Active failures are associated with processes; inappropriate actions taken as a result of latent conditions within a system. Although the schematic is useful, it is oriented around what not to do and what not to achieve, which is how the definition of safety is presented; as a process of avoidance. In Figure 3.5: SPO applied to the Swiss cheese model, the SPO model is mapped onto the Swiss cheese model to demonstrate how they are related and how the SPO model is a systems approach to safety.

The SPO model provides a theoretical foundation upon which to base an evaluation of quality or safety. However, Donabedian (195) himself acknowledged that evidence to prove the relationship between the three was lacking and would prove difficult to achieve; however, since this time, evidence has become available.
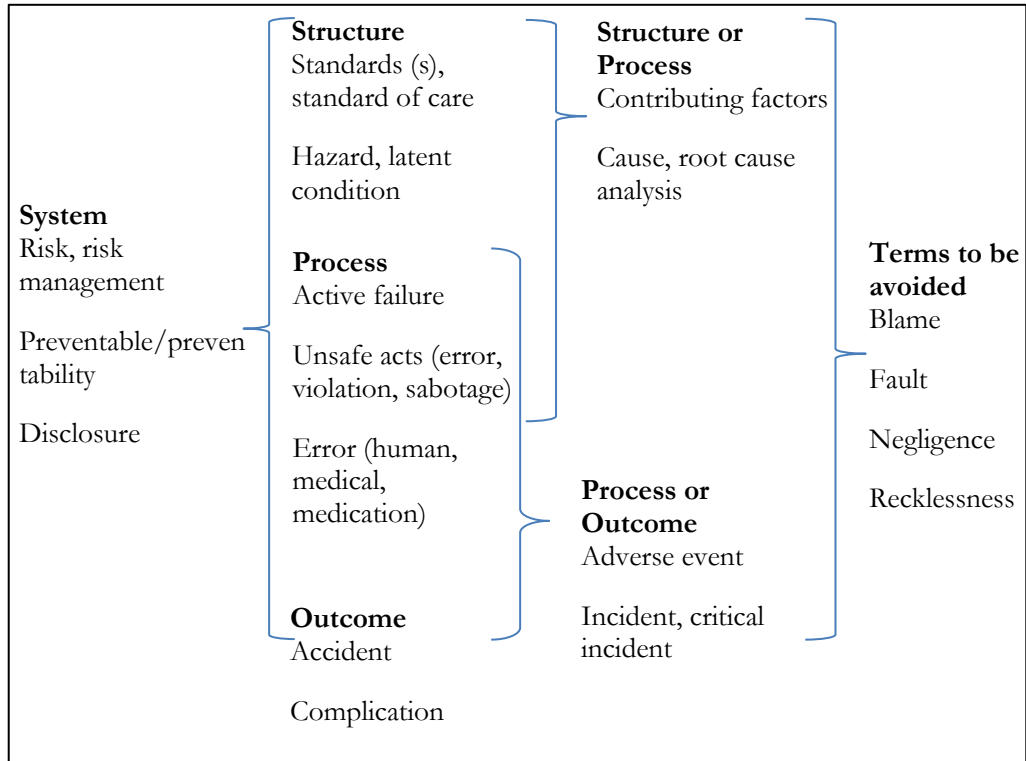
Figure 3.4: SPO applied to a systems approach to patient safety
(Davies et al. (5))
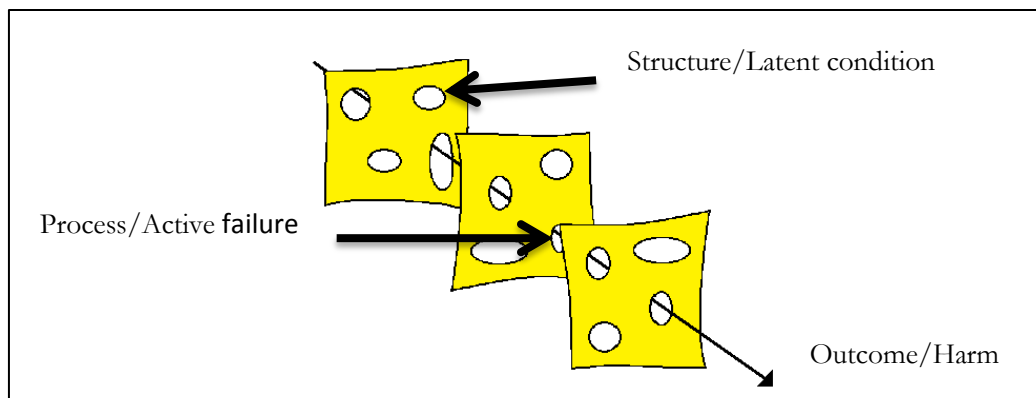
Figure 3.5: SPO applied to the Swiss cheese model

3.5.1: Evidence for and against the SPO model

Evidence is available to support the existence of relationships between the three domains of the system.

Rademakers et al. (196) were able to conclude that improvements in structure and processes could lead to

improved patient assessments of healthcare quality. Sainfort (197) identified the need for a method of causal modelling built on the domains of structure, process and outcome, to assess the quality of care in nursing care facilities. Kunkel et al. (198) conducted a large quantitative study to determine the significance of the relationships between structure, process and outcome and found it to be representative of the quality systems of hospital departments in Sweden. They were able to demonstrate that structure can influence both processes and outcomes, and, that processes directly influence outcomes. This can be seen in Figure 3.6: The relationships between SPO.
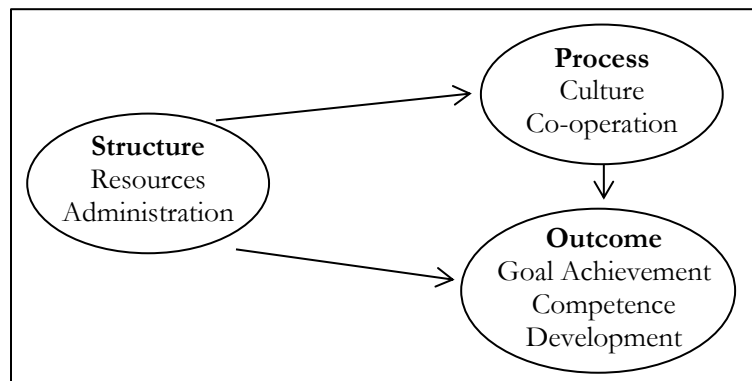
Figure 3.6: The relationships between SPO
(Kunkel et al. (198))

Carayon et al. (199) criticised the SPO model for being too process and outcome oriented, leading to punitive action against individuals. However, their alternative model: the Systems Engineering Initiative for Patient Safety (SEIPS) is predicated on the SPO model. The SEIPS model is however, more focused on structure, arguing that this is where more attention is required in a true systems approach to patient safety. Instead of using the term structure, the SEIPS model refers to structure as the work system, and breaks it up into smaller components: person, organisation, technologies and tools, tasks and environment. Carayon et al. (199) suggest that the model can be patient centred, with patients being allocated as both recipients of care who are subject to good or bad outcomes, and active participants involved in their care. Interestingly however, the model is ignorant of the patient contribution to the work systems, which are mostly related to the structure of care that organisations provide. This is unsurprising considering that in their study, the model was applied only to an outpatient surgery i.e. where care is

delivered in an environment controlled and regulated by the healthcare provider. Given the organisation derived nature of the model and its application to secondary care, it is deemed inadequate to reflect the care of the CM programme, but it does reinforce the usefulness of the SPO model as a foundation for a systems approach to patient safety, that can be built upon. Conversely to Carayon et al. (199), a literature review conducted on the structure, process and outcome characteristics of a crisis resolution and home treatment (CRHT) service for mental health, identified the strengths of the structural components in the literature, and criticised the evidence for outcome measures as being less substantial (200).

The Nursing Role Effectiveness Model is another example of the application of the SPO concept in the acute setting but specifically evaluates the care delivered by acute care nurse practitioners (ACNP). This model is more descriptive of the types of indicators within each of the SPO domains and can be seen in Figure 3.7: The Nursing Role Effectiveness Model. Multiple studies were carried out to empirically test the validity of the model. Doran et al. (201) found that for the most part, the hypothesised relationships between SPO were supported using a cross sectional survey design and structural equation modelling. Sidani et al. (202) made further adaptations to the model to propose relationships between SPO and included patient in the structure of care. However, this only related to their personal characteristics such as: demographics, illness/health and resources. Other studies have further validated the Nursing Role Effectiveness Model in the acute care setting including: the organisational factors that influence the role of the nurse (203), practice patterns of nurses (204) and organisational changes resulting from the implementation of the ACNP role in the acute care setting (205).

The Nursing Role Effectiveness Model informs the measurement of indicators that are sensitive to nursing care by operationalising the nursing role in terms of the independent and interdependent roles, which are essential in identifying the performance of nurses. However, because the model is focused solely on the care provided by nurses, it does not examine the whole system of care. For these reasons, it is deemed inadequate as a foundation for a model in the community, which is dominated by patient self-care and where the nurse role is less clinical. The validation and extensive studies on the Nursing Care

Effectiveness Model provides evidence of the accuracy of the SPO theory as a component of the quality of healthcare, in particular, in the acute care setting.
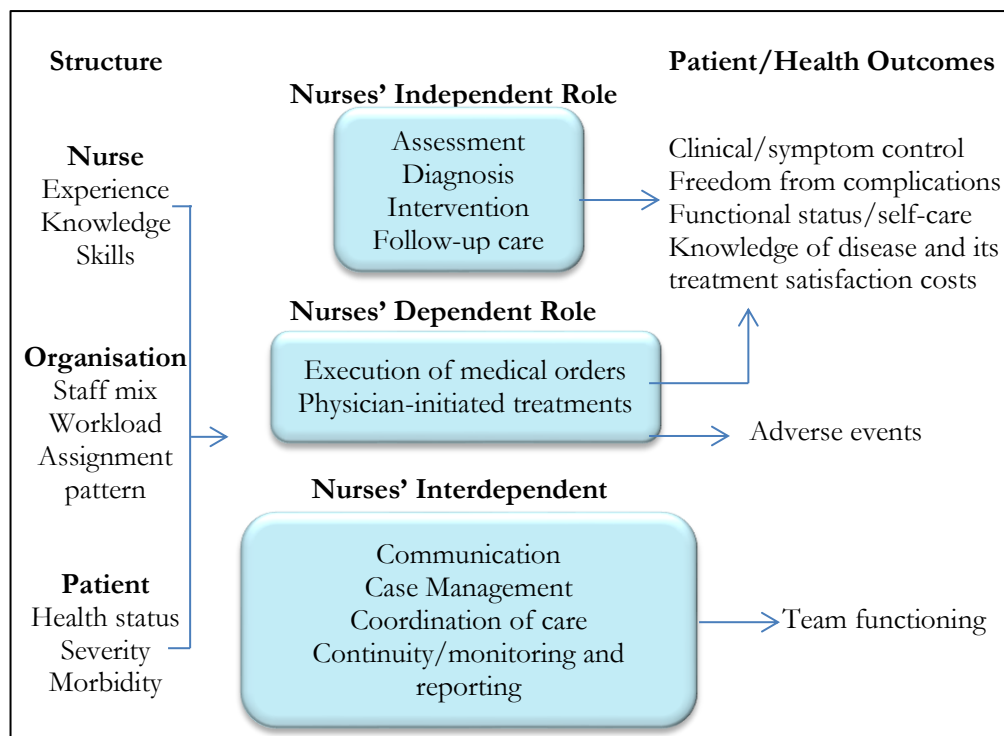
Figure 3.7: The Nursing Role Effectiveness Model
(Doran et al. (201))

The SPO model can also be applied to the unnecessarily high incidence of mortality at Mid-Staffordshire NHS Foundation Trust. The public inquiry report (12), published by Robert Francis QC, was conducted following complaints of poor care and unnecessary deaths. The investigation uncovered between 400-1200 unnecessary deaths during the period 2005-2008. The report highlighted the main contributory factors, which are provided in Table 3.8: Findings from the Francis Report, as well as an explanation of their contribution.

Table 3.8: Findings from the Francis Report
(Francis (12))

Factor	Explanation
Negative culture	A tolerance of poor standards, focus on financial targets, denial of concerns and isolation from practice elsewhere
Professional disengagement	Professionals did not pursue management with concerns they had – a degree of passivity
Patients not heard	Inadequate processes for dealing with complaints, even when patient data was collected, it was not acted upon
Poor governance	Poor grip on accountability and governance structures
Lack of focus on standards of care	Leadership was expected to focus on financial issues with little attention paid to the risk to quality
Inadequate risk assessment at staff reduction	The hospital was deprived of proper levels of nursing staff in order to meet financial demands of foundation trust status review
Nursing standards and performance	Inadequate standard of nursing, inadequate staffing levels, poor leaders and recruitment and training – declining professionalism and tolerance for low standards. Staff did report many incidents which occurred because of short staffing, exhibited poor morale in their responses to staff surveys, and received only ineffective representation of concerns from the RCN.
Wrong priorities	The Trust prioritised its finances and its FT application over its quality of care, and failed to put patients at the centre of its work.

The contributory factors can be categorised by structure or process. Negative culture, poor governance, lack of focus on standards of care, nursing standards and performance, and wrong priorities are all components of the structure of care. Communication is a process, and thus in instances where communication is failing, so are processes. Risk assessment is also a process, and thus inadequate risk assessment is a component of a failing process.

The components of the SPO model can also be applied to the system of care presented in the NHS and Social care long term conditions model (this can be seen in Figure 3.2). The infrastructure, including: community resources, decision support tools and clinical information systems, and health and social care system environment, represents the structure of care. Similarly, the four delivery systems are processes of care. Both of which, the DoH argues, will produce better outcomes in the form of empowered and informed patients, as well as prepared and pro-active health and social care teams.

3.5.2: Summary of the utility of the SPO model

The use of the SPO model in quality and safety has proven to be effective in places. Table 3.9: Evidence of the utility of the SPO, has synthesised the information of the applications of the SPO model presented throughout this chapter. Although the relationships between the domains remains unclear, possibly because of the multi-factorial nature and complexity of outcomes, some generic relationships have been identified. The need to understand contributing factors in structures and processes has recently been endorsed by an assistant director of the Health Foundations who said:

> *'High quality care is dependent on having safe structures and safe processes that support good outcomes: we need to have good measures of these structures and processes to predict current and future safety, as well as having measures of outcomes that tell us how safe care was in the past.' (206)*

The SPO model has been available for debate in the literature for over 50 years, and theoretically provides an opportunity to tackle patient safety measurement from a systems perspective. Despite its availability, healthcare has been slow to adopt the SPO model as a form of systems safety measurement; though this is perhaps less reflective of the usefulness of SPO, but rather, the culture of healthcare.

Table 3.9: Evidence of the utility of the SPO

Model/Figure	Structure	Process	Outcome	Comments
The NHS and Social Care long term conditions model	✓ referred to as 'infrastructure'	✓ Referred to as 'delivery system'	✓	This model uses different language which in effective, describe the three components of the care system.
Relationships between patients' rights and empowerment in healthcare safety	✓	✓	✓	The SPO mode is also cross-cut by the macro, meso and micro levels within the system.
SPO applied to a systems approach to safety	✓	✓	✓	This model identifies the relationships between the dialogues used within the SPO context.
SPO applied to the Swiss cheese model	✓ Originally describes as 'latent conditions'	✓ Originally describes as 'active failures'	✓	This model refers to latent conditions (dormant errors within the system) and active failure (errors committed at the sharp end). These occur within the structure and process components of the system respectively.
The relationships between SPO	✓	✓	✓	This model identifies potential relationships between the components: structure affects process and outcome, and process affects outcome.
The Nursing Role Effectiveness model	✓	✓	✓	This model retains linear relationships but identifies specific indicators.

Utilising structure, process and outcome as domains for measurement, will enable the contributory factors of adverse outcomes to be understood and deficiencies in the system to be identified before adverse outcomes are experienced. Definitions of each of the domains for use in a measurement system design model can be found in Table 3.10: Glossary of structure, process and outcome terms.

Table 3.10: Glossary of structure, process and outcome terms

Domain	*Definition*
Structure	The environment in which care is delivered: both physical and theoretical
Process	The actions of care
Outcome	Results of care

3.6: The integrated safety measurement model

Chapter 2 critically analysed the literature on the measurement of safety in healthcare. Limitations of current safety measurement were identified, and included:

- A dependency on outcomes
- An absence of patient engagement in the design
- An absence of patient contribution in the identification of error and harm

Subsequently, this chapter offers the principles of performance measurement as an alternative approach. The development of a safety performance measurement system for the CM programme would enable the quantification of the efficiency and effectiveness of action. This could be achieved by translating both the organisations safety vision, and the patients' and service users' requirements into a set of metrics. Furthermore, a whole systems approach would facilitate the measurement of metrics that:

- Measure components of the system that are responsible for outcomes

- Measure components of the system that are amenable to intervention
- Are not susceptible to manipulation
- Promote positive behaviour change in favour of improved outcomes

There is little doubt that safe healthcare is a vision of healthcare organisations. Patient safety has been a global priority since the publication of the IoM report (6), which highlighted the extent of medical error. In the English NHS, patient safety has recently been subject to criticism following the problems identified at Mid-Staffordshire NHS Foundation Trust and the following 11 Trusts that were placed into special measures as a result of further investigation.

Performance measurement dictates that patients, as consumers of healthcare, are key stakeholders of care. This is further enhanced by the new philosophy of care in programmes such as CM, which aim to empower and educate patients to undertake better self-care. Consequently, patients are no longer just consumers of healthcare, but also engaged producers. This philosophy also extends to patient engagement in safety. Evidence has been presented (section 3.4: Patients as stakeholders), which demonstrates that research is seeking to explore the patient perspective of safety, their involvement in safety improvement efforts, and how they inhibit or facilitate the condition of safety. Safety measurement however, as described in Chapter 2, is still dominated by traditional stakeholders, namely providers and their staff. As patient-centred care grows to encompass patient engagement, they increasingly become key stakeholders of care, and of their safety.

In attempting to address the issue of lagging indicators, performance measurement favours metrics across the system, from the inputs and processes that determine the outputs. Donabedian's structure, process, outcome model, is a healthcare equivalent of a whole systems approach to measurement, and evidence has been provided to support its utility in its potential application as an underlying model to patient safety measurement.

The proposition that the development of a safety performance measurement system could address the limitations of current safety measurement systems is welcomed in this thesis. However, it is recognised

that the current understanding of safety in home healthcare is limited by the small number of studies conducted in this setting. Prior to the development of relevant measures, further research is required to elicit more knowledge on:

- What it means to be safe in the home
- How patients maintain safety
- What risks are present that need to be addressed
- What outcomes are expected
- How each of the stakeholders contributes to patient safety
- What structural variables contribute to safety
- What processes or actions are required to maintain safety or facilitate error

The identified key stakeholders and the structure, process, outcome model are proposed as the basis of a measurement system design model that has been born out of the preceding literature review, and can be found in Figure 3.8: Integrated safety measurement model (ISMM).

Kunkel et al. (198) empirically determined the relationships between the three domains in a Swedish hospital: structure impacts on process and outcome, and process only impacts on outcome (see Figure 3.6). However, argument could be presented for the cyclical impact of process on structure; this is dependent on the inclusivity of each domain. In the case where process is specific to actions of clinical care, Kunkel et al.'s (198) conclusion might well hold true. However, in instances where processes include system assessment, such as risk assessment, it would appear reasonable to hypothesise that processes might influence the structure. As one would expect a poor result from a risk assessment to result in changes to the structure. This may not be so relevant in an environment where the structures are regulated and controlled, and even standardised in some cases, but when care is being delivered outside these environments, such as in the home, and risk assessments become core to the care of patients, processes might impact on structure. For this reason, the structure and process domains have been presented as cyclically impacting upon each other and both feeding into outcomes.
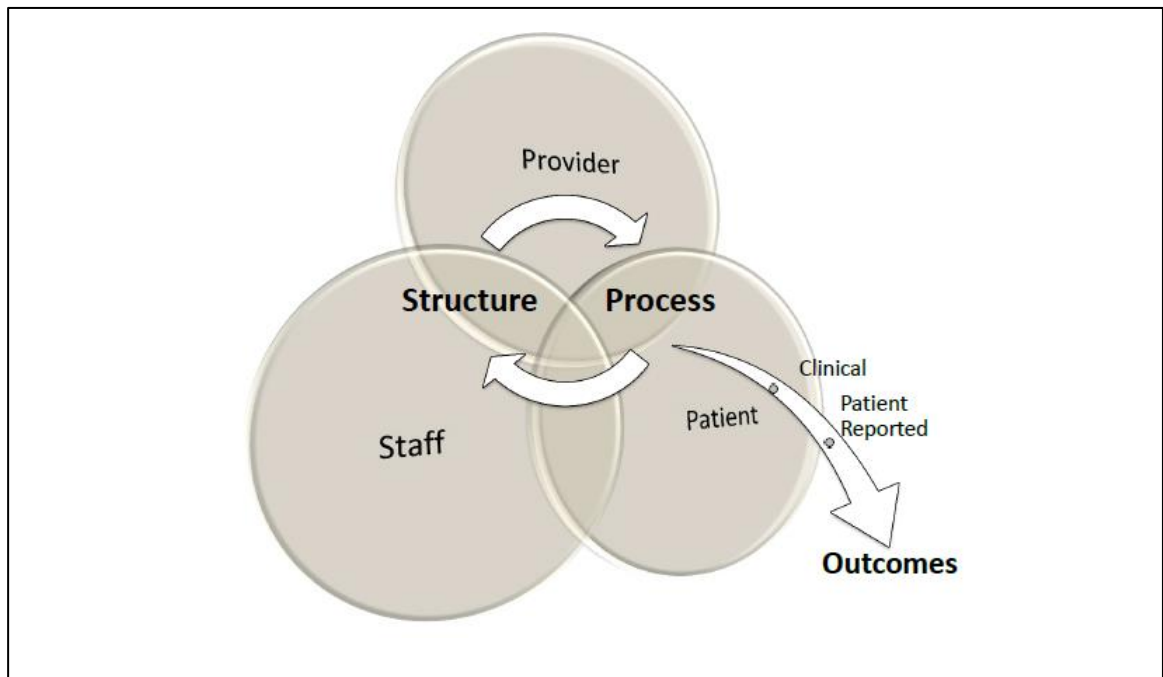
Figure 3.8: The integrated safety measurement model

The ISMM is a theoretic model to assist in the method of constructing a safety measurement system. It identifies key stakeholders whom are essential in the design of the system and with whom, engagement should be sought. Key stakeholders are those who have an interest in the outcomes and/or a contribution to make to the outcomes. This is over arched by three measurement domains: structure, process and outcomes. Structure is the environment in which the care is delivered, beyond the physical but into the organisational and social. Processes are the actions of care and outcomes are the consequences of care delivery.

3.7: Summary

Presented in this chapter are four core themes, which contribute to the underlying research problem, upon which this thesis is built. Firstly, that the discipline of performance measurement offers an opportunity to address the limitations of safety measurement outlined in Chapter 2. Secondly, patients are key stakeholders of care and should be engaged in the development of measures relating to patient safety. They also have a perspective of safety, which differs to that of other stakeholders such as healthcare

professionals and thus are a valuable source of information that is currently underutilised. Thirdly, patient involvement in healthcare is increasing, demonstrated by services such as the CM programme. The new philosophy of care is to educate and empower patients to take a bigger role and greater responsibility in their healthcare. This is being achieved in non-traditional care settings such as the patient's home, rather than the hospital or GP surgery. These environments are not designed, nor necessarily equipped for healthcare delivery, as they are not controlled or regulated by the healthcare provider, but rather the patient. Finally, the literature on safety in community care settings such as the home is spare in comparison to the hospital setting. The RRR, first utilised in the Harvard Medical Study in 1990, wasn't deployed in home healthcare until 2013. Canada has been pursuing a home healthcare safety agenda, and gives us some indication of the complexities of safety in home healthcare.

The ISMM informs the design of safety measurement by identifying key stakeholders who should be involved in the design of the system and three overarching measurement domains. Using this model, this research will conduct a research methodology that seeks to explore the perspectives of key stakeholders of safety, through the lens of structure, process and outcome measurement domains. This is supported by generic performance measurement models, which advocate stakeholder involvement, in order to understand their expectations and their contributions to achieving the desired outcomes. In doing so, successful identification of components of each of the measurement domains will act to validate the model with respect to face validity: the degree to which something is considered to measure its intended phenomenon.

The capacity of this research to progress beyond this is limited by the time required to deliver on the other characteristics. For instance, benchmarking of indicators will require time and further research efforts to understand what standards to set, and to generate evidence of their effectiveness at reducing harm to patient. This point also relates to the ability of performance measures to be easily changed as the circumstances change; evidence will be required to support this given the sensitivity and risk of what is being measured. Nevertheless, lessons can be learnt from the discipline of performance measurement,
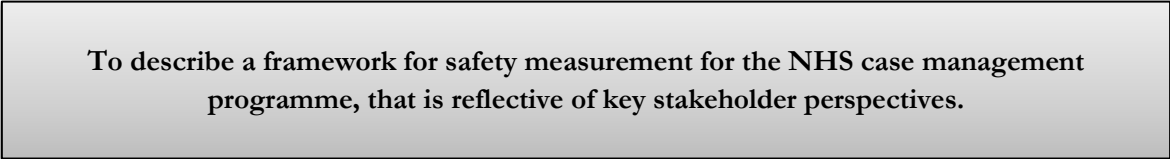
particularly in the engagement of key stakeholders such as patients and staff, namely that they should stimulate improvement, and that they must provide fast feedback. All of which are currently lacking in safety measurement.

Chapter 4

Research Design

4.1: Introduction

This chapter presents the philosophical and methodological approaches adopted to address the research aim and objectives proposed in Chapter 1. The aim of this chapter is to present a philosophically and methodologically coherent argument for the research design proposed. In doing so, the philosophical position of the researcher will be defined, followed by the selected methodology and methods to meet the philosophical demands. The aim of the research is presented in Figure 4.1: Research aim.

> **To describe a framework for safety measurement for the NHS case management programme, that is reflective of key stakeholder perspectives.**

Figure 4.1: Research aim

Before the commencement of research, the researcher must first understand their philosophical perspective; specifically, their ontology and epistemology. The importance of this has been succinctly articulated by Guba and Lincoln (207): '*questions of method are secondary to questions of paradigm*' (207)[pg105]. A researchers ontology and epistemology dictates how they perceive the world and how knowledge is generated respectively, hence the need to be explicit in the research design; the way in which knowledge is generated during the research process is a consequence of the researcher's ontology and epistemology.

The researcher presents a critical realist philosophy that supports their personal interpretation of reality as well as meeting the demands of the research aim. Subsequently, a methodology is presented, which is more than the process of data collection and analysis (methods), but rather, is an encompassing strategy or plan of action, which postulates the use of particular methods (208). A range of data collection and analysis techniques are discussed and appropriate ones have been selected. The quality of the research design is supported through the use of validating techniques, individual to both the qualitative and quantitative approaches.

A framework of the research design is presented in Figure 4.2: Research design framework. A mixed methods approach is proposed, using an exploratory sequential mixed method design (42). Deploying two sequentially related studies, the perspectives of key stakeholders will be explored using a qualitative case study (study I), validated and generalised using a survey (study II). From this deep and generalisable understanding, a framework for measuring safety can be devised.

Exploratory Sequential Mixed Method Design

Critical Realist Philosophy

Study 1

Data Collection	→	Data Analysis	→	Develop Survey	→

Study 2

Data Collection	→	Data Analysis	→	Knowledge

Procedure
Instrumental, single, embedded case study. Patient (n=9) & carer (n=6) interviews Staff (n=17) Focus groups all purposively sampled

Procedure
Framework analysis

Procedure
Dimensions as items Classified into domains

Procedure
Randomly sampled survey population (patient n=35 Carer n=19) Staff n=26)

Procedure
Descriptive and inferential statistics

Procedure
Abstraction, retroduction, deduction, induction. Examination and interpretation of all findings

Products
Field notes Transcripts

Products
Coded texts – themed Dimensions of safety

Products
35 item survey

Products
Numerical item scores

Products
P-values from hypothesis tests

Products
Description of perspectives. Dimensions of safety within each domain. Safety measurement framework.

Figure 4.2: Research design framework
(Creswell and Plano Clark (42)[pg124])

4.2: Philosophy

4.2.1: Ontology and epistemology

Ontology is concerned with how we exist, and epistemology with how we obtain knowledge of existence; a person's philosophical position drives the nature of the research enquiry and ultimately the design. According to Guba and Lincoln *(207)*, *'inquiry paradigms define for the inquirers what it is they are about, and what falls within and outside the limits of legitimate research' (207)*[pg108].

The term paradigm refers to a collective assumption about the world and how knowledge is derived from it, which ultimately directs how research should be conducted (209). The researcher presents the philosophical paradigm of critical realism (originally described by Bhaskar as transcendental realism (210)), as that which underpins the researcher's beliefs and therefore the research design. The selection of this is somewhat inherent; however, logical argument can be communicated through the inadequacies of alternative paradigms in relation to the research aim. Prior to the development of the philosophical language that coherently explains the critical realist paradigm, a dichotomy of inversely related philosophical paradigms existed, namely positivism and constructivism (207). From the positivist perspective, ontologically, reality is independent of the mind and thus can be epistemologically, objectively observed and measured. This paradigm is strongly associated with traditional science (207). Conversely, the constructivist perspective dictates that there are multiple ontologically and epistemologically, socially constructed realities.

Neither perspective is adequate to support the research aim, which implicitly assumes a socially constructed element to reality as well as the possibility of commonalities. This draws from both constructivist and positivist paradigms. The critical realist perspective, therefore, provides an alternative middle ground, to capitalise on the shortcomings of the opposing paradigms. Critical realism, presents

that, ontologically, *'the world is structured, differentiated, stratified and changing'* (211)[pg5]. Bunge (212) similarly considers critical realism to arrange reality into levels, within which are underlying mechanisms, which can generate events. Bhaskar (210) outlines ontology to exist within three domains: the empirical, the actual and the real. In describing this, Bhaskar promotes that there are mechanisms that may or may not lead to events, which, may or may not lead to experiences, yet only events are empirically observable (see Table 4.1: Ontological domains of critical realism). Therefore, critical realism supports the notion that in order to attain knowledge of the phenomenon, you must understand the underlying, unobservable mechanisms, in addition to the empirically observable events. Critical realism, therefore, concedes that reality is independent of the mind; however, it acknowledges there is a dimension that is socially determined and therefore dependent.

Table 4.1: Ontological domains of critical realism
(adapted from (210)[pg13])

	Domain of real	*Domain of actual*	*Domain of Empirical*
Mechanisms	X		
Events	X	X	
Experiences	X	X	X

In reference to the research aim posed, it is implicit that a component of safety is socially determined through experience. In proposing to engage with multiple stakeholders of safety, it can be inferred that there will exist multiple experiences, which is aligned with critical realism. By exploring the concept of safety from multiple perspectives, knowledge on underlying generative mechanisms can be determined in order to identify opportunities for events, which may result in the experience of adverse events.

4.2.2: Intensive and extensive research design

Rather than present a divide between qualitative and quantitative research, critical realism suggests the use of intensive and extensive research designs (211). Intensive research shares commonalities with qualitative research, and extensive with quantitative research. Critical realism advocates that both could be present at

the same and/or different times during the research process. Traditionally, qualitative modes of inquiry are an opportunity to explore and understand the meaning of a phenomenon and quantitative modes of inquiry enable objective testing of relationships between variables (213). Popay (214) states that qualitative research '*explores the meanings people attach to their experiences and identifies and describes the social structures and processes that shape these meanings*' (214)pg100. Thus generalisabilty of the findings is limited to the participants being studied. However, it can develop concepts and themes, which can be transferred to similar contexts, situations or populations.

Similarly, Danermark et al. (211), describe intensive research design as the study of one particular case (or several) in their context. Contrastingly, extensive research designs, study larger populations and try to find regularities and patterns using statistical analysis. Because critical realism advocates the use of both intensive, and extensive research design, a critical, multiple, methodological approach has been adopted.

4.3: Methodology – mixed method design

The research aim (see Figure 4.1: Research questions) has two key components: to explore the phenomenon of safety and to be able to devise a conceptual framework for safety measurement. Intrinsically, the research requires both an intensive and an extensive design: a single case and large population study respectively. The use of both in a pluralistic methodology is advocated by the critical realism paradigm. Therefore a mixed method design is proposed. (213) Creswell explains that:

> '*a mixed method design is useful when either the quantitative or qualitative approach by itself is inadequate to*
>
> *best understand a research problem or the strengths of both quantitative and qualitative research provide the*
>
> *best understanding*' (213)pg18

The critical realist paradigm implicates the inadequacy of the individual adoption of either qualitative or quantitative research methods. Quantitative studies are unable to establish underlying mechanisms

because they are not observable in the domain of the empirical. On the other hand, qualitative studies are unable to exert the statistical generalisabilty of these mechanisms, because they cannot support the numbers and control, required to test them. Creswell (213) promotes the use of mixed methods when there is a need to understand a phenomenon followed by a need to generalise the findings to a population, which cannot be achieved by either mode of inquiry independently.

Early definitions of the mixed method approach described it as a study that collected data with both quantitative and qualitative properties (215). Following further debate in the literature (216), the definition was extended to be inclusive of data collection techniques, analysis procedures and modes of inference *for the purpose of breadth and depth of understanding and corroboration'* (216)[pg123]. Creswell and Plano Clark (42) describe five core characteristics of mixed methods research:

1. Rigorously collect and analyse both qualitative and quantitative data, mixing the two forms by either combining them, building sequentially on each other or embedding one within the other
2. Priority is given to one or both forms dependent on the research question
3. Uses them in a single, or multi-phase study
4. Frames them within a philosophic paradigm
5. Combines them into specific research designs to direct the study plan

Greene et al. (215) suggest five reasons for selecting a mixed method approach. These can be found in Table 4.2: Reasons and relevance of a mixed method research design, as well as their application to the research design presented here.

Table 4.2: Reasons and relevance of a mixed method research design
(Greene et al. (215))

Reason for Conducting Mixed Method Research	Description	Relationship to research presented
Triangulation	Seeks convergence and corroboration	The quantitative study (study II) will determine whether there is corroboration with larger populations and between stakeholders.
Complementary	Seeks elaboration enhancement and clarification	The quantitative data (study II) will enable clarification of differences between stakeholders if differences exist.
Development	Seeks to use results from one method to inform another method	The results from the qualitative study (study I) will inform the survey design of the quantitative study (study II).
Initiation	Seeks to discover paradox and contradiction	Not relevant to the research as the quantitative study seeks corroboration and confirmation of qualitative findings rather than contradictions. However, should a paradox present itself between the two data sets, it will be exposed and examined.
Expansion	Seeks to extend breadth	The quantitative study (study II) captures a greater sample size.

According to Creswell and Plano Clark (42), there are six mixed method designs. The convergent design aims to derive a complete understanding by collecting both quantitative and qualitative data because individually, each provides only a partial view. The explanatory sequential design aims to explain the mechanisms in a trend by first collecting quantitative data to identify the trend, then qualitative data to explain the trend. The embedded design lifts up the voices of participants in the case of injustice to provide evidence for a call for action. The transformative design is used '*within a transformative theoretical perspective to help address injustices or bring about change for an underrepresented or marginalised group*' (42)[pg127]. The multiphase design requires multiple mixed methods over a long period of time to meet an overall objective. Finally, the exploratory sequential design first explores a topic through qualitative methods and them aims to make the findings generalisable through quantitative methods. Exploratory sequential design

can be used to develop a test instrument when a better understanding of the phenomenon is required beforehand (217). It is also suitable for generalising qualitative findings (218).

Little is known of the multiple key stakeholder perspectives of safety in case managed care, as described in Chapter 3, and therefore, it is essential, in order to develop a framework that is reflective of them, that they be explored using qualitative means. Once an understanding has been achieved, an instrument in the form of a survey can be used to determine the representativeness of the perspectives gained to a larger population. Given this, the exploratory sequential design has been selected for use in this research.

4.4: Method

In mixed method designs, multiple modes of inquiry are deployed. In the case presented for the use of a sequential exploratory design, it is evident that each mode seeks to contribute to the overall aim. Each mode of inquiry also has its own research questions and objectives which contribute to achieving this aim. Therefore, the methods (data collection and analysis techniques) are presented as two studies: study I – case study and study II – survey. The methods in relation to the overall research design are discussed and the argument for their selection over other methods is presented. The details of the protocol are described in full in Chapter 5.

4.4.1 Study I – case study

The selection of the exploratory sequential mixed method design indicates that Study 1 aimed to explore and understand a concept or phenomenon, qualitatively. Therefore, the purpose of this study was to explore and understand the perspectives of key stakeholders of safety, when healthcare is delivered in the home. It strived to answer: how do key stakeholders perceive safety, and how do the perceptions differ between key stakeholders?

There are several strategies for conducting qualitative research including, but not limited to: ethnography, grounded theory, phenomenology, case study and narrative inquiry. According to Reeves et al. (219), ethnography explores the social interactions and behaviours within a culture (a team, an organisation or a community). It does not seek to test hypotheses; it is the investigation of a small number of participants through the power of observation. This enables the researcher to 'get inside' the culture and see how they see the world. However, the current research was concerned with understanding the perspectives of stakeholders from how they describe it, rather than the ethnographic approach, which is interpreted through the observation of behaviour. Therefore ethnography was rejected.

Alternatively, grounded theory, originally developed by Glaser and Strauss (220), offers a strategy to develop an understanding of a phenomenon that is entirely derived from the data collected. As with ethnography, the strategy does not test hypotheses but rather, theory is drawn out of the data through an iterative study design and systematic analysis. The strategy strongly advises against using predetermined theories to remove bias from the analysis. This renders the strategy redundant here, as the literature review and subsequent model derived from the literature review, have strongly influenced the study design, data collection techniques and data analysis techniques selected.

Narrative inquiry is a process of storytelling through researcher interpretation (221). The analysis of narrative inquiry is distinctively different from the thematic nature found in grounded theory because of the integration of time and context into the interpretation (222). Narrative inquiry is able to determine how people make sense of the world and like grounded theory, it is also exclusive of *a priori* interests. The researcher acknowledges that the perceptions and perspectives of the participants might differ over time, dependent on the individual's experience. However, this research does not seek to examine the change of participants' perceptions over time but commonalities across individuals, and therefore, narrative inquiry was rejected as a suitable mode of data collection and analysis

Phenomenological research is another strategy, which is deployed without preconceptions. It aims to describe, rather than explain phenomenon (223). Therefore, this was also unsuitable as an appropriate method.

Alternatively, the case study method allows and encourages the researcher to *'move in and out of the literature before, during and after the case study has begun'* (224)[pg6]. In doing so, the researcher can construct meaningful questions at the beginning of the research process to elicit meaningful responses. Continuous referral to the literature can occur during the process of analysis, which persists from start to finish. The method employs an iterative-parallel process moving between stages of the research process. According to Stake (225), *'case study is the study of the particularity and complexity of a single case, coming to understand its activity within important circumstance'* (225)[pgxi]. Yin (43) describes case studies as empirical modes of enquiry that explore active phenomenon in depth and within real life contexts i.e. without controls.

Case study does not advocate an ability to make generalisations to larger populations because of its specific nature (226); however, patterns within the data are discernible, enabling generalisations of the specific sample studied (224). Furthermore, multiple data collection methods are promoted including the use of both qualitative (intensive) and quantitative (extensive) methods as a form of triangulation, providing a strong analytical strategy (43). Yin (227) considers the use of a broad variety of techniques a must, supported by Patton (228), to enhance the quality and credibility of the findings. Triangulation and other forms of validity will be discussed in 4.5.1: Validity of the qualitative approach.

Critical realism is considered to be tolerant of many research methods (229), including case study, because it is associated with specific question types such as *'what caused the events associated with the phenomenon to occur'* (230)[pg123]. With respect to this research, critical realism supports the drive to understand the underlying contributory conditions, which support or fail to generate, the condition of safety. Therefore, case study has been selected as a suitable critical realist approach.

4.4.1.1: The case

A case can be described as an entity such as a person, an organisation, a social group, or a service (43). In this instance, the case is the case management (CM) programme within the English National Health Service (NHS). Yin (43), describes four types of case study design: single, holistic case; single, embedded case; multiple holistic cases and multiple embedded cases. Holistic case studies can be single-case or multiple-case in design but focus on one unit of analysis within each case. Contrastingly, embedded case studies explore more than one unit of analysis. In this research, the case has been defined as the service under investigation (the case management programme) irrespective of the data being collected from multiple care providers. Therefore, the data will be not cross analysed by geographical location. However, the key stakeholders will be analysed separately and then cross compared. The identified themes will be presented for the entire data set and comparisons of the different stakeholder groups made within the themes and differences clearly stated. This study, therefore, is a single case study with multiple, embedded units of analysis.

Yin (43) provides five example case types for the selection of single case study design:

1. The critical case – to test a well formulated theory
2. The extreme or unique case – to investigate a rare phenomenon
3. The representative – captures commonplace situations
4. The revelatory – investigation of a previously undescribed phenomenon
5. The longitudinal – studies the same case over two different points in time.

Alternatively, Stake (225) has characterised three main types of case study:

1. Intrinsic – to investigate a unique phenomenon
2. Instrumental – uses a particular case
3. Collective – use multiple cases

Theoretical Design Type

Content

Embedded (multiple unit of analysis)

Embedded Unit of Analysis 1

Case

Embedded Unit of Analysis 2

Application of Design Type

Content

Embedded (multiple units of analysis)

Patients and Carers

Case Management Programme

Case Management Nurses
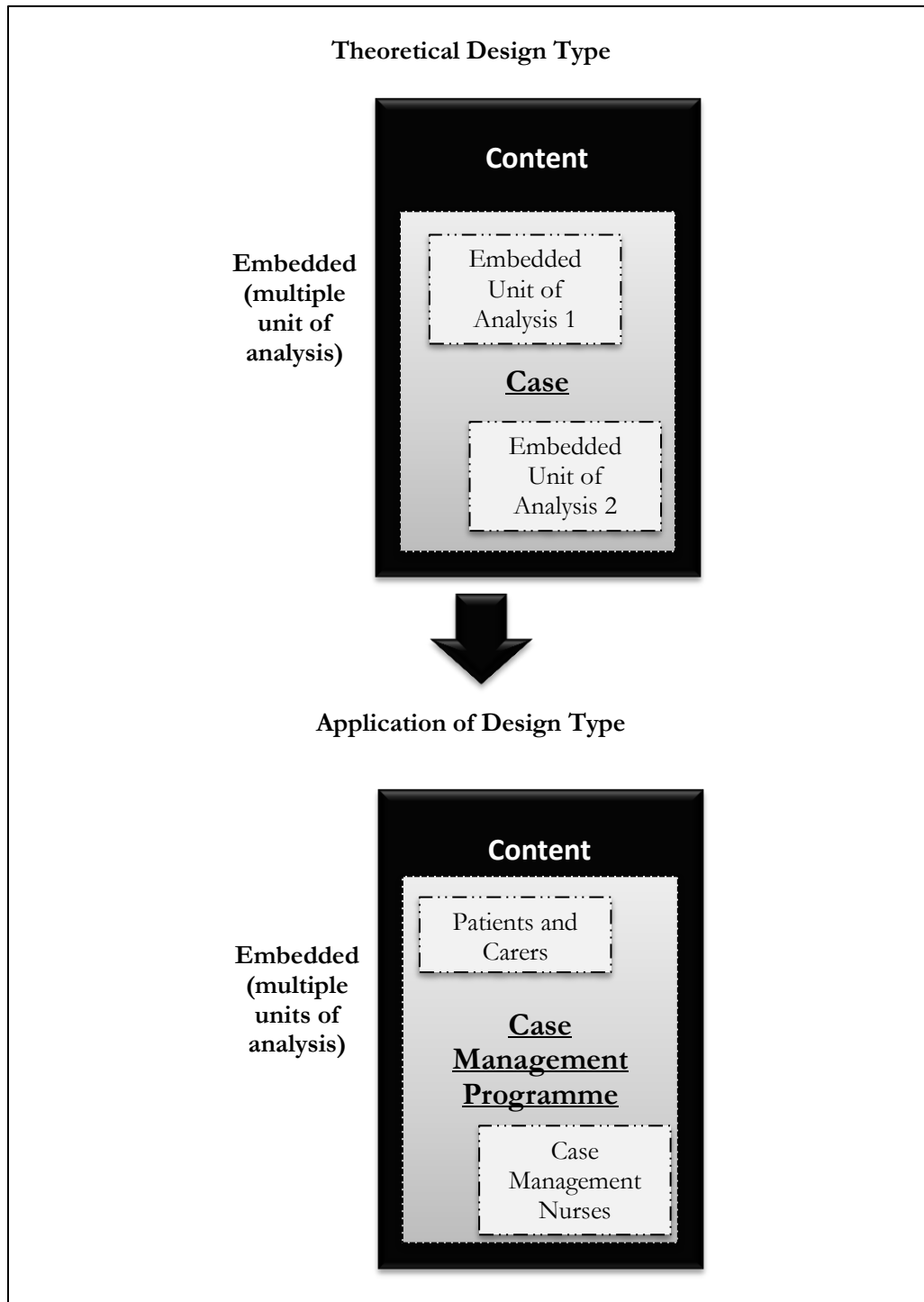
Figure 4.3: Case study design type proposed
(adapted from Yin (43)pg46)

Implementation of the CM programme, as outlined in the Chapter 3, began across England in 2005 and was a relatively new service at the inception of the current research process. The significance of the service was its focus on the growing burden of the ageing population and increasing prevalence and extent of long term conditions (LTCs). The service was therefore considered a long term solution to the evolving health demographic by reducing reliance on acute services at times of crisis through better preventative management. Despite the shifting responsibility for outcomes and safety from healthcare workers to patients, to date, no research exists that explores the perspectives of its key stakeholders. Given this, the case study is revelatory in nature (43), and poses an opportunity to generate knowledge on a previously unexplored phenomenon. By Stake's (225) characteristics, the research is instrumental by using the CM programme as a particular case by which to explore safety.

A non-probabilistic, purposive sampling method was utilised. Purposive sampling directed the recruitment of individual participants, which sought participants with specific characteristics (231). Firstly, NHS provider organisations were recruited to gain access to the service. All participants were selected based upon the following basic selection criteria:

- Be older than 18 years of age
- Be well enough to participate in the activity
- Speak English
- Be *compos mentis*

4.4.1.2: Data collection techniques

Case studies are not subject to a single data collection technique, but rather, are supported in a multiple method approach (43, 227), which supports the critical realist philosophy. Yin (43) presents six common data collections methods: direct observations, interviews, archival records, documents, participant observation and physical artefacts. However, this is not exhaustive and many more methods of qualitative data collection techniques can be used in the case study design. In addition to these, focus groups will also be discussed and their utilisation justified.

Archival record and document review have been conducted on publically available data on adverse events or patient safety incidents. Where relevant, these were accessed to draw conclusions on a fourth stakeholders' perspective: the organisation.

The research aim did not call for participant-observation in which the researcher is an active participant in the activities being conducted. Observation provides relatively little insight when exploring peoples' perceptions through their expression of language. However, informal observations of the participants, their environments and their behaviour were noted during interview and focus group data collection, to draw on during analysis. Making observations of the social world is implicit in the daily activities one does: nurses observe their patients on the ward and police officers observe the gang of youths being disruptive at the local park. In a more social context, commuters observe the behaviour of fellow commuters on the train, or the shopper in a queue observes those ahead of them. It was this natural curiosity to observe that was utilised and documented as part of the research process. It is recognised that the process of observation loses some context but adds new dimensions (232).

According to Yin (43), interviews enable the researcher to focus the discussion on a particular topic and explore in depth, generating insight on perceived causal inferences. The interview schedule is important in articulating questions. Interviews can be inaccurate due to poor recall and reflexivity where the respondent gives the interviewer responses that they want to hear (43). This research did not ask for participants to recall particular events and therefore this was not considered to be problematic. As with all qualitative research, the dynamics between the participants and researcher are influential on the data. The researcher endeavoured to encourage an open and honest dialogue to engage participants in open and honest conversation, in order to elicit knowledge of the socially constructed world. In essence, 'how do participants perceive safety in relation to their home healthcare?'

Physical artefacts such as technical devices, instruments or works of art, can also be a useful source of evidence. During interviews some participants wanted to show physical artefacts such as mediation storage and bathrooms and this was documented in field notes.

Focus groups are another technique for collecting qualitative data. Bowling (231) describes focus groups as *'unstructured interviews with small groups of people who interact with each other and the group leader'* (231)[pg394]. For a focus group, participants are assembled, an interactive discussion guided and personal experiences elicited to answer a research question (233). Focus groups, as a form of group interview offer an opportunity to collect multiple views and large amounts of data in a convenient and more time efficient manner (234). Furthermore, focus groups can enable participants to explore their own views with others, which is less likely in a one-to one interview with a stranger (234). However, Fern (235) demonstrated that focus groups did not produce significantly more or better ideas than individual interviews. Focus groups are commonly used in addition to other data collection techniques including in-depth interviews or surveys (236), both of which are being deployed here. Kitzinger (234) also recommends homogeneity within the group to avoid hierarchical structures forming; although diversity has its place in the focus group method. Limitations in the method include potential intimidation within the group that might inhibit interaction (237), which can be reduced with homogeneity. In this research, the focus groups were homogenous, consisting entirely of the CM nurses who deliver front line care.

The dominant primary data collection techniques utilised were in-depth interviews and focus groups. In addition to these, the researcher made observations of the environment as well as behaviours exhibited by participants during the primary data collection. Furthermore, an informal examination of physical artefacts was warranted during some interviews, where participants brought them to the attention of the researcher.

4.4.1.3: Data Analysis Techniques

4.4.1.3.1: Modes of Inference

Reasoning is a fundamental prerequisite for knowledge development. The ability to analyse, interpret and draw conclusions from data is critical to the research process. Danermark et al. (211) describe four modes

of inference that support and complement the philosophy of critical realism: deduction, induction, abduction and retroduction, each of which is described.

Deduction is a logical mode of inference in which we draw valid conclusions based on correct premises. Its limitation lies in its inability to inform us of anything new about reality, beyond what is already known. Because its conclusions are analytical (conclusion is implicit in the premise), new knowledge cannot be gained about the abstract structure or mechanisms that make the phenomenon possible.

Induction, like deduction is also a form a logical inference. However, inductive conclusions do not always follow the premise, but rather, entail the generation of new knowledge beyond the premise. Inductive knowledge draws conclusion of a larger population, over time, from a smaller sample. Also like deduction, induction is limited to inference of the empirically observed and lacks the capacity to identify underlying structures and mechanisms. Induction is also limited to a level of uncertainty of the generalisability and risks drawing the wrong conclusions despite the correct premise.

In addition to the logical forms of inference (deduction and induction), critical realism supports abduction and retroduction. Abduction enables general patterns from observation to be described. From this, abduction enables inference of how something might be rather than deduction's ability to prove that something must be (238). The essence of abduction is the possibility of gaining a deeper conceptualisation of something through interpretation (211), to reconceptualise by observing, describing, interpreting and placing in a new frame of ideas. Abduction is not an empirical generalisation, which can be achieved through induction, neither is it logically rigorous, which can be said of deduction, but generalisations of the case being examined can be made, but not extrapolated to larger, representative samples (44).

Retroduction seeks to derive the underlying structures of the empirically observed, Danermark et al. (211) present retroduction as the:

'…advancing from one thing (empirical observation of events) and arriving at something different (a conceptualisation of transfactual conditions). Where conditions are the circumstances that are required to exist.' (211)[pg96]

Although abduction and retroduction are not logically valid, they are complimentary to deductive and inductive inference by allowing knowledge of structures and mechanisms to be generated whilst recognising their limitations in line with critical realism. All four types of inference form the basis of knowledge generation in the critical realist paradigm, and thus were utilised in this research.

4.4.1.3.2: Potential Data Analysis Techniques

A variety of data analysis techniques were available to the researcher. The selection is dictated by a number of factors, including, but not limited, to the type of data collected, the purpose of the research and its underlying academic assumptions, and the philosophical position of the researcher. Discourse analysis, thematic analysis, interpretative phenomenological analysis and framework analysis are all suitable for the analysis of qualitative data; their suitability for the data collection methods outlined previously is discussed.

Discourse analysis has multiple approaches and can be used on a wide variety of data including interview transcripts, samples of conversation and published literature (219). Reeves et al. (219) define discourse analysis as the study and analysis of language in order to reveal psychosocial characteristics of the generator. However, this research is more concerned with understanding what people say and their perspective of a phenomenon rather than how or why it is said, and therefore discourse analysis was considered inappropriate for this purpose.

Thematic analysis is most recognisably associated with the grounded theory strategy of research, first articulated by Glasser and Strauss (220) as a methodology. It analyses data by coding textual data in a systematic way to generate themes. Done in two phases, the first phase intensively codes small sections and the second phase applies the codes to larger exerts of text (239). Grounded theory analysis is iterative;

it should be conducted continuously throughout the data collection process, in order to inform further data collection. Adaptations of grounded theory coding have contributed to the development of thematic analysis as a method of analysis in its own right, without the need to have conducted a grounded theory study. However, both insist on the themes being drawn solely from the data, with little or no preconceptions to be made by the researcher. In fact, in the case of grounded theory, it is advised that a literature review not be conducted until after the primary data collection to prevent influence (220), and therefore neither were sufficiently suitable for the research to be conducted here.

Another analytical approach is that of interpretative phenomenological analysis, which aims to explore psychological perspectives of a given topic (240, 241). Osborn (242) acknowledges the absence of a prescriptive method for conducting IPA and that it is more forgiving of the researcher's influence and bias as the research instrument, and is associated with a constructivist philosophy. Consequently it was rejected as a plausible method of analysis for this critical realist study.

Framework analysis, although originally designed for use in applied social policy research in the 1990's (243), has since been applied to a broad spectrum of research (244-246) and has proved versatile. It is an analytical approach to qualitative data, which can be applied to answer research questions that fall into one or more of the following four categories (243):

1. Contextual – identifying the form and nature of what exists
   ➤ What are the perspectives of key stakeholders of safety in home healthcare and how does safety operate in the home?

2. Diagnostic – examining the reasons, or causes for what exists
   ➤ What factors contribute to the condition of safety?

3. Evaluative – appraising the effectiveness of what exists
   ➤ What affects the success or failure of a safe system?

4. Strategic – identifying new theories, policies plans or actions
   ➤ How can safety be measured better to encourage improvements?

As indicated previously, the research proposed can be considered from the perspective of any one of the four categories, therefore, demonstrating the applicability of the framework analysis technique to the research aim posed in this thesis. In addition to its relevance to the aim of this research, its suitability over other analysis techniques for use in this research lies within its acceptance of *a priori* influences over the thematic framework. Therefore, it is considerate of any model, or measurement domains identified from the literature prior to data collection. This makes it the most appropriate method of analysis for the qualitative data being collected in this research.

Qualitative data is unstructured and unwieldy, and is usually presented in large volumes as textual script. The qualitative researcher is required to categorise, explore and map participant's accounts, experiences and descriptions. Framework analysis provides a systematic and repeatable process for achieving this. In addition to the process, software such as NVivo (247) is available to enable the qualitative researcher to manage data more efficiently and will be used to facilitate the framework analysis of the qualitative data generated. Specifically, the researcher can index textual data into the thematic framework and use functions of the software to chart through framework matrices. Details of the process of conducting framework analysis are provided in the study protocol in Chapter 5.

4.4.2: Study II – survey

Surveys include multiple data collection techniques but are characterised by the systematic and structured collection of data of the same variables across at least 2 different cases (248). Standardisation is fundamental and it is required that consistent answers are generated from consistent questions (249).

Fink (250) identifies four forms of data collection technique for the survey design: self-administered questionnaires, interviews, structured record reviews and structured observation. Survey design specifically generates quantitative data in all forms of data collection (213). Using surveys, the qualitative findings can be extrapolated to be applicable to larger populations (44).

The benefits of using a self-administered questionnaire to gain opinions on the qualitative findings include: enabling engagement with larger populations, it is less resource intensive and it removes the researcher from the data collection process. The purpose of the survey is threefold:

1. To determine the level of agreement with findings of the qualitative study

2. To examine the differences between key stakeholder responses

3. To contribute to the conceptual framework for safety measurement in home-delivered healthcare

Quantitative data can be subjected to statistical analysis where *'statistics is a branch of applied mathematics that deals with collecting, organising and interpreting data using well defined procedure'* (251) [pg4]. Statistics enable researchers to describe and summarise information, make predictions or generalisations and identify associations or relationships (251).

The purpose of this study was to determine the representativeness of the findings from the study I. This was achieved by investigating the perspectives of a larger sample of key stakeholders through the use of a self-administered postal questionnaire. The items examined the level of agreement with key findings and enabled the opportunity to cross examine different stakeholder group's responses.

4.5: Validity

The concept of validity differs between quantitative and qualitative approaches but it essentially serves the purpose to ensure the quality of the data collected and the interpretation of the results (42).

4.5.1: Validity of the qualitative approach

Qualitative research serves a distinctively difference purpose to quantitative; primarily to explore the experiences of individuals, with little intent to generalise. Therefore, the way in which validity is determined must meet this different purpose. Guba and Lincoln (207) suggested a framework of four

criteria for assessing the quality of qualitative research: credibility, transferability, dependability and confirmability. These address trustworthiness and authenticity rather than validity and reliability.

Trochim and Donnelly (252) describe credibility of qualitative research as the believability of the results from the participants' perspectives. Participants are seen as the best judge to determine the credibility of the results obtained from them. In the current research, the credibility of the findings was determined by asking the participants of study I to pilot the survey in study II, which was subsequently conducted in a fourth NHS provider organisation.

Transferability, according to Guba and Lincoln (207), is the ability of the findings to be applied to other contexts and relates to external validity. Transferability is inherently difficult to establish in qualitative research. However, the quantitative study enabled some generalisations to be made and therefore supported the transferability of the qualitative study.

Dependability is concerned with achieving the same results twice (252). This is also difficult to establish given the nature of qualitative research, which is built on the premise that everyone is subject to their own realities, influenced by their own experiences. Therefore, on any particular day, participants might respond differently, the interaction between the participant and researcher could change or the researcher might interpret differently. Similar to dependability, confirmability refers to the corroboration of findings between researchers rather than over time, which is limited by the same limitations as dependability.

Despite difficulties associated with establishing trustworthiness and authenticity through credibility, transferability, dependability and confirmability, the conduct of an exploratory sequential mixed method design, enhances the quality of the qualitative findings.

Immy (232) describes four considerations for describing the validity of qualitative research. By being reflexive and transparent, by leaving an audit trail and ensuring naturalism of the participants, there is a mechanism for ensuring the quality of the research:

1. Reflexivity – continuously reflect on the researchers influence on the data

2. Transparency – it is important to be transparent to demonstrate reflexivity through leaving an audit trail

3. Audit trail – leave a record on the research design as the study progresses

4. Naturalism – to use a design that reflects the beliefs of the participants and to leave them as undisturbed as possible

Field notes were taken during and after the data collection, which included thoughts and experiences of a reflexive nature of the researcher. Finally, all data was collected at locations that had been selected by the participants themselves.

4.5.2: Validity of the quantitative approach

The concept of validity for the quantitative approach can be divided into seven categories: face, construct, content, criterion-related, predictive, internal and external. The definition of these can be found in Table 4.3: Types of quantitative validity. In addition to validity in the quantitative approach, one must consider the reliability of the instrument: the consistency and stability of the instrument over time.

Table 4.3: Types of quantitative validity

Type of Validity	Description of validity
Face Validity	The assessment of the logical link between the questions of the survey and the objectives of the study (253), which is achieved through subjective assessment by the investigators (231).
Construct Validity	To ascertain the contribution of each construct to the total variance of the observed phenomenon (253), and whether the item measures what it is intended to measure (42).
Content Validity	The assessment of the representativeness to ensure full coverage of the range of issues (42).
Criterion related validity	Whether the results relate to an external standard (42), comparison to a gold standard (231).
Predictive Validity	The degree to which an instrument can foresee an outcome (253).
Internal validity	If there is a relationship, is it causal (42), and the extent to which the investigator can conclude there is a cause and effect relationship (254)
External Validity	The application to a larger population (231) in order to generalise (254)

4.5.3: Triangulation

Triangulation, as argued by Denzin (255), has the potential to reduce investigator bias and raise the researcher '*above the personalistic biases that stem from single methodologies. By combining methods and investigators in the same study, observers can partially overcome the deficiencies that flow from one investigator or method*' (255)[pg300]. This can be achieved in four ways (256):

1. Data triangulation – the use of different sources in an effort to see if what we are observing and reporting carries the same meaning when found under different circumstances (this includes different times, places , people and groups of people)
2. Investigator triangulation – use of multiple investigators to analyse and interpret data
3. Theory triangulation -using multiple theoretical viewpoints to analyse data, normally from multiple investigators
4. Methodological triangulation – use of multiple methods to collect data

In addition to this, Yin (43) expands on data triangulation as having two conditions: convergence of evidence and non-convergence of evidence. Convergence of evidence occurs when the facts of a single study are corroborated by multiple sources. Non-convergence occurs when multiple sources have been used but not to confirm facts, but typically to compare.

4.6: Summary

This research is predicated on a critical realist's view of reality and thus the design presented in this chapter is aligned to the critical realist philosophy; there is a reality independent of the mind, which is influenced by underlying, unobservable mechanisms. Consequently, a sequential, exploratory mixed method has been deployed to meet the critical realist philosophy and the demands of the research question that require exploration of perspectives and generalisability of findings. As part of a qualitative study (study I), a case study of the CM programme will be conducted primarily using interviews with patients and carers and focus groups with staff (CM nurses). Other methods might be utilised informally such as observation and physical artefact examination. These findings will be tested in a quantitative study (study II), using a survey to determine the level of agreement with the findings from a larger population. From this, a framework for safety measurement can be proposed that is reflective of key stakeholders of the CM programme.

The research design has enabled both data triangulation and methodological triangulation. Data triangulation will be conducted in a non-convergent matter: multiple stakeholder views will be collected to

compare rather than corroborate. The mixed method design has utilised both qualitative and quantitative data collection strategies (case study and survey) and multiple data collection techniques (primarily interview, focus group and questionnaires).

Chapter 5

Study protocols

5.1: Introduction

In Chapter 4, the research design was constructed following an examination of those available in the literature. A sequential, exploratory mixed method was proposed, incorporating a case study and a survey. The case study was deployed in study I, with the aim of understanding safety from the perspectives of three key stakeholders; namely patients, carers and case management (CM) nurses. The survey was deployed in study II to determine if some of the key findings were applicable to a larger population and to uncover any differences between the stakeholder groups. This chapter presents the two study protocols as they were conducted in the current research.

5.2: Study I protocol

Study I aimed to achieve three things:

1. An understanding of the perspectives of safety in the case management (CM) programme

2. Validation of the integrated safety measurement model (ISMM) developed in Chapter 3

3. To devise dimensions of measurement for each domain of the model, that are derived from understanding contributing factors as perceived by the three key stakeholder groups identified.

This study was awarded a favourable ethical opinion by South Birmingham Research Ethics Committee (see Appendix 1). Subsequently, all other approvals were granted from each participating organisation, however, in order to maintain confidentiality, these are not included.

5.2.1: Setting and participants

In order to engage with a larger population, three NHS organisations were recruited. They were conveniently selected; they were the first three approached who agreed to participate. Upon completion of all the necessary procedures and on approvals being granted, recruitment began. Study I engaged with three stakeholder groups. CM nurses and patients were included in this study following their identification as key stakeholders from the literature. Prior to the commencement of the research, the ISMM was presented to a group of CM nurses registered on a post-graduate qualification in long term conditions, who proposed the inclusion of carers in the study because they perceived them to be vital in the care of this patient group. Subsequently, carers were incorporated into the design of the research.

5.2.1.1: Case management nurse recruitment and participation

Presentations were delivered at a monthly team meeting of each organisation. This allowed the researcher to fully inform and interact with potential participants and answer any questions arising from the presentation. Attendees were provided with a staff participant information sheet (PIS) (Appendix 2) and Consent Form (Appendix 3). Contact details of those interested were obtained. A decision to participate was not required at the time of the presentation; attendees were given two weeks to go away, read the written material and make an informed decision. After two weeks, those who had shown an interest by leaving their details were contacted, and written consent gained by means of a signed consent form. Those who were unable to attend the presentation were sent the written material via the local collaborator. Those who had not left their details were encouraged to contact the researcher directly, should they choose to participate.

In total, 17 staff members agreed to participate in the study. All were female and all held a community matron or case manager post. For anonymity, the names of the participating NHS organisations are not provided, however the staff participant numbers can be seen in Table 5.1: Staff participant numbers.

Table 5.1: Staff participant numbers

NHS organisation	Participant Numbers
Trust 1 (T1)	4
Trust 2 (T2)	8
Trust 3 (T3)	5
Total	17

5.2.1.2: Patient and carer recruitment and participation

During the recruitment presentations delivered at the team meetings, where CM nurses were recruited, all CM nurse members of the team were asked to identify and recruit patients and carers through the delivery of a recruitment pack upon their next natural visit. The following selection criteria were used to purposively identify potential patient and carer participants:

- Must be aged 18 or over
- Must be a patient or carer of a patient being case managed
- Must be able to speak English
- Must be able to participate in an interview for approximately an hour

Patients and carers who were identified as suitable by the CM nurses were given a recruitment pack, which included a patient participant information sheet (PIS) (Appendix 4), and a carer PIS (Appendix 5), and an eligibility questionnaire (Appendix 6). The PIS advised patients and carers of the study, their potential involvement and asked them to complete and return the eligibility questionnaire. Patients, who returned the questionnaire and expressed an interest in participating, were contacted via telephone. An appointment was made to conduct the interview at a location, date and time convenient for them. All participants requested the interview take place in their home and the researcher accommodated all

requests. Patients and carers signed a consent form (Appendix 7) prior to the commencement of the interview.

Although it was originally intended that patient and carer interviews would be conducted separately, two groups of respondents (two patients and two carers), instigated by the patient, requested that the interviews be conducted as one. This was because they did not feel comfortable or confident to participate in isolation from their carer. Given that this supported the notion of the importance and reliance on carers, the researcher felt it was important to explore their joint views rather than to omit their views. The analysis attempted to disentangle their views where they reflected only one of the participant groups. It is acknowledged that in qualitative interviewing, the process is co-creative and thus influence is naturally exerted onto participants when describing their experiences (257). Parahoo (258) explains that an interview with couples generates the potential for three different perspectives: the researcher/participant one, the researcher/participant two and the researcher/participant one and two. Therefore, by conducting them jointly, the third perspective has been gained. The presence of the partner can inhibit or facilitate the narrative (259), therefore, the researcher actively observed the nature of their behaviour, language, and interactions and considered it in the interpretation of the data.

The qualitative nature of the single case study limits the use of statistical inference and thus the sample size denotes less importance than in a quantitative study. Rather, in qualitative research, the term 'saturation' is frequently used to determine the sample size as the process persists. Saturation is the point at which no new information is being extracted from participants and therefore, continuing to collect data holds no value as nothing new is being learned. Guest et al. (260) examined the operationalisation of the saturation concept and found it to be inadequate in the literature. Guest et al. (260) set out to identify a figure, which could be quoted to support proposals and protocol development prior to data collection. In doing so, they found that data saturation occurred within the first 12 interviews with basic metathemes being present from 6. Therefore 15 patients and carers (in total) were recruited.

Patient and carer configuration is detailed in Table 5.2: Patient and carer participant numbers. In total, patient participation was 9 (Pn=9) and carer participation was 6 (Cn=6).

Table 5.2: Patient and carer participant numbers

NHS organisation	Patient Interviews	Carer Interviews	Joint Interviews
T1	1	1	0
T2	3	2	2
T3	3	1	0

Patients and carers are coded in the thesis as follows:

- CP*** and CC*** are patients and carers, respectively of Trust 1 (T1)
- DP*** and DC*** are patients and carer, respectively, of Trust 2 (T2)
- NC*** and NP*** are patients and carers, respectively, of Trust 3 (T3)

5.2.2: Data collection

5.2.2.1: Case management nurse data collection

Qualitative focus groups were held with CM nurses at convenient locations within the host organisation, arranged by the local collaborator. Dates and times were agreed between participants to ensure all of those who were interested in participating were able to do so. The focus groups lasted 1h 35m (T1), 1h 25m (T2), and 2h 02m (T3), which is approximately within the parameters defined by Robinson (261) of between 1-2 hours. They were held in private rooms, which limited interruptions, and were within close proximity to amenities such as toilets and refreshments. Participants were able to leave for breaks at any time and help themselves to refreshments throughout. Robinson (261) defines focus groups as being typically 5-8 participants; however, one group was restricted to four members due to the comparatively small size of the team being invited to participate.

The focus group schedule was designed with the assumption that the focus group would take 1 hour and 30 minutes. Therefore time was allocated to an introduction (15 minutes), model review (15 minutes) and idea generation (65 minutes). The introduction was an opportunity for the researcher and participants to introduce themselves to one another. The model review enabled participants to look at and critically appraise the ISMM, which was presented to them. Following this, participants were encouraged to express their perspectives of safety in relation to: what safety in the home means; the conditions and actions, which support or fail it; and the outcomes of safety. Because the research was interested in understanding the perspectives of safety, no pre-determined questions were devised to bias the conversation; however, a flexible plan (as per timing details above) was implemented to manage time. The researcher actively interacted in the discussion in order to fully explore ideas, concepts and perspectives identified in the focus groups. This was done carefully to avoid introducing new ideas that were not identified by participants.

Field notes were taken during the interviews and further documentation was taken immediately after leaving the organisation. Focus groups were digitally recorded and videoed with consent obtained from all participants. Data was transcribed by an external company (TypeOut (262)), which is used by the University of Warwick for transcription services and stored in accordance with the Data Protection Act 1998 (263). Participation was confidential and the data was anonymised so only the researcher would know who had participated or have access to the single file that could identify participants.

5.2.2.2: Patient and carer data collection

Qualitative, in-depth interviews were conducted with nine patients and six carers. Single interviews, which were expected to last up to an hour but across the cohort, varied from between 31m to 1h 13m. The two joint interviews lasted 01:24 and 01:37. The focus group interview schedule was deployed in order to be able to cross compare the findings across all participant groups. Details of the focus group schedule can be found in 5.2.2.1: Case management nurse data collection. Field notes were taken during the interviews and further documentation was taken immediately after leaving the property. All data was collected at the

patients' and carers' homes, as requested by them, at dates and times suitable to them. Interviews were digitally recorded with consent from all participants, transcribed verbatim using an external source (TypeOut (262)) and stored in accordance with the Data Protection Act 1998 (263). Participation was confidential and the data was anonymised so that only the researcher would know who had participated and have access to the single file that could identify participants.

5.2.3: Data analysis

Framework analysis (243) was conducted on all transcribed data collected, enabled by NVivo (247). Framework analysis was conducted using the five step process: familiarisation, identification of a thematic framework, indexing, charting and mapping (243). The formal, documented process for conducting framework analysis can be found in Table 5.3: Process of framework analysis. Translation of this into practice has been described here.

Prior to commencement of analysis, the *a priori* framework was developed, which included five overarching key domains derived from both the literature and the experience of the data collection:

1. Definition of safety
2. Multiple key stakeholders
3. Structures
4. Processes
5. Outcomes

The framework was applied to the patient and carer data, which were treated as a single unit of analysis because of the combining of two of the participant couples' interviews. However, where differences did occur, they were documented. The same framework was applied to the CM nurse data, which were treated as a different unit of analysis. Where relevant, new themes were populated and attributed to CM nurses. In addition, differences in previously identified themes were documented.

Following the transcription of the audio recordings, all were checked by the researcher to ensure no meaning or data had been lost. Audio files were listened to with the transcripts, for the researcher to reacquaint themselves with the discourse context of the transcriptions and additional notes were made, concluding the familiarisation phase.

From the listening process, further themes were identified within the five overarching domains. These themes were coded in NVivo (247) as nodes (thematic). The transcripts were uploaded to NVivo (247), re-examined and all of the text allocated to the previously identified themes in the process of indexing. In some cases, no theme appeared appropriate to allocate the text to and thus a new theme was generated.

Following indexing, the sections of texts within the themes were charted into a table. An example of a chart can be found in Appendix 8. The left hand column of the chart detailed the themes and/or sub-themes found, and the top row identified the participant or focus group. This enabled the researcher to determine the level of presence each theme had across the participants. Where data is presented as a theme in Chapter 6, it infers a level of agreement across a large proportion of participants. The charting process identified some themes and subthemes that lacked a consistent presence across participants. Where this was the case, data was: amalgamated with another theme where appropriate; used as isolated examples; or disregarded.

Relationships that were identified during the course of the analysis were mapped. Finally, the data were interpreted in relation to the current understanding available in the literature: this has been conducted in Chapter 8.

Table 5.3: Process of framework analysis
(adapted from (243))

Step	Description
Familiarisation	The process of becoming familiar with the data by listening to audiotapes, and reading transcripts and field notes. This is best achieved with all data; however, if the data set is large, a sample can be selected. For this study, familiarisation was feasible with all data collected.
Identification of a thematic framework	Themes are identified following the familiarisation step, which will have multiple sources. These sources include issues and theory informed by the original research aims and objectives that were present in the interview guides, emergent issues raised by participants and analytical themes derived from the recurrence of participant views and experiences.
Indexing	The systematic application of the thematic framework to all of the data set in its textual form. In a single passage, multiple themes can be present and need to be referenced.
Charting	Data can now be removed from their original context and rearranged according to their theme. Each chart might be of a theme, and each column represents a subtheme. Each row contains quoted data of individual participants.
Mapping and Interpretation	Key characteristics can be drawn from the data and an interpretation can be made. It is here that the researcher can define concepts, map the nature of phenomena, create typologies, find associations, provide explanations and develop strategies

5.3: Study II protocol

The purpose of this study was twofold: to quantify the level of agreement of an additional sample of a case managed population with the qualitative findings of study I; and, to examine the perspectives of each of the key stakeholder groups and identify any statistically significant differences. A substantial amendment was made to the original ethics application and granted approval by South Birmingham Research Ethics Service (see Appendix 9).

5.3.1: Data collection

A fourth NHS organisation granted approval for the study to be conducted within its clinical case management service. Following advice from the ethics committee, the survey was piloted with the original patient and carer participants, over fears that the language was incomprehensible. A glossary was inserted to ensure all participants had the same understanding of some of the terms. All of the patient and carer participants were asked to participate, however due to ill-health or death, only two patients and two carers were retained. Conducting the study in a fourth organisation i.e. a different organisation to those that participated in study I, was perceived to improve transferability and credibility of the findings, therefore allowing the findings to be generalised.

5.3.1.1: Patient and carer data collection

A list of all of the patients on the case load was obtained following ethical approval. As this list contained the names and addresses of patients, it was not handled by the researcher, but rather an appointed person within the organisation's research and development department. There were 807 patients on the list. A random number sequence was generated from an online random number generator (264). The sequence was assigned to the patient list in a Microsoft, Excel spread sheet (265). The patient names were then re-ordered in ascending order. An invite to participants included: the participant invitation sheet (Appendix 10); and two surveys (Appendix 11), which was posted with a reply envelope to the first 200 patients

(numbers 1 - 200). This was repeated in batches of 200 until all patients on the list had been invited to participate. The surveys were posted in batches of 200 for two reasons. Firstly, if the response rate was deemed sufficient, given that the invites were posted in a random order, there would have been no need to invite more, reducing the burden on patients to participate and maintaining an ethical position. Secondly, production and management of the survey invites was time consuming and intensive; breaking them into batches improved the manageability of the task. Each batch of two hundred took approximately 5 days to despatch and this was achieved over several weeks.

The invites were personalised to each patient and requested the participation of their carer, if they had one. Although the study had selection criteria (see Table 5.4: Selection criteria for study II), the researcher was unable to know which of the patients on the case load met them. Therefore, patients self-selected. Informed consent was assumed with each completed questionnaire, as was the fact that the participant had sufficient competency of the English language to comprehend the questions.

Table 5.4: Selection criteria for study II

Selection Criteria

A patient on a case management programme, a carer of a patient on a case management programme or a CM nurse

Over the aged of 18 years old

Competent to read and understand English

Capable of providing informed consent

5.3.1.2: Case management nurses data collection

CM nurses were invited to participate via email, sent by the clinical case manager lead. The body of the email contained the invite and requested the attached participant information sheet (Appendix 10) and survey (Appendix 11) be printed and return by post to the researcher. This invite was repeated twice.

Following a poor return rate, the clinical case manager lead handed out the participant information sheets and surveys at the team meeting and offered CM nurses the opportunity to complete them during the team meeting.

5.3.2: Data Analysis

For quantitative data, analysis can be broadly categorised into either descriptive statistical analysis or inferential statistical analysis. Descriptive statistics were undertaken in Microsoft, Excel (265). Inferential statistics were undertaken in SPSS (266).

Descriptive statistics were applied to all of the questions in the form of frequency and/or percentages and are presented using graphs such as bar charts where applicable. Given the small sample size, it was deemed inappropriate to attempt to use inferential statistics to establish any association between groups.

5.4: Summary

Two studies were conducted using the protocols detailed above. The findings are presented in Chapter 6 for study I and Chapter 7 for study II. They are jointly discussed in Chapter 8.

Chapter 6

Study I

A qualitative exploration of key stakeholder perspectives of safety in healthcare delivered in the home

6.1: Introduction

The integrated safety measurement model (ISSM), proposed in Chapter 3, captures the key stakeholders of the case management (CM) programme, as evident in the published literature. Additionally, it proposes three dimensions from which to approach the measurement of safety to ensure a comprehensive assessment is achieved. Presentation of the ISMM to a group of case management (CM) nurses resulted in the incorporation of carers into the methodology. Chapter 4 identified the critical realist position of the researcher, described and explained the adoption of a mixed methods approach and discussed the appropriate data collection and analysis techniques available. The study protocol has been provided in Chapter 5.

This chapter explores the perspectives of three of the key stakeholders (patients, carers and CM nurses) and the conditions that they believe, support or fail the generation of safety through the exploration of structures, processes and outcomes. The purpose of this chapter is to present the findings of study I, which aimed to understand the perceived contributing factors to safety in home healthcare, and in the process, qualitatively validate the ISMM. Little discussion of the findings is offered here, except where to justify further investigation. Discussion of the work is available in Chapter 8.

6.2: Findings

The interviews and focus groups conducted were constructed and performed to explore five key themes. These five key themes formed the *a prior* framework, which was built on and added to during the familiarisation and thematic framework development stages. The thematic framework can be found in Appendix 12. These themes are presented here. Table 6.1: Participants of study I, details the coding of the participants and aligns them with the units of analysis (please refer to Table 4.3).

Table 6.1: Participants of study I

Unit of Analysis	Identification Code		
Patients and Carer	Patients	Carers	
	CP001	CC001	
	DP002	DC002	
	DP003	DC003	
	DP004	DC004	joint interview
	DP006	DC001	joint interview
	DP005	NC001	
	NP001		
	NP005		
	NP006		
Case management nurses	T1 (n=4)		
	T2 (n=8)		
	T3 (n=5)		

6.2.1: Definition of safety

CM nurses participating in focus groups, and patients and carers participating in interviews, were asked to explore the definition of safety. Initially, some patients and carers struggled to articulate what being safe in the home meant: *"I'm stumped…I will have to come back to that one"* [(DC003)], but most were able to at least describe safety, if not define safety i.e. give an account of the characteristics rather than explicitly give a meaning. The themes identified within each group are presented here (and visualised in Figure 6.1: Thematic framework for the *a priori* theme of 'definition of safety.), comparisons are drawn between CM nurses, and patients and carers, and definitions described.
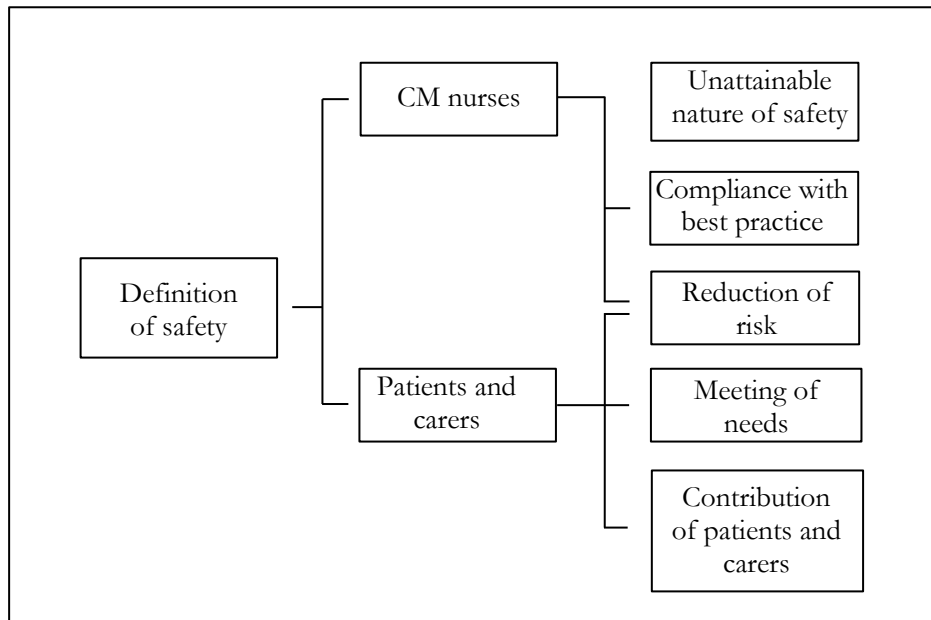
Figure 6.1: Thematic framework for the *a priori* theme of 'definition of safety

Safety was commonly described by the CM nurses as the action or process of risk reduction for the purpose of preventing harm. This was expressed by participants across all three focus groups, examples can be found in Table 6.1: Examples of risk reduction. In addition, one particular CM nurse expressed the interchangeable nature of the terms safety and risk: *"I think instead of safety you could almost substitute risk actually, I think they're, I think they're actually interchangeable in this coz we tend to think of risks"* [T1]. This was then accepted by the other three participants of that particular focus group. Similarly, patients and carers in this study also expressed risk reduction as a component of safety (also see Table 6.2). However, as is evident in Table 6.2, patients and carers don't use words like 'avoiding harm', unlike the CM nurses, instead choosing to describe activities that they believe contribute to safety, which involve reducing the risk of harm. In addition, patients and carers described preparedness as a component of risk reduction; to be ready to implement risk reduction at a later date as their disease deteriorates. For example, CP001 talks about how she has purchased a sofa bed for the lounge, ready for the day that she can no longer get up the stairs as a result of her chronic obstructive pulmonary disease (COPD): *"originally I was going to make the bedroom down here, because this goes into a bed, we brought it especially…but I didn't want to go down that avenue until it was really desperate"* [CP001].

As indicated in Table 6.1, CM nurses strive to prevent patients coming to harm. In addition to this, they suggest that safe healthcare is unachievable. One CM nurse said: *"I'm not sure that there's any such thing as safe healthcare"* [T3]. Another said *"I think with things like safety you can reduce risk, but you can't always guarantee"* [T2]. Some CM nurses did place some onus on the patients and their family for being unable to ensure safety: *"I mean one mustn't just say that I won't come to harm because patients can be living with family who are actually abusing them"* [T1], but this was not consistently expressed across the three groups.

Another component of safety expressed by the CM nurses was the concept of compliance to best practice and evidence based care. Evidence of this can be seen in Table 6.2: An example of compliance with best practice.

Table 6.2: Examples of risk reduction

CM nurse quotes	***Patient and carer quotes***
"So whatever we're doing we're trying to steer them or support them or guide them, um, in ways that they don't come to any harm because that's not what we want them to, to come to." [T1]	*"He just generally keeps an eye on me; if I have to come down in the night to go to the bathroom he comes with me, I have to wake him up and he comes with me…because I'm frighten to come down on my own, in case I'm taken ill"* (CP001)
I think it stood out to me that there was no sort of mention of risk management within that definition of safety. [T3]	*"I try and be responsible, you know, not put myself into anything, to a dangerous position when I'm on my own."* (DP002)
"We assess them for risk of things like pressure sores which is detrimental to safety." [T2]	*"Well, to me her would never get in the bath, right, and I thought well the best thing to do is get rid of the bath and have the shower where it is and hers got more room to hang onto thing"* (DC002)
"I suppose that it means that you are delivering healthcare that's going to keep the patient safe and it's not going to cause them any harm." [T2]	*"Making sure there's no obstacles that you can fall over… That's why I had fitted carpets in the hall and passage, because I'd got loose carpets."* (NP001)

Table 6.3: An example of compliance with best practice

Transcript of conversation in T3

"I mean we've got, we've got to put in there somewhere haven't we evidence based care."

"So we're not just going round willy nilly on a whim."

"Making things up."

"Yeah make things up as we go, we stick to what we know is tried and tested through research."

"Yeah so, so we're, we're approaching it from the point of view that we're delivering the highest standard of care as we can."

Three themes were identified by the CM nurses in relation to the definition of safety, these were: risk reduction; compliance to best practice; and the unattainable nature of safety in healthcare. In addition to this, T1 did distinguish between different outcomes of patient safety. They differentiated between psychological safety: *"But to me emotional and psychological safety for the patient as well too"* [T1] and social safety: "*I want to make a point about social safety as well bearing in mind physical and emotional safety and nowadays families are fragmented and you may have somebody living in a block of flats, families may be miles away and they [patients] have lots of services going in but nothing really substitutes for that close family support*" [T1]. Furthermore, participants of T1 believed that patients would place greatest emphasis on, and be most concerned about their physical safety. This differentiation wasn't made by the other focus groups, however, T3 did raise the question of staff safety, but didn't expand on this; they just presented it as a component of safety.

Patients and carers shared the belief with CM nurses that risk reduction was a component of safety, but this was as far as their common agreement went. Patients and carers didn't use words such as harm or adverse event; instead they discussed specific events that were relevant to them, commonly falls. Patients and carers also believed that meeting patient needs by being 'looked after' was a component of what it meant to be safe. When asked what safe home healthcare was, one patient responded: *"it's to know that somebody is there to look after me in case I'm ill"* [CP001], another: *"What it means is somebody looking after you, just to help out"* [NP006]. The meeting of needs was expressed by some of the CM nurses too, but not to the extent and consistency across participants as the patients and carers did.

131

Another theme identified from the patient and carer data was that of the contribution made by carers. The 24 hour nature of the carer role inherently places some responsibility on them, as well as the obligation of spouses to perform this role regardless.

"Well I am aren't I, 24 hours a day, yes… Because I mean okay when DP004 goes to hospital the nurses attend to her there, but when she's back I'm her nurse really for 24 hours a day." (DC004)

Wherever I can, I try to keep an eye on it as well you know… Well I would as her husband anyway, wouldn't I? (CC001)

The CM nurse perspective of safety shared in common with patients and carers the concept of risk reduction. However, CM nurses gave focus to compliance with best practice and acknowledged an inability to guarantee safety. Conversely, patients and carers discussed safety in the context of meeting needs and acknowledged the role of the carer, and to some extent themselves, by participating in risk reduction activities.

6.2.2: The existence of multiple stakeholders

The existence of multiple stakeholders was identified from the literature and presented in the ISMM, and thus, formed *a prior* theme in the framework analysis approach. Stakeholders were considered to be those who had a role or a contribution to make in ensuring the safety of patients who are being cared for in their homes. From the data, three key themes arose: the role of patients; the irreplaceable role of carers; and the role of many other provider organisations and their staff (see Figure 6.2: The existence of multiple stakeholders).
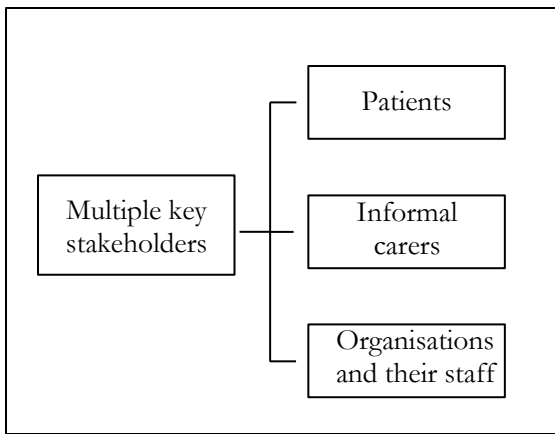
Figure 6.2: The existence of multiple stakeholders

6.2.2.1: Patients as stakeholders

Some patients, and carers of patients, who identified patients as stakeholders of safety, acknowledged the patient role as one of compliance. For example, DP003 expressed their role to be 'to do as told':

> *"I think I have a responsibility to do as I'm asked and to make sure as I umm, stick to the, the drugs that*
> *I'm provided with and not abuse them, because I, I'd hate to do so, you know, the drugs, when I'm trying to*
> *help you. So that's a responsibility of mine."* (DP003)

NP005 places ultimate responsibility on the patient and in contrast to DP003, affords patients the opportunity to choose whether or not to comply:

> *"Yes, yes, the patient is bigger than the other three, if you like, because ultimately any decision taken by the*
> *other three bodies or people must come finally from yourself. They cannot make the decision for you."* (NP005)

Although not many patients and carers explicitly acknowledged the role of patients in patient safety, all patients and carers described activities, which they undertook to reduce the risk of harm. Examples of this have been provided in Table 6.1, where patients and carers were defining safety as the activity of risk reduction.

CM nurses in T2 talked about the role of the patient in relation to their capabilities: *"I think some patients are more able to than others"* [T2]. Whereas T3 discussed how focus and attention was given to other parts of the system, such as the structures and processes, but not the patients: *"I think my point is all the reporting we do is around the structure and the process and around the staff and the provider but not necessarily" (T3)*.

It appears that there was some agreement as to the involvement and contribution of patients, however, the exact nature of this role remains unclear. Where some patients believed that ultimate responsibility for decision making lay with them, others felt their role was to be compliant with orders. CM nurses acknowledge that the capability of the patient determines the level of responsibility they should be afforded, but conversely, also place some of the final responsibility on patients as ultimate decision makers.

6.2.2.2: Informal carers as stakeholders

It was acknowledged that patients had a role, although the nature of this role was not consistently defined. Where there was consistency, was in the role and responsibility of informal carers performed by friends and family.

The CM nurses acknowledged that it was important not to forget the carers' involvement in looking after the patients, as they provided more care than people realise. The importance of carers was epitomised by this quote: *"they're kind of linchpins when they are involved"* [T1]. This particular team felt that the contribution carers made was vital, predominantly because they felt that they linked the patient with healthcare professionals, providing information and being the voice of the patient; acting as an advocate. They also believed that as resources decrease, greater onus would be placed onto them. Supporting quotes from the T1 focus group for carers as stakeholders can be found in Table 6.3: Examples of the importance of carers from T1.

Table 6.4:Examples of the importance of carers from T1

CM nurse quotes from T1

"They're linking the patient, they're linking with staff because they're providing lots of information as well, so they're sort of being the voices for the patient as well." (T1)

"There's less and less formal services around, there's less money to go around that it will be more of an onus on sort of family and informal carers." (T1)

In relation to the ISMM, T2 were confused as to where carers might be placed because they were not included on the original model. They discussed them as a provider, but didn't believe this quite met the definition of provider in the 'strictest sense', and concluded that they needed to be clearly identified as a separate stakeholder.

Patients, who had carers, and the carers themselves, also expressed the importance of the carer role. From just keeping an eye on patients: *"he just generally keeps an eye on me"* (CP001), to being the informant to the healthcare professionals: *"she [wife carer] has a lot of input into, well I'll tell you, they'll grass me up if I don't do something, if I'm trying to be clever or they'll warn me to you know, be sensible"* (DP003). This concurs with the CM nurses perspective, where they believed that the carers were a source of information on the patient. Carers expressed a sense of duty of care for their loved ones: *"Whenever I can, I try and keep an eye on it as well you know, well I would as her husband anyway, wouldn't I?"* (CC001). One carer acknowledged the care that the CM nurses provided, but attributed final responsibility and demand to himself: *"They do have their work cut out you know, but by and all it's myself that looks after her. I want to do anyway"* (NC001). Evidence has been provided to demonstrate the role of informal carers in the care of this particular patient population.

6.2.2.3: Multiple provider organisations and their staff as stakeholders

This project selected the CM programme as the target population. Despite the large input made by this service to patients, many other services and providers are also heavily involved. The types of organisations involved varied according to the needs of the patients. For instance, one patient (DP006) received help

from a charity for the blind because his diabetes had severely affected his sight. This same patient frequently used the services of an optician. Other more commonly used services and organisations included: the council and social services; hospitals and specialist consultants; other community allied health professionals, the GP and third sector organisations. Given the variation and complexity of the health of this patient population, the types of services utilised were broad, especially when concerning specialist voluntary organisations as shown by the diabetic patient. The CM nurses participating in the focus groups listed the same types of organisations as patients and carers. This has been presented graphically and can be seen in Figure 6.3: Types of organisations involved in the care of NHS case managed patients.
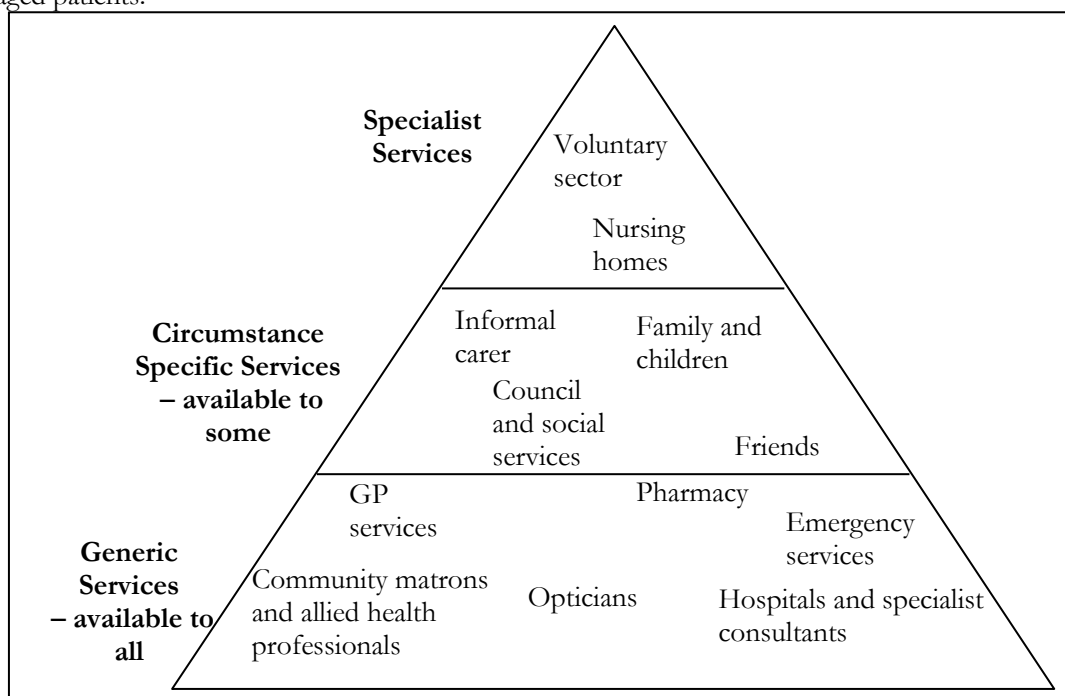
Figure 6.3: Types of organisations involved in the care of NHS case managed patients

Participants in T3 discussed some concerns they had observed with private care providers, and implicated them heavily in the safety of patients:

"I've just had to deal with an adult referral for one of my chaps who had dementia and COPD and heart failure because the care agency were documenting that they were giving him his medication and they weren't, as a result he had a hospital admission and was ill."[T3]

136

In this example, the participants are highlighting that non-NHS care providers and their staff contribute to patient safety. Therefore, it is important to realise that the providers of care, and similarly the staff, are not solely those of the NHS, but many other organisations who assist in the management of this patient group, as can be seen in Figure 6.1. These providers are broad and can be specific to the nature of the disease being suffered by the patient.

6.2.3: Structure of care delivered in the home

All participants were forthcoming with structures of care, which contribute to the safety of patients and nine key themes were identified (see Figure 6.4: Thematic framework for the domain of structure). An explanation for each as a dimension of structure is discussed in the proceeding sections.
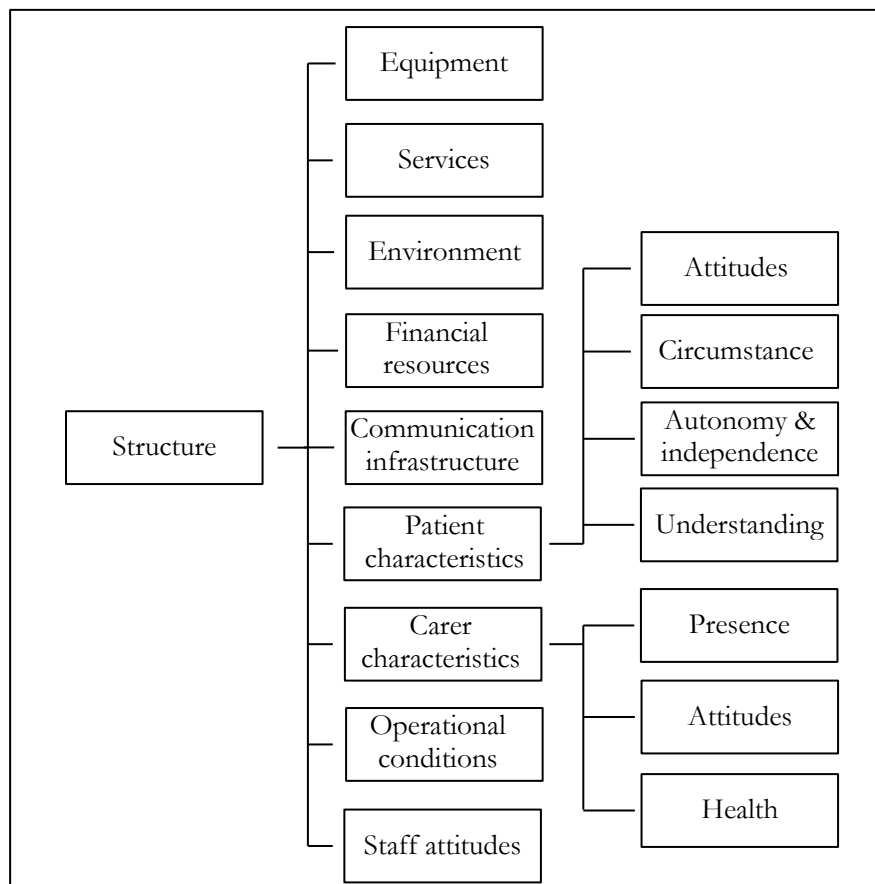
Figure 6.4: Thematic framework for the domain of structure

6.2.3.1: Equipment

Equipment was a key theme that emerged from across all of the participants in the study. The majority of patients and carers discussed equipment, referring to the positive impact its provision had had on their lives. For example, DP005 had recently had a stair lift fitted to assist him up and down the stairs because he felt he was at risk of falling:

> *"Also, had a stair lift fitted a few weeks ago, um because I was having trouble getting up and down stairs, and it was a bit of a risk coming downstairs, although it wasn't risky going up it was difficult"* [DP005]

Others expressed how essential the equipment was to their wellbeing:

> *"the machinery that's provided now ... well I think I'd ... you know, if they took it off me, I would be extremely, extremely stressed"* [DP003]

> *"If it hadn't been for all the medication and the various aids she's been given… I think she'd have been in and out of the hospital all the time."* [CC001]

In some cases, patients and carers discussed the negative implications, which were experienced when equipment wasn't available to them. DP003 (DC003's husband), can't get up the stairs to get to bed because he gets out of breath, so he sleeps on the sofa in the lounge: *"A stair lift so he hasn't got to sleep on the settee…because he gets out of breathe going to bed."* [DC003]. After the recorder was turned off, DP003 explained that he slept on the sofa, rather than have a bed in the lounge, because the lounge was the social place where his family visited and he did not want to compromise this (permission was granted to use this in the thesis). Inadequate equipment provision can impact on carers also, DP006 and DC001 explain:

> [DP006]*: "Erm – a shower would help considerably"*

> [Interviewer]*: "What difference would that make?"*

More examples can be found in Table 6.4: Examples of patient and carer quotes in relation to the absence of equipment.

Table 6.5: Examples of patient and carer quotes in relation to the absence of equipment
Patient and Carer Quotes

DP006: *"It would be a lot easier. I'm not very good on my legs at all, and it's blooming awkward to stand in the bath."*

DC001: *"So when I wash him and he turns round he has to hold onto a wall, because he couldn't just stand up on his own"*

"And, the same thing could apply to the front door, but apparently Social Services said, we can only fund one half step [laughing]." (DP005)

Patients and carers related equipment to the functional activities they would like to be able to achieve, for example, getting around the house and up the stairs. In contrast, T1 discussed equipment in relation to telecare. T1, as well as T2 and T3 raised an important issue on the availability of the equipment and the speed at which they are available to patients: *"And sometimes it's about getting access to those things quickly which is, can be the problem. Like you might refer to an aid... but they might have a three-month waiting list"* (T1).

6.2.3.2: Environment

The environment, in which the patients are being cared for, and also living in, was identified as a component of the structure of care. Similarly to the equipment theme discussed in section 6.2.3.1, the environment was discussed, predominantly, in one of two ways: the identification of environmental conditions that have been resolved to improve safety; or environmental conditions, which remain and present a risk.

CP001 and CC001, as well as other patient and carer participants, identified the traditional bathroom as a risk, which had been resolved by the installation of a wet room:

"Before my shower, was in the bath so I had to climb in the bath. I used to love having a bath but I couldn't even sit in the bath. I had to kneel in the bath because I couldn't sit down because I couldn't get out. And then I'd kneel in the bath and then end up with cramp in my feet. So I couldn't do anything then." (CP001)

"The wet room that's been put in. Previously of course she had extreme trouble getting in and out of the bath when we had a bath there…but now they've put the show in it's not a problem you know. That's been a big plus, certainly." (CC001)

Steps and stairs were also a component of the environment that were frequently identified as presenting a risk:

"Also, had a stair lift fitted a few weeks ago, um because I was having trouble getting up and down stairs, and it was a bit of a risk coming downstairs" (DP005)

CP001 had even considered relocating her bedroom into the lounge to avoid having to use the stairs:

"Yes, because originally I was going to make the bedroom down here, because this goes in to a bed, we brought this especially in case, you know, but I really didn't want to go down that avenue unless it was really desperate." (CP001)

CM nurses also identified the environment as a structure of care. T2 identified stairs: *"Stairs, things like stairs."* (T2), and related this to accessibility of the property:

"And I would say accessibility as well."

"Yeah,"

"Whether they are able to get in or out of the property so that they can go out for their own mental health really."

Source: T2 conversation

Although not identified by the majority of participants, some suggested: cleanliness, heating, space/clutter and security, as can be seen in Table 6.5: Evidence relating to the environment as a component of safety.

Table 6.6: Evidence relating to the environment as a component of safety

Patient, carer and CM nurse quotes

"Oh definitely, absolutely. I think a clean home is most important. Because many germs, germs don't take prisoners, they don't go, they don't particularise themselves where they go. The germs are everywhere." (NP005)

"The house and sanitary conditions, yeah" (T3)

"Things like temperature in the house, if the house is cold." (T1)

"Well um, that there's adequate heating in the home…Um, would have to be one of the prime concerns." (CC001)

"Well obstacles for a start. You know, a way, you know whenever you're walking round you certainly don't want no loose cables, loose wires, loose carpets." (DC004)

"DC003's (wife) very err, safety conscious with making sure everything's locked and everything's ... and all that at night, err, you know, so ... um, without like err the various things we've had done to the house to make it secure, the security light and that." (DP003)

The CM nurses were in agreement with patients and carers in relation to heating and cleanliness. In addition, T2 and T3 also identified the state of repair of the property as a component of structure, an example is provided from T3:

"Umm I guess umm poor lighting and umm well sort of ill repair of house can affect their risk of falling or umm also even their sort of mental health really as well, particularly." (T3)

T3 discussed how the condition of a patient's home might affect the length of time they spend there, and how it impacts on their relationship with the patient. They talked about patients, for whom, they needed to wear over shoes when entering the property because the house was so dirty and you couldn't sit on the sofa:

"I guess it could umm effect your umm comfort with seeing that particular individual more so than the follow on visit, I would guess it effects your umm the time you might want to spend within a house"

"Yeah and extremely damp, extremely cold and you know it's bound to effect how, how long you want to spend with that particular patient, you know I mean obviously you try and give them the best service you can but clearly I couldn't sit down in that environment so I was stood throughout my consultation which is gonna effect the patient's ease at talking to you as well."

"Umm so I think it does effect your care to a degree, you know I mean you try to minimise that and you try to amend that for future as well but you know obviously you do have restricted control over that and it doesn't always happen instantly as well."

Source: T3 conversation

A range of environmental conditions have been identified by all stakeholder groups; specifically, they relate to the physical environment of the patients home.

6.2.3.3: Services

Patients and carers identified a range of health and care services as being important in the safety of their care, most related to their availability. For example, DC001 and DP006 talked positively in their joint interview about the generic availability of the NHS:

DP006*: "We're coming back now to the National Health. What country in the world can you do that?"*

DC001*: "I mean, they're always there for me if I need help. Like, you know, and they'll say, "Bring him up and I'll-I'll check him over."*

NP001 talked about the service availability of the CM programme as a good alternative to the long waits to see a GP, which could result in hospitalisation:

"Oh yes. Because you couldn't get an appointment at the doctors for three or four days and by that time your chest infection had taken hold and it was difficult and you ended up in hospital." (NP001)

NC001 and his wife were looked after by a multi-disciplinary care team including case managers, which they believed provided better service provision:

> *"Well they've got ... they've got about a dozen or so nurses up there and they're on like a rosta throughout the week, they work seven days a week some of them. Some of them have to be on at weekends, Sunday and what have you. But err, they do a good job. They're on call there and they ... if they want rebandaging or anything like that, you've only got to call them and that day, it might not be straightaway but they'll be there to look after [wife] and rebandage her leg or what have you"* (NC001)

For others, service availability was related to the service being available to use when needed, rather than using them all the time:

> *"I mean *name* from the Chest Clinic rang me up the other day and she said what we'll do now is because you're managing better with your antibiotics and that, erm, she said I won't be ringing you up so often, but she said if ever you need us, you just pick up that phone, she said and we'll talk you through it, so".* (CP001)

> *"They are concerned, well I, I, they are concerned they'll say, "Well, you know where ... if you need us you know where we are. And I do call them, I have done in the past because ... and they don't mind coming."*
>
> (NP005)

T3 considered the availability of the CM programme and raised the issue of possibly offering a 7 day a week service. However, they believed this would impact on the core competency of the service, which was to have a single point of contact for patient care, and they felt this may be lost with a 7 day service. An extract of this conversation is available in Table 6.6: Extract from a conversation in T3 about a 7 day service.

Table 6.7: Extract from a conversation in T3 about a 7 day service

"Think it's very hard to say because part of our role is to work as individuals and provide a one-to-one support with umm you know a particular named person and umm it's about knowing your patients and them knowing you so that you can detect changes in them, and that close working relationship I believe improves health outcomes largely but I guess the fact that you don't necessarily have umm, you know 7 day cover. You know it might avoid patient admissions and that might improve health outcomes but then you couldn't provide the same person to provide those 7 day covers."

"So it could have a detrimental impact in the fact that you wouldn't necessarily be dealing with the same person as often you know, you'd lose that personal contact so it's a hard balance to say because it's never been tried I guess."

"Whether, which way round would be the best. Whether having that particular individual that they know and trust, is the health benefit or whether having a 7 day a week service is, would be a better health benefit."

"And I would say largely from a patient reporting aspect that they value having a particular individual that they can go to which would be lose if we start doing cover 7 days a week."

<div align="right">Source: T3 conversation</div>

T3 further justified why the service should not be 7 days; they believed their role to be a facilitator, and that patients who required weekend assistance needed acute and reactive care, which was not their role:

"Dunno our role's very much one of a facilitator rather than reactive delivery of care in an acute situation."

"But we do have patients that go in over a weekend when they might not if they've got somebody to call, I'm not suggesting that we should really."

<div align="right">*Source: T3 conversation*</div>

T1 identified lack of knowledge of services as a component. One participant in particular went into detail about patients needing to know what services were available, but also needing to know what services were required, and questioning whose responsibility it was to aid people in choosing the right services. The transcript can be found in Appendix 14.

Patients and carers identified the availability of healthcare services as a component of safe healthcare. This did not necessarily translate to service utilisation but rather, the option to access services on an *ad hoc* basis

or when perceived to be required by them. CM nurses, on the other hand, provided a different perspective. Some CM nurses raised issues of the delays between referrals to service access, which had not been expressed by the patient and carer group. In addition, T3 in particular, toyed with the concept of a 7 day service who highlighted the benefits and disadvantages. They concluded that it would not be advantageous, mostly because it would interfere with their relationships with patients, which they perceive to be vital to their role as care facilitator.

6.2.3.4: Financial Resources

The identification of financial resources as a structure of safe care was led by the CM nurses. All three focus groups discussed in some detail the implications of financial resources on safe care.

T1 and T2 highlighted concerns they had for patients who had financial resources at their disposal. They argued that those with financial resources were more at risk and that this came down to one fundamental reason: those without financial resources receive support from the state and thus use of services did not incur any financial penalty. These discussions can be seen in Table 6.7: Examples of CM nurses identifying non-state funded patients as at greater risk. Consequently, patients with financial resources have a choice to make: whether to spend their money on social care provision or leave it to loved ones when they pass away. T1 raised the point that regardless of whether patients choose to fund their own social care, ultimately, where provision falls short at keeping people safe, the NHS picks up the difference.

Table 6.8: Examples of CM nurses in T1 identifying non-state funded patients as at greater risk

CM nurse quotes from T1

"In terms of safety as well, um, if you haven't got any money it would seem that you are right. It'd mean that you can actually, services are there for you" (T1)

"If they are in private accommodation…they have to pay for the pendant alarms. If they are council accommodation that's free." (T1)

"I find it quite difficult when you see people making choices that compromise their safety either from wanting to stay independent or not wanting to spend money, and you're, you know, and it's just like you save a for a rainy day, it's raining, like spend the money" (T1)

"Sometimes it's a bit perverse because what you were saying about your lady who's at risk of falling, she, if she doesn't want to pay for her Careline, then why can't we for whatever amount of money it is a month when it could cost what £300 a night for her to be in hospital, spend 30 quid a month?" (T1)

In other examples, T2 identified the abuse of financial support given to patients, who sometimes use funds to cover the cost of things like gardeners and window cleaners. Some of the CM nurses perceived this to be inappropriate. However, in the same focus group, others argued that the money was to aid them in remaining dependent at home, and for them to determine their own needs and spend accordingly (see Table 6.8: Evidence of the CM nurse perception of the use of state funds). Others who are eligible for funding don't use it at all because they don't want to be seen as charity.

Table 6.9: Evidence of the T2 CM nurses perceptions of the use of state funds

CM nurse quotes

"Some people like gardeners, window cleaners."

"It's not supposed to be for that, is it? It is actually to help provide personal care, isn't it?"

"Hmm."

"Attendance allowance really, it isn't necessarily for gardens."

"It's for personal care."

"But I thought it was to provide support"

"to maintain people's independence at home"

"But it's for them to choose."

"their need to choose sort of …"

Source: T2 conversation

"But it's like heating allowance, I mean they have the heating allowance, we go in some houses and they are colder inside than they are outside and it's not that they haven't got the finance to pay" [T2]

"They know it's not means tested because we explain to them. Still won't accept it because it's deemed as charity." [T2]

For patients and carers, discussion around financial resources was dominated by not being eligible for funding to pay for things. This either resulted in having to pay for things themselves, or going without, these can be seen in Table 6.9: Examples of the patients' perceptions of finance.

Table 6.10: Examples of the patients' perceptions of finance

Patient Quotes

"The same thing could apply to the front door, but apparently Social Services said, we can only fund one half step" (DP005)

"Everything costs money. I mean to have day carers every single day would cost me err £30/£50 odd a week. So err, I don't much like paying out that sort of thing so make do myself" (NP005)

"But no, they wanted £2,000 and I says, "No SON, you're not paying that, no". I mean (laughter) he's got himself, his wife and his home." (DP004)

Patients who were in receipt of a lot of financial support, such as CP001 and NP001, made no comments that implicated financial resources as a barrier to safe care Instead they appeared to have sufficient service and equipment provision. This supports the themes that were identified within the CM nurse focus groups, where they believed patients who had access to financial resources, did not make decisions that were best for their safety, but rather to maintain their wealth.

6.2.3.5: Communication Infrastructure

Communication infrastructure was identified by all of the stakeholder groups, as being an important structural component of home healthcare. This was further supported by the identification of communicating as a process (see section 6.6.4.3), which could not be achieved without an available infrastructure. Participants described communication infrastructure as the physical and organisational facilities required to assist communication. This included telephone lines that were used to make contact with health professionals, family and other services. Some patients had specialist communication infrastructure installed because of their vulnerability. For instance, DP005 and NP001 had care lines installed. Others simply ensured they carried mobile phones with them for emergencies. See Table 6.10: Evidence of the patient and carer perspective of communication infrastructure.

"Well I've got a mobile phone, DC003 got a mobile phone, so you know, that's something else to be honest with you, mobile phones have really helped didn't they you know, because they keep you in touch, you know what I mean." (DP003)

"A lifeline. Er - phoning the hospital. My children, friends." (DP006)

"Yeah. But you see if I'm here I can get to there. If I'm here I can get to this. If I'm anywhere round about there's a phone there, there's a phone there. So there's plenty of contact, and that machine there… From out in the kitchen, they can hear you from the kitchen, the bathroom, the bedroom, anywhere." (NP001)

When the CM nurses of T1 discussed communication infrastructure, they talked about it in the context of the relationships they had developed with the patients They believed greater communication resulted in more trust and subsequently patients revealing more information to them: *"I suppose it's about trust, trusting us. I think from what patients tell us, they, they trust us a great deal but maybe don't trust A&E as much or, um, their GP"* (T1). T3 discussed it in relation to their incident reporting process acting as an infrastructure for patients to feel they were having complaints heard: *"I think when, when you report an incident that involves the patient sometimes the patient and the relative feels that that's their complaint, that's their, their mode of complaint if you like that you've reported an incident."* (T3). The presence of a communication infrastructure is perceived to facilitate the process of communication, which supports an exchange of information to achieve safer care.

6.2.3.6: Patient Characteristics

From the analysis, four patient characteristics were identified as having a potential role in safety: attitudes, patient understanding, circumstance, and autonomy and independence. Evidence of each is available in Table 6.11: Evidence relating to patient characteristics from patients and carers.

Patient attitudes was a broad micro theme that encompassed things such as a reluctance to change or use services, a sense of coping, and putting on people. CP001 insists on still ironing the towels like she has always done, even though it is exhausting for her. DP006 is in pain, but he feels he just has to *"learn to live*

with it" (DP006). And DP002 doesn't talk much about how she feels because she fears people will get fed up with her. Another patient attitude was that of a general feeling of being safe in their homes.

CM nurses perceived some patient attitudes to negatively impact on health outcomes, in particular they highlighted: pride, denial, poor understanding, fear of vulnerability, and institutionalisation. These are inter-related and undistinguishable as independent factors. For instance, CM nurses believed some patients to be proud and unwilling to accept their deteriorating health: *"they are very proud and won't want to accept they have got a problem"* (T2). CM nurses attributed the majority of these behaviours to the patient groups 'war time' up-brining in which they were made to 'make do': *"they're brought up in the war…and they had to keep going"* (T2). Ultimately, the CM nurses find this difficult to overcome: *"it's not anything we can sort of risk manage you know"* (T3).

Patient understanding appears to be quite important in some instances. For example, DP002 and DC001 both highlight the importance of understanding diabetes, to prevent hyperglycaemia. And NP005 talks about how he feels that asking questions to learn more is promoted in the CM service.

Patient circumstance mostly relates to the conditions of the individual patients; their multi-morbidities, and the way in which they affected that patient's ability to undertake particular activities. The impact of DP002's multi-morbidities has meant that when she started to have bladder trouble, there was little that could be done to relieve her because of the greater implications of the treatment on the multi-morbidities. Similarly, DP006 can't have the heart transplant he needs because another component of his treatment isn't sufficiently effective. In some cases, patients can accommodate their own characteristics: DP003 can't walk very far without falling, but enjoys his garden. In order to enjoy his garden he has to walk to the garden bench and sit down, and take a mobile phone with him, just in case.

Table 6.12: Evidence relating to patient characteristics from patients and carers

Micro theme	Patient and carer quotes
Patient Attitudes	Reluctance to change *"I know, I know, it's silly isn't it. Oh dear. But I thought no I'm not going to give everything up, you know."* (CP001)
	Sense of coping - *"It does get you down but I mean, I'm in pain now… but you learn to live with it."* (DP006)
	Putting on people - *"Well, not really because I think they get fed up, don't they? They're hearing the same, 'Oh, moaning again,' you know. So now I don't, erm don't tell him."* (DP002)
	Being safer – *"Erm, it's knowing how to put it in to words really. Erm, I just feel safer"* (CP001)
Patient understanding	*"Yeah, well I've got with me, you know, I, I have those little thick tablets, what are they? For diabetes?"* (DP002)
	"Oh yeah, the more information I get, I ... I ... on what's the matter with me, the more information I get, the better understanding of the disease, the better to cope with it" DP003
	"In fact we are encouraged nowadays to say what we think, to err, ask questions. Now this is the most vitally important of all, if you don't ask questions, you don't get to know." (NP005)
Patient characteristics	*"Yes, the bladder. Erm, the, the doctor there … I can't have an operation, a proper operation because of my heart. I can't err, I can't have an anaesthetic."* (DP002)
	"You see, with the operation and things like that, if my pump had been good I should have had-I should have had a heart transplant but my pump is no good." (DP006)
	"In the better weather I can sort of have a walk in the garden and sit on the garden bench you know, something like that, which err ... well I've got a mobile phone" (DP003)
Autonomy and independence	*"I don't always act on it but I do listen… And I know that whatever they're doing is for my own good, you know, for my own health"* (CP001)
	"I don't think I could cope." (DP005)

Patients are afforded a degree of autonomy and independence whilst being cared for in the home; having the option not to follow the advice or instructions of the healthcare professionals. CP001 admitted to not always acting on the advice given to her, despite knowing it was for her own good. DP005 talked about how having his car to drive himself to places helped to maintain his independence and that he does not think he would cope if he did not have his independence. DP003 recognised that the more information he had on his disease, the better he could cope with it.

6.2.3.7: Carer Characteristics

Three carer characteristics were identified within the structure of care: carer attitudes, carer presence and carer health. The carer attitudes that were expressed were truly humbling. Carers explained the inherent and obligatory nature of their role as carer. Quotes of evidence are available in Table 6.12: Evidence of carer characteristics.

Table 6.13: Evidence of carer characteristics

Patient and carer quotes
"As her husband I would be her carer anyway wouldn't I?... I wouldn't be much of a husband would I, if I didn't?" (CC001)
"Well I'm here to keep [her safe] – I was a carer before all this lot started." (DC002)
"No it's easy, he's my husband. I have told him." (DC003)
"Well I don't grumble about it. It don't upset me being a carer because I mean I've been married to her 65 years next January. I mean if I can't help her now" (DC004)
"I most definitely believe umm, I want ... I want to be a carer if I've got sufficient knowledge to do what I want to do to get her better." (NC001)

Carer health is also important, not only for themselves, but to maintain the care and support they give to their loved ones. Similarly to the patient, they cannot do all of the things they used to: "*I can't do all that I used to be able to do. You don't as you get older.*" (CC001). DP003 talked about the pharmacy service that delivers

her drugs, which saves her husband from having to do it: *"I don't want DC003 to rush about with stuff like that"* (DP003). For DC001, she had been supporting her husband to bathe, but it was getting difficult for her. Having a shower installed would not only prevent harm to the patient but to her, as the carer also: *"a shower would help considerably… it would be a lot easier, especially for me."* (DC001). DC004 told a harrowing story, of the time he had walked to the paper shop and whilst out he had a heart attack and was taken by ambulance to the hospital, leaving his wife at home. The hospital did arrange for her to be put into a care home whilst he was receiving treatment, but he refused to let that happen to her and discharged himself from the hospital so that he could return home to his wife. In other instances, patients and carers told stories where the carer was participating in activities which were putting themselves at considerable risk. For instance, DC002 would walk behind DP002 every time she walked up the stairs because she was likely to fall. As part of their supporting role, carers are also at risk of harm as a result of caring for the patient.

Some patients and carers identified the intensity of the role played by the carer: *"Now if I tell you this would you believe me or not? I'll tell you I've worked from 14 until 65, this is the hardest job I've had. It's a 24 hour job"* (DC004). Some carers had accommodated the patient to meet their needs, such as DC003, who only worked two hours a day at a school within walking distance so she could easily return if needed by her husband: *"I only work at the school, I only do two hours cleaning for the school, I'm right there… if anything happens, I'm back."* (DC003). This was despite having their income squeezed as a result.

Another characteristic of carers that T3 highlighted was their potential to be challenging and unco-operative: *"Perhaps we should talk about aggressive and challenging relatives?"* (T3). A section of transcript is provided in Table 6.13: Exert of a conversation on challenging carers of the discussion on challenging carers. Essentially, T3 have some patients with carers who cause them stress, which results in a conscious effort trying not displace this stress on the patient. The CM nurses of T3 described a patient, who isn't receiving a particular care service because the service does not want to engage with the difficult family. Difficult carers could have a detrimental effect on patient health if they are not receiving adequate care provision.

Table 6.14: Exert of a conversation on challenging carers

T3 transcript

"Yeah well they directly cause us stress."

"Right."

"Increase our stress levels and you have to constantly try and be conscious that you don't want to spend less time or energy with the patient because of how the relative is behaving to you so it's a confident balance in trying to work with the relative and not let them have a negative effect on how you deliver the care to, to the patient."

"And they can be very time consuming can't they?"

"Yeah."

"And, and add to your workload."

"Yeah definitely."

"As well."

"I know one of my ladies is quiet a, I can't prove it but she's currently been refused a service 'cause this, her daughter who I suspect has personality disorder and err they say that she hasn't got, we have potential and I don't agree with them but I suspect that because they've encountered this daughter they are umm more reticent about providing a service and I'm not blaming them, I can understand 'cause this woman has lost me sleep over the last 10 years since I've known her so, it can be very challenging trying to balance umm the needs of the patients against your relationship with the carer and the relatives."

6.5.3.8: Operational conditions

The operational conditions were raised by two of the focus groups (T2 and T3) and not by any patients or carers. These related specifically to the organisational environment required to undertake occupational activities. However, the extent of the discussions held within T2 and T3 around the personal experiences they had had, raised concerns over the possibility of this being present in more organisations, and thus significantly contributing to patient safety.

154

Caseload was discussed by both focus groups, but not necessarily in relation to the number of patients being served by any one staff member, but rather the dependency of individual patients in the context of the patient numbers: *"I suppose it's a dependency in one patient in context of your caseload, it is isn't it?"* (T2), which impacts on the *"frequency and time, how long you spend"* (T2) with those individual patients. Even if caseloads were considered by the number of patients, T2 described how their caseloads were determined by a minimum number of patients they were required to serve, with no cap on the maximum and they *"can't say that we're closed, we would still take a patient on if they needed"* T3. One participant explains how in the past, they have had to overcome rising demand with stable or decreasing capacity:

"We had an issue a few years ago where we were just packed to capacity and breaking, you guys probably all know about this, and we did create a waiting list and it enabled us to get more staff because we were putting in incident forms every week saying this many patients have been waiting this long, this is at the end of the week how much System 1 work hasn't been done and we're putting those forms in every week." (T3)

Another participant of T3 talked about everyone going through a meltdown because of the intensity of caseloads and the implications of this: *"you've just got yourself so overwhelmed by the workload that you think it's only a matter of time before something goes wrong, and that was all due to intensity of caseloads"* (T3). This was related back to the intensity of the caseload rather than the volume or the number of patients: *"Because we were all just going under with the volume of visits and the sort of level of intensity of the patients at that time, it wasn't the case they were bigger it was just that the patients on the caseload were all really unstable"* (T3).

From this, T3 described a situation where caseloads could be managed by large numbers of staff, but if they were not sufficiently trained it was not very effective: *"Intensity of caseloads maybe, but then you can have all the staff in the world but if they're not trained"* (T3). However, both focus groups concluded that training does not necessarily prepare you for the individuality of each case, which can be eased with experience: *"A lot of it's experience"* T2 and *"I think we have adequate training but whether you encounter a certain, already you've encountered a certain symptom or a problem before, the training can't prepare you for every eventuality can they?"* (T3). The participants in T3 were complimentary about how their organisation managed competency through *"supervision and one-*

155

to-ones" [T3]. However, when asked whether having more training would improve patient outcomes, they admitted to feeling that some training was a 'box ticking' exercise: "*some of the feel like ticking boxes, other are really, really useful.*" [T3]. Participants of T2 and T3 identified the importance of caseload, its intensity and adequate training as being important in patient safety and outcomes.

6.2.3.9: Staff attitudes

Staff attitudes to patient safety revolved around a core theme: their role and how it was hindered by the care setting. Off the back of this, the CM nurses absolved themselves of responsibility because they believe ultimate responsibility lies with the patient.

The CM nurses were confident in defining their role as the 'empowerer': to engage patients in taking responsibility for themselves, and to facilitate integrated working between other contributing services. For example, CM nurses described their role as "*to make patients take responsibility for themselves*" [T3] and "*that's what we've tried to facilitate [integrated working]*" [T1]. This was echoed amongst the focus group participants across the three locations. Despite their role to empower patients, they placed ultimate responsibility for safety and health outcomes on the patients, who they believe to be the decision makers. In some cases, this led to the CM nurses feeling powerless to influence patients: "*it's still their home and they're very much at the centre of their care, it's their decision whether they take on board your advice or recommendations*" [T2] and "*you know sometimes we can be seen as being responsible for somebody's blood glucose being poor but you know in actual fact sometimes know matter what you put in it's the patient's responsibility that falls down really*" [T3].

CM nurses perceived themselves to have less control than their hospital based counterparts as one participant indicated "*there's also a power balance, because in the community people are much more in change of themselves…but often once you've been in hospital you're a little but more vulnerable…which means patients are more likely to accept [recommendations] if it means they can go home*" [T1]. Consequently, the CM nurses were left feeling frustrated by this power-shift and feeling like they were "*banging [their] head[s] against a brick wall*" " [T1]. This was exacerbated by two factors: staff felt more experienced than patients to make judgement calls, but felt

they had less power and influence in comparison to the hospital setting. For example, one CM nurse expressed that *"the patient obviously knows themselves but we also know the grand scheme of all the hundreds of patients that we come into contact with and what could happen"* [T2]. Another participant explained that in the hospital environment, care *"is more imposed upon you"* [T3] and another expressed that *"by the very nature that you visit somebody in their own home, you can't really influence what goes, what happened when you've walked out of that house"* [T2].

6.2.4: Processes of home healthcare

Processes of healthcare delivered in the home were categorised according to three broad themes: self-care and management; clinical care of the case manager and communicating (see Figure 6.5: Processes of healthcare).
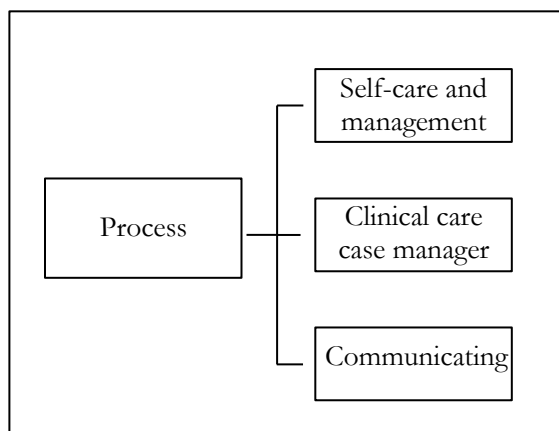
Figure 6.5: Thematic framework for the domain of structure

6.2.4.1: Self-care and management

Patients and carers dominated the identification of self-care and management activities, with CM nurses contributing comparatively little. Self-care and management can be categories into seven subthemes (see Figure 6.6: Self-care and management subtheme framework): medicating; adjusting to LTC; personal care, home care, diet management, functional mobility and exercise. A description of each of these can be found in Table: 6.14: Self-care and management sub-themes, and evidence of each of these themes can be found in Table 6.15: Evidence of processes of self-care and management sub-themes.
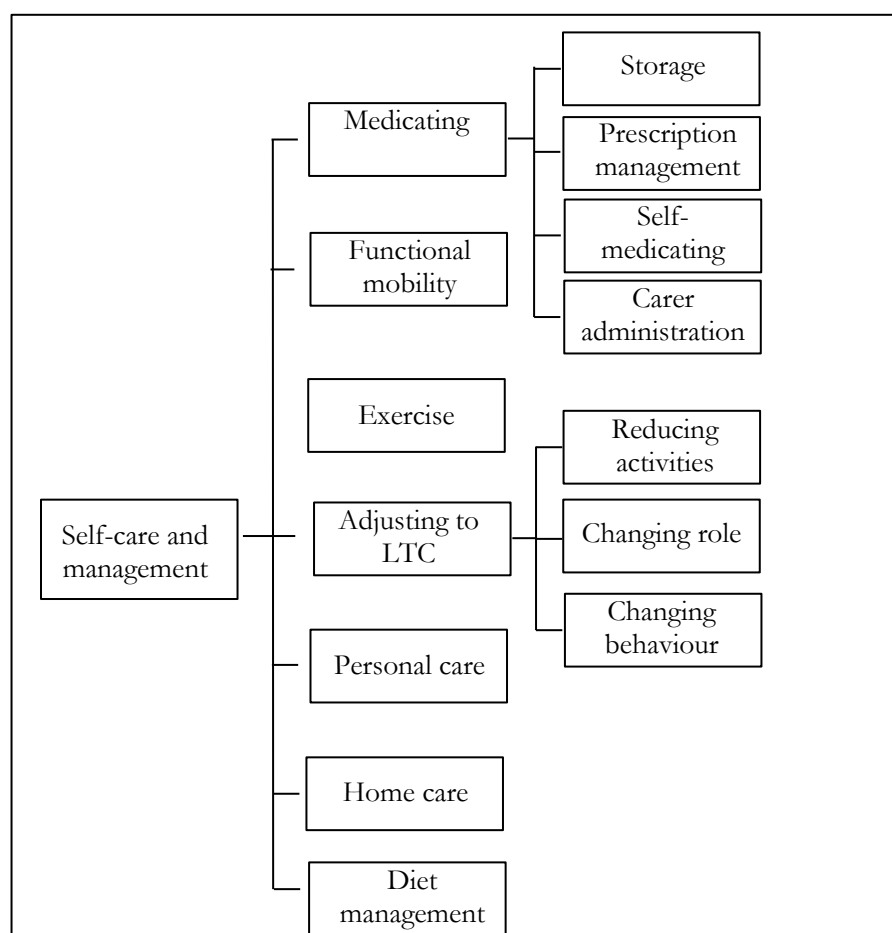
Figure 6.6: Thematic framework for the domain of structure

Table 6.15: Self-care and management subthemes

Process	*Description*
Medicating	Taking medication
Personal care	Attending to the physical and emotional needs such as bathing
Home care	Attending to the physical living environment such as cleaning
Diet management	Attending to nutritional needs
Functional mobility	The mobility of an individual in relation to their ability to conduct self-care
Exercise	Activities to sustain or improve health and fitness

Medicating was a commonly identified process across all patient and carer participants in the study. The complexity of medicating is evidenced by the multiple micro-themes that were also identified, these were: storage, prescription management, self-medicating, and carer administration. Examples of these can be found in Table 6.16: Evidence of the micro-theme of medicating.

Storage of medication was important, and some patients, such as CP001 opted to use pill organisers. The volume of her medication requirements meant she needed to use three pill organisers to be able to manage her medication safely and effectively. Other patients had their carers keep them out of reach and the carers would bring them down when the medication was due. Another alternative was for patients to use prescribed blister boxes, which supply a week's medication in all the correct doses, as does NP006.

Prescription management is the identification of the need for further supplies of medication, and the actions taken to ensure the availability of the supplies when necessary. For DP003, a pharmacy does this for him. For DP002, DC002 ensures this is done. Another micro theme within medicating was the process of self-medicating. In the case of DP003, not self-medicating properly has previously resulted in emergency visits from a doctor, and he now believes that educating patients to understand why they need to take their medication is important. For some patients, their carers manage their drugs and assist in administering them. For example, DC004 believes DP004 wouldn't remember to take them unless he instructed her to.

Table 6.16: Evidence of the micro-theme of medicating

Micro-theme	Patient and carer quotes
Storage	*"Yes, I've got 3 pill organisers…Otherwise I wouldn't know what I was taking."* (CC001)
	"All the safety, they're up in the – because hers got little boxes and, err, I came down the other day to the breakfast and I get them out for her. I get the things out for her jabs, you know, and by the time hers had her breakfast and done that, it's ten o'clock!" (DC002)
	"I have them delivered in box form…Well individual days, there's a weeks supply in one box." (NP006)
Prescription Management	*"Yeah because the chemist will go and fetch my prescriptions for me and they'll deliver them to the door. That's Lloyds Pharmacy."* (DP003)
	"Oh yes. I have the prescription off the doctors and I take it up to the chemist and then bring them back too." (DP002)
Self-medicating	*"Yeah, and of course one doctor come, an emergency doctor who was only very young, and err he says err, you know ... I said to him, oh I think I've got some of them, she said okay show me them and when he see them he said, I think you'd better take those to your doctor. I thought oh dear, because I wasn't taking the course like. So education is important."* (DP003)
Carer administration	*"If I didn't she wouldn't have them, she'd just forget she's got to have them…Yeah, I shall do all that, and they're all … some of them on the shelf in there you'll see, on the window sill and they're all marked up."* (DC004)
	"Perhaps as I say, the nebuliser sometimes, I have to say, oh look you know, how about having a go on your nebuliser you know." (CC001)
	"Well of course he has a 34 and then I have to twist it again, but of course he couldn't do that, because he couldn't see." (DC001)

Adjusting to LTC was another sub-theme within self-care, which had micro themes. The action of adjusting to living with an LTC heavily revolved around reducing activities, which could otherwise cause harm. NP005 recognises that he can't do gardening anymore and has had to replace this with other hobbies. Others, like DP005, have recognised the need to reduce activities and be realistic about their situation. There is also a component of changing roles within the relationship. For instance, CC001 is used to doing all of the house work to her own standard, but now her husband has to do it. DP003 is no

longer the earner in the family and this isn't something he is comfortable with but is having to adjust to. Another component is that of changing behaviours. NP001 has to change the way in which she gets to the telephone to ensure she doesn't fall over. Evidence of all of these can be found in Table 6.17: Evidence of micro-themes of adjusting to LTC.

Table 6.17: Evidence of micro-themes of adjusting to LTC

Micro-theme	Patient and carer quotes
Reducing activities	*"Many people have different ideas of what their quality of life wants to be. Err, the things that I did before active, gardening, I can no longer do, so I have to adjust for that to my other hobbies."* [NP005]
	"It's difficult, you know I've had to work hard to accept in this situation that I can't do as much as I'd like to do but er, you've got to be a bit realistic about things and face facts and bite the bullet as they say and, deal with your problems the best you can." [DP005]
Changing role	*"I do like to try and keep things clean, you know. Erm, and bless him, I mean *husband* does a lot, you know, but obviously it's not as you always want it is it? But no, I've had to let that go over my head now because there's nothing I can do about it, you know. And he does it, you know"* [CP001]
	"The quality of life I have now is I can err, I can't work, which I did ... I did used to err like being a ... you know, bringing money into the house, being a breadwinner if you like." [DP003]
Changing behaviours	*"Now, in looking after yourself, like say the phone rings, I'll go round there, because I know if I think I'm going to fall, or I start to fall, I can grab something close and hang on to it. he same if I go there. I'll hold on that door."* [NP001]

For patients in this study, their carers were heavily supportive of self-care and management activities. They either assisted or delivered care that aimed to sustain or improve the well-being of the patients. In Table 6.16: Evidence of micro-themes of adjusting to LTC, multiple carers, including CC001, DC002,

DC003 and NC001, discuss how they support self-care and management activities. These range from assisting with bathing, to cooking, cleaning and medicating.

In comparison, CM nurses contributed very little to identifying processes of self-care and management. T3 were the only focus group to give self-care activity of patients any consideration and it only related to medicating. One participant explained how one of her patients with dementia had experienced ill health and was admitted to hospital because her formal carer was documenting administration of medication but wasn't actually giving it to him:

> *"So for example I've just had to deal with an adult referral for one of my chaps who had dementia and*
>
> *COPD and heart failure because the care agency were documenting that they were giving him his medication*
>
> *and they weren't, and as a result he had hospital admission and was ill."* [T3]

However, this could be considered a clinical care process of a trained care giver, rather than supporting self-care. T3 also acknowledged that they could place their patients at risk through clinical error, this will be discussed next.

6.6.4.2: Clinical care of the case manager

Patients and carers identified clinical care activities undertaken by the case managers that contributed to their health and well-being, thus, subsequently their safety. Patients described activities such as: listening to the chest, taking measurements such as blood pressure and weight, administering medication, prescribing medication, and wound management. Examples of which can be found in Table 6.18: Evidence of clinical care processes identified by patients and carers. This was echoed by T3 and the CM nurses who described a minimum data set *"that would include blood pressure, heart rate, listening to their chest, temperature"* [T3].

Table 6.18: Evidence of clinical care processes identified by patients and carers

Patient and carer quotes

"Erm, she tests all my chest thoroughly and I mean thoroughly" (CP001)

"She weighs you, does your blood pressure" (DP002)

"Yes, that's another job they go, I have some of these patches, it's a pain patch." (DP005)

"She'll leave me a prescription err if your sputum turns green with having COPD." (NP001)

"They can dress the leg, they've got the bandages and the ointment and the expertise, I don't possess that." (NC001)

In addition to identifying the clinical care processes listed above, CM nurses also described the care they provided at a higher level. They described the individuality and personalisation of the care they provide, through information and education:

"it's the whole idea is actually using words that will actually suit the patient or individual that we actually end up using, we can't use, all the same as and say it's, it's not one sentence or one phrase that's going to suit everyone"(T1)

"very much needs led, then you go in as often as they need you once they start to pick up then we can back off a little bit and they are more self-managing" (T2)

For some patients, the clinical care provided by the case managers was described as vital, and kept them out of hospital, see Table 6.19: Evidence of how vital patients and carers believed the case managers to be.

Table 6.19: Evidence of how vital patients and carers believe the case managers to be

Patient and carer quotes

"So if he, they didn't have these nurses come in, he would have to go up in hospital so... These nurses come in and they keep him going don't they?" (DC003)

"The virtual ward as it's called, err, do all sorts for me, to stop me going in hospital. In fact they have stopped me going in hospital recently, with an intravenous umm, you know, antibiotics. They've avoided me going into hospital." (DP005)

"They're vitally important, they're very, they're very important. Vital in fact, a lifeline" (NP005)

T3 also acknowledged that they could place their patients at risk if they mis-diagnosed or wrongly prescribed drugs: *"we could do them physical harm if we mis-diagnose or incorrectly prescribe"* (T3). It was discussed by T3, that drug errors made by themselves would be self-reported, but errors that patients made were not because *"we'd be there all day with incident forms."* (T3). Another cause for concern for T3, was when patient medication regimes were altered whilst admitted to hospital: *"there has been cases where patients have had their medication changed and ended up going straight back into hospital because the hospital have changed their medication."*(T3). This indicates the need for adequate communication between care services to maintain the most effective drug regime. T3 discussed how it could take months of trial and error for the most effective regime to be identified, to then be undone when admitted to hospital.

6.6.4.3: Communicating

The action of communicating was a commonly identified process across patients and carers and CM nurses, with all participants except two carers and one patient identifying communicating as a process of care. Examples of which can be found in Table 6.20: Evidence of communicating as a process of care. CP001, can ring for an ambulance and inform them of his deterioration, when needed, in order to receive medical care that will hopefully prevent further harm. DP003 appears to have gained an understanding of his role in his care as executing instructions that have been communicated to him. DP005 raises the issue of the difficulty some individuals experience in communicating, which he believes can lead to abuse.

Table 6.20: Evidence of communicating as a process of care

Patient and carer quotes
"I know that if I need help or if I'm not well, then he's here to either ring up for an ambulance or ring somebody." (CP001)
"I think I have a responsibility to do as I'm asked to do and to make sure as I umm, stick to the ... the drugs that I'm provided with and not abuse them, because I ... I'd hate to do so, you know, the drugs, when I'm trying to help you. So that's the responsibility of mine." (DP003)
"I know what I'm talking about, and I know what I'm saying and, I can understand other people's point of view and that sort of thing. A lot of older people can't stick up for themselves and I can... And I have seen older people miss treated in hospitals." (DP005)

Similarly to service in structure, patients and carers identified the option to communicate with others just as comforting as communicating with others. Evidence of this can be seen in Table 6.21: Evidence of the availability to communicate.

Table 6.21: Evidence of the availability to communicate

Patient and carer quotes
"Well, I feel safe in the home. And I know that the nurses they come in, they've got a telephone number that I can, err, if I'm in trouble I can phone them and that's nice. I don't like being left on my own" (DP002)
"But, erm, as I say, if I go out it's always on my mind. And I mean I've got a mobile here, I very hardly use it, I always take it with me and I think well if I'm in trouble or anything and I've … she wont pick it up." (DP004)
"I mean *name* from the Chest Clinic rang me up the other day and she said what we'll do now is because you're managing better with your antibiotics and that, erm, she said I won't be ringing you up so often, but she said if ever you need us, you just pick up that phone, she said and we'll talk you through it." (CP001)

For CM nurses, communicating with patients about their disease is also a part of their clinical role, indicated by the nature of their role to inform and educate: *"we're walking around with information that we have to share with patients and give them as an when they actually need it"* (T1). T3 believed this to be quite important in patient safety:

165

"I think a big safety aspect of our role is that fact that you know it's whether patient you know sort of engage or you know follow through on advice, whether they are compliant with their medicine or whatever which equals their outcome." (T3)

Use of appropriate language in communicating with patients was recognised as important because there had been instances where patients claimed to not know of their conditions, when they had probably been told about them. T1 discussed how the word harm was sometimes inappropriate as it could scare patients, but that also, sometimes scare tactics were required:

"Well, every patient is different so you'll use the word harm if necessary, er, cos it's not one size fits all. So if you think frightening tactics are going to work with somebody you'll use them, um, and then you, you pitch it according to how, how the patient is, is playing it really." (T1)

T2 discussed the use of multiple terminologies depending on who they were talking to:

"Because there's a professional, perhaps… terminology and a patient terminology." (T2)

6.2.5: Outcomes of home healthcare

Four categories of patient-related outcomes were identified: clinical care sensitive outcomes, functional health status, psychosocial outcomes and adverse events, each of which is discussed (see Figure 6.7: Outcomes of healthcare).
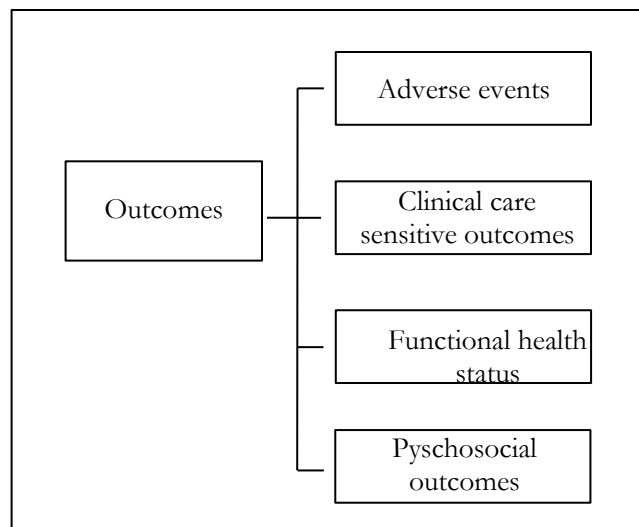
Figure 6.7: Thematic framework for the domain of structure

6.2.5.1: Clinical care sensitive outcomes

Clinical care sensitive outcomes for patients centred on two broad types of clinical outcomes: disease specific outcomes and hospital admissions. CM nurses did not identify disease specific outcomes in relation to patient safety. However, patients and their carers described disease specific outcomes along with how these impacted on other outcomes. For example, CP001 suffers with breathlessness because she has COPD, which she finds very frightening: *"it's not breathing that is one of the most frightening things, is when you can't breathe"* (CP001), resulting in the experience of a negative psychological outcome. The type of disease specific outcomes varied between individuals. For NP001, the colour of her sputum was important to warn of any infection on her chest as a result of her COPD. For NP005, he was interested in his prostate specific antigen, which indicated the seriousness of his prostate cancer. For DP006, it was his vision, which he was losing because of his diabetes. Patients and carers as well as CM nurses identified hospitalisation as a clinical outcome, which was avoided where possible, evidence of which can be found in Table 6.22: Evidence of the avoidance of hospitalisation.

Table 6.22: Evidence of the avoidance of hospitalisation

Patient, carer and CM nurse quotes

"the nurse is what try and keep him out of hospital" (DC003)

"the virtual ward as it's called, do all sorts to stop me going into hospital" (DP003)

"because of all the medication she has been getting…" (CC001)

our key role is to prevent people where clinically possible from going into hospital. (T2)

6.2.5.2: Functional health status

Given the importance allocated to self-care and management as processes of care for patients being case managed, there is evidence to suggest the importance of a person's ability to conduct such activities as a desired outcome of care. Particularly, when the primary aim of the CM programme is to support patients to self-care and manage their own health and disease. Evidence of the importance of self-care and management as processes of care can be found in Appendix 13 and will not be repeated here. One's ability to undertake basic and physical activities as well as activities of daily living is described as functional health status. One component of functional health status that patients specifically identified as an outcome was mobility, and not necessarily ability to walk but ability to get around: *"whilst I can drive the car I can't walk anywhere when I've got out of the car other end, as I say, half lying on a trolley, er I can then cope."* (DP005). Poor mobility, or a lack, of mobility impacted on psychosocial outcomes: *"And she gets frustrated with it."* (DC004). An individual's functional health status could be seen as a measure of how well they can be safe, this was further evidenced by the CM nurses indicating that a patients responsibility for their safety was competency dependent (see section 6.2.2.1 for more information).

6.2.5.3: Psychosocial Outcomes

Patients, carers and CM nurses identified a large range of psychological and social outcomes, which occur as result of their ill health. Examples of the types can be found in Table 6.23.Evidence of psychosocial outcomes.

Table 6.23: Evidence of psychosocial outcomes

Negative psychosocial outcome	Quotes
Depression	*"I think we can contribute unfortunately to depression sometimes, you know umm I guess sometimes we sort of bring up end of life care and people might be in denial and it's difficult to always pitch it right I guess, you know."* (T3)
Embarrassed	*"I found it difficult to get in and out of the bath. If I got in, I couldn't get out and then I'd have to ring somebody and come and get me out of the bath and that was embarrassing."* (NP001)
Frustrated	*(I mean, years ago I used to, I can't do what I used to do and I get very frustrated, like cleaning windows and washing walls. I mean I used to do all that, but I just can't do that now and I do get very frustrated because I can't do all what I used to."* (CP001)
Social outcome	*"Whether they are able to get in or out of the property so that they can go out for their own mental health really."* (T2)
Vulnerable	*"The crooks and the drug crazed people that break into houses, that worries me a bit because I can't do a lot about it if they do."* (DP003)

The detail of each of the outcomes isn't necessarily important. What is important, is that patients do experience poor psychological outcomes and depleting social interactions with their diseases. Similarly to the disease specific outcomes, where insufficient care is not achieving optimum outcomes, unnecessary psychological and social harm could be experienced by the patient. Despite this, some patients experienced feeling grateful. CP001 said she was happy to be alive: *"Well I mean by happy to be alive is when I've seen, I could have been on oxygen on permanently"* (CP001). DP003 expressed similar feelings: *"my dad god bless him, I felt sorry for him lying in a bed in hospital with all his faculties here, and couldn't do nothing, stare at four walls. I've got to be honest, I'm never ungrateful about life, I don't know whether I could cope with that."* (DP003). In the case of CP001 and DP003, both were aware of the possible alternative situations for their conditions and were grateful they do not suffer in that way. The psychosocial outcomes were mostly identified by patients, but some carers did identify specific emotions experienced by their loved one. CM nurses also recognised the

generic mental health of patients as being important. One focus group (T3), discussed how they contributed to the psychological harm of patients by inadvertently enforcing the sick role onto them by being so heavily involved in their care. This discussion can be found in Table 6.24: CM nurse contribution to psychological harm.

Table 6.24: CM nurse contribution to psychological harm

CM nurse discussion

"Yeah I don't think we, I think it'd be hard to say that we sort of harm their social aspect, I can see much more how we harm their, we could harm their psychological aspect if it leads to this."

"I think like NS017 said about the sick ones think we can sometimes reinforce what people can't do or how ill they are inadvertently."

"I agree yeah to help move on."

"Just the fact that we're monitoring them so regularly and, and we tend to umm"

"be focussing on what's wrong with them as opposed to what they can do."

"It can do yeah. Umm it can add to them sort of seeking healthcare, more readily taking less responsibility from themselves, umm and I think we can contribute unfortunately to depression sometimes, you know umm I guess sometimes we sort of bring up end of life care and people might be in denial and it's difficult to always pitch it right I guess, you know. I think our approach you know obviously needs to be different to each patient in terms of discussing some sensitive issues."

6.2.5.4: Adverse events

Adverse events were identified as a safety outcome. Falls were a commonly identified adverse outcome by both patients and carers, for which evidence can be found in Table 6.25: Evidence of falls as an adverse event. A severe consequence of falling appeared to be the fear of repeat falling, which resulted in patients altering their behaviour to try to prevent a reoccurrence. These behaviour changes lead to patients being

more home bound or restricted in the activities they could undertake without supervision, evidence of this can be found in Table 6.26: Evidence of the impact of falls.

Table 6.25: Evidence of falls as an adverse event

Patient and carer quotes

"coming down the stairs her fell down, the last three steps, and it shattered, well when I took her down, err, to the hospital, they found out it had shattered all of her ankle" (DC002)

"the last time I went in was last June because I fell down the stairs before I had the chair and broke my ribs" (CP001)

"I was coming out the shower when I missed the Zimmer frame. I fell back and hit my head on the tiles at the back" (NP005)

Table 6.26: Evidence of the impact of falls

Patient and carer quotes

"I have phases where I can't get out on my own and that's now because I had a lot of falls and I'm frightened to go out on my own. So I do feel safer when I'm in the house." (DP002)

"I'm always frightened of falling down." (DP004)

"Because, I daren't go out without my sticks. I'm frightened of falling." (NP001)

In addition to falls, all three key stakeholder groups identified infection as an unwanted outcome. Some patients described infection as a complication of chronic obstructive pulmonary disease (COPD). For patients with COPD, preventing infections of the chest appeared vital in maintaining a stable health status and preventing hospital admissions. For example, DP003, who suffers with COPD, describes a time where IV antibiotics for a chest infection were given at home by the CM nurse, which prevented him from going into hospital. In addition, he acknowledges that keeping the house clean would reduce his exposure to infection. Other patients, carers and CM nurses described infection as an adverse event rather than a complication of the primary diagnosis of the patient, which is related to hygiene and the condition

of the environment. Evidence of this can be found in Table: 6.27: Evidence of infections as adverse events.

Table 6.27: Evidence of infections as adverse events

Patient, carer and CM nurse quotes

"Well we're, we're a walking infection control risk aren't we if we don't adhere to what we should, our protocols so. (T3)

"Oh definitely, absolutely. I think a clean home is most important. Because many germs, germs don't take prisoners, they don't go, they don't particularise themselves where they go. The germs are everywhere." (NP005)

"Oh gosh, yeah, I mean err, really strictly speaking, if we went to the letter, I don't suppose I should have the dog here." "DP003"

"The house and sanitary conditions, yeah." (T3)

CM nurses briefly identified medicating as a self-care process and the possibility of medication errors (see section 6.2.4.1). However, they recognised that errors that occurred as a result of patients or carers were not reported to their incident reporting system, unlike errors they had committed.

6.3: Areas of further investigation

There are limitations of qualitative research, which raise doubt as to the generalisability of the findings of this study. Consequently, this research adopted an exploratory, sequential, mixed methods design, to increase the validity of the findings by using a survey to question a fourth sample of the population on components of the findings. The purpose of this was to determine their level of agreement, or the extent to which a difference between stakeholders exists. Identified here are the findings that warrant further investigation in the confirmatory quantitative study.

6.3.1: Competing definitions of safety

This chapter has explored in depth, the perspectives of safety in the CM programme of the patients, their carers and CM nurses. In 6.2.1, patients and carers described a definition that was different to the CM nurses. In previous research, the perceptions of safety in various settings have also been shown to differ between key stakeholders (40). Language disparities between patients and carers, and CM nurses could indicate that the terms commonly used by health professionals, and in the literature, such as 'harm' and 'adverse events' are not familiar to patients. The CM nurses implicated that they might contribute to this phenomenon by classifying terminology for patients differently to other health professionals. A disparity in language in a service that is dependent on co-operation and co-production of health outcomes, could cause confusion and make achieving expectations difficult as priorities are misaligned. However, the CM nurses believed that medical terminology could scare patients and be difficult for them to comprehend. Given the divergent definitions described in this study, further examination is required to understand the extent to which these differences exist, and thus will be explored in the quantitative survey in study II.

6.3.2: Identification of responsible stakeholders

The ISMM informed the underlying design of this research. It did so by identifying key stakeholders of the case management programme for engagement, as per the principles of performance measurement. The design of safety measurement is predominantly undertaken by researchers, health professionals and policy makers, rarely by patients, and less so their carers. This study has given a voice to previously unheard key stakeholders. The inclusion of carers in the design of the study is a result of a pilot presentation of the ISSM to a room of case managers studying for a post graduate qualification in long term conditions. They implicated carers as the unsung heroes in the care of this patient population. The participants of this study, regardless of which stakeholder group they were a member of, identified a range of individuals, groups and organisations as having a role to play in ensuring the safety of patients in the case management programme, including: patients; their carers, and CM nurses. However, this study has

been unable to elicit who has the greatest responsibility, not only for patients as the end users of the care service, but those who are facilitators of care, such as carers and CM nurses.

6.3.3: Elements of structure, process and outcome

This study has identified dimensions for each of the structure, process and outcome domains. From this study, it cannot be concluded that this is reflective of the key stakeholders of the CM programme, only for those in this study. It is not possible to determine if all of the components identified here are generalisable, however, it is feasible to examine some. Selection for inclusion in the survey will be based on five criteria:

1. There was overwhelming support and agreement between participants in this study, suggesting that this is relevant for the majority and to what extent, needs to be determined

2. It has previously been identified in other patient safety literature and thus want to know if it adds to the body of evidence

3. The findings seemed counterintuitive to theory, and thus, it is important to determine if there is a new, opposing contribution to knowledge

4. The findings were expressed by only one key stakeholder group and further investigation is required to understand if this is generalisable to that group and whether differences exist between groups

5. There is little or no research to confirm the finding and thus additional measures to this are required

Structures selected for further investigation are presented in Table: 6.28: Structures for further investigation. Processes selected for further investigation are presented in Table 6.29: Processes for further investigation.

Table 6.28: Structures for further investigation

Element (dimension)	Findings selected for further investigation	Justification
Caseload (Working conditions)	The greater the number of patients that a single case manager is responsible for, the greater the risk to patients.	2 & 4
Patient funding (Finances)	Patients who are self-funded are at greater risk of harm than those who are state-funded.	3 & 4
Equipment provision (Equipment)	Adequate equipment provision reduces patient risk and improves safety (equipment such as such as zimmer frames, hand rails etc)	1
Service availability (Services)	The availability of services is important for patient safety. For example the ambulance service, self-care classes and hospital clinics.	1
24 hour case management (Service availability)	A 24 hour case management service would improve patient safety.	2 & 4
Trained staff (Working conditions)	Specifically trained staff reduce risk to patients and increase positive patient outcomes.	2 & 4
Service knowledge (Services)	Knowledge of available services is important for correct and suitable utilisation of services.	4
Clutter (Environment)	Having a less cluttered and tidy environment reduces patient risk and improves safety.	2
Supported communication (Communication infrastructure)	An environment in which communication between key stakeholders is encouraged can support patient safety.	2
Uncooperative carers (carer characteristics)	Uncooperative carers and family members can negatively influence patient care, putting them at risk of poor outcomes.	4
Communication equipment (Communication infrastructure)	Communication equipment such as care lines can reduce risk and improve patient safety.	2 & 1

Table 6.29: Processes for further investigation

Dimension	*Findings selected for further investigation*	*Justification*
Self-care and management	Patients can be safer if they adhere to the care plan (maintain self care).	4
Self-care and management	Patients can be safer if staff adhere to policy and procedure.	4
Self-care and management	By managing medication effectively, patients can be safer.	1 & 2
Self-care and management	Participating in social activities such as visiting friends generates better outcomes (physical, psychological and social).	4 & 5
Communicating	Communication between key stakeholders is important in managing outcomes.	1 & 2
Communicating	Communication between key stakeholders is important in ensuring patients remain safe.	1 & 2
Self-care and management	It is important for patients to have a suitable diet.	4 & 5
Self-care and management	It is important for patients to participate in exercise.	4
Self-care and management	Accepting life with a chronic illness and making adjustments facilitates better outcomes.	4 & 5
Clinical care	The role of the case manager is to empower patients to deliver their own care more effectively.	4 & 2
Self-care and management	Carers are an invaluable resource in managing patient outcomes and safety.	1 & 3

Patient outcomes in this study were classified as: clinical care sensitive; functional health status, psychosocial and adverse events. Each classification has numerous specific outcomes. However, given the small number of participants in this study, a level of significance for individual outcomes cannot be determined. Therefore, participants will be offered a selection of outcomes, which relate to the four dimensions identified above, and asked to rank in order of importance.

6.4: Summary

Study I has accomplished several things:

1. It has described two alternative definitions of safety in home delivered healthcare according to patients and carers, and CM nurse
2. It has confirmed the presence of multiple stakeholders existing in a multilevel nested system complex
3. Provided evidence for the suitability of the structure process and outcome model as domains for safety measurement through the identification of 9 dimensions of structure, 3 core processes and 4 classifications of outcomes
4. Validated the Integrated Safety Measurement Model

Therefore, it can be concluded that this study has met its aims and objectives. In order to determine the level of generalisabililty of the findings, an exploratory, sequential, mixed method design was adopted. Elements for further investigation have been proposed for inclusion in the survey, which is presented in Chapter 6: Study II.

Study II

Quantitative examination of key stakeholder perspectives of safety in healthcare delivered in the home

7.1: Introduction

In Chapter 5, the perspectives of key stakeholders of the case management (CM) programme were explored. However, as indicated in Chapter 4, the small sample size of qualitative research impedes the generalisabililty of the findings. Therefore, a mixed method design was proposed in order to ascertain whether a larger sample of the participant types were in agreement or conflict with the qualitative findings. The aim of this chapter, therefore, is to extend the sample size and triangulate the data using methodological triangulation through the deployment of a quantitative survey. The study protocol was presented in Chapter 5, section 5.3: Study II protocol. Presented here are the findings only. The survey is available in Appendix 11, justification for its content was presented in Chapter 6, section 6.3: Areas of further investigation.

7.2: Results

807 patients were posted the survey with an invite for them and their carers to participate. There were 62 responses:

- 7 responses advised that the patient was deceased

- 3 responses advised that the patient was hospitalised

- 11 responses advised that the patient had moved address

- 7 responses advised that the patient was too unwell to participate

- 35 patients completed the survey

- In addition, 19 carers completed the survey

A patient return rate of 4.3% was achieved for completed surveys with a 7.7% return rate when counting all responses, including non-completed surveys. The return rate for carers cannot be determined, as the (CM) programme does not know how many of its patients have informal carers. 50 CM nurses were invited to participate, 26 completed the survey. A CM nurse return rate of 52% was achieved.

7.2.1: Demographics

The demographic data (resulting from questions 1-6 of the survey) are presented in the following figures:

- Figure 7.1: Percentage of total participants by stakeholder group

- Figure 7.2: Percentage of patient participants with and without an informal carer

- Figure 7.3: Breakdown of participant's gender by stakeholder group
- Figure 7.4: The average age of the participants within each stakeholder group

Percentage of total participants by stakeholder group.
(patient n=35, carer n=19, CM nurse n=26)
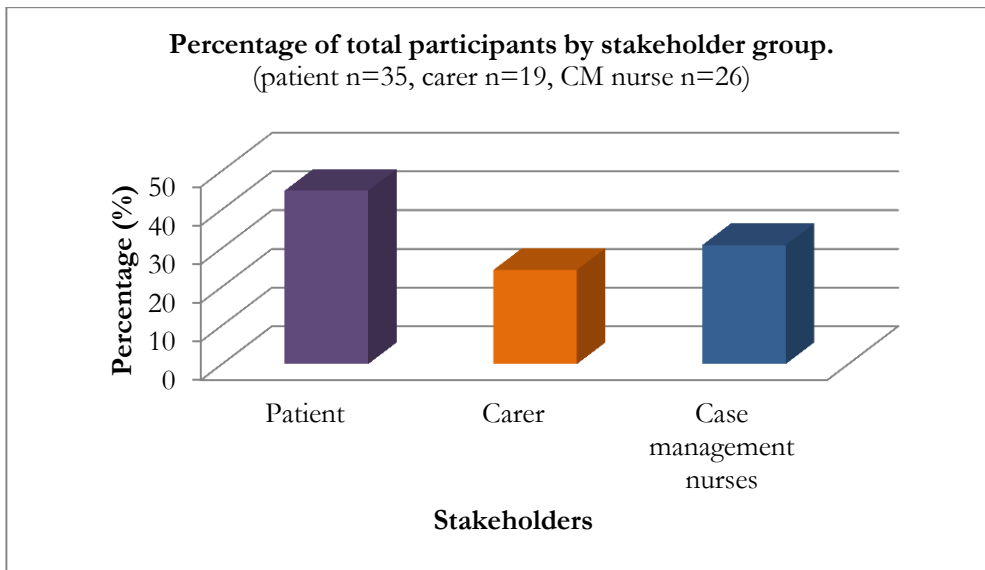
Figure 7.1: Percentage of total participants by stakeholder group

Patient participants represent the largest group (45%), followed by CM nurses (31%) and carers (24%).

Percentage of patient participants with and without an informal carer.
(patient n=35)

with carer   without carer
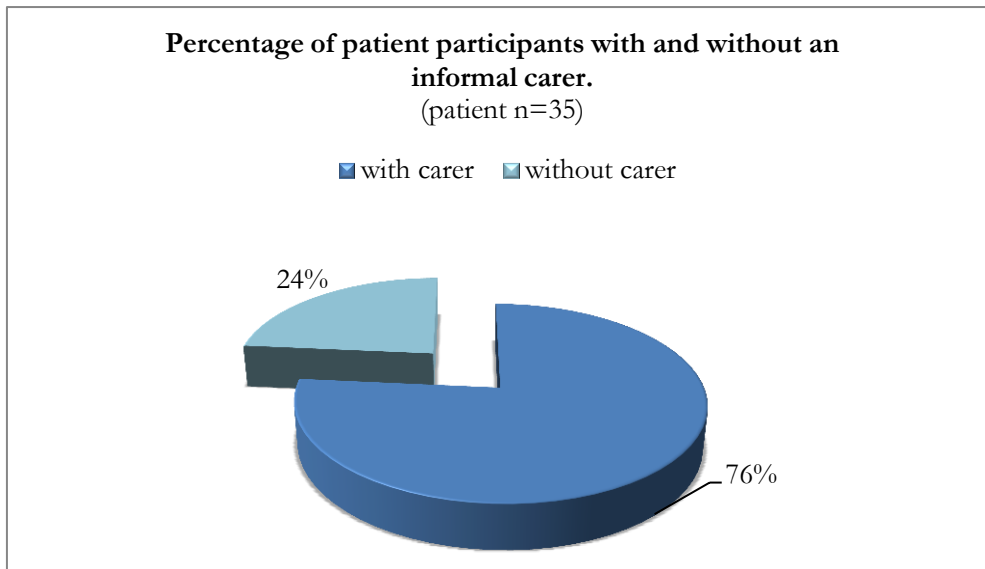
Figure 7.2: Percentage of patient participants with and without an informal carer

More patient participants had informal carers than didn't (76% with to 24% without).
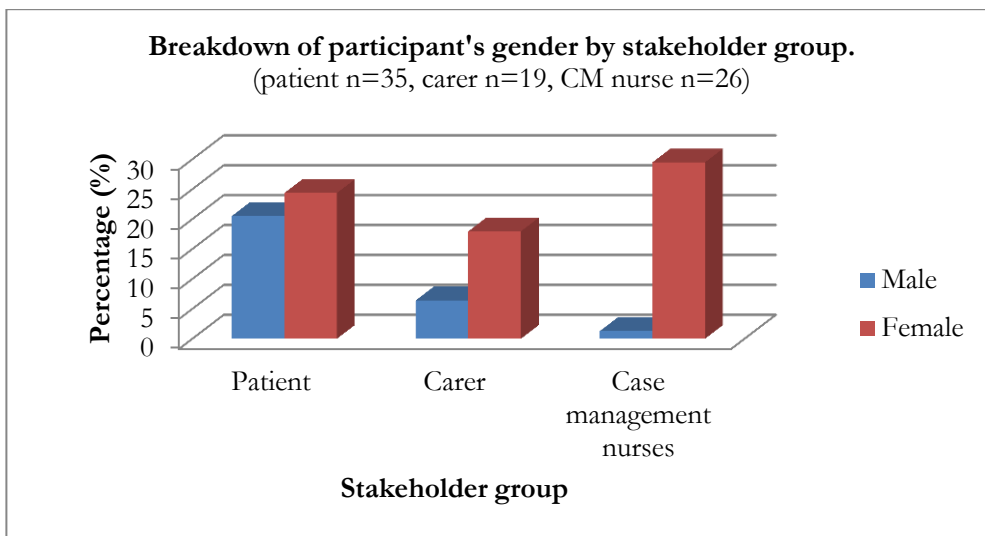
Figure 7.3: Breakdown of participant's gender by stakeholder group.

Across all stakeholder groups, more women responded than men. This was most apparent in the CM nurses responses, which came mostly from women, with only 1% of total responses from men. More female carers responded than men, as did patients but to a lesser degree than carers.
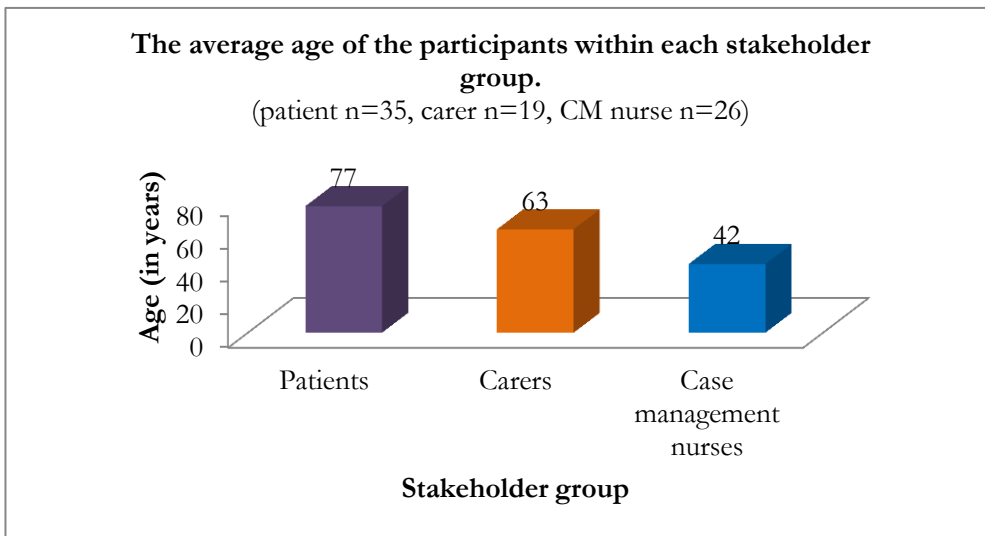
Figure 7.4: The average age of the participants within each stakeholder group

On average, patients were the oldest group of participants, being 14 years older than carers and 35 years older than CM nurses.

7.2.2: Selecting a definition of safety

Question 7 of the survey invited particiants to select from three defitinions of safety. Figure 7.5: Preferred definition of safety by stakeholder group, shows that all three stakeholder groups showed a preference for the patient and carer derived definition. Further descriptions of the data can be found in Figure 7.6: Preferred definition of safety by stakeholder group.

Preferred definition of safety by stakeholder group
(patient n=35, carer n=19, CM nurse n=26)
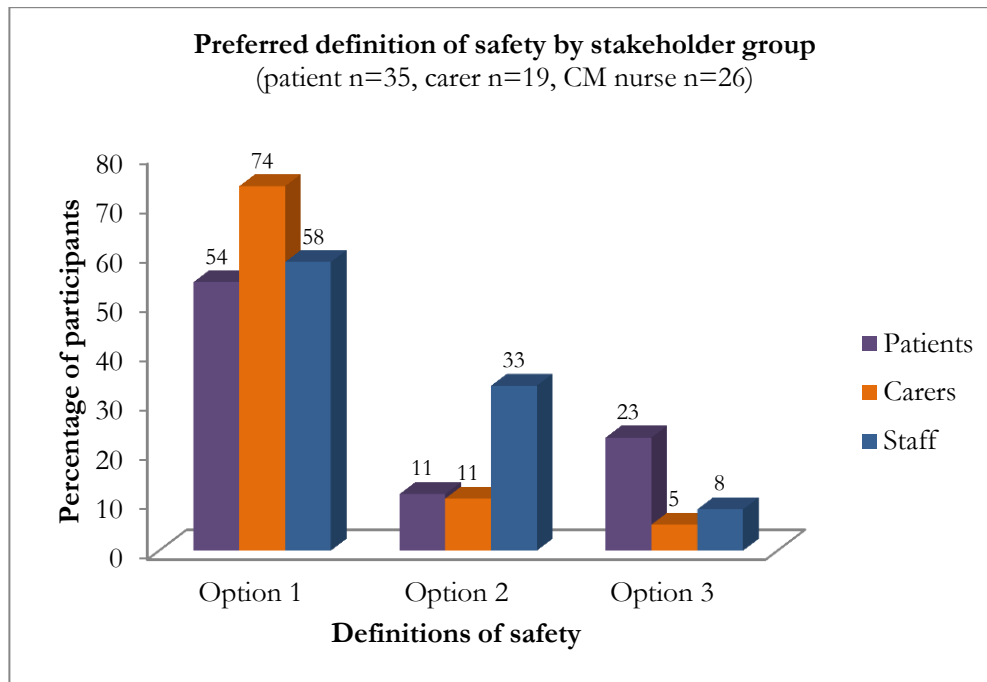
Figure 7.5: Preferred definition of safety by stakeholder group

All three stakeholders showed a preference for the definition derived by patients and carers (option 1) in study I (patients = 54%, carers= 74% and CM nurses = 58%). Second to the patient and carer derived definition, patients then showed preference for the literature definition (option 3) and lastly the CM nurse derived definition (option 2). The CM nurse derived definition was second preference for both carers and CM nurses, followed by the literature derived definition.

Figure 7.6: Total responses (as a percentage) for each definition of safety, indicates a preference for the patient and carer derived definition across all stakeholder groups, with 60% of all participants selecting this definition as being most reflective of their own in relation to home delivered health care.
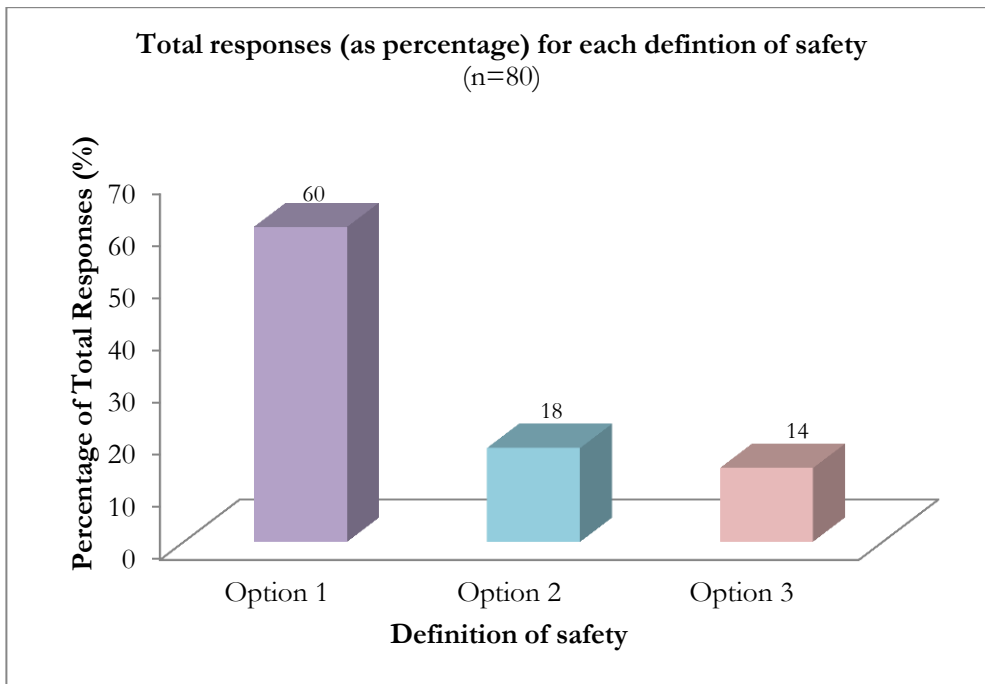
Figure 7.6: Total responses (as a percentage) for each definition of safety

In total, 60% of all respondents indicated that the definition derived from patients and carers (option 1) in study I was the most reflective of their definition of safety in the home. 18% of the total responses selected the CM nurse derived definition of safety (option 2) as most reflective, and 14% selected the literature derived definition (option 3).

7.2.3: Responsibility for key stakeholders

Questions 8, 9 and 10 of the survey invited participants to identify who they perceived to have the greatest responsibility for the safety of each of the key stakeholders (patients, carers and NHS staff). The results for each question are described in the following figures:

- Figures 7.7: Q8. Who do you think has the greatest responsibility for ensuring the safety of patients?

- Figure 7.8: Q9. Who do you think has the greatest responsibility for ensuring the safety of carers?

- Figure 7.9: Q10. Who do you think has the greatest responsibility for ensuring the safety of NHS staff?

Q8. Who do you think has the greatest responsibility for ensuring the safety of patients?
(patient n=35, carer n=19, CM nurse n=26)
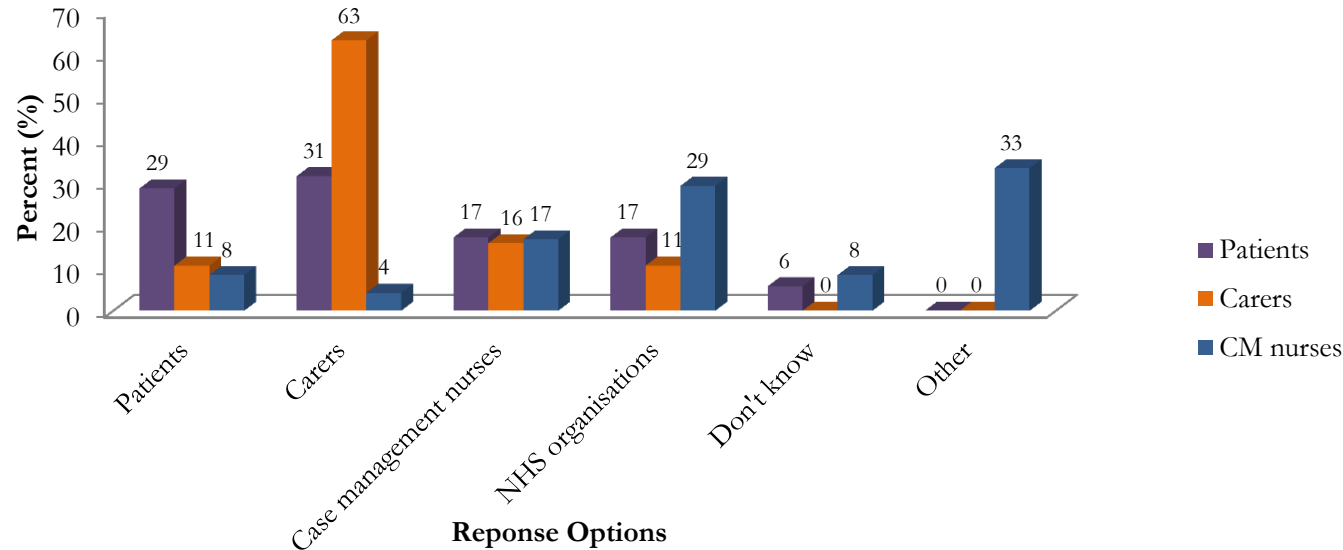
Figure 7.7: Q8. Who do you think has the greatest responsibility for ensuring the safety of patients?

Patients showed no clear preference in response: 29% believed patients to have the greatest responsibility and 31% believed carers have the greatest responsibility. However, 63% of carers believed that they had the greatest responsibility for the safety of patients. Similarly to patients, CM nurses showed no clear preference for who had the greatest responsibility, however, their responses were more heavily split between the NHS organisation (29%) and 'other' options (33%), with only 8% indicating patients and 4% indicating carers as being ultimately responsible for patient safety.
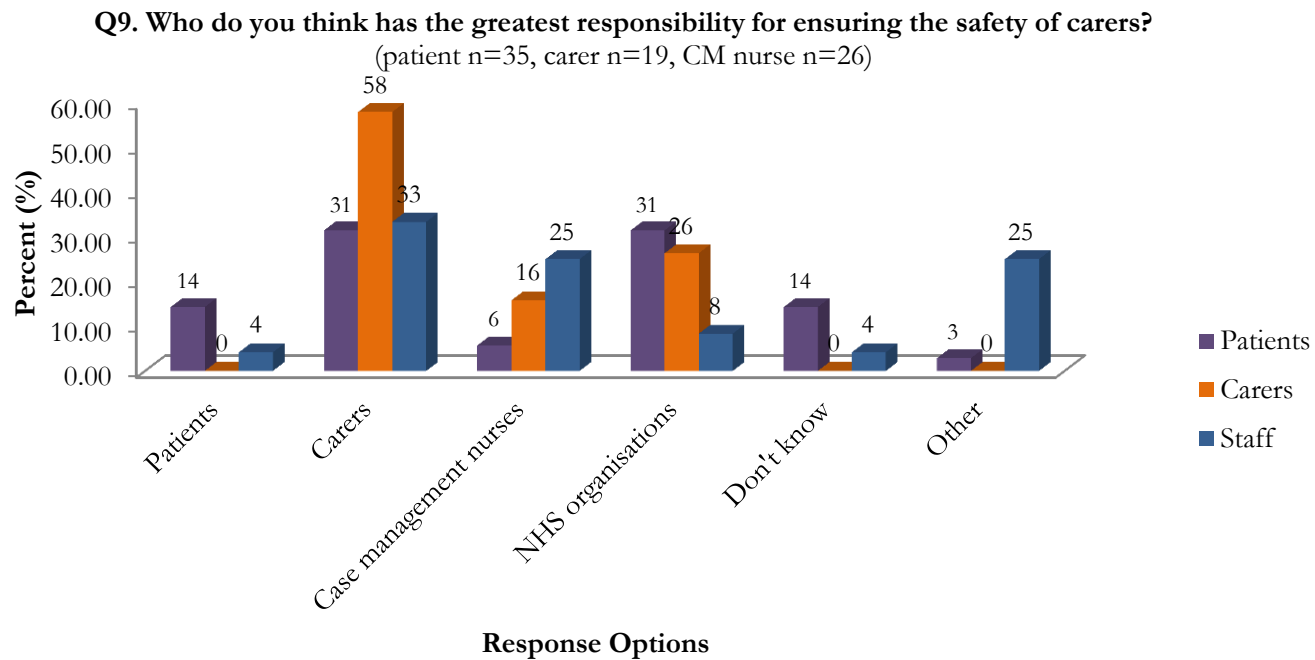
Q9. Who do you think has the greatest responsibility for ensuring the safety of carers?
(patient n=35, carer n=19, CM nurse n=26)

Figure 7.8: Q9. Who do you think has the greatest responsibility for ensuring the safety of carers?

Carers were the only stakeholder group to indicate a majority response; 58% of carers believed carers had the greatest responsibility for their own safety. Patients showed no clear preference in response, with 31% indicating carers as being most responsible and another 31% indicating NHS organisations. 14% of patients answered that they did not know. 33% of CM nurses believed carers to have the greatest responsibility, which was similar to the opinion of patients, but 25% indicated CM nurses as being most responsible and 25% responded 'other'.

Q10. Who do you think has the greatest responsibility for ensuring the safety of NHS staff?
(patient n=35, carer n=19, CM nurse n=26)
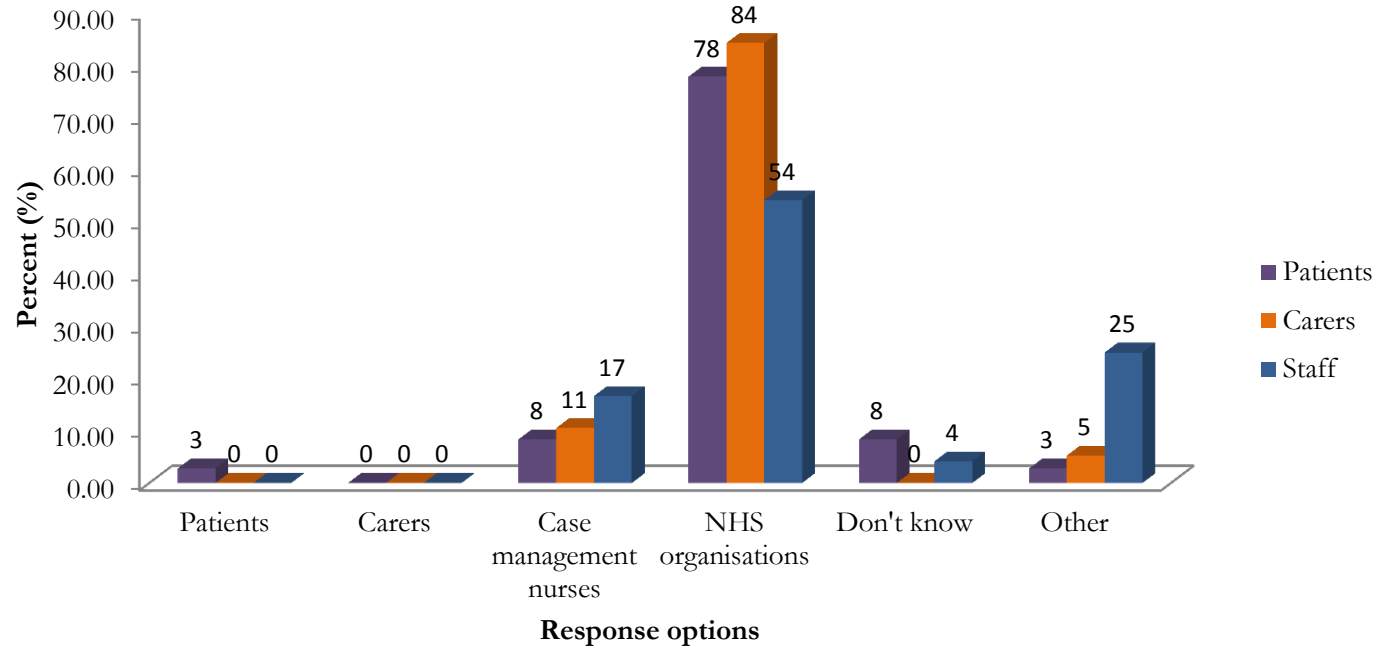
Figure 7.9: Q10. Who do you think has the greatest responsibility for ensuring the safety of NHS staff?

Patients, carers and CM nurses all indicated the NHS organisation as having the greatest responsibility for NHS staff (78%, 84% and 54% respectively). 25% of CM nurses selected the 'other' response.

In summary, stakeholder groups did not achieve agreement on who was most responsible for the safety of patients and carers. In relation to the safety of staff, NHS organisations were perceived to have the greatest responsibility.

7.2.4: Elements of structure

The results, in the format of percentages, for all questions relating to structure (11-21) can be found in Appendix 15: Results for questions relating to structure (questions 11-21). The results for each question are graphically presented in the following figures and text.

Q11. The greater the number of patients that a single case manager is responsible for, the greater the risk to patients.
(patient n=35, carer n=19, CM nurse n=26)

Figure 7.10: Q11. The greater the number of patients that a single case manager is responsible for, the greater the risk to patients

76% of patients, 89% of carers and 67% of CM nurses agreed or strongly agreed that the greater the number of patients that a case manager is responsible for, the greater the risk to patients. 9% of patients and 8% of CM nurses disagreed or strongly disagreed, but no carers disagreed. 8% of patients, 5% of carers and 21% of CM nurses neither agreed nor disagreed.

Q12. Patients who are self-funded are at greater risk of harm than those who are state-funded.
(patient n=35, carer n=19, CM nurse n=26)
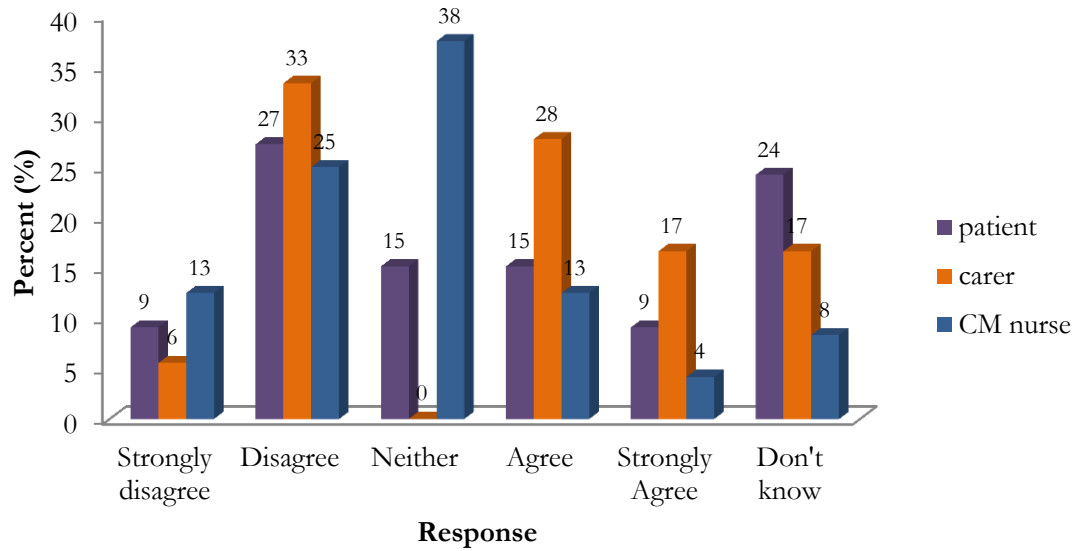
Figure 7.11: Q12. Patients who are self-funded are at greater risk of harm than those who are state funded

There was no clear agreement from the stakeholder groups about whether patients who are self-funded are at greater risk of harm than those who are state-funded In fact, more patients and more CM nurses disagreed (disagreed and strongly disagreed) than agreed (agreed and strongly agreed).

Q13. Adequate equipment provision reduces patient risk and improves safety (equipment such as such as zimmer frames, hand rails etc).
(patient n=35, carer n=19, CM nurse n=26)
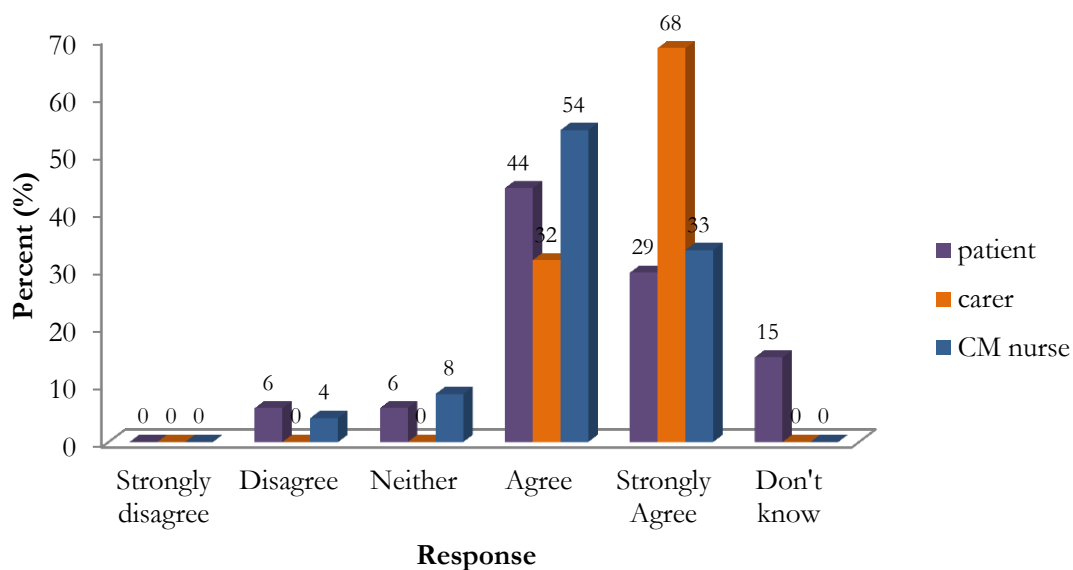
Figure 7.12: Q13. Adequate equipment provision reduces patient risk and improves safety

74% of patients, 100% of carers and 86% of CM nurses either agreed or strongly agreed that adequate equipment provision reduces patient risk and improves safety. 15% of patients did not know the answer and 6% of patients and 4% of CM nurses disagreed.

Q14. The availability of services is important for patient safety. For example the ambulance service, self-care classes and hospital clinics.
(patient n=35, carer n=19, CM nurse n=26)
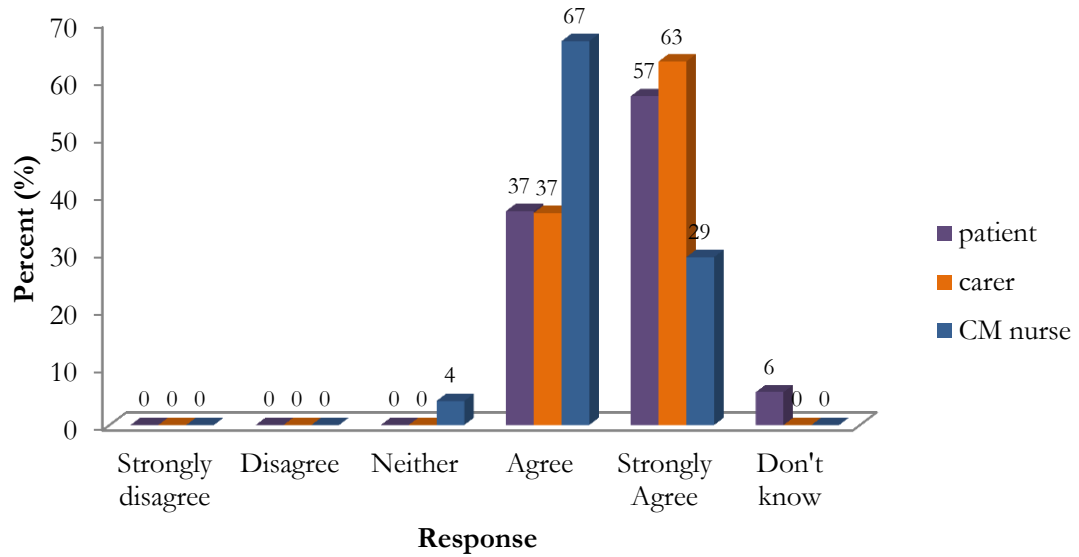
Figure 7.13: Q14. The availability of services is important for patient safety.

The availability of services was considered important by 94% of patients, 100% of carers and 96% of CM nurses, indicated by an agree, or strongly agree response.

Q15. A 24 hour case management service would improve patient safety.
(patient n=35, carer n=19, CM nurse n=26)
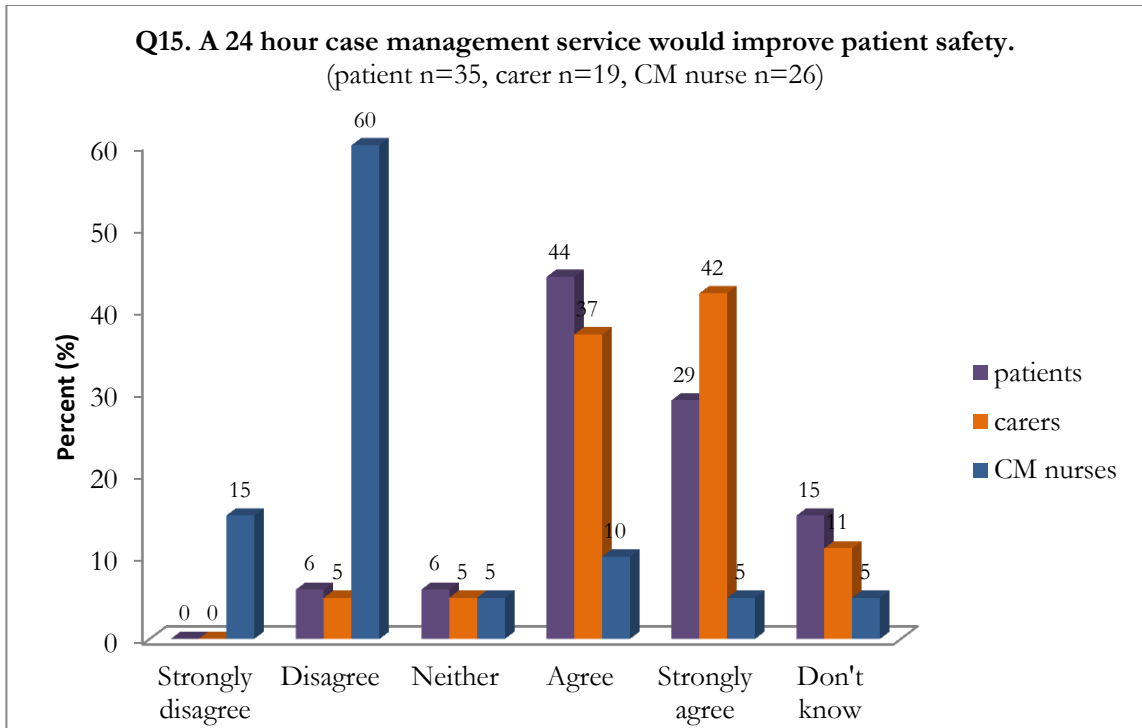
Figure 7.14: Q15. A 24 hour case management service would improve patient safety.

The importance of a 24 hours case management programme for the safety of patients generated contrasting responses from the key stakeholders. CM nurses indicated a preference to disagree with this statement, with 60% disagreeing and 15% strongly disagreeing (75% in total disagreed). Contrastingly, 77% of patients and 79% of carers either agreed or strongly agreed that a 24 hour case management service would improve the safety of patients.

It can be seen from the evidence provided, that patients and carers, by giving a majority response in agreement with the statement, believe that a 24 hour case management service would improve patient safety. In contrast, CM nurses disagree.
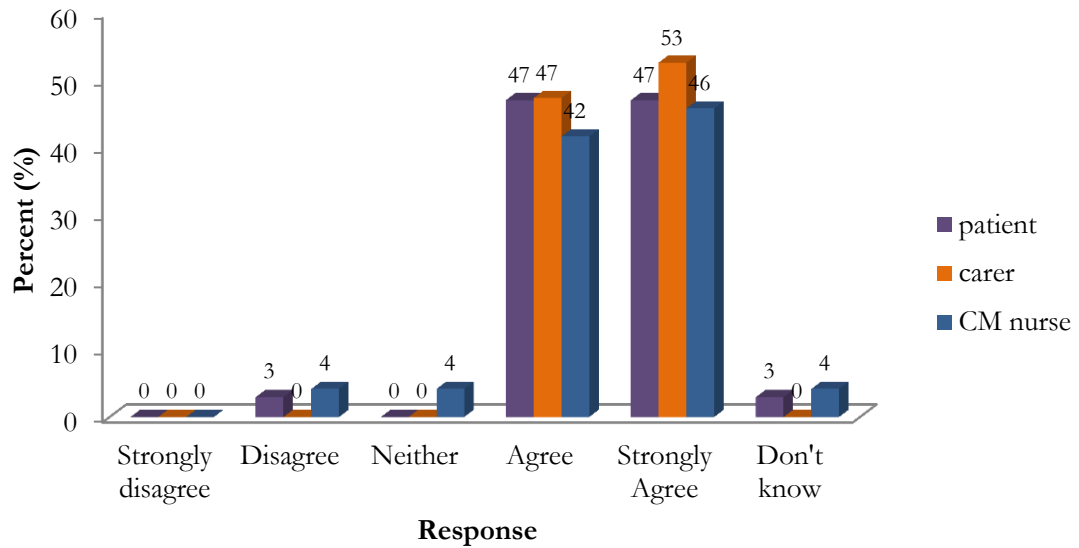
Figure 7.15: Q16.Specifically trained staff reduce the risk to patients and increase positive patient outcomes

General agreement was obtained that specifically trained staff reduce the risk to patients and increase positive outcomes. 94% of patients, 100% of carers and 86% of CM nurses either agreed or strongly agreed.

Q17. Knowledge of available services is important for correct and suitable utilisation of services.

(patient n=35, carer n=19, CM nurse n=26)
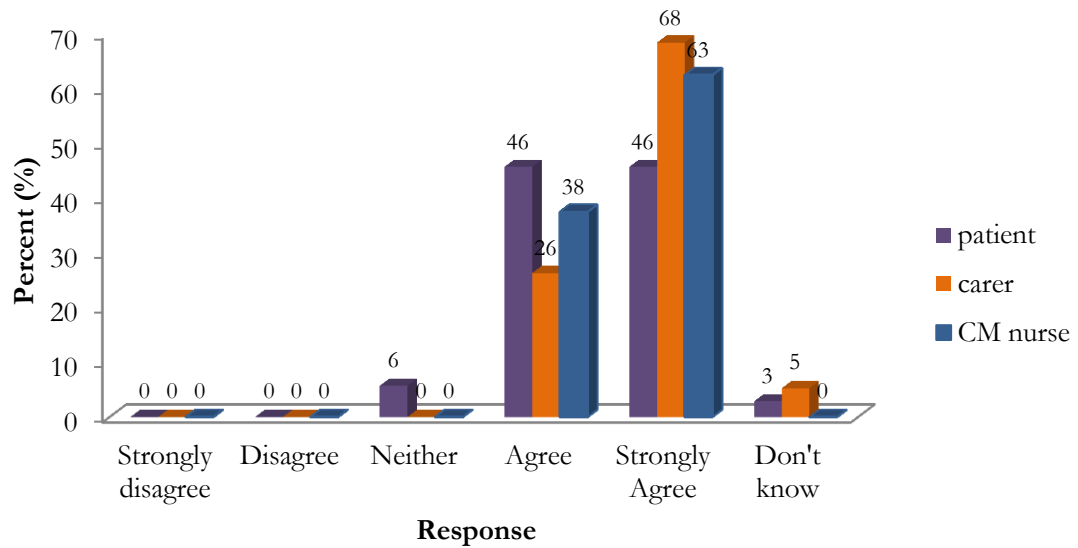
Figure 7.16: Q17.Knowledge of available services is important for correct and suitable utilisation of services

General agreement was obtained that knowledge of services is important for their suitable and correct utilisation. 91% of patients agreed or strongly agreed, as did 94% of carers and 100% of CM nurses. 3% and 5% of patients and carers respectively did not know the answer.

Q18. Having a less cluttered and tidy environment reduces patient risk and improves safety.
(patient n=35, carer n=19, CM nurse n=26)
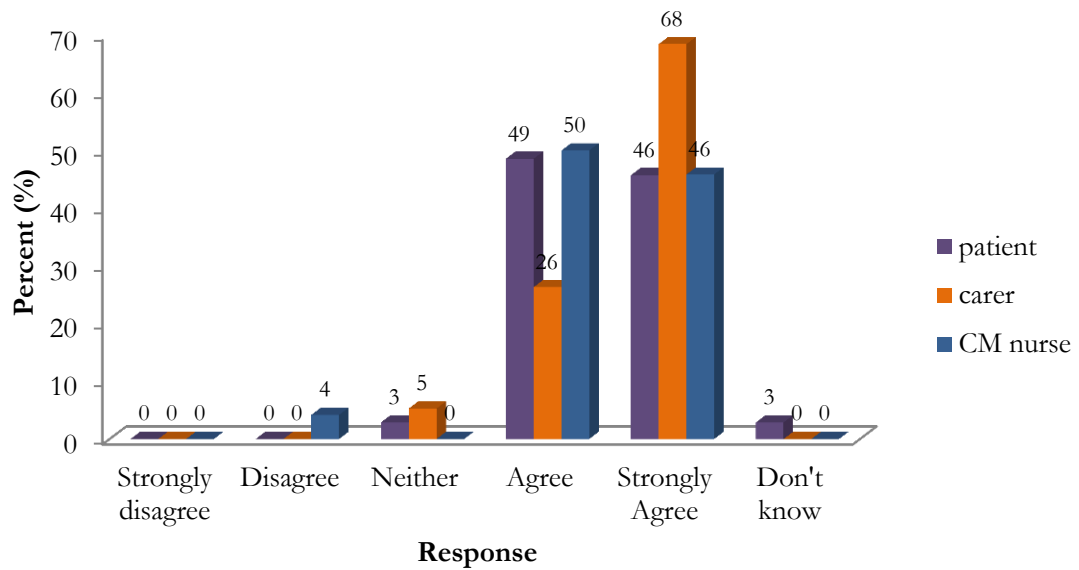
Figure 7.17: Q18. Having a less cluttered and tidy environment reduces patient risk and improves safety

Across all participants, the general consensus was with agreement. 94% of patients, 95% of carers and 96% of CM nurses either agreed or strongly agreed that having a less cluttered and tidy environment reduces patient risk and improves safety. 3% of patients did not know the answer and 4% of CM nurses disagreed.

Q19. An environment in which communication between key stakeholders is encouraged can support patient safety.
(patient n=35, carer n=19, CM nurse n=26)
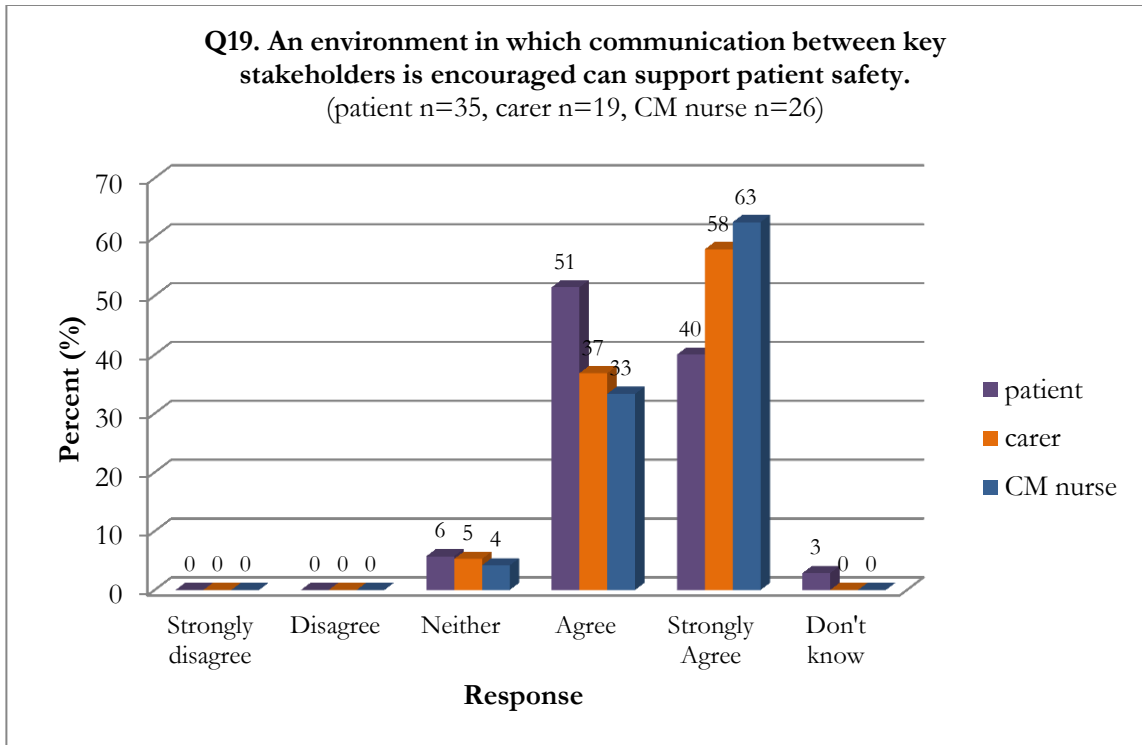
Figure 7.18: Q19. An environment in which communication between key stakeholders is encouraged can support patient safety

3% of patients did not know if an environment in which communication between key stakeholders is encouraged can support patient safety. However, 91% of patients either agreed or strongly agreed that it did, as did 95% of carers and 96% of CM nurses.

Q20. Uncooperative carers and family members can negatively influence patient care, putting them at risk of poor outcomes.
(patient n=35, carer n=19, CM nurse n=26)
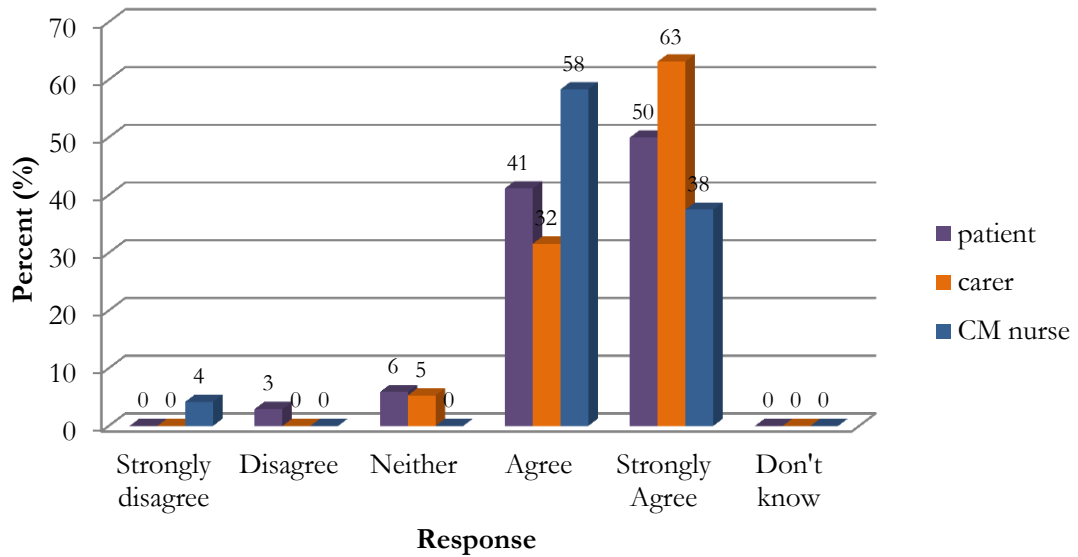
Figure 7.19: Q20. Uncooperative carers and family members can negatively influence patient care, putting them at risk of poor outcomes

4% of CM nurses strongly disagreed and 3% of patients disagreed that uncooperative carers and family members can negatively influence patient care, putting them at risk of poor outcomes. However, 96% of CM nurses and 91% of patients either agreed or strongly agreed, as did 95% of carers.
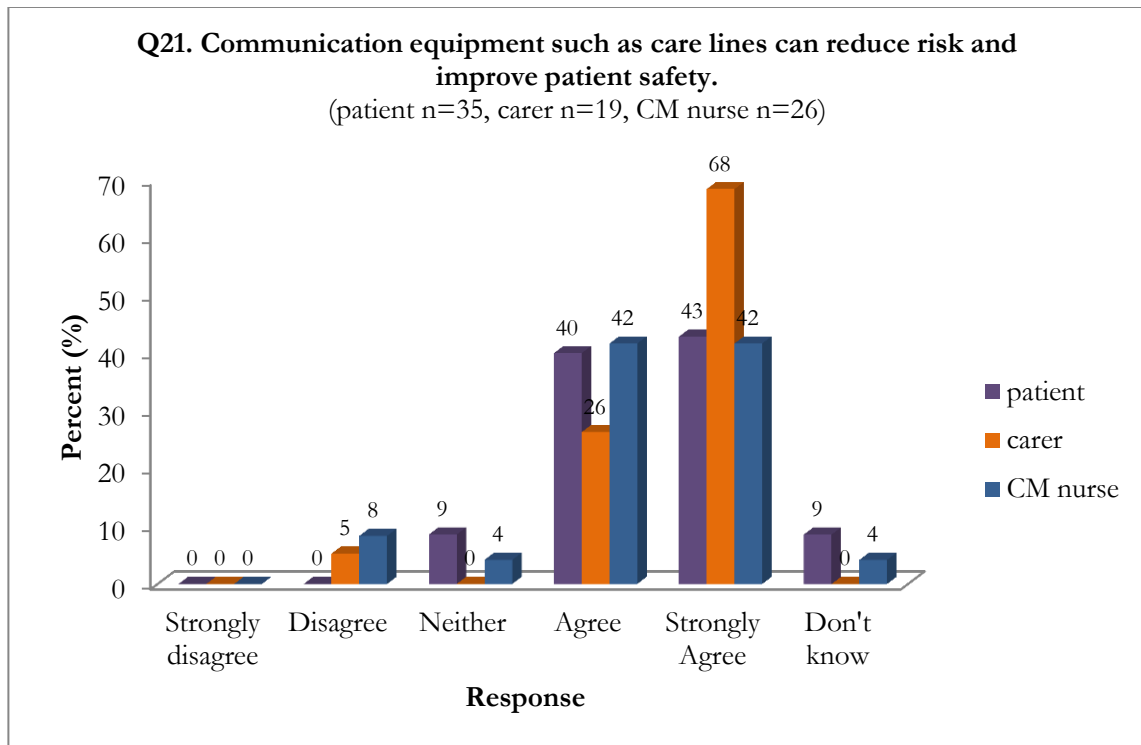
Figure 7.20: Q21. Communication equipment such as care lines can reduce risk and improve patient safety

9% of patients and 4% of CM nurses did not know if communication equipment such as care lines can reduce risk and improve patient safety and 8% of CM nurses and 5% of carers disagreed. Despite this, the majority of patients (83%), carers (95%) and CM nurses (83%) either agreed or strongly agreed.

In summary, when the responses were aggregated into agreed or disagreed, agreement was achieved on the following ten questions:
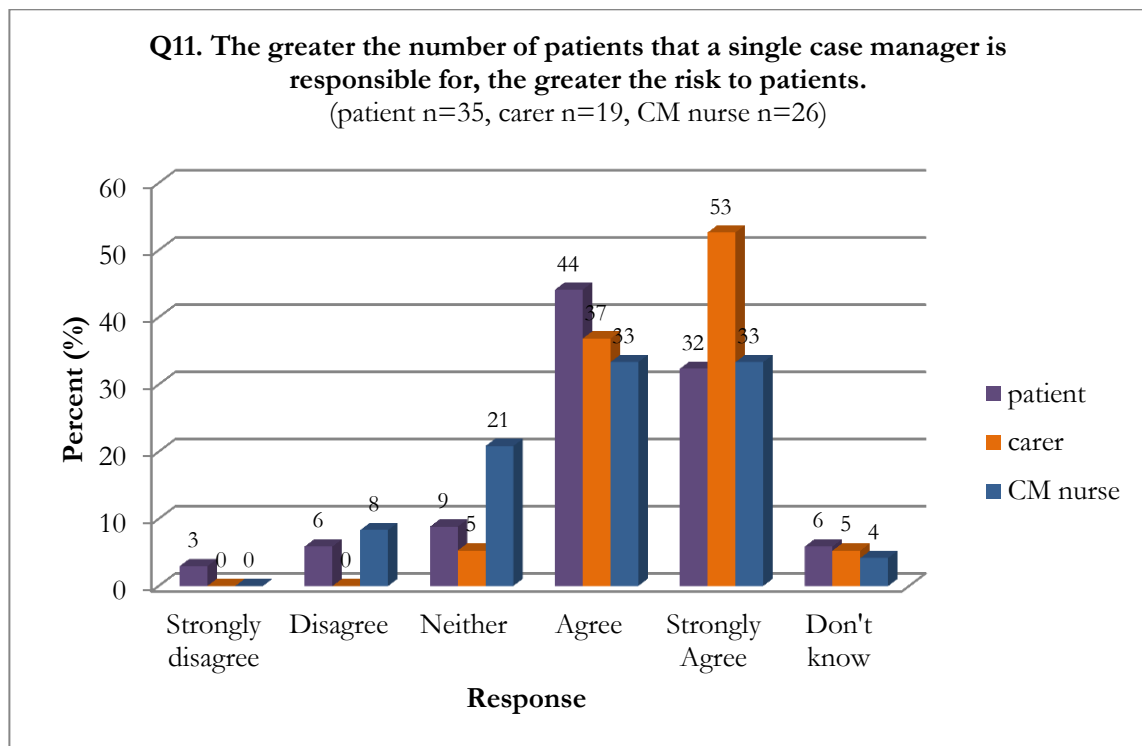
- Q11. The greater the number of patients that a single case manager is responsible for, the greater the risk to patients.

- Q13. Adequate equipment provision reduces patient risk and improves safety (equipment such as such as zimmer frames, hand rails etc)

- Q14. The availability of services is important for patient safety. For example the ambulance service, self-care classes and hospital clinics.

- Q15. A 24 hour case management service would improve patient safety.

- Q16. Specifically trained staff reduce risk to patients and increase positive patient outcomes.

- Q17. Knowledge of available services is important for correct and suitable utilisation of services.

- Q18. Having a less cluttered and tidy environment reduces patient risk and improves safety.

- Q19. An environment in which communication between key stakeholders is encouraged can support patient safety.

- Q20. Uncooperative carers and family members can negatively influence patient care, putting them at risk of poor outcomes.

- Q21. Communication equipment such as care lines can reduce risk and improve patient safety.

For question 12, concerning whether being self-funded influences patient safety, no majority was achieved, although more participants disagreed than agreed (37% to 27%). The remaining participants either expressed indifference (19%) or did not know (17%). Although question 15 achieved a majority agreement, the responses were clearly split between stakeholder types (see Figure 7.14), and therefore should be considered with prudence. A summary of the total findings in relation to agreement and disagreement can be found in Figure 7.21: Disagree and agree aggregated responses for all stakeholder groups for questions 11 to 21.
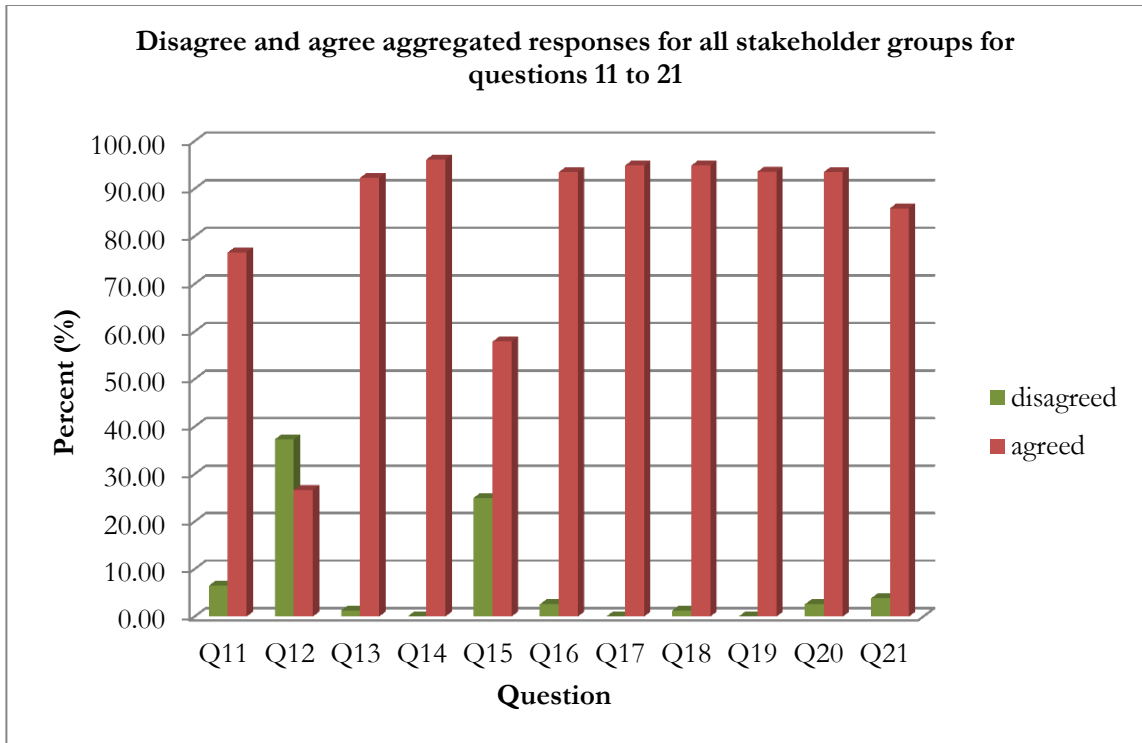
Figure 7.21: Disagree and agree aggregated responses for all stakeholder groups for questions 11 to 21.

In all questions except 12, a majority of participants were in agreement with the findings from study I, which were presented as statements in this survey.

7.2.5: Elements of Process

The results, in the format of percentages, for all questions relating to process (questions 23-33) can be found in Table 7.8: Results for questions relating to process (questions 23 to 33). In conclusion, all statements had a high level of agreement (either agreed or strongly agreed) across all participants.

Table 7.1: Results for questions relating to process (questions 23 to 28)

Question	Stakeholder	Strongly disagree	Disagree	Neither	Agree	Strongly Agree	Don't know
23 Patients can be safer if they adhere to the care plan (maintain self care).	patient	0%	3%	3%	66%	23%	5%
	carer	0%	0%	11%	63%	26%	0%
	CM nurse	0%	4%	25%	54%	17%	0%
24. Patients can be safer if staff adhere to policy and procedure.	patient	0%	6%	3%	66%	25%	0%
	carer	0%	11%	11%	39%	39%	0%
	CM nurse	0%	0%	13%	58%	29%	0%
25. By managing medication effectively, patients can be safer.	patient	0%	0%	6%	54%	40%	0%
	carer	0%	0%	0%	42%	53%	5%
	CM nurse	0%	0%	4%	46%	50%	0%
26. Participating in social activities such as visiting friends generates better outcomes (physical, psychological and social).	patient	0%	0%	3%	50%	44%	3%
	carer	0%	0%	5%	47%	48%	0%
	CM nurse	0%	0%	4%	50%	46%	0%
27.Communication between key stakeholders is important in managing outcomes.	patient	0%	0%	0%	51%	37%	11%
	carer	0%	0%	5%	32%	63%	0%
	CM nurse	0%	4%	0%	38%	58%	0.
28. Communication between key stakeholders is important in ensuring patients remain safe.	patient	0%	0%	0%	49%	42%	9%
	carer	0%	0%	5%	26%	69%	0%
	CM nurse	0%	0%	0.0%	42%	58%	0%

Table 7.2: Results for questions relating to process (questions 29 to 33)

Question	Stakeholder	Strongly disagree	Disagree	Neither	Agree	Strongly Agree	Don't know
29. It is important for patients to have a suitable diet.	patient	0%	0%	0%	51%	49%	0%
	carer	0%	0%	0%	47%	53%	0%
	CM nurse	0%	0%	4%	46%	50%	0%
30. It is important for patients to participate in exercise.	patient	0%	0%	6%	61%	33%	0%
	carer	0%	0%	11%	63%	26%	0%
	CM nurse	0%	4%	13%	62%	21%	0%
31. Accepting life with a chronic illness and making adjustments facilitates better outcomes.	patient	3%	3%	3%	57%	31%	2.86%
	carer	0%	0%	11%	42%	42%	5%
	CM nurse	0%	4%	13%	50%	33%	0%
32. The role of the case manager is to empower patients to deliver their own care more effectively.	patient	3%	0%	6%	53%	24%	15%
	carer	0%	5%	11%	47%	26%	11%
	CM nurse	0%	0%	8%	33%	58%	0%
33. Carers are an invaluable resource in managing patient outcomes and safety.	patient	0%	6%	3%	41%	50%	0%
	carer	0%	0%	0%	42%	58%	0%
	CM nurse	0%	4%	0%	38%	58%	0%

In order to visually represent the level of agreement and disagreement with each of the statements, the disagree and strongly disagree responses were aggregated, and the agree and strongly agree responses were aggregated and are presented as a bar chart in Figure 7.22: Disagree and agree aggregated responses for all stakeholder groups for questions 23 to 33.

Figure 7.22: Disagree and agree aggregated responses for all stakeholder groups for questions 23 to 33

When data is aggregated for all stakeholder groups, agreement is achieved at 75% or higher in every statement. Disagreement occurs in no more than 5% of the sample.
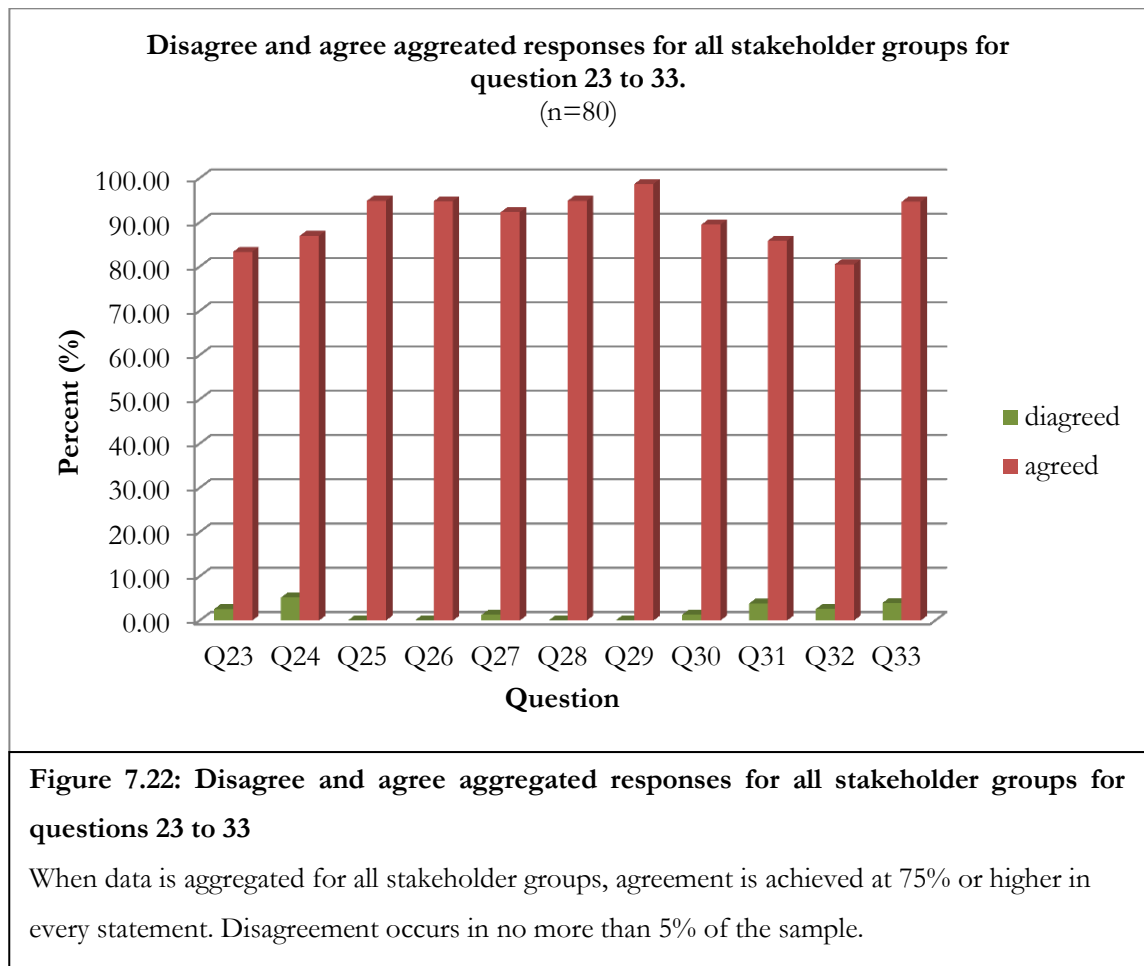
In summary, overall agreement was achieved with each of the 11 statements relating to elements of process.

7.2.6: Elements of outcome

Question 35 asked respondents to rank, in order of importance, 15 outcomes (35.1-35.15). Analysis has been conducted on ranks 1, 2 and 3 (the three most important outcomes). It is important to note, that in the free text (question 36), respondents repeatedly commented that it was difficult to assign a level of importance to each outcome, as they were all important. Therefore, not all participants completed question 35 (patients = 7, carers =3 and CM nurses = 4 did not complete this question). The data is presented and summarised in the following figures.

Outcomes ranked 1st by stakeholder group.
(patient n=28, carer n=16, CM nurse n=21)
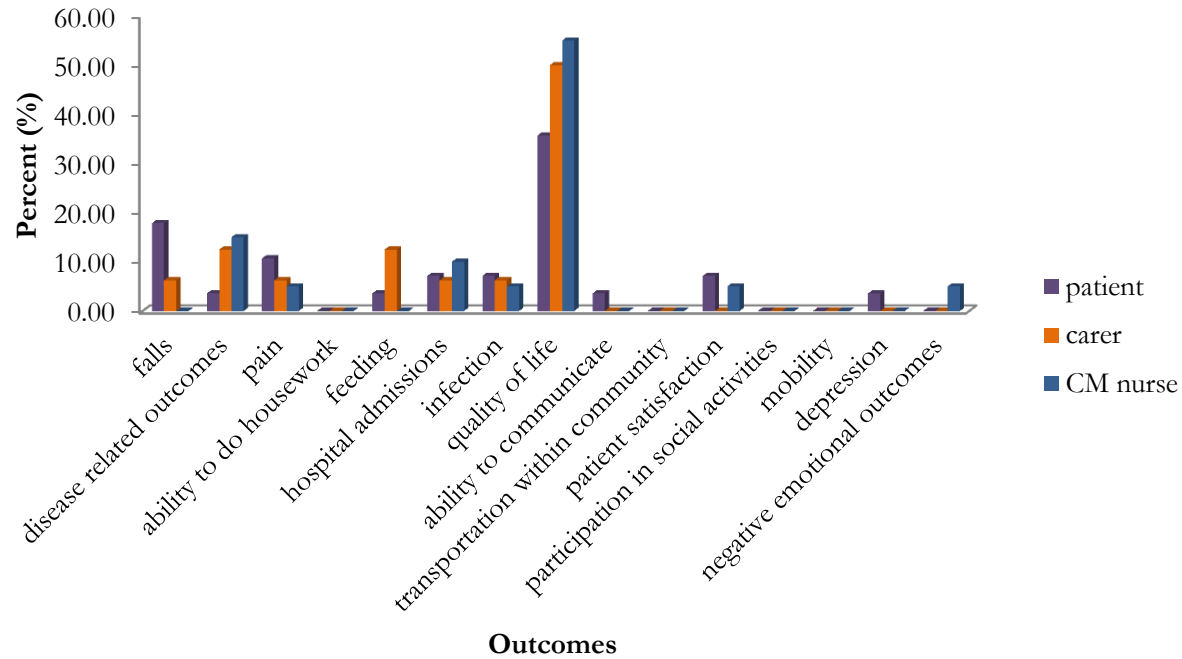
Figure 7.23: Outcomes ranked 1st by stakeholder group

Quality of life was the outcome most commonly ranked 1st by all stakeholder groups. For CM nurses, quality of life was followed by disease related outcomes (15%) and hospital admissions (10%). For patients, the next most popular 1st choices were falls followed by pain. For carers, it was disease related outcomes followed by feeding.

A comparison of outcomes ranked 1st, 2nd and 3rd (aggregated) by stakeholder group.
(patient n=28, carer n=16, CM nurse n=21
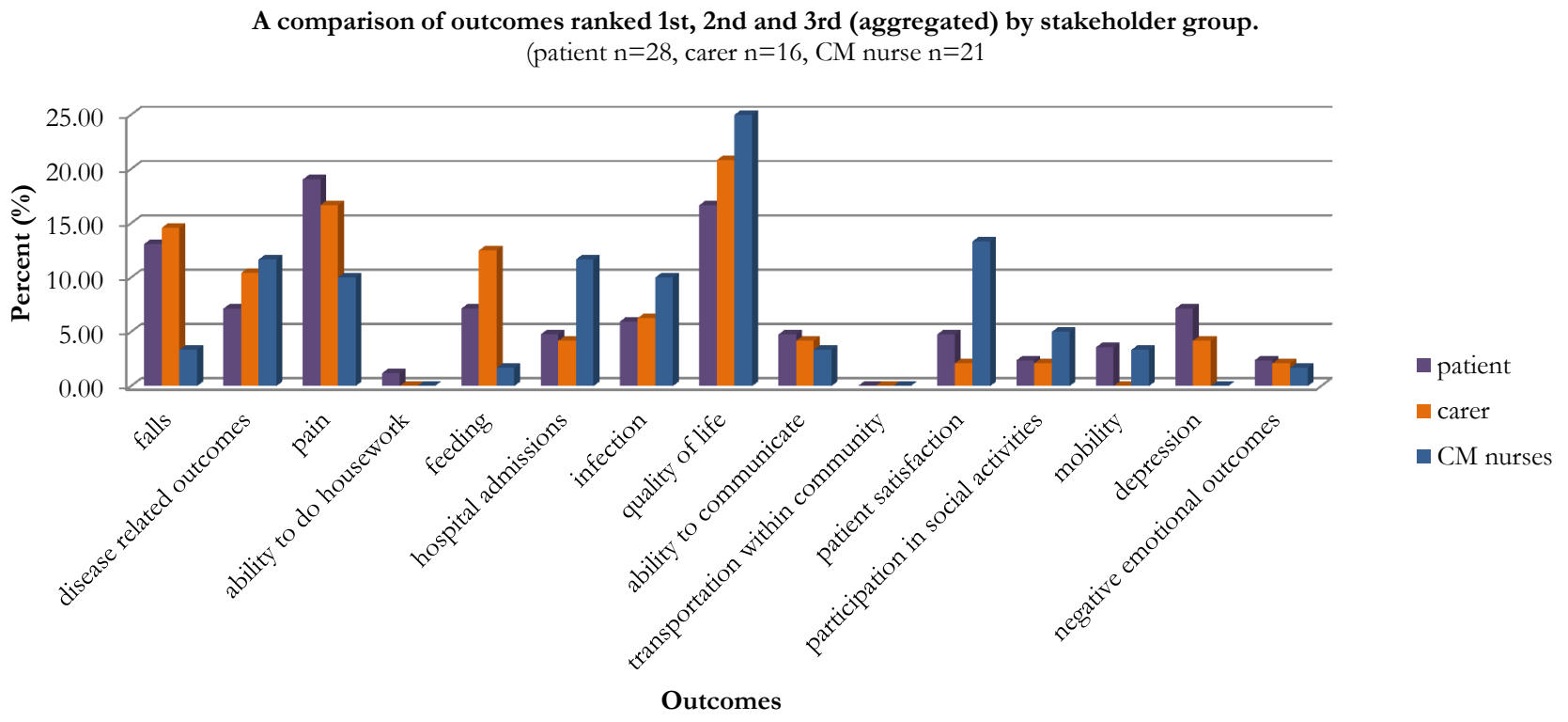
Figure 7.24: A comparison of outcomes ranked 1st, 2nd and 3rd (aggregated) by stakeholder group

When aggregating the data for the top 3 most important outcomes, quality of life remains the most popular for both CM nurses and carers. However, patients more favourably rank pain, followed by quality of life and then falls.

7.3: Summary

Using methodological triangulation, Study II has been able to identify where participants agreed or disagreed with the findings of study I. Patients, carers and CM nurses have indicated a preference for the patient and carer derived definition of safety. This study has been unable to determine who is perceived to be most responsible for the safety of patients and carers, however it was able to implicate the NHS organisation as being responsible for the CM nurses. For the majority, patients, carers and CM nurses agreed with the statements on structure and process derived from study I. With the exception of self-funded patients being at greater risk, with which, patients, CM nurses and to a lesser extent carers, disagreed. Also, CM nurses did not agree that a 24 hour case management service would improve safety, unlike patients and carers. Quality of life was the most important outcome as indicated by all stakeholder groups. Explanations of these findings and further discussion are available in Chapter 8.

Chapter 8

Discussion

8.1: Introduction

An analysis of the safety measurement literature in Chapter 2 identified a series of limitations that rendered the majority of widely used measurement methods as counts of harm, rather than measures of safety. In some cases, these methods were useful as epidemiological tools or to facilitate the execution of further improvement processes, such as root cause analysis, through the identification of error and harm. However, the focus of these tools on the sharp end of the system, on outcomes, limits the understanding one can derive of the cause of harm and/or error. Consequently, the methods measure past performance and lack any predictive capability. Performance measurement suggests that the measurement of determinants of outcomes boosts predictive capabilities and should be devised in collaboration with stakeholders, including consumers. This research, therefore, aimed to describe a framework for safety measurement for the NHS case management (CM) programme that is reflective of key stakeholder perspectives. The objectives of this research were to:

6. Create a model that identified the key stakeholders of the CM programme and overarching domains for measurement to inform the research design

7. Validate the model

8. Explore the concept of safety from the stakeholders' perspectives

9. Understand what it means to be safe in the home for the key stakeholders of this patient group and determine desired outcomes and influencing factors

10. Devise a safety performance assessment framework that manifests the perspectives of the key stakeholders

The purpose of this chapter is to critically interpret the findings in relation to the literature and understand what contribution this research has made. In doing so, and in line with the proposed aim and objectives, this chapter will present a previously unknown understanding of safety in the CM programme. From this new understanding, validation of a model to aid in the design of measurement systems will be achieved, along with a proposal of an alternative definition of safety and the construction of a conceptual framework for safety measurement in the CM programme.

8.2: Understanding patient safety in the case management programme

In exploring the key stakeholders' perspectives of safety in the CM programme, a new understanding of safety has been achieved. An alternative definition of patient safety in home delivered healthcare has been proposed, extensive outcomes identified, processes inclusive of the patient determined, and structures across the whole system have been established.

8.2.1: An alternative definition for patient safety in home delivered healthcare

The exploration of the different stakeholders' perspectives of safety in study I resulted in the construction of two different definitions of safety: one derived from the patients and carers (jointly) and one derived from the CM nurses. CM nurses and patients and carers shared the belief that risk reduction was a component of safety. However, beyond this, their definitions of safety differed.

The CM nurse definition of safety: ***safety is the prevention of harm through risk reduction and compliance with procedure or care plan. There is inherent risk in healthcare: it will not be harm free.***

The patient and carer definition of safety: **safety is the meeting of complex care needs to generate positive clinical, physical, psychological and social outcomes and the reduction of risk of negative outcomes. Patients and carers can actively participate in efforts to be safe in addition to healthcare provider contributions.**

The CM nurses definition of safety is similar to the definition found in the academic literature and health policy documents. The CM nurses make reference to adhering to procedure or care plan, which is also found in the Davies et al. (18) definition of patient safety: *'…use of best practices shown to lead to optimal patient outcomes.'* (18)pg12. The CM nurses also acknowledge the infeasibility of an environment in which no harm occurs. This reflects the Runciman et al. (9) definition, which describes safety as the *'reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum'* (9)pg19. Given that nurses are educated using academic literature, and their daily work activities are dictated by policy, it is unsurprising that the CM nurses' definition of safety resembles those available in the literature.

Patients and carers, however, describe safety from an alternative perspective as a condition of positive outcomes, rather than the avoidance of negative outcomes. Patients and carers consider the meeting of patients' needs a component of safety, which is more traditionally aligned with the definition of quality. For example, Lord Darzi (147) describes the *effectiveness of care* dimension of quality, noting that it *'may extend to people's well-being and ability to live independent lives'* (147)pg47, whereas the definition of safety is more commonly described as the avoidance of additional harm and is exclusive of the underlying condition (6). However, the CM programme does not seek to cure acute illness or injury, but rather, to optimise the management of long term disease to sustain quality of life. Care that does not meet patients' needs could result in unnecessary disease progression and, therefore, unnecessary harm to the patient.

Although the definitions of safety commonly share the process of risk reduction/harm avoidance, the existence of otherwise divergent definitions of safety between key stakeholders may be problematic, especially when engaging patients in safety improvement efforts. This is becoming increasingly important

in healthcare as large, globally influencing organisations announce efforts to involve patients in safety and safety improvement (186). Where differences exist, patients could strive to achieve different outcomes as dictated by their own perspectives of safety. Given the multitude of barriers already recognised in patient involvement in safety (179, 187), any additional barriers to successful and cohesive outcomes are not welcome.

In order to ascertain the level of agreement with the qualitatively derived definitions, a larger sample of patients, carers and CM nurses were afforded the opportunity to select their preference from the patient and carer derived definition, the CM nurse derived definition or the Runciman et al. (4) definition. The purpose of the survey was to elicit which definition of safety key stakeholders felt most closely reflected their own views in relation to care in the home. Despite one of the definitions (option 2 on the survey) being derived from the CM nurse data in study I, the majority of CM nurses in the survey study selected the definition derived from the patients and carers (option 1). As one might expect, the majority of patients and carers also selected option 1. These findings, if taken at face value, indicate that the stakeholders' definition of safety was most closely reflected by the definition derived from patients and carers.

There are several theories that may explain this; one commonly reported in the literature is the response order effect. This occurs when the order of response options effects the respondent's selection (267). Krosnick and Alwin (268) argue that respondents preferentially select items early in the list as a result of *'primacy effects'* (268)[pg203]. Consequently, later items aren't afforded the same level of consideration and thus may be selected less frequently than those earlier in the list. This could potentially explain the high level of affiliation with option 1 across all key stakeholders. However, Krosnick and Alwin (268) were also able to determine that this was more apparent in respondents who displayed less cognitive sophistication (those with a high school education or lower with Word Sum scores less than 6), which suggests that this would have influenced the CM nurses less.

Alternatively, the CM nurses selection might have been influenced by the choice of definitions available. Zaller and Feldman (269) argue that a presupposition of a survey is that when respondents indicate a preference for X, it is a result of a well-defined, pre-existing state of favour for X. In actual fact, respondents are susceptible to partially constructed ideas, which, when questioned are subject to influence by the options offered. Therefore, the CM nurses might have showed preference for the patient and carer derived definition of safety because they did not have a previously well-defined definition and were influenced by its presence. After all, this definition encompasses reducing risk, which is commonly associated with safety, but is also more comprehensive. It includes the meeting of positive needs, rather than the mere avoidance of negative occurrences and is more reflective of the evolving care model, where harm can be experienced through unnecessary disease progression.

8.2.2: Extended outcomes of safety

This research presents four categories of outcomes relating to patient safety as perceived by the investigated key stakeholders. These are: adverse events, psychosocial outcomes, functional health status and clinical care sensitive outcomes. In addition, health-related quality of life (HRQOL) has been proposed as an outcome because of its relationship with the four categories of outcomes.

8.2.2.1: Adverse events: common measures of safety

Study I implicated falls, infections and medication events as important adverse events. Adverse events are the most commonly measured outcome of patient safety (19, 21, 61). In this study, falls were especially troublesome because patients who experienced falls subsequently suffered a fear of repeated falling. There is evidence to suggest that as many as one in three elderly fallers develop a fear of falling (270). This fear becomes a risk factor for further falls (271). Blais et al. (39) and Sears et al. (38) found falls with injury to be the most common type of adverse event present in the medical records of home care patients in Canada. In addition to falls, both infections and medication errors were also identified as adverse events

experienced by home care patients (38, 39). Falls and infections (specifically of the urinary tract) are measured by the NHS safety thermometer as targeted outcomes for improvement by policy makers (21).

In addition, the NHS safety thermometer also measures pressure ulcers (21), which are also prevalent in the medical records of home care patients (38, 39). The perceived importance of pressure ulcers to care providers can be inferred from the financial incentive placed on them in the Commissioning for Quality and Innovation (CQUIN) payment framework (272), which prioritises the improvement of pressure ulcer prevalence. It is recognised that the subjective and experiential nature of qualitative research does not exclude pressure ulcers or other adverse events as relevant measures of safety, simply because they were not identified in the sample of study I. There is evidence to suggest that adverse events, in addition to those identified in this research, remain important in the delivery of safe care to patients receiving care in the home.

8.2.2.2: Non-traditional outcomes of safety

Adverse outcomes are the traditional measure of safety in healthcare; however, this study has identified other types of outcomes that were perceived to be important to the investigated stakeholder groups. These were categorised as: psychosocial outcomes, functional health status and clinical care sensitive outcomes.

Runciman et al. (4) give some consideration to psychosocial outcomes in their classification of safety, in particular, in relation to harm. They describe harm as including disease, injury, suffering, disability and death, where *'disability is the experience of anything subjectively unpleasant, any type of impairment of body structure or function, activity limitation and/or restriction of participation in society'* (4)pg21 and disease is *'physiological or psychological dysfunction'* (4)pg21. However, the clinical focus of the adverse events measured, suggests that psychosocial outcomes are not well reflected in current safety measurement. Previous research has reported that patients identified more psychological harms than physical harms (89). This study supports the notion that patients, and also carers in this case, place emphasis on these types of harm.

The healthcare of patients of the CM programme is mostly delivered by the patients, or their carers, in the process of self-care and management. Patients and carers in study I described self-care activities that prevented hospital admission and other negative outcomes. This was further supported by CM nurses in study II. Evidence suggests that patients who are more able to self-care are less likely to be hospitalised (273). Therefore, it is important for patients to be able to maintain independence through adequate self-care provision. A lack of self-management skills has also been implicated in an increased risk of early readmission to hospital (274). Functional health status can be used as a measure of someone's ability to perform daily activities to meet basic needs, such as self-care (275). Functional health status, therefore, is proposed as a safety outcome. It is hypothesised that measuring and monitoring functional health status could identify patients at risk of being unable to adequately perform self-care, who would consequently be at greater risk of harm.

Clinical care sensitive outcomes were outcomes that were perceived to be amenable to clinical care interventions. Mainz (276) describes these as the five D's:

1. Death: a bad outcome if untimely

2. Disease: symptoms, physical signs and laboratory abnormalities

3. Discomfort: symptoms such as pain, nausea, or dyspnoea

4. Disability: impaired ability connected to usual activities at home, work or recreation

5. Dissatisfaction: emotional reactions to disease

Some of these are captured in other types of non-traditional outcomes. For example, emotional reactions to disease and disability can be captured in psychosocial outcomes and functional health status. In this research, clinical care sensitive outcomes are outcomes that are mostly amenable to clinical care with little influence from social or psychological functions. One such example is the prescription of prophylactic antibiotics to patients prone to chest infections because of chronic obstructive pulmonary disease (COPD).

The non-traditional outcomes presented contribute to a person's quality of life and thus form the patient's health-related quality of life (HRQOL). In patients with heart failure, poor HRQOL is associated with hospital readmission and is comparable to other predictors, such as a history of diabetes, previous hospitalisations, and treatment with angiotensin-converting enzyme inhibitors (277).

8.2.3: Patient inclusive processes

Chapter 2 has discussed the absence of process measures in safety measurement, despite research indicating that patients place greater emphasis on these aspects of care (89, 174, 177). The findings of this research suggest that there are three broad categories of processes that relate to the CM programme: communicating, self-care and management, and clinical care processes of the CM nurse.

8.2.3.1: Communicating

In study I, communicating was identified as a process of care, one that appeared especially important in the prevention of disease progression and episodes of crisis. In study II, there was overwhelming support from the three key stakeholder groups, who believed that communicating was important in managing both outcomes and safety. For CM nurses, the process of communicating enabled them to empower and educate patients: a key component of their role. For patients and carers, it was perceived as a means of advising healthcare professionals of their health status, particularly when at risk of experiencing an episode of crisis.

The term communicating represents the process of information exchange. In other literature, however, the term communication is preferred. For instance, Scott et al. (174) and Dean et al. (177) identified communication as a key theme in patient safety, which encompassed the means by which to communicate. In this research, the communication infrastructure is: the mechanisms used to facilitate the flow of information and understanding through the process of communicating, it has been separated

from the process of communicating and identified as a structure of care (see section 8.2.4.4: Communication infrastructure).

The CM nurses highlighted the use of multiple terminologies, which were dependent on whom they were communicating with. With patients, they were reluctant to use terms such as harm. This corresponds to the findings of Lang et al. (40), who discovered that patients did not identify with the term 'home care safety' instead choosing language such as 'challenges' or 'concerns'. When discussing the definition of safety with key stakeholder groups, patients and carers used positive language (meeting needs) to describe safety. In comparison, CM nurses used negative language (avoiding harm). The CM nurses' reluctance to use what they perceived to be 'professional language' with patients could explain this phenomenon.

8.2.3.2: Clinical care processes of the case management nurse

Patients, carers and CM nurses identified activities that were undertaken by the CM nurses as part of their role. Sargent et al. (278) have previously been able to elicit five categories of case management tasks as perceived by patients and carers: clinical care, co-ordination of care, education, advocacy and psychosocial support. In comparison, the patients and carers of this study mostly identified tasks associated with the clinical care category. However, this could be because the patients and carers did not associate safety with the other four categories previously determined by Sargent et al. (278). CM nurses, on the other hand, did emphasise their need to empower and educate patients and to integrate care provision. CM nurses also highlighted that mis-diagnosing or mis-prescribing could put patients at risk. There is evidence of an overall prevalence of 42% for potentially inappropriate prescribing among community dwelling elders, which doubles their likelihood of an adverse drug event and is associated with a two-fold increased risk in emergency room visit (279), implicating the clinical care role heavily in the safety outcomes of patients.

8.2.3.3: Self-care and management

The patient and carer participants of study I identified a range of activities that described the process of self-care. This was further supported by all stakeholder groups in study II, with the majority from each stakeholder group agreeing upon the importance of self-care. Carers assist heavily with self-care activities. Within this research, self-care extends to incorporate the activities that carers support patients to perform. The importance of self-care and management in preventing hospital admissions has already been identified in section 8.2.2.2: Non-traditional outcomes of safety. This is considered a fundamental process of care.

There are measurement tools available in the literature that could possibly assist in the identification of patients who struggle to perform self-care. Fillenbaum (280) describes a measure of instrumental activities of daily living specifically for the elderly that was able to predict mental and physical health function. Fillenbaum (280) proposes that this tool could be used to identify patients in need of additional interventions. The Functional Status Questionnaire is an alternative measure of how well a patient is functioning (281), and others are available. Further testing of such tools would be required to determine their predictive capability for poor outcomes and their validity in the elderly, community dwelling population. There is further evidence to support the significant contribution of the patients and carers in patient safety. Johnson (169), and Blais et al. (39) have published data that implicates patients and informal caregivers in the cause of adverse events in homecare. Romagnoli et al. (188) concluded that their contributions were a result of an inability to perform particular self-care tasks such as caring for wounds, following medication regimes, managing durable equipment and keeping their homes free of hazards.

8.2.4: Whole system structures

Traditionally, the structure of care is mostly considered from the organisation's perspective: their facilities, their staff, etc. This research heavily implicates the patient in the structure of care.

8.2.4.1: Environment and equipment

The environment and equipment were both identified as dimensions of structure and are closely related. The environment is the surroundings within which the patient resides and conducts healthcare; it can be significantly influenced by the provision, availability and use of appropriate equipment, which can enable patients to remain safely independent and prevent harm. In addition to this research, there is empirical evidence available to support the inclusion of the environment and equipment in the structure of care. For the visually impaired, home assessment and modification, which aimed to reduce hazards in the environment or provide equipment, has shown to be effective at reducing falls by up to 41% (282). In a study examining the reason for this improvement in falls, La Grow et al. (283) concluded that the environment was better adapted to the patient's disability. La Grow et al. (283) recorded an average of 4.7 hazards per home, some of which were comparable to the hazards identified in this research, including: steps/stairs, bath/shower, tidiness/cleanliness and carpets/rugs. In a more heterogeneous population, Clemson et al. (284) conducted a meta-analysis and discovered a 21% reduction in falls, following environmental interventions for the community dwelling elderly. Other research, however, has indicated that home hazard reduction is not effective in the general older population, although it is effective in targeted populations with a history of falls and limited mobility (285).

Hazards in the home are increasingly recognised as a safety threat in home healthcare. In 2012, Gershon et al. (286) devised a home hazard identification checklist to facilitate visual inspection to detect hazards. Further work is needed to determine if the identification of hazards leads to improved patient outcomes. In a previous study, Gershon et al. (287) discovered a range of environmental conditions that home healthcare workers perceived to compromise safety, including, but not limited to: clutter; poor light, unsanitary conditions, damp/mould, air pollution and animal hair (some of these have also been raised in this research).

Falls have previously been implicated in this research as an adverse outcome, and improving the conditions that contribute to their occurrence is important in reducing their prevalence. The evidence suggests that improvements to the physical environment, which can be adapted with specific equipment, as well as the removal of other hazards, can reduce the risk of falling (284). The use of a safety assessment checklist to identify hazards is a process of care that, following the introduction of relevant interventions, could influence the structure of care as well as the outcomes of care.

The environment has previously been implicated in the Systems Engineering Initiative for Patient Safety (SEIPS) model as a structure of care (199). However, it is not implicated in the Nursing Role Effectiveness model (201). This could be because the former is promoted as examining the system, as is this research, whereas the latter is specific to the role of the nurse. The physical environment of the hospital setting might not be sensitive to nurse intervention because the environment is more rigid and standardised. In the home, however, the environment is not subject to regulation and is difficult to standardise (40), so further consideration is required to ensure the safety of the homecare environment.

8.2.4.2: Services

Services – especially their availability and accessibility – were identified as a structure of care for the CM programme. However, this is absent from both the SEIPS model (199) and the Nursing Role Effectiveness model (201). This may be because these two models were designed to reflect hospital care where patients receive an integrated care service from a range of health professionals, such as doctors, nurses and occupational therapists, all whilst temporarily residing at the hospital. However, for patients of the CM programme, their health is dependent on a variety of care services; part of the CM nurse role is to facilitate their integration. The lack of availability, and access to, services such as domiciliary care (288) and mental health services (289) have previously been criticised for putting patients at risk.

CM nurses raised the possibility of extended hours for the CM management programme, but rejected this as a viable option because they believed it would negatively impact the relationship-dependent service

currently provided. This was further supported by CM nurses participating in the survey, 70% of whom disagreed that a 24-hour CM service would improve safety; however, 74% of patients and 79% of carers believed that a 24-hour CM service would improve safety. General practitioner (GP) working hours have been implicated in the overuse of Accident and Emergency. David Cameron explains that 'sometimes people using Accident & Emergency really just need to see a GP but for hard-working people it is often too difficult because [they] are at work, [and] can't get an appointment at the time that fits.' (290). This suggests that extending the available hours of primary care services could reduce the burden on hospitals. Further work is required to understand whether the service hours of the CM programme influences outcomes such as hospital admissions.

8.2.4.3: Financial resources

In study I, CM nurses felt that patients with sufficient resources to fund additional social care did not necessarily make choices that were best for their health. In comparison, CM nurses felt that patients without financial means were adequately supplemented by the state. Patients and carers didn't explicitly acknowledge this in study I. However, some patients with financial means did describe delaying paying for things or going without. In healthcare, financial resources have been implicated in the safety of patients. For example, the Francis Report (12) highlighted how the Mid-Staffordshire NHS Foundation Trust prioritised cost cutting exercises in response to reduced financial resources, which contributed to an unacceptably high mortality rate. There is the possibility that budget holders could put patients receiving home healthcare at similar risk if patients' needs are not prioritised. However, for the patients of this research, finances weren't discussed in relation to those providing care but rather, in relation to the patient.

Conversely, in study II, more patients and CM nurses disagreed than agreed with the statement that 'patients who were self-funded were at greater risk of harm than those who were state funded'. Patients who are self-funded could be reluctant to acknowledge that they are at greater risk as a result of their

financial resources. In contrast, patients who are state funded might find it difficult to understand why people with means would not choose to spend their money on ensuring their safety. Low socioeconomic status is associated with poor health outcomes (291) and patients of this group are more vulnerable to adverse events (292), which could explain why CM nurses are also reluctant to agree with this sweeping statement. There doesn't appear to be any research that investigates the relationship between financial means for social care provision for community dwelling elders and patient safety outcomes. Therefore, more research is needed to understand the impact that self-funding has on patient outcomes.

8.2.4.4: Communication infrastructure

Communication infrastructure was identified as a structure of care and is further supported by the identification of communicating as a process. Communication is frequently identified in the literature in relation to patient safety (174, 177), and the Nursing Role Effectiveness model allocates communication to the process of care (201). This study categorises communicating as a process and communication infrastructure as a structure, acknowledging that the process is better enabled with the appropriate infrastructure in place.

8.2.4.5: Patient and carer characteristics

Four broad categories of patient characteristics were identified as contributing to patient safety: attitudes, patient understanding, circumstance and autonomy/independence. Patient circumstance related to the disease profile and the co-morbidities suffered by this patient population. Other research has also found that patient characteristics might possibly contribute to their risk of adverse events. In particular, in hospitalised care, the complexities of both the disease and the treatment have been linked to an increased risk of adverse drug events (2). This is enhanced in the elderly, who are also more at risk, possibly because of the complexity of their care and not necessarily because of age discrimination (293). Being female and being 80 or older, are independent risk factors for adverse drug events (294). Ethnicity has also been implicated as a risk factor: McDowel et al. (295) found that black patients were at a threefold higher risk

of angiodema (an adverse drug reaction to cardiovascular drugs) than non-black patients. In homecare, Blais et al. (39) calculated that for each additional comorbid condition, the risk of experiencing an adverse event increased by 15%. In addition, they also found that the level of risk increases as the client (patient) becomes more dependent (39).

The Nursing Role Effectiveness model explicitly identified patient structural variables in the quality of care, including: medical diagnosis, length of stay, age, gender and education (201). In this research, the level of patient understanding was also implicated, and it was hypothesised that the greater the understanding, the safer the patient. In the SEIPS model, where the structure of care was replaced by the concept of the work system, 'person' was a component, comprising elements of education, skill and knowledge, motivation and needs, physical characteristics and personal characteristics (199). Carayon et al. (199) claimed that the 'person' could be the patient.

Patient attitudes have not explicitly been identified as contributing to safety in the current literature base. Similarly, neither has patient autonomy and independence. However, Blais et al. (39) did find that as patient dependency increased (autonomy and independence decreased), the risk of adverse events increased. In a care environment such as the home, where patients exert more control over their healthcare, their attitudes towards health could contribute towards their safety.

In the CM programme, carers have been identified as being vital to the care of this vulnerable patient population. Unsurprisingly then, their characteristics were also identified as potentially contributing to the patients' safety. Similarly to patients, their attitudes to health and their own health were implicated in patient safety. The carers and patients of study I all discussed the carer positively. However, CM nurses highlighted the possibility that carers, and other family members, could hinder care.

Research has indicated that informal caregiving to patients with chronic disease impacts the physical and mental well-being of the carers (296, 297). This research suggests that the ill-health of carers has consequences for patients and could possibly leave them unable to remain independent at home. The

burden on caregivers of patients with chronic disease is of growing importance, and research suggests that there are multiple factors that predict the breaking-point for caregivers. These include: the amount of caregiving time, an impaired sense of own identity, misidentification, clinical fluctuations, and nocturnal deterioration (298). Carers form a vital component of the structure of care and it is important to ensure that they are also capable, competent and well resourced, just like other components of the structure.

8.2.4.6: Operational Conditions

CM nurses highlighted a range of operational conditions that impacted their ability to perform safely. Operational conditions were characterised as the physical, social and organisational environment in which occupational activities were undertaken. In particular, the CM nurses identified caseload and training. Caseload is the demand on the services divided across the CM nurses, and increases if there are insufficient staff numbers. Following the Francis Report (12), which implicated insufficient staffing levels in the high mortality rate at Mid-Staffordshire NHS Foundation Trust, staffing levels became a controversial topic in healthcare in England. This relationship is apparent across the healthcare system. Aiken et al. (299) found surgical patients experienced higher risk-adjusted 30-day mortality and failure-to-rescue rates, when patient-to-nurse ratios were high. In addition, high patient-to-nurse ratios facilitated nurse job dissatisfaction and job-related burnout. Similar to caseload and staffing levels, the skill mix of the nurses has been found to affect the incidence of adverse events. Blegan et al. (300) found that the higher the registered nurse skill mix, the lower the incidence of adverse events on inpatient care units. Needleman et al. (301) also found that higher nursing care hours were associated with better care for hospitalised patients. Workload and education/skills were acknowledged as components of structure in the SEIPS model (199) and the Nursing Role Effectiveness model (201). The findings of this study are aligned with evidence available in the literature: caseload, staff mix and training are components of structure, which have the potential to impact patient safety.

8.2.4.7: Staff attitudes

The CM nurses of study I expressed attitudes and feelings, which they believed hindered their ability to be entirely effective. Mostly, these attitudes and beliefs related to the clinical care setting in which they were working. More specifically, they believed that healthcare professionals practising in institutionalised settings had more control and power to influence patients to conform to behaviours that would result in better outcomes. They suggested that delivering care in the community relinquished them of this power, which was transferred to the patients, and inhibited their ability to get patients to do what they perceived to be best for them. The attitudes of the staff in an organisation in relation to safety is often referred to as safety culture (108, 109), and can be assessed with the use of tools that identify the presence of conditions that support the identification of adverse events (20). The attitudes expressed by the CM nurses do not immediately relate to the 'safety culture' as defined here, but this does not render it unimportant.

8.3: A qualitatively validated model for the design of safety measurement systems

The proposed integrated safety measurement model (ISMM) was developed to inform the design of this research. The literature around patient safety measurement was dominated by provider and staff involvement. However, the principles of performance measurement dictated that patients, as consumers of care, should be involved in the design and implementation of safety measurement. This was further corroborated by the growing literature on patient involvement in patient safety. Therefore, patients were identified as an additional key stakeholder. The ISMM was presented to a group of CM nurses who advised that carers were fundamental in the delivery of care services to this patient group. Although not originally recognised by the ISMM, because of their absence in the literature, they were included in the research design.

The findings of this research confirm the presence of a range of key stakeholders, including those identified on the ISMM and the representativeness of the components of the SPO model, as domains of the system. This constitutes the qualitative validation of the fundamental components of the model. However, limitations have been addressed through the revision of the visual representation of the ISMM, and presented in the holistic safety measurement model (HSMM).

8.3.1: Key Stakeholders

In the originally proposed ISMM (Chapter 3), three key stakeholders were identified: patients, staff and providers. This study indicates that there are a range of individuals who have direct contact with patients and who contribute to their immediate safety, all of whom appear to strive to place patients at the centre of their activities. These individuals include, but are not limited to: informal carers, extended family and friends and health and social care professionals. Similarly, Lang and colleagues (168, 302) found an extended and inter-related community of individuals involved in the care of home care patients, which adds to the complexity of the safety of this patient group. Beyond those that have direct contact with patients, there are a variety of organisations that contribute indirectly to the care of patients. These organisations are governed by, and conform to, laws and regulations set at national and international levels. This complexity was not apparent in the original ISMM, and thus a revised model has been proposed. The key stakeholders are inter-related and exist in a more complex state. The WHO (186) presents the system of healthcare within a nested macro-meso-micro set of systems. This has been applied to the CM programme, a representation of which can be seen in Figure 8.1: A nested system for the complex care of patients being case managed.

Figure 8.1: A nested system for the complex care of patients being case managed.

Patients are at the centre of the micro system, supported directly by multiple individuals including but not limited to, informal carers, family, friends and health and social care professionals. The micro system is nested within the meso system through non-direct patient contact (at the provider level). Both the micro and meso systems are nested within the macro system (national and international level), which is governed by legislation and regulation.

Individuals, who have direct contact with the patient, form the micro system: a group of people who interact and work with the patient to achieve a shared goal (the health of the patient). The microsystem is where care is delivered; quality, safety, reliability, efficiency and innovation are realised; and outcomes are achieved. The micro system is nested within the meso system, which incorporates the provider organisations of the health and social care staff. Finally, both the meso and micro systems are incorporated within the macro system, which includes the relationships and networks of these provider organisations within a legislative and regulatory framework.

This study has been focused on the patient, their carers and the CM nurses, who form the core of the microsystem for patients being case managed. As active participants within the micro system, patients and carers identified that they had a role to play in ensuring safety, but they did not explicitly acknowledge

who was responsible for what and who was responsible for whom. There is evidence to suggest that patients believe their role to be of a passive and complicit nature (185). However, patients and carers described activities that they undertook that amounted to actively reducing risk. CM nurses, and patients and carers expressed risk reduction as a component of safety. These risk reduction activities described by patients and carers were both clinical (related to treatment of the patient) and non-clinical (for example, improving security and alterations to the physical environment to prevent falls). It could therefore be inferred that patients who describe participating in risk reduction activities are implicitly describing their contribution to safety.

In study I, patients expressed a need to reduce risk. This was achieved through activities not traditionally associated with the institutional care setting, which is focussed on the clinical safety of patients. Instead, for patients in receipt of CM in this study, safety extended to their 'living safety', because the environment has to accommodate both care and life. The NHS Constitution insists that it is the NHS's responsibility *'to ensure that services are provided in a clean and safe environment that is fit for purpose, based on national best practice' (150)*[pg7]. It is not clear whether and how this extends to patients being cared for in the home. The patients and carers in this study described the importance of maintaining a clean environment, thus taking it upon themselves to be responsible. CM nurses, on the other hand, provided examples where the living conditions of some patients could pose a risk to their health. If more care is going to be delivered in the home, further consideration is required of how the NHS Constitution translates into home healthcare.

Study I identified a range of key stakeholders who exist in a state of complex nested systems, though it was unable ascertain who was perceived to be most responsible for the safety of each of the key stakeholders. Three questions on the survey (study II) asked respondents to identify who they believed had the greatest responsibility for ensuring the safety of each of the key stakeholders. The most cohesion was achieved in identifying who was responsible for NHS staff, with the majority of all stakeholder groups selecting NHS organisations. No such consensus was achieved for patients and carers. An issue that arises from not being able to determine where responsibilities reside is the subsequent lack of

accountability in the face of error or poor outcomes. Prior to the implementation of the CM programme, these patients would have received repeated hospitalised care, where responsibility and accountability are more clearly defined. The ambiguity of this aspect of the CM programme could leave patients in a vulnerable position. Although this research did not intend to determine these responsibilities, it does raise questions as to who has accountability for this patient population and its immediate informal carers.

Responsibility for safety and outcomes when care is delivered in the home setting may never be as clearly defined as it is in the hospital setting, for several reasons. Despite the home becoming a clinical care setting, it is foremost a home, where patients and their families live. The physical environment cannot feasibly be adapted to meet the demands of a full time clinical care environment like a hospital. Instead, the environment needs to meet the needs of the household, as well as the clinical needs of the patient. In addition, the majority of the clinical care is not provided by a qualified healthcare professional, or in the presence of one. Instead, it is conducted by the patient themselves or by their carer. Seemingly, patients have far greater responsibility than if receiving care in a hospitalised environment. However, since CM has been instigated by the NHS to reduce hospital admissions, it could be argued that responsibility should rest with the NHS.

The NHS Constitution (150) identifies several responsibilities of the patient, stating: *'Please recognise, that you [the patient] can make a significant contribution to your own, and your family's, good health and wellbeing, and take personal responsibility for it' (150)[pg11]*. However, the NHS Constitution commits to ensuring that the environment in which services are delivered is safe and clean (150). Some of the patients participating in study I were living in environments in which adaptations could bring about a better quality of life, a safer environment and potentially better outcomes. This suggests that the NHS is not successfully ensuring services are provided in clean and safe environments that are fit for purpose, when care is delivered in the patient's home. Further work is required to establish the applicability of this constitutional right to care delivered in the home.

8.3.2: The holistic safety measurement model: a revised model for safety measurement design

The ISMM was predicated on the domains for quality care, namely structure process and outcome. The identification of dimensions for each of the domains provides a qualitatively obtained validation of the utilisation of SPO model as domains of safety measurement. The dimensions can be found in Table 8.1: Dimensions of care in the CM programme.

In order to accommodate the complex nested system the ISSM has been revised and the holistic safety measurement model (HSMM) proposed; see Figure 8.2: The holistic safety measurement model.
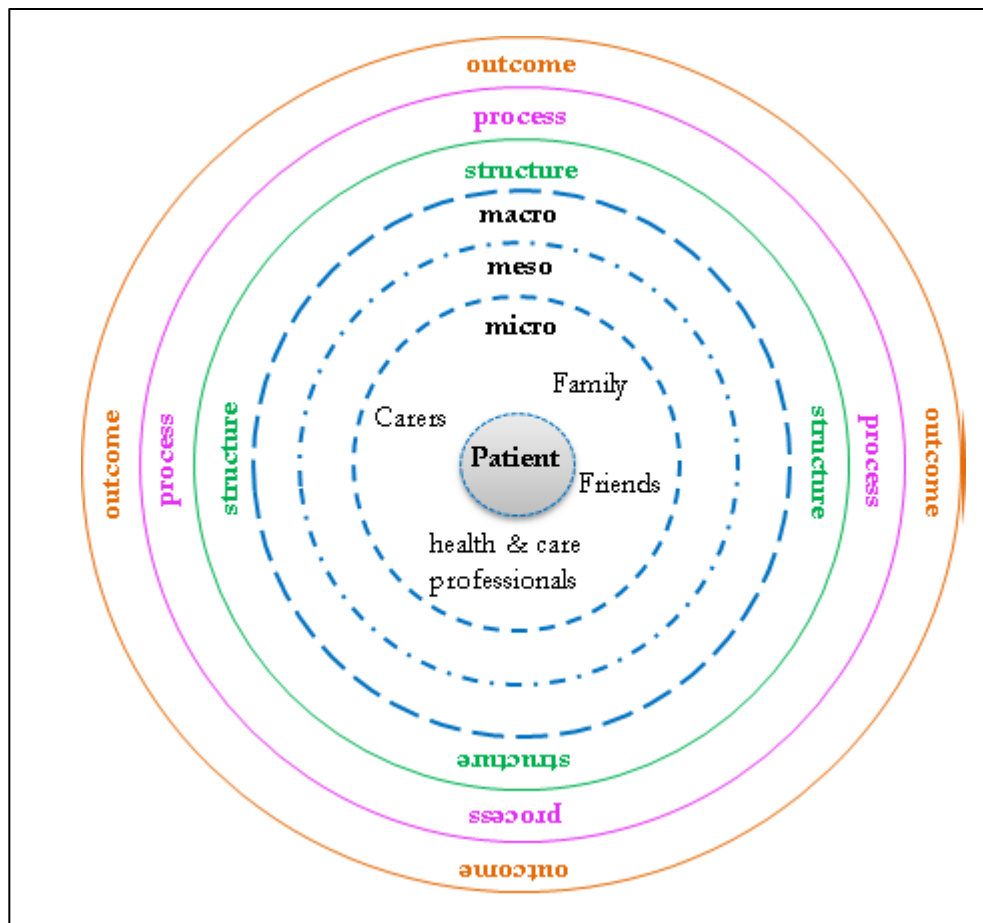
Figure 8.2: The holistic safety measurement model

Table 8.1: Dimensions of care in the CM programme

Dimensions	Description
Equipment (S)	The provision, availability and use of appropriate equipment that can support help patients remain safely independent and prevent harm.
Environment (S)	The condition of the surroundings that the patient resides in and conducts healthcare.
Services (S)	The provision, accessibility and utilisation of services that can help patients remain safely independent and prevent harm.
Financial resources (S)	The economic means available to support the health, well-being and safety of patients.
Communication infrastructure (S)	The mechanisms used to facilitate the flow of information and understanding through the process of communicating.
Patient characteristics (S)	Qualities or features of patients which contribute to the condition of safety including: their attitudes, the circumstance their understanding and their desire for autonomy and independence.
Carer characteristics (S)	Qualities or features that contribute to the condition of safety including: their presence, their health and their attitudes.
Operating conditions (S)	The physical, social and organisational environment in which occupational activities are undertaken.
Case management nurse attitudes (S)	The way the CM nurses think and feel.
Self-care and management (P)	The activities associated with taking care of one self from brushing teeth to taking medication.
Clinical care processes (P)	The specialist activities of a healthcare professional to improve health.
Communicating (P)	The action of information sharing.
Assessment(P)	The action of determining the current state of the system and proceeding to intervene when it is insufficient.
Adverse events (O)	An adverse consequence for a patient.
Psychosocial(O)	Consequences that relate to the mental and social well-being.
Clinical care sensitive outcomes (O)	Consequences that are amendable to clinical care.
Functional health status (O)	The ability to perform typical activities of daily living.
Health-related QoL life (O)	The holistic well-being of a patient as a consequence of his or her disease.

8.4: A proposed conceptual framework for safety measurement

This research has established a new understanding of the concept of safety in the CM programme. A conceptual framework for assessing the performance of safety in the CM programme has been proposed. A conceptual framework can be defined as *'a network, or "plane," of linked concepts that together provide a comprehensive understanding of a phenomenon…not merely collections of concepts, but, rather, constructs in which each concept plays an integral role'* (33)[pg57].

8.4.1: Propositions

The conceptual framework proposes relationships between the structure, process and outcome domains, which are exhibited within a nested micro-meso-macro system in order to represent the complex network within the CM programme. The major propositions of the framework are:

1. Structure affects process – The ability of caregivers to safely perform care activities (processes) is dependent on the dimensions of structure. For example, patients, who are unable to use a traditional bathroom to perform personal hygiene, are subject to the constraints of financial resources to supply the appropriate equipment and install a suitable environment in which the patient can safely perform self-care.

2. Structure affects outcome – Particular dimensions of the structure domain are capable of directly impacting outcomes. For example, patient characteristics such as the diagnosis of chronic obstructive pulmonary disease (COPD), might impact on infection rates, as this patient population is more susceptible to infection.

3. Structure affects structure – Some dimensions within the structure domain influence other dimensions. In particular, financial resources could determine the available funds for equipment provision, environment adaptations and service provision.

4. Process affects outcome – Outcomes are a direct result of the care activities (processes) undertaken by a variety of caregivers. For example, the prescribing of antibiotics by CM nurses prevents patients with COPD who develop chest infections from being admitted to hospital.

5. Process affects structure – Some activities of care impact on the dimension of structure. For example, when patients are unable to self-care appropriately, they might struggle to keep their homes free of hazards.

6. Outcomes affect structure and process – The outcomes of patients and carers influence their ability to perform activities of care and sustain safe dimensions of structure. For instance, if a patient's functional health status declines, he or she is less able to maintain self-care.

The Nursing Role Effectiveness model proposed the following relationships: effects of structure on process; effects of structure on outcomes; and effects of process on outcomes (202). However, the model did not determine that dimensions within structure impacted each other, or that outcomes impacted structure and process. With respect to the latter, this may be because the conceptual framework for evaluating the ACNP role is designed for the acute care setting. In the acute setting, patients contribute very little to the conditions of structure or activities of process; these are the responsibility of the provider and its staff. Similarly, Kunkel et al. (198), in examining the quality system of a hospital, also found structure to influence process and outcome, and process to influence outcome. However, in the home healthcare setting, the patient controls the physical environment and the majority of care is undertaken in the absence of a healthcare professional. If patient outcomes are poor, this could inhibit the patient's ability to sustain a safe environment and conduct adequate processes of self-care.

8.4.2: Components

The framework is comprised of three measurement domains, predicated on the model for the assessment of quality care (3). The structure domain is constructed of dimensions that represent the underlying conditions of the system, which typically include things such as the adequacy of equipment, the skill and knowledge of healthcare professionals, and staffing levels. Traditionally, the organisation or the health professional is the unit of assessment (303). However, the findings of this study heavily implicate the patient in the assessment of structure, predominantly because:

1. Patients conduct most of their healthcare in the absence of healthcare professionals, and

2. This care takes place in their own home, rather than in an institutionalised setting

The process domain consists of dimensions that reflect the types of activities undertaken in the CM programme that can influence both health outcomes and safety. Process measures traditionally assess the activities of the healthcare professionals who deliver care to patients (304). Similar to the structure domain, this research has identified activities that only the patients and/or their carers undertake: mostly self-care activities. Self-care is important in this type of care to achieve the desired outcomes and to prevent adverse events and hospitalisation. Poor self-care can reduce health outcomes, which can inhibit a patient's capacity to self-care and place him or her at risk of harm.

Chapter 2 discussed the characteristics of current safety measurement methods, most notably, that they were dominated by outcome measures (specifically measures of harm). This research has identified a range of harms that patients, carers and CM nurses implicated in the safety of the CM programme. It has also recognised the value of some of the other measures of harm available in the literature. In addition, this research has identified a range of non-traditional measures of safety that serve a purpose in assessing the safety of care in the CM programme. Outcomes such as functional health status, clinical care sensitive outcomes and health-related quality of life are more commonly associated with the quality of care (147). However, in the CM programme, they are also associated with the safety of care. By not meeting these outcomes, the patient's ability to maintain a safe structure and sustain the delivery of essential care processes is reduced, which was previously discussed, puts them at risk of hospitalisation and adverse events (274).

Following the critical evaluation of the findings in relation to the literature a conceptual framework is proposed in Figure 8.3: A conceptual framework for the assessment of safety in the CM programme.

Structure			
	Macro	Meso	Micro
Environment **Equipment** **Services** **Financial resources** **Communication infrastructure** **Patient characteristics** **Carer characteristics** **Operating conditions** **Staff attitudes**	European Law UK law The economy Government budget NHS Constitution	Local budgets Local training and development Service/product availability	Ability Desire Socioeconomic considerations

Process

Communicating

Self-care and management

Clinical care processes

Assessments

Outcomes (patient)

Adverse events
e.g. falls
medication events
infection
pressure sores*

Psychosocial
e.g. depression

Functional Health Status

Clinical care sensitive outcomes
e.g. prostate-specific antigen
LDL and HDL (cholesterol)

Health-related quality of life

Figure 8.3: A conceptual framework for assessment of safety in the case management programme

233

The framework implies that safety outcomes of the CM programme should be more inclusive of generic indicators of quality, rather than just harm. There are several reasons for this. Firstly, patients and carers originally described safety as the meeting of needs and subsequently identified these needs as desired outcomes of care. Having these needs met enables patients to maintain an adequate quality of life and to continue to perform self-care and management activities. Without the latter, patients could be at greater risk of falls, infection, hospital admissions and other adverse events. Secondly, in a care service that seeks to maintain quality of life, rather than to treat an acute illness, not meeting the care needs of patients might facilitate an unnecessary deterioration in health status. Therefore, this framework further implies that the omission of quality care, which results in unnecessary disease progression, is a symptom of unsafe care i.e. care that is ineffective at delivering optimum outcomes in LTCs care is unsafe and can lead to unnecessary harm through the worsening of the disease state. Finally, because the framework is focused on the delivery of safe care across the system, rather than the avoidance of unsafe care, positive outcomes also ought to be monitored. By measuring the requirements for safe care, it is proposed that an issue in the system could be detected before an adverse event occurs.

8.5: Limitations of the research

8.5.1: Limitations of study I

The purpose of study I was to explore and understand the views of the participants in relation to their perception of safety. The limitations of study I relate specifically to the design and analysis required to achieve this purpose. The case study design is predominantly qualitative. The most prohibitive limitation of such research is its inability to generalise the conclusions beyond the sample population. This occurs for two reasons: 1) the small sample size and 2) the type of data collected cannot be subjected to statistical testing. This limitation is recognised and the findings presented are the cumulative views, experiences and perceptions of those participating in the study, interpreted by the researcher.

In order to overcome the shortcomings in satisfying the statistical power of analysis in qualitative research, Luborsky and Rubinstein (305) prefer the term 'qualitative clarity': *the aim of making explicit, for open discussion, the details of how the sample was assembled, the theoretical assumptions and the pragmatic constraints that influenced the sampling process'* (305)pg 109. Chapter 5 makes explicit the details of the sampling method and the constraints that were placed upon this method are discussed in detail in section 8.6: Challenges of the research, adding to the qualitative clarity. In addition, the case study method has been encompassed into an exploratory, sequential mixed methods design to determine whether these findings might be extrapolated to a larger population.

The framework analysis approach to qualitative data analysis has been criticised for lacking a theoretical approach, in comparison to other qualitative analysis techniques, which are underpinned by a philosophical assumption (306). An advantage of framework analysis is the transparency afforded to the approach and the easy retrieval of data due to the charting process (307). Charting allows for easy cross-reference to the data, post-interpretation. Framework analysis provided a methodical and systematic approach to the unstructured and unwieldy data collected during the interviews and focus groups (243). As evidence of transparency and the ease by which charting can enable retrieval, an example of a chart is available in Appendix 8. Furthermore, data collection and analysis were conducted by the same researcher, thus it is argued that the full context of the data was understood and considered during interpretation, affording the analysis a level of consistency.

Qualitative research serves a different purpose than quantitative research: to explore the lived experiences of individuals, which cannot be achieved through observation. Subsequently, the criteria by which the quality of qualitative research is judged differs from the quantitative concepts of validity and reliability. Instead, qualitative research is judged by its credibility, transferability, dependability and confirmability. Credibility refers to the believability of the findings, best judged by the original participants (252). To some degree, this was achieved by engaging with the original patient and carer participants to pilot the survey for study II. However, it is acknowledged that, as only two patients and two carers were retained,

further limitations are placed on the conclusions. Credibility of the findings has also been achieved with the deployment of the survey in a fourth organisation. The concept of transferability (to achieve the same results twice) is inherently difficult in qualitative research. This is because the very nature of qualitative research explores the individual's lived experiences. Consequently, the individuals might respond differently on any given day. In addition, the nature of doctoral research, as an independent piece of study, has inhibited the confirmability of the findings with corroborating researchers.

By meeting the criteria for quality qualitative research, trustworthiness and authenticity have been established for study I. However, in recognition of the limitations of qualitative research in drawing generalisable conclusions, a quantitative study was conducted within a mixed method approach to determine whether another sample of the population was in agreement with the findings. The utility of a mixed methods design is that it acts as a form of triangulation (data triangulation and methodological triangulation). Methodological triangulation enabled the following:

- The unknown experiences of participants to be explored and identified using the case study approach,
- The experiences to be extrapolated and examined by an additional sample using the survey method, which has been subject to relevant statistical analysis.

Data triangulation has enabled different sources of data to be obtained to explore convergence or non-convergence of evidence.

8.5.2: Limitations of study II

Study II was proposed to address some of the issues around sample size and data type in qualitative research as part of an exploratory, sequential mixed methods study. However, it introduced its own set of limitations, some of which have been incorporated into the discussion to explain the findings. Examples are the response order effect and the skill and ability of participants to self-assess their behaviour (section

8.2.1: An alternative definition of safety for patient safety in home delivered healthcare). The survey method provides a quantitative assessment of people's beliefs and perceptions. However, the data is still susceptible to subjective assessment, which can be affected by the characteristics of the individuals participating in the research. Some may not take the questionnaire seriously or give the correct amount of thought and consideration to the items; others might want to conceal their true responses (308).

Another issue in survey research is the representativeness achieved of the total population. This study excluded those who could not read English and thus is not representative of the non-English reading community. The level of representation can further be inferred by the response rate. Poor response rates reduce the statistical power of the study and can introduce bias if those who did not respond, represent a different group within the population. The power of the study is of less concern here, because the study aimed describe the population and identify differences between stakeholder groups, not to quantify that difference. What is of concern in this study is the sampling bias that is introduced as a result of the 4.3% patient response rate.

It is worth pointing out that the 4.3% return rate has been calculated by establishing the percentage of responses received from the total number of people invited to participate – all patients on the participating organisations caseload. The method of recruitment, which has been dictated by data protection laws, inhibited the researcher from establishing which patients on the caseload did and did not meet the inclusion criteria. Ordinarily, in such research methods, the response rate represents the percentage of responses received from an eligible population. Therefore, if it were feasible to determine who was ineligible to participate, they would not have been invited to participate and the response rate would have been higher. It is argued that the calculated response rate is inaccurate and would be higher if the invited population only reflected the potential participants who met the inclusion criteria. Those who would have been ineligible to participate include patients and carers who did not have sufficient comprehension of the English language to complete the survey, patients and carers who lacked the capacity to consent such as those with a dementia for example, and patients for whom it was

inappropriate to participate such as those on the end of life pathway (with a life expectancy of two weeks or less). Given the nature of the patients targeted by the case management programme, those ineligible to participate could have accounted for a significant amount of the population invited to participate.

Through the sampling method, efforts were made to reduce sampling bias by randomly selecting patients in batches of 200 at first, and then by eventually inviting all patients to participate. This study is however, subject to self-selection bias, in that participants with particular characteristics are more likely to participate. This is examined further in section 8.6: Challenges of the research. Consequently, because of the nature of postal questionnaires, it is difficult to appreciate the characteristics of the non-respondents, and the actual representativeness of the findings cannot be determined (309).

8.6: Challenges of the research

The greatest challenges experienced during this research have mostly related to the characteristics of the patient population, in particular to: gaining access to potential patient participants, inadequate recruitment and poor representativeness, and poor retention of the elderly patient population. These have consequences and contribute to the limitations of the research (see section 8.5: Limitations of the research), which have implications on the conclusions one can draw from the findings.

8.6.1: Access to potential participants

Gaining access to patients in study I was difficult due to the isolated location of the patient population, which prohibited the researcher from even making direct contact without prior patient consent. Consequently, patients had to be recruited through the CM nurses, who were asked to take a recruitment pack to all patients whom they felt met the selection criteria. However, they declined, due to workload, to record how many recruitment packs were delivered. In comparison, in settings of the care provider, where patients assemble in a public place (e.g. the hospital, the outpatient clinical or GP surgery), the researcher

can more freely approach potential participants, once the required approvals have been granted. The recruitment process of patients living in the community is inhibited by ethical conduct and data protection laws. Under the Data Protection Act, 1998 (310) , data kept by the NHS (and other compliant organisations) must only be *'used for limited, specifically stated purposes'* (310). It is not stated that patient data can be used for research, and, therefore, personal identifiable data cannot be used to recruit patients to for research.

The sampling method of patients is heavily dependent on the ways in which a researcher can gain access, and some advice is available on the recruitment of vulnerable or hard-to-reach participants. Faugier and Sargeant (311) suggest snowball sampling as an alternative to quantitative sampling frames for hard to reach populations, whereby study members refer other members through a perceived network of behaviours within the population. However, the isolated nature and poor social visibility of the patient and carer populations rendered this method inappropriate. Another possible alternative sampling method for recruiting hard-to-reach populations is the venue-based method proposed by Nuhib et al. (312), in which the researcher identifies a day and time when the target population gathers at specific venues. The delivery of care in the home is the only known shared 'venue' and each patient is in his or her own home, making it difficult to deploy a venue-based sampling method. Instead a sampling frame was designed in which the CM nurses purposively sampled patients who met the selection criteria from the whole population.

8.6.2: Achieving a representative sample

There is evidence to suggest that the demographics of a sample, particularly age, can differ from the target population (313, 314), resulting in an underrepresentation of the elderly (315, 316). Across all ages, participation by self-selection results in a healthier study population (317, 318). This is increased in elderly populations (319), since they experience higher morbidity and mortality. This has been particularly problematic in this research. When designing the protocol for study I, the selection criteria excluded the

less well members of the population by only seeking to recruit those who were well enough to participate in the interview for an hour. This was determined by the recruiting CM nurse. Therefore, this would have biased the sample population to patients who were healthier. In the survey, patients self-selected. Given that the criteria for the service of the CM programme selects for those with multiple admissions to hospital in the preceding 12 months, co-morbidities and poly-pharmacy, it is reasonable to hypothesise that this patient sample has also suffered sampling bias due to the age and morbidity of the patient population.

The self-selection of healthier individuals in the population could explain the poor return rate experienced in study II. Given that the elderly are underrepresented in clinical research, it is difficult to know what an acceptable return rate is. Although, this does not excuse the limitations of the reduced representativeness of the sample, it does provide some credibility as to the methodological validity of the research.

8.6.3: Retention of participants

Although issues of retention were not significantly experienced in this research because neither study was longitudinal, it is worth identifying it as a potential limitation for future research. It can also give credit to the theory that the morbidity and mortality of this patient population presents recruitment issues and sampling bias. When undertaking the pilot for the survey, all patient and carer participants were contacted by telephone and invited to partake. However, only two patients and two carers were happy to participate. The remaining participants had either passed away or were too unwell. In longitudinal studies, where participants are required to remain in a study for an extended period of time, the elderly might be difficult to retain for this reason.

8.6.4: Establishing consistency

Surveys enable the examination of multiple variables across at least two different cases (248), in this survey, three different cases. It is important to achieve consistent answers across consistent questions

(249), which demanded that the survey be identical for all three cases. However, given the demographic differences between the cases, most significantly, respondent age, this was probably not appropriate. A survey which was more visually appealing with an increased font size and more appropriate language might have enabled more patients and carers to participate and capture a greater number or perspectives of these hard to reach populations. Consequently, this would have reduced the consistency of the survey because different cases would have, effectively, been responding to different surveys, making any comparisons across groups difficult. However, given that statistical inference was not feasible between the cases because of the small sample size, this would have had little bearing on the current output.

8.7: Conclusion

This research has proposed and validated a safety measurement design model, which identified patients as integral members of the CM programme: a community care service available in England for the systematic and targeted care of patients at risk of hospital admissions due to multiple and complex LTCs. In Chapter 4, the integrated safety measurement model provided the foundations for the methodological design of this research by identifying the key stakeholders of the CM programme from the academic and public policy literature. As indicated by the discipline of performance measurement, in order to ascertain whether an organisation is meeting the right outputs, corroboration with stakeholders must be achieved.

This research sought to understand safety in home care as perceived by those that are key in the delivery of safe care. Through the exploration of these perspectives, a new understanding of the definition of safety and the conditions that support or fail to support the generation of safety in home delivered healthcare, has been developed. From this understanding, a conceptual framework has been constructed to guide the assessment of safety in home delivered healthcare. The conceptual framework presented, proposes an alternative approach to safety performance assessment, to overcome the limitations of current methods, which are detailed in Chapter 2. Specifically, the framework conceptualises the

components of care within the CM programme to guide the development and/or selection of indicators that reflect the contributions made by a variety of stakeholders across a complex nested system. It is characterised by the incorporation of the structure, process and outcome model, which ascertains that outcomes are a reflection of what precedes them. In addition, the framework delineates the complex inter-relationships between structure, process and outcome. In particular, it suggests that structure can directly impact outcomes, outcomes can directly influence both processes and structure and processes can influence structure.

Chapter 9

Conclusion

9.1: Introduction

According to the principles of performance measurement, lagging indicators fail to deliver improvements in performance, and consumers should be involved in the design of the measurement system. However, current safety measurement methods in healthcare are outcome dependent, restricting their ability to improve safety. Moreover, they are neither designed nor implemented in collaboration with key stakeholders, like patients and carers. The need to engage patients is becoming increasingly clear, but a greater understanding of what contributes to safety is required, particularly in non-institutionalised care settings, such as the home.

This research set out to explore the perspectives of key stakeholders in relation to the safety of the case management (CM) programme in order to comprehend the conditions that facilitate or inhibit the delivery of safe care. In doing so, this research has:

1. Validated a model to aid in the design of safety measurement systems,

2. Proposed an alternative definition of safety for the CM programme that reflects both the key stakeholders and the type of care delivered, and

3. Constructed a conceptual framework for the assessment of safety in the CM programme.

The primary purpose of this chapter is to summarise the contribution to knowledge generated as a result of the research conducted and subsequently presented in this thesis. Research is the systematic process of generating new knowledge in a way that reduces a variety of biases and recognises the limitations of the

work, insofar as they exist. These limitations have been discussed in detail in Chapter 8 but will be summarised here. Finally, this chapter will propose future work.

9.2: A model to inform the process of safety measurement design

The integrated safety measurement model (ISMM) presented in Chapter 3 was a visual representation of high-level relationships that were apparent in the literature regarding the measurement of safety in home delivered healthcare. It was developed to inform the design of the research presented in this thesis, which amounted to the early phases of the process for designing a safety measurement system.

The ISMM acknowledged the commonly accepted stakeholders of care providers and their staff, but also incorporated the patient as a key stakeholder. Patients are becoming increasingly responsible for engaging in healthcare activities through health services like the CM programme (35, 157, 320, 321). Furthermore, patients are becoming increasingly involved in research related to understanding (172-176) and improving safety (179, 182, 184, 186). Consequently, the research design targeted the recruitment of both patients and staff of the CM programme (i.e. CM nurses). Carers did not appear to feature as heavily in the literature as patients, but after presenting the ISMM to a group of CM nurses, they identified carers as having an integral role in the care of this particular patient population. This was further confirmed when some of the patients who had agreed to participate in the study requested that the interviews be held jointly with their carer because they did not feel sufficiently confident to participate without them.

Following the exploration of the concept of safety in home healthcare in study I, the key role carers have in the care provision of this patient group became apparent. In addition, many other providers of care external to the NHS were identified, each contributing to different, or overlapping, components of care provision. The large range of stakeholders identified in study I introduced a level of complexity that was not previously considered in the ISMM. The acknowledgement of the simplicity of the key stakeholders

of the original ISMM required adaptations to be made to the model that more accurately reflected the complexity of care. Instead, a nested model of macro, meso and micro systems has been proposed with patients located at the centre of care. The revisions have been made and are presented in the holistic safety measurement model (HSMM) (see Figure 8.2: The holistic safety measurement model). This model is characterised by the recognition that the components of the system are inextricably linked and only explicable in reference to the whole. These components are:

- Macro - the connection of multiple systems within a legislative and regulatory framework
- Meso - the connection of multiple micro systems without direct contact to the core of the micro system at the provider level
- Micro - connectivity of individuals striving to achieve a shared goal

This nested system can now account for multiple provider organisations that sit in the meso level, with staff members providing care at the micro level. All of whom, however, are constrained by legislative governance at the macro level.

In adopting a proactive systems approach to safety measurement, the structure, process and outcome model of quality care (3) was proposed as a foundation for the domains of safety measurement in the homecare setting. It was selected following an examination of the literature, which concluded that its use in healthcare quality and safety thus far, evidenced its utility to measure and/or monitor safety. Using these domains to guide the qualitative data collection across all participant types, the findings have demonstrated, through the identification of dimensions within each domain, that the structure, process and outcome framework is capable of describing the underlying factors (structures) and activities (processes) that contribute to the outcomes of the patients of the CM programme.

9.3: An alternative definition of safety for the case management programme

The exploration of safety from the key stakeholders' perspectives uncovered an alternative definition of safety, one that could be applied specifically to the CM programme. This research has presented evidence that a more appropriate definition of safety in CM care could be:

> *"the meeting of complex care needs to generate positive clinical, physical, psychological and social outcomes and the reduction of risk of negative outcomes. Patients and carers can actively participate in efforts to be safe in addition to healthcare provider contributions."*

Like the definitions found in the literature (4-6, 59), this alternative definition recognises the reduction of risk of negative outcomes, or adverse events, as a component of safety. However, unlike the preceding definitions, it uses positive language about delivering safe care, rather than negative language that about avoiding harm. This is reflective of a whole systems approach, rather than a systems approach specifically to safety. This means that it does not de-compartmentalise safety as an independent component of care that can be tackled in isolation (in a somewhat reductionist approach), but incorporates it into the whole. This is important because of the nature of care being delivered: by not producing optimum outcomes (the best outcomes under the circumstances), patients may experience unnecessary harm as their health deteriorates more quickly. This research describes a contemporary definition of safety that reflects the perceptions of patients and carers who are increasingly active participants in their healthcare.

It is acknowledged that the alternative definition of safety presented is only representative of the CM programme. This is because of limitations relating to the design of the research, specifically, the targeted exploration of key stakeholders solely of the CM programme.

9.4: A conceptual framework for safety assessment in the case management programme

The literature review identified limitations of the current mechanisms for measuring safety. It also highlighted deficiencies in the research community's understanding of safety in home-delivered healthcare, in particular in the CM programme. A conceptual framework, presented in this thesis, defines what is meant by safety in home-delivered healthcare. It has been constructed from an understanding achieved from multiple methods. Firstly, the patient, carer and CM nurse perspectives' were explored using interviews and focus groups. Components of these perspectives were further examined in a quantitative survey to investigate their generalisability. Finally, these perspectives were compared to the perspective presented in the literature, and where appropriate, the literature has been incorporated.

The framework conceptualises the system of safe care within the CM programme, as perceived by the key stakeholders. Its purpose is to guide the development and/or selection of indicators in the assessment of safety. It is aligned to the alternative definition of safety presented in this thesis and is characterised by the delineation of the complex inter-relationships between structure and process and outcome. There are three central tenants that are innovative to the proposed framework and can be attributed to the level of control afforded to the case managed population:

1. **There are patient dependent dimensions of structure, including: the patient's living environment and therefore, clinical care environment; resources; and the characteristics of informal caregivers**

2. **There are patient dependent dimensions of process: self-care and management activities**

3. **The measurement of non-traditional outcomes that pose a risk to the patient's ability to safely conduct self-care**

The opportunity to identify patients with deteriorating health through a sensitive and responsive measurement system could facilitate targeted interventions. These interventions could rescue patients from deterioration and reduce their risk of traditional adverse outcomes. This research therefore, also supports the measurement of traditional outcomes of safety, such as adverse events. There are tools currently available to measure both non-traditional safety outcomes identified in this thesis and the ability of patients to perform self-care. The conceptual framework highlights a range of factors across the domains of structure, process and outcome that facilitate or hinder the condition of safety, encapsulated within a macro-meso-micro nested system.

9.5: Limitations and challenges of the research

The limitations and challenges of the research have been addressed in detail in sections 8.6 and 8.7 respectively and the main issues are reiterated here. The qualitative nature of study I reduced its generalisability. However, this was addressed by the mixed method research design, in which a quantitative survey was deployed sequentially to determine the generalisaibilty of key findings. Unfortunately, the 4.3% return rate for patient surveys reduced the representativeness of the findings. Thus the ability to conclude that the findings are generalisable is compromised. The poor representativeness of study II is mostly likely a combination of self-selection bias of the invited participants and the mechanism of recruitment which forced the researcher to invite individuals who did not meet the inclusion criteria. Self-selected study populations tend to attract the healthiest members of the population (317, 318); this holds particularly true in elderly populations (319). Those who did not meet the inclusion criteria included those who could not read and/or write English and who did not have the capacity to consent. However, it is important to recognise the value in achieving an understanding of the sample and the implications this has.

This research contributes to a body of evidence on the difficulties and challenges of conducting research in elderly patient groups. Despite the challenges raised previously and the limitations they impose on the research and the implications for the conclusions, it is important to engage this patient population in research. As it grows in size, generating a greater burden on healthcare services worldwide, new care services, interventions and drug therapies will become available to reduce the burden. Consequently, there will be a greater need to undertake research with this patient population, and a greater demand will be placed on the patients to participate. Crosby et al. (322) argue that research has a tendency to overvalue large sample sizes and undervalue small samples sizes; this could inadvertently direct research interest away from studies that involve under-served and difficult to reach populations, such as the isolated elderly population targeted here.

Research in elderly populations is underrepresented in the literature, owing to the specific challenges – some of which have been experienced in this research - of engaging with this patient population. Although these challenges impose limitations on the research, it is argued that 'unrepresentative' research that is credible is better than no research at all. This is because, in order to develop solutions to the very serious problems identified, further research that reflects the cause of these challenges and how they might be overcome is needed.

9.6: Implications of the research

Since the inception of this research, the literature has been populated with several articles that enhance the implications of this work. Lang has described the complexities of safety in home healthcare, which are derived from a series of research undertaken by the Canadian Patient Safety Initiative (CPSI) in collaboration with VON Canada. It has been established that the homecare environment is both uncontrolled and unregulated. Consequently, safety in this environment is most concerned with mitigating

the risks (168). The home is particularly complex because it cannot be easily standardised (40). Lang (323) recommended that research:

- Engage with a range of stakeholders, including: patients/clients, family members and paid and unpaid caregivers to develop an understanding of safety in the home

- Develop a definition of safety specific to home healthcare to contribute to the development of a comprehensive framework

- Explore research designs and methodologies to capture the complexities of safety in home healthcare

The research presented in this thesis has, in some way, responded to the recommendations made by Lang (323), thus contributing to the theoretical evidence base on safety in home healthcare. This research engaged with patients, their family members (who were unpaid carers) and healthcare professionals of the NHS to achieve a novel understanding of safety in the context of case managed care in England. A definition of safety is now available that reflects key stakeholders at the micro level, as well as the type of care provided in the unique setting of patients' homes. This understanding has been collated into a descriptive framework that can be used to inform the assessment of safety performance. Furthermore, the HSMM can be used to inform the design of future work to capture the complexities of safety in home healthcare in a range of care services. Firstly, this can be achieved by advising the research of the complex nested system, to ensure consideration is given to the large network of key stakeholders. Secondly, this can be achieved by proposing the system is broken down into its component parts, namely, structure, process and outcomes.

In addition to the theoretical and possible methodological implications, this research could have practical implications too. The application of the conceptual safety assessment framework presented here, could be applied in practice and stimulate safety improvement. Several research activities that would facilitate this have been proposed in 9.7: Future work.

More recently than Lang and colleagues, Vincent et al. (148) (first presented in 2.6: A recent proposal for progress), proposed a five-dimension framework that reflects the information thought to be required to generate a comprehensive and rounded picture of safety. The research presented in this thesis, which was devised and conducted prior to the publication of the Vincent et al. (148) framework, is inadvertently aligned. This alignment is described in more detail in Table 9.1: Alignment of research with recent thinking.

Table 9.1: Alignment research with recent thinking

Current thinking – five dimension for safety measurement (adapted from (148))	Alignment of proposed framework
Measures of harm, both psychological and physical.	This research supports the current use of physical and clinical adverse event measures, as well as those that are psychological and social in nature.
Measures of reliability, which encompass behaviours, process and systems	This research has proposed the use of both structure and process measures (originally described by Donabedian) in order to encompass measures of behaviours and the underlying system.
The information and capacity to monitor safety on an hourly basis	This research has not proposed specific indicators. However, the framework has been constructed and dimensions that imply the need for sensitivity have been included. For example, the framework indicates the measurement of functional health status as an outcome of safety in order to detect patient deterioration and promote rescue to prevent worse outcomes. The development of indicators for the framework has been discussed in 9.7: Future work.
The ability to anticipate problems and be prepared	Through continuous or frequent monitoring of structures and processes, patterns that lead to poor outcomes can be established. In recognising these, limits or standards can be devised to prevent a breach of optimum conditions that lead to harm.
Integration and learning from safety information	The conceptual framework proposed is a central component of the process of assessment and its use should become integrated into the process of care. Assessment should always facilitate interventions to improve care and provide evidence of good practice.

Vincent et al. (148) claim that their framework can assist in the progress of safety measurement and monitoring; the alignment of the framework proposed in this thesis can also contribute to this progress.

9.7: Future work

Despite the number of implications, the findings have raised additional questions worth further examination. These newly identified research questions relate to one of three things:

1. Further development of the conceptual framework in its current setting in order to:

    a. Quantify the strength of the relationships between the dimensions of the framework

    b. Validate the application of the framework in a safety improvement capacity

2. Development of the conceptual framework in alternative settings using the same methodology informed by the holistic safety measurement model

3. Examination of some of the intricate findings of the research

This project set out to begin the process of designing a measurement system. In the early phases of measurement design, stakeholders need to be engaged in order to understand their expectations and their contributions. This project has had to develop a fundamental understanding of safety in healthcare that is delivered in the home. It has not sought, however, to quantify the relationships between the dimensions of the framework, validate the framework as a method for improving safety or make it applicable to other settings. Nevertheless, all of these provide opportunities to conduct further work, which can be done by either building on the current application with the intent to prove it viable in the improvement of safety, or by applying the theory to another setting. Furthermore, some of the details of the findings raised questions that warrant further investigation. Three pathways for future work are depicted in Figure 9.1: Opportunities for further work.
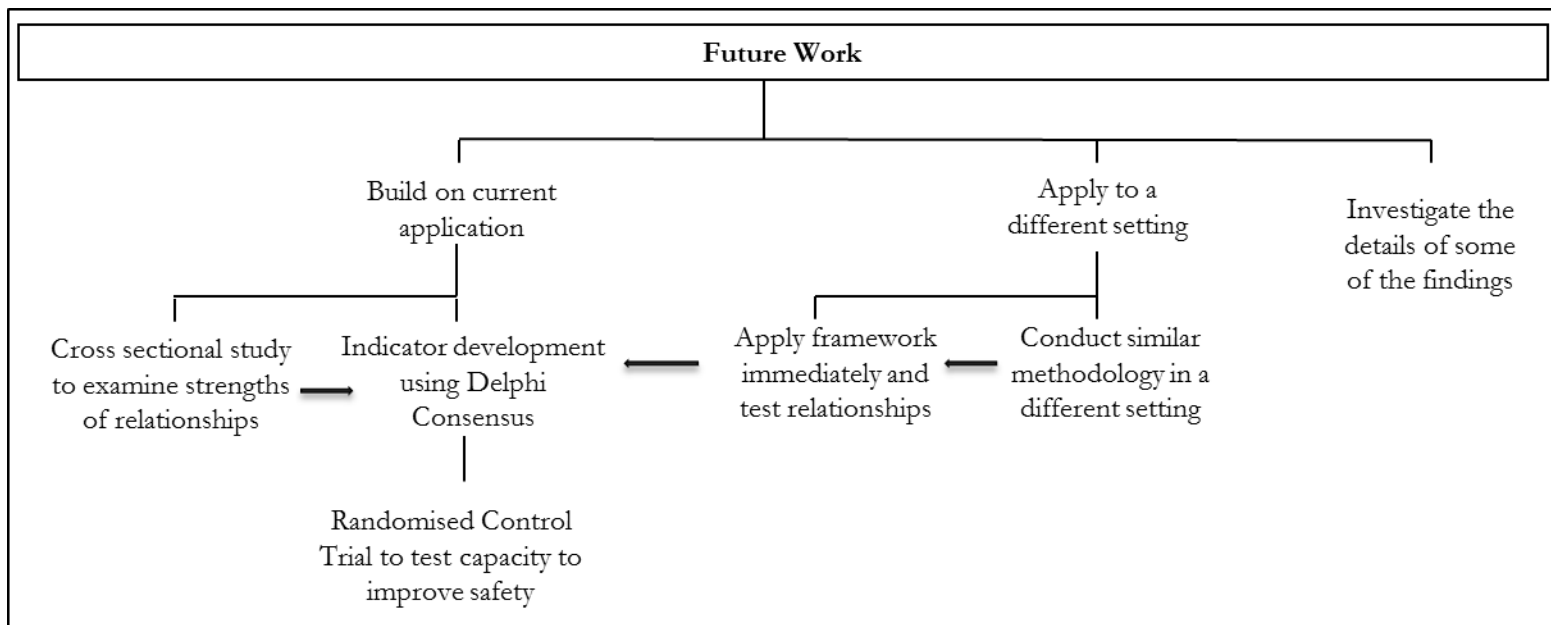
Figure 9.1: Opportunities for future work

This research has developed a conceptual framework, predicated on the structure, process, outcome model, which identifies components of a system that generate the condition of safety. This has primarily been derived from the perspectives of key stakeholders, namely patients, carers and CM nurses in studies I and II. The literature perspective has been considered in Chapter 8 and incorporated into the framework, where relevant.

Further research could be undertaken to test the significance of the relationships between each of the dimensions. This could be achieved using structural equation modelling. Kunkel et al. (198) used a cross sectional design in which they delivered a questionnaire derived from an interview study that asked basic yes or no questions on each of the three domains of quality. A progressive, systematic procedure of statistical analyses was conducted on the survey data including, in order of application: exploratory factor analysis, confirmatory factor analysis and structural equation modelling. These enabled Kunkel et al. (198) to establish significant relationships between the three, as depicted in Figure 3.6. Presented in Chapter 3 (Figure 3.7), the Nursing Role Effectiveness model was also subject to structural equation modelling using a cross sectional design questionnaire, which demonstrated it to be a well-defined conceptual framework in which the relationships were, for the most part, supported by empirical testing (201). Similar to Kunkel et al. (198) and Doran et al. (201), a cross sectional study could be deployed to collect data on each of the dimensions identified from this study using a questionnaire.

The next phase in the development of a safety measurement system would entail the identification of indicators relevant to the dimensions identified in the framework. The indicators to be used would need to be agreed upon in a preliminary study, which could be achieved through a method such as a Delphi Consensus (324). Then, the data could be collected over a period of time, and the relationships could be tested using structural equation modelling. Once the relationships have been established, indicators of the linked dimensions can be selected. When a full measurement system is developed, a randomised control trial (RCT) could be implemented to test whether the presence of the measurement system actually leads to more improvements, than a control group. An RCT randomly assigns participants to either the

intervention or control group, which reduces the risk of error and softens the impact of other variables that might contribute to the outcomes, enabling a cause and effect relationship to be established (325).

Alternatively, the work conducted here could be transferred to a different, untested setting. This could be done in two ways: by testing the HSMM model as a method and developing a specific framework for the new setting and compare the findings to those achieved in this project, or by taking the measurement framework proposed here, and directly applying it to a different setting in much the same way as described previously.

In addition to continuing to make progress in the development of a safety measurement system, as described previously, further research could be undertaken to investigate some of the more intricate questions that stem from the findings of this research. In particular, CM nurses raised the possibility of extended care hours, but CM nurse agreement was not achieved. However, patients and carers did agree that a 24-hour CM service would improve safety. Further investigation could be undertaken to examine whether there is any association between the restricted hours service provision of the CM programme and out-of-hours hospital admissions. A retrospective record review could compare the number of hospital admissions for the case managed population during the hours that the service is available and unavailable.

9.8: Contribution to knowledge

This research provides contributions to knowledge in the domains of both the conceptual and methodological. Furthermore, coupled with further research, it has potential to contribute to the practical and to policy.

Following an extensive literature review, a model was devised that described the key stakeholders of safety and proposed the use of the structure, process and outcome (SPO) components of care as measurement domains in a systems approach to safety measurement. This model was used to inform the design of the

256

research as far as it pertained to the participation of multiple key stakeholders (discussions with whom were guided by the SPO model). Although the original visual representation of the model has been revised to better reflect the system of care, the fundamental principles upon which the original was built have been qualitatively validated; specifically, that there are multiple key stakeholders of safety including patients, front line staff and provider organisations, and that the SPO domains sufficiently categorised the contributory factors of safety. In addition, carers have been identified as key stakeholders. A range of provider organisations and their front line staff have also been identified, in addition to the NHS, within a complex nested system.

Methodologically, the model provides an opportunity to support the design of other measurement systems by helping users engage with key stakeholders such as patients, their carers and front line staff. Using this model, a methodological contribution has been made to the general body of knowledge.

Through the newly acquired understanding of safety, a definition of safety in home healthcare has been described as:

"the meeting of complex care needs to generate positive clinical, physical, psychological and social outcomes and the reduction of risk of negative outcomes. Patients and carers can actively participate in efforts to be safe in addition to healthcare provider contributions".

This definition of safety reflects the patient-dominated care provided by the CM programme. In particular, failing to meet patients' needs could result in disease progression and unnecessary harm. The importance of the patient contribution is further recognised in the conceptual framework. Non-traditional outcomes of safety are proposed, such as functional health status, because of the influence they have on the patient's ability to sustain patient-dominated structures and processes of care, which in turn influence traditional measures of harm. The conceptual framework specifies a range of factors within the domains of structure and process that are contributory to the outcomes of care. This framework provides a holistic overview of the system to guide the assessment of safety.

Although not tested in this research, the project could potentially provide a contribution to practice. The use of the framework in healthcare organisations could in the future assist in monitoring and measuring the safety of a system. Future work has been proposed in detail in Chapter 9 to support this progress.

This research has queried the transferability of hospital-derived models of patient safety to the community setting and provided evidence that the patient-controlled environment renders these models limited in their application as healthcare professionals have less influence over the structures and processes of care. The need to better understand this care environment and the complex, dynamic relationships between patients and healthcare professionals could be identified as a policy priority as these services grow in demand in line with an ageing population.

9.9: Conclusion

The research presented within this thesis, has led to a novel understanding of safety in the setting of home care. The research has shown the importance of recognising the change in care delivery setting and the distinct difference in contribution made by the different stakeholders upon traditional methods of operating within health care, specifically examining the effect of this change upon safety in the CM programme.

By bringing patients from the hospital setting to their own homes (the CM programme), the considerations for safe healthcare must be re-appraised. The setting becomes highly varied and under the control of the individuals receiving the care, rather than under the control of professionals. These individuals have different expectations of safe care than to those receiving care in the hospital setting. These expectations have been examined in this research, and an alternative definition of safety is proposed that reflects both the key stakeholders investigated and the type of care delivered to this patient population.

The patients receiving care within the CM programme are characterised by the effects of their long term condition, and an important aspect of their safety is the avoidance of the unnecessary progression of their disease. A necessity of the CM programme is its reliance on patient self-care; whereby, the patient is expected to take responsibility for aspects of his or her own care. Anything that inhibits a patient's ability to self-care leads to a reduction in safety.

Through critical examination of the state of the art of safety measurement, it has been possible to elucidate the inappropriateness of isolated outcome measurement use, which, since the inception of this research, is becoming increasingly recognised. Consequently, this research has sought to identify factors contributing to the condition of safety that have been incorporated into a safety measurement framework. From this framework it is possible to identify new factors for measurement, which could potentially lead to the improved safety of patients within the CM programme.

References

1. Brennan TA, Leape LL, Laird NM, Hebert L, Localio AR, Lawthers AG, et al. Incidence of adverse events and negligence in hospitalised patients. Results of the Harvard Medical Practice Study I. *N Engl J Med*. 1991;324(6):370-6.

2. Leape LL, Brennan TA, Laird NM, Lawthers AG, Localio AR, Barnes BA, et al. The nature of adverse events in hospitalised patients. Results of the Harvard Medical Practice Study II. *N Engl J Med*. 1991 February 7, 1991;324(6):377-84.

3. Donabedian A. *Evaluating the quality of medical care*. Milbank Q 1966;44(3):166-206.

4. Runciman W, Hibbert P, Thomson R, Van Der Schaaf T, Sherman H, Lewalle P. Towards an international classification for patient safety: key concepts and terms. *Int J Qual Health Care*. 2009 February 1, 2009;21(1):18-26.

5. Davies J, Hebert P, Hoffman C. *The Canadian patient safety dictionary*. Royal College of Physicians and Surgeons of Canada. 2003; Available at: http://rcpsc.medica.org/publications/PatientSafetyDictionary_e.pdf, Accessed on 06.03.2014.

6. Kohn LT, Corrigan JM, Donaldson MS. To err is human: building a safer health system. Washington, DC: National Academy Press, Institute of Medicine. 1999.

7. Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. *BMJ*. 2001;322(7285):517-9.

8. Wilson RM, Runciman WB, Gibberd RW, Harrison BT, Newby L, Hamilton J. The quality in Australian health care study. *Med J Aust*. 1995;163(9):458-71.

9. Baker GR, Norton PG, Flintoft V, Blais R, Brown A, Cox J, et al. The Canadian adverse events study: the incidence of adverse events among hospital patients in Canada. *CMAJ*. 2004;170(11):1678-86.

10. De Vries EN, Ramrattan MA, Smorenburg SM, Gouma DJ, Boermeester MA. The incidence and nature of in-hospital adverse events: a systematic review. *Qual Safety Health Care*. 2008;17(3):216-23.

11. Department of Health. *An organisation with a memory: a report of an expert group on learning from adverse events in the NHS*. London: The Stationery Office; 2000.

12. Francis R. *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry*. London: The Stationery Office; 2013.

13. Neale G, Woloshynowych M. Retrospective case record review: a blunt instrument that needs sharpening. *Qual Safety Health Care*. 2003;12(1):2-3.

14. O'Neil AC, Petersen LA, Cook EF, Bates DW, Lee TH, Brennan TA. Physician reporting compared with medical-record review to identify adverse medical events. *Ann Inter Med*. 1993;119(5):370-6.

15. Brennan TA, Localio AR, Leape LL, Laird NM, Peterson L, Hiatt HH, et al. Identification of adverse events occurring during hospitalization. A cross-sectional study of litigation, quality assurance, and medical records at two teaching hospitals. *Ann Inter Med*. 1990;112(3):221-6.

16. Thomas EJ, Lipsitz SR, Studdert DM, Brennan TA. The reliability of medical record review for estimating adverse event rates. *Ann Intern Med*. 2002;136(11):812-6.

17. de Wet C, Bowie P. The preliminary development and testing of a global trigger tool to detect error and patient harm in primary-care records. *Postgrad Med J*. 2009;85(1002):176-80.

18. World Health Organisation. *WHO draft guidelines for adverse event reporting and learning systems - from information to action. World Health Organisation*; Available at: http://www.who.int/patientsafety/events/05/Reporting_Guidelines.pdf; Accessed 09.03.2014; 2005.

19. Agency for Healthcare Research and Quality. *AHRQ quality indicators - guide to patient safety indicators*. Rockville, MD: AHRQ Pub. 03-R203; 2003.

20. Nieva VF, Sorra J. Safety culture assessment: a tool for improving patient safety in healthcare organizations. *Qual Safety Health Care*. 2003;12(suppl 2):ii17-ii23.

21. Health and Social Care Information Centre. *NHS Safety Thermometer*. Available at: http://www.hscic.gov.uk/thermometer Accessed on 06.03.2014.

22. Reason J. Human error: models and management. *BMJ*. 2000;320(7237):768-70.

23. Reason J. *Human Error*. New York: Cambridge University Press; 1990.

24. Degani A, Wiener E. *On the design of flight deck procedures*. NASA Ames Research Centre Contractor Report. 1994.

25. Otley DT. *Accounting control and organizational behaviour*. London: Heinemann 1987.

26. Keegan DP, Eiler RG, and Jones CR. Are your performance measures obsolete? *Management Accounting*. 1989:45-50.

27. Azzone G, Masella C, and Bertele` U. Design of performance measures for time-based companies. *International Journal of Operations & Production Management*. 1991;11(3):77-85.

28. Kaplan RS, Norton DP. The balanced scorecard - measures that drive performance. *Harvard Business Review*. 1992.

29. Lynch RL, Cross KF. *Measure up! The essential guide to measuring business performance*. London: Blackwell Publishers; 1991.

30. Fitzgerald L, Moon P. *Performance measurement in service industries: making it work*. London: The Chartered Institute of Management Accountants; 1996.

31. Brown MG. *Keeping score: using the right metrics to drive world-class performance*. New York: Quality Resources; 1996.

32. Neely A, Gregory M, Platts K. Performance measurement system design: a literature review and research agenda. *International Journal of Operations & Production Management* 1995;25(12).

33. Jabareen YR. Building a conceptual framework: philosophy, definitions, and procedure. *Int J Qual Method*s. 2009;8(4):49-62.

34. Department of Health. *Choosing health: making healthier choices easier*. London: The Stationery Office; 2004.

35. Department of Health. *Supporting people with long term conditions: An NHS and social care model to support local innovation and integration*. London: The Stationery Office; 2005.

36. Romagnoli KM, Handler SM, Hochheiser H. Home care: more than just a visiting nurse. *BMJ* Qual Saf. 2013;0:1–3. doi:10.1136/bmjqs-2013-002339.

37. Craven C, Byrne K, Sims-Gould J, Martin-Matthews A. Types and patterns of safety concerns in home care: staff perspectives. Int J Qual Health Care. 2012;24(5):525-31.

38. Sears N, Baker GR, Barnsley J, Shortt S. The incidence of adverse events among home care patients. Int J Qual Health Care. 2013;25(1):16-28.

39. Blais R, Sears NA, Doran D, Baker GR, Macdonald M, Mitchell L, et al. Assessing adverse events among home care clients in three Canadian provinces using chart review. Qual Saf 2013 July 4, 2013;22:989-97.

40. Lang A, Macdonald M, Storch J, Elliott K, Stevenson L., Lacroix H, et al. Home care safety perspectives from clients, family members, caregivers and paid providers. *Healthc Q*. 2009;12(Sp):97-101.

41. Lang A, Macdonald MT, Storch J, Stevenson L, Barber T, Roach S, et al. Researching triads in home care: perceptions of safety from home care clients, their caregivers, and providers. *Home Health Care Management & Practice*. 2013.

42. Creswell JW, Plano Clark VL. *Designing and conducting mixed methods research*. (2nd ed.) Sage Publications, Inc; 2011.

43. Yin R. C*ase study research - design and methods*. (4th ed.) Sage Publications, Inc; 2009.

44. Babbie E. *Survey research methods*. Belmont, California: Wadsworth Publishing Company; 1990.

45. Ehsani JP, Jackson T, Duckett SJ. The incidence and cost of adverse events in Victorian hospitals 2003-04. *Med J Aust.* 2006;184(11):551-5.

46. International Air Transport Association. *IATA. Fact sheet* - safety. Available at : http://www.iata.org/pressroom/facts_figures/fact_sheets/pages/safety.aspx Accessed on 06.03.2014.

47. Gaba D. Human error in anesthetic mishaps. *Int Anesthesiol Clin*. 1989;27(3):137-47.

48. Dinges DF, Pack F, Williams K, Gillen KA, Powell JW, Ott GE, et al. Cumulative sleepiness, mood disturbance, and psychomotor vigilance performance decrements during a week of sleep restricted to 4-5 hours per night. *Sleep*. 1997;20(4):267-77.

49. Phillips O, Capizzi L. Anesthesia mortality. *Clin Anesth*. 1974;10(3):220-44.

50. Eichhorn JH. Prevention of intraoperative anesthesia accidents and related severe injury through safety monitoring. *Anesthesiology*. 1989;70(4):572-7.

51. Lunn JN, Devlin HB. Lessons from the confidential enquiry into perioperative deaths in three NHS regions. *Lancet*. 1987;330(8572):1384-6.

52. Gaba DM. Anaesthesiology as a model for patient safety in health care. *BMJ*. 2000;320(7237):785-8.

53. Elder NR, Pallerla H, Regan S. What do family physicians consider an error? A comparison of definitions and physician perception. *BMC Fam Pract*. 2006;7:73.

54. Runciman WB. Shared meanings: preferred terms and definitions for safety and quality concepts. *Med J Aust*. 2006;186(10Suppl):541-3.

55. Reason J. Understanding adverse events: human factors. *Qual Saf Health Care*. 1995;4(2):80-9.

56. Reason J. The contribution of latent human failures to the breakdown of complex systems. *Philos Trans R Soc Lond B Bio Sci*. 1990;327(1241):475-84.

57. Madigan EA. A description of adverse events in home healthcare. *Home Healthc Nurse*. 2007;25(3):191-7.

58. National Patient Safety Agency. *Patient safety incident*. Available at: http://www.npsa.nhs.uk/nrls/reporting/what-is-a-patient-safety-incident/. Accessed 07.03.14.

59. Cooper JB, Gaba DM, Liang B, Woods D, and Blum LN. The National Patient Safety Foundation agenda for research and development in patient safety. *MedGenMed*. 2000;2(3):E38.

60. Oxford Dictionaries. *Definition of measure in English*. Available at: http://www.oxforddictionaries.com/definition/english/measure?q=measure; Accessed 08.03.2014.

61. Hiatt HH, Barnes BA, Brennan TA. A study of medical injury and medical malpractice: an overview. *New Engl J Med*. 1989;321(7):480-4.

62. Zegers M, de Bruijne MC, Wagner C, Hoonhout LH, Waaijman R, Smits M, et al. Adverse events and potentially preventable deaths in Dutch hospitals: results of a retrospective patient record review study. *Qual Saf Health Care*. 2009;18(4):297-302.

63. Soop M, Fryksmark U, Koster M, Haglund B. The incidence of adverse events in Swedish hospitals: a retrospective medical record review study. *Int J Qual Health Care*. 2009;21(4):285-91.

64. Caplan RA, Posner KL, Cheney FW. Effect of outcome on physician judgements of appropriateness of care. *JAMA*. 1991;265(15):1957-60.

65. Michel P, Quenon JL, de Sarasqueta AM, Scemama O. Comparison of three methods for estimating rates of adverse events and rates of preventable adverse events in acute care hospitals. *BMJ.* 2004;328(7433):199.

66. The Health Foundation. *Evidence scan: global trigger tools*. London The Stationery Office; 2010.

67. Classen DC, Resar R, Griffin F, Federico F, Frankel T, Kimmel N, et al. 'Global trigger tool' shows that adverse events in hospitals may be ten times greater than previously measured. *Health Aff (Milwood)*. 2011;30(4):581-9.

68. Takata GS, Mason W, Taketomo C, Logsdon T, Sharek PJ. Development, testing, and findings of a pediatric-focused trigger tool to identify medication-related harm in US children's hospitals. *Pediatrics*. 2008;121(4):e927-e35.

69. Franklin BD, Birch S, Savage I, Wong I, Woloshynowych M, Jacklin A, et al. Methodological variability in detecting prescribing errors and consequences for the evaluation of interventions. *Pharmacoepidemiology Drug Saf*. 2009;18(11):992-9.

70. Sharek P. The North Carolina harm study: validating the IHI global trigger tool (GTT) as a potential national harm measure*,* In: *Stanford Health Policy Research in Progress Seminar;* Available at: http://healthpolicy.stanford.edu/events/the_north_carolina_harm_study_validating_the_ihi_glo bal_trigger_tool_gtt_as_a_potential_national_harm_measure/; Accessed 08.03.2014; 2009.

71. Naessens JM, O'Byrne TJ, Johnson MG, Vansuch MB, McGlone CM, Huddleston JM. Measuring hospital adverse events: assessing inter-rater reliability and trigger performance of the global trigger tool. *Int J Qual Health Care*. 2010;22(4):266-74.

72. Mattsson TO, Knudsen JL, Lauritsen J, Brixen K, Herrstedt J. Assessment of the global trigger tool to measure, monitor and evaluate patient safety in cancer patients: reliability concerns are raised. *BMJ Qual Saf*. 2013;22(7):571-9.

73. NHS Institute for Innovation and Improvement. *Background*. Available at: http://www.institute.nhs.uk/safer_care/primary_care_2/background.html Accessed 30.07.13.

74. Reason J. *Managing the risks of organisational accidents.* Aldershot, U.K.: Ashgate Publishing Limited; 1997.

75. Thomas MJ, Schultz TJ, Hannaford N, WB. R. Mapping the limits of safety reporting systems in health care--what lessons can we actually learn? *Med J Aust*. 2011;194(12):635-9.

76. Runciman WB, Williamson JAH, Deakin A, Benveniste KA, Bannon K, Hibbert PD. An integrated framework for safety, quality and risk management: an information and incident management system based on a universal patient safety classification. *Qual Saf Health Care*. 2006;15(suppl 1):i82-i90.

77. Pronovost P, Morlock L, Sexton J, Miller M, Holzmueller C, Thompson D, et al. Improving the value of patient safety reporting systems. In: Henriksen K, Battles JB, Keyes MA, et al., (eds). *Advances in patient safety: new directions and alternative appraoches (Vol 1: Assessment)*. Rockville (MD): Agency for Healthcare Research and Quality; 2008.

78. National Patient Safety Agency. *Building a memory: preventing harm, reducing risks and improving patient safety*. London: The Stationery Office; 2005.

79. Battles JB, Stevens DP. Adverse event reporting systems and safer healthcare. *Qual Saf Health Care*. 2009;18(1):2.

80. Institute for Safe Medication Practices. *Discussion paper on adverse event and error reporting in healthcare*. Available at: https://www.ismp.org/Tools/whitepapers/concept.asp; Accessed 08.03.2014; 2000.

81. Lawton R, Parker D. Barriers to incident reporting in a healthcare system. *Qual Saf Health Care*. 2002;11(1):15-8.

82. Vincent C, Stanhope N, Crowley-Murphy M. Reasons for not reporting adverse incidents: an empirical study. *J Eval Clin Pract*. 1999;5(1):13-21.

83. Evans SM, Berry JG, Smith BJ, Esterman A, Selim P, O'Shaughnessy J, et al. Attitudes and barriers to incident reporting: a collaborative hospital study. *Qual Saf Health Care*. 2006;15(1):39-43.

84. Barach P, Small SD. Reporting and preventing medical mishaps: lessons from non-medical near miss reporting systems. *BMJ*. 2000;320(7237):759-63.

85. Aspden P, Corrigan JM, Wolcott J, Erickson SM. *Patient safety: achieving a new standard for care*. Washington, DC: National Academy Press, Institute of Medicine. 2004.

86. Pronovost P, Thompson D, Holzmueller C, Lubomski L, Dorman T, Dickman F, et al. Toward learning from patient safety reporting systems. *J Crit Care*. 2006;21:305-15.

87. Agency for Healthcare Research and Quality. *AHRQ quality indicators - guide to patient safety indicators* Rockville, MD.2007, Version 3.1 (March 12,).

88. Rivard P, Elwy A, Loveland S. Applying patient safety indicators (PSIs) across health care systems: achieving data comparability. In: Henriksen K, Battles JB, Marks ES, et al., (eds). *Advances in patient safety: from research to implementation (Volume 2: Concepts and Methodology)*. Rockville (MD): Agency for Healthcare Research and Quality (US); 2005.

89. Kuzel AJ, Woolf SH, Gilchrist VJ, Engel JD, LaVeist TA, Vincent C, et al. Patient reports of preventable problems and harms in primary health care. *Ann Fam Med*. 2004;2(4):333-40.

90. McLoughlin V, Millar J, Mattke S, Franca M, Jonsson PM, Somekh D, et al. Selecting indicators for patient safety at the health system level in OECD countries. *Int J Qual Health Care*. 2006;18(suppl 1):14-20.

91. Hurtado MP, Swift EK, Corrigan JM. *Committee on the National Quality Report on Health Care Delivery: Envisioning the National Health Care Quality Report*. Washington, DC: National Academic Press, Institute of Medicine; 2001.

92. Bottle A, Aylin P. Application of AHRQ patient safety indicators to English hospital data. *Qual Saf Health Care*. 2009;18(4):303-8.

93. Raleigh VS, Cooper J, Bremner SA, Scobie S. Patient safety indicators for England from hospital administrative data: case-control analysis and comparison with US data. *BMJ.* 2008;337:a1702.

94. Weller WE, Gallagher B.K., Cen L, E.L. H. Readmissions for venous thromboembolism: expanding the definition of patient safety indicators. *Jt Comm J Qual Patient Saf*. 2004;30(9):497-504.

95. Rosen AK, Zhao S, Rivard P, Loveland S, Montez-Rath ME, Elixhauser A, et al. Tracking rates of patient safety indicators over time: lessons from the Veterans Administration. *Med Care*. 2006;44(9):850-61.

96. Zhan C, Miller M. Excess length of stay, charges and mortality attributable to medical injuries during hospitalisation. *JAMA*. 2003;290(14):1868-74.

97. Grobman WA, Feinglass J, Murthy S. Are the Agency for Healthcare Research and Quality obstetric trauma indicators valid measures of hospital safety? *Am J Obstet Gynecol*. 2006;195(3):868-74.

98. Stats Direct. *Prospective vs. Retrospective Studies*. Available at http://www.statsdirect.com/help/#basics/prospective.htm?Highlight=prospective. Accessed on 08.03.2014.

99. Bellomo R, Goldsmith D, Russell S., and Uchino S. Postoperative serious adverse events in a teaching hospital: a prospective study. *Med J Aust*. 2002;176(5):216-8.

100. Cravero JP, Beach M, Blike GT, Gallagher SM, Hertzog JH, Havidich JE, et al. Incidence and nature of adverse events during pediatric sedation/anesthesia for procedures outside the operating room: report from the pediatric sedation research consortium. *Pediatrics*. 2006;118(3):1087-96.

101. Andrews LB, Stocking C, Krizek T, Gottlieb L, Krizek C, Vargish T, et al. An alternative strategy for studying adverse events in medical care. *Lancet*. 1997;349(9048):309-13.

102. Donchin Y, Gopher D, Olin M, Badihi Y, Biesky M, Sprung CL, et al. A look into the nature and causes of human errors in the intensive care unit. *Crit Care Med*. 2003;23(2):294-300.

103. Thomas EJ, Petersen LA. Measuring errors and adverse events in health care. *J Gen Intern Med*. 2003;18(1):61-7.

104. Dominiczak P. Former Mid Staffs chief executive was allegedly 'gagged' at taxpayers' expense. *The Telegraph*. March 26 2013.

105. Leape L. Error in medicine. *JAMA*. 1994;272:1851 - 7.

106. Leape LL, Woods DD, Hatlie MJ, Kizer KW, Schroeder SA, Lundber GB. Promoting patient safety by preventing medical error. *JAMA*. 1998;260(16):1444-7.

107. Cox S, Flin R. Safety culture: philosopher's stone or man of straw. *Work and Stress*. 1998;12(3):189-201.
108. Pidgeon NF. Safety culture and risk management in organizations. *J Cross Cult Psychol*. 1991;22(129-40).
109. Clarke S. Perceptions of organisational safety: implications for the development of safety culture. *J Organ Behav* 1999;20(185-98).
110. The Health Foundation. *Evidence Scan: does improving safety culture affect patient outcomes?* London: The Stationery Office; 2011.
111. Hansen LO, Williams MV, Singer SJ. Perceptions of hospital safety climate and incidence of readmission. *Health Serv Res*. 2011;46(2):596-616.
112. Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat AH, Dellinger EP, et al. Changes in safety attitude and relationship to decreased postoperative morbidity and mortality following implementation of a checklist-based surgical safety intervention. *BMJ Qual Saf*. 2011;20(1):102-7.
113. Mardon RE, Khanna K, Sorra J, Dyer N, Famolaro T. Exploring relationships between hospital patient safety culture and adverse events. *J Patient Saf*. 2010;6(4):226-32.
114. Colla JB, Bracken AC, Kinney LM, Weeks WB. Measuring patient safety climate: a review of surveys. *Qual Saf Health Care*. 2005;14(5):364-6.
115. Singla AK, Kitch BT, Weissman JS, Campbell EG. Assessing patient safety culture: a review and synthesis of the measurement tools. *J Patient Saf*. 2006;2(3):105-15.
116. National Patient Safety Agency. *Manchester Patient Safety Framework (MaPSaF)*. Available at: http://www.nrls.npsa.nhs.uk/resources/?entryid45=59796. Accessed 27.05.2013.
117. Shields L, Tywcross A. The difference between incidence and prevalence. *Paediatric Nursing*. 2003;15(7):50.
118. Department of Health. *Guidance to support the NHS in implementing the NHS Safety Thermometer*. Available at: https://www.gov.uk/government/news/guidance-to-support-the-nhs-in-implementing-the-nhs-safety-thermometer-published; Accessed 08.03.2014.
119. University of Leicester; Department of Health Sciences. *Research projects*. Available at: http://www2.le.ac.uk/departments/health-sciences/research/soc-sci/research-projects; Accessed 08.03.2014.
120. Grundy SM, Pasternak R, Greenland P, Smith JS, Fuster V. Assessment of cardiovascular risk by use of multiple-risk-factor assessment equations: a statement for healthcare professionals from the American Heart Association and the American College of Cardiology. *J Am Coll Cardiol*. 1999;34(4):1348-59.
121. Goetzel RZ, Anderson DR, Whitmer RW, Ozminkowski RJ, Dunn RL, Wasserman J, et al. The relationship between modifiable health risks and health care expenditures: an analysis of the multi-employer HERO health risk and cost database. *J Occup Environ Med*. 1998;40(10):843-54.
122. Etminan M, Gill S, Samii A. Comparison of the risk of adverse events with pramipexole and popinirole in patients with Parkinson's disease. *Drug Saf*. 2003;26(6):439-44.
123. Cohen MR. *Medication errors: causes, prevention, and risk management*. Sudbury, MA: Jones and Bartlett Publishers, Inc; 1999.

124. World Health Organisation. *The conceptual framework for the international classification for patient safety.* World Health Organisation; Available at: http://www.who.int/patientsafety/taxonomy/icps_full_report.pdf; Accessed 09.03.2014; 2009.

125. Dückers M, Faber M, Gruijsberg J, Grol R, Schoonhoven L, Wensing M. *Safety and risk management in hospital.* The Health Foundation, Quest for Quality Improvement; Available at: http://www.health.org.uk/public/cms/75/76/313/578/Safety%20and%20risk%20management%20in%20hospitals.pdf?realName=a1pE7U.pdf; Accessed 09.03.2014; 2009

126. Uberoi RS, Swati E, Gupta U, Sibal A. Root cause analysis in healthcare. *Apollo Medicine*. 2007;4(1):72-5.

127. Wu AW, Lipshutz AM, Pronovost PJ. Effectiveness and efficiency of root cause analysis in medicine. *JAMA*. 2008;299(6):685-7.

128. Mills PD, Neily J, Luan D, Stalhandske E, Weeks WB. Using aggregate root cause analysis to reduce falls. *Jt Comm J Qual Patient Saf*. 2005;31(1):21-31.

129. Mills PD, Neily J, Luan D, Osborne A, Howard K. Actions and implementation strategies to reduce suicidal events in the Veterans Health Administration. *Jt Comm J Qual Patient Saf*. 2006;32(3):130-41.

130. Iedema RAM, Jorm C, Long D, Braithwaite J, Travaglia J, Westbrook M. Turning the medical gaze in upon itself: root cause analysis and the investigation of clinical error. *Soc Sci Med*. 2006;62(7):1605-15.

131. Wallace LM, Spurgeon P, Adams S, Earll L, Bayley J. Survey evaluation of the National Patient Safety Agency's root cause analysis training programme in England and Wales: knowledge, beliefs and reported practices. *Qual Saf Health Care*. 2009;18(4):288-91.

132. Braithwaite J, Westbrook MT, Mallock NA, Travaglia JF, Iedema RA. Experiences of health professionals who conducted root cause analyses after undergoing a safety improvement programme. *Qual Saf Health Care*. 2006;15(6):393-9.

133. DaimlerChrysler, Ford Motor Company, General Motors Corporation. *Potential failure mode and effects analysis (FMEA): reference manual*: DaimlerChrysler Corporation; 2001.

134. Reiling JG, Knutzen BL, Stoecklein M. FMEA - the cure for medical errors. *Quality Progress*. 2003:67-71.

135. Woloshynowych M, Rogers S, Taylor-Adams S, Vincent CA. The investigation and analysis of critical incidents and adverse events in healthcare. *Health Technol Assess*. 2005;9:1-143.

136. Bonnabry P, Cingria L, Sadeghipour F, Ing H, Fonxo-Christie C, Pfister R. Use of a systematic risk analysis method to improve safety in the production of paediatric parenteral nutrition solutions. *Qual Saf Health Care*. 2005;14:93-8.

137. Robinson DL, Heigham M, Clark J. Using failure mode and effects analysis for safe administration of chemotherapy to hospitalized children with cancer. *Jt Comm J Qual Patient Saf*. 2006;32(3):161-6.

138. Wensing M, Wollersheim H, Grol R. Organisational interventions to implement improvements in patient care: a structured review of reviews. *Implement Sci*. 2006;1:2.

139. Terry A, Mottram C, Round J, Firman E, Step J, Ashby S, et al. *A safer place for patients: learning to improve patient safety*. In: National Audit Office, editor. London: The Stationery Office; 2005.

140. NHS Litigation Authority. *Clinical Claims*. Available at:
http://www.nhsla.com/Claims/Pages/Clinical.aspx; Accessed 27.05.2013.

141. NHS Litigation Authority. *NHSLA Risk Management Standards 2013-14 for NHS Trusts providing Acute, Community, or Mental Health & Learning Disability Services and Non-NHS Providers of NHS Care*. In: NHS Litigation Authority, editor.2013; Available at:
http://www.nhsla.com/safety/Documents/Staffordshire%20and%20Stoke%20on%20Trent%20P artnership%20NHS%20Trust%20-%20May%202013.pdf; Accessed 09.03.201.

142. Nursing and Midwifery Council. *Safeguarding adults: if you don't do something, who will?* 2010; Available at: http://www.nmc-
uk.org/Documents/Safeguarding/Toolkit/FACT%20SHEET_Safeguarding%20adults.pdf, Accessed: 27.05.2013.

143. Care Quality Commission. *Our safeguarding protocol: the Care Quality Commission's responsibility and commitment to safeguarding*. 2013; Available at:
http://www.cqc.org.uk/sites/default/files/media/documents/20130123_800693_v2_00_cqc_saf eguarding_protocol.pdf; Accessed 09.03.2014.

144. Jaques H. Doctors brand CQC as not fit for purpose. BMJ. 2013;346:f4243.

145. Department of Health. Equity and excellence: liberating the NHS. London: The Stationery Office; 2010.

146. Department of Health. The NHS Outcomes Framework 2013/14. London: The Stationery Office; 2013.

147. Department of Health. *High quality care for all: NHS next stage review final report*. London: The Stationery Office; 2008.

148. Garratt A, Bjertnaes O, Barlinn J. Parent experiences of paediatric care (PEPC) questionnaire: reliability and validity following a national survey. *Acta Paediatr*. 2007;96(2):246 - 52.

149. Lewis RQ, Fletcher M. Implementing a national strategy for patient safety: lessons from the National Health Service in England. *Qual Saf Health Care*. 2005;14(2):135-9.

150. Department of Health. *NHS Constitution: the NHS belongs to us all. London*: The Stationery Office; 2013.

151. Neely A, Adams C, Crowe P. The performance prism in practice. *Measuring Business Excellence*. 2001;5(2):6-13.

152. Wisner JD, Fawcett SE. Linking firm strategy to operating decisions through performance measurement. Production and Inventory Management Journal. 1991;Third Quarter:pp5-11.

153. Kaplan RS, Norton DP. Putting the balanced scorecard to work. *Harvard Business Review*. 1993;September-October:pp134-47.

154. Neely A, Mills J, Platts K, Richards H, Gregory M, Bourne M, et al. Performance measurement system design: developing and testing a process-based approach. *International Journal of Operations & Production Management.* 2000;20(10):1119 - 45.

155. Office for National Statistics. *Statistical bulletin: life expectancy at birth and at age 65 for health areas in the United Kingdom, 2003-05 to 2007-09*. 2011; Available at:
http://www.google.co.uk/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=1&ved=0CC0QFj AA&url=http%3A%2F%2Fwww.ons.gov.uk%2Fons%2Frel%2Fsubnational-health4%2Flife-expectancy-at-birth-and-at-age-65-for-health-areas-in-the-united-kingdom%2F2003-05-to-2007-

09%2Fstatistical-bulletin.pdf&ei=O2EcU49A5JXsBvfxgeAC&usg=AFQjCNF_VCKsCbjbF36IG62bJ6LzQCPEgQ&sig2=j4jDpwpQPd30fwcTw1FDWQ&bvm=bv.62578216,d.ZGU; Accessed 09.03.2014.

156. Department of Economic and Social Affairs Population Division. *World Population Ageing: 1950-2050 - Executive Summary.* United Nations; Available at: http://www.un.org/esa/population/publications/worldageing19502050/pdf/62executivesummary_english.pdf; Accessed 09.03.2014; 2002.

157. Department of Health. *Chronic disease management: a compendium of information*. London: The Stationery Office; 2004.

158. Department of Health. *Raising the profile of long term conditions care: a compendium of information*. London: The Stationery Office; 2008.

159. Brudgwood A, Lilly R, Thomas M, Bacon J, Sykes W, Morris S. *Living in Britain: results from the 1998 General Household Survey*. In: Office for National Statistics, editor. London: The Stationery Office; 2000.

160. World Health Organisation. *Face to face with chronic disease.* Available at: http://www.who.int/features/2005/chronic_diseases/en/index.html; Accessed 09.03.2014.

161. Wagner EH, Austin BT, Von Korff M. Organizing care for patients with chronic illness. *Milbank Q*. 1996;74(4):511-44.

162. Royal College of Nursing. *Advanced nurse practitioners: An RCN guide to advanced nursing practice, advanced nurse practitioners and programme accreditation.* Royal College of Nursing; Available at: http://www.rcn.org.uk/__data/assets/pdf_file/0003/146478/003207.pdf; Accessed 09.03.2014; 2012.

163. Gravelle H, Dusheiko M, Sheaff R, Sargent P, Boaden R, Pickard S, et al. Impact of case management (Evercare) on frail elderly patients: controlled before and after analysis of quantitative outcome data. *BMJ*. 2007;334(7583):31.

164. Steventon A, Bardsley M, Billings J, Georghiou T, Lewis G. *An evaluation of the impact of community-based interventions on hospital use*. London: Nuffield Trust; 2011.

165. Sutherland D, Hayter M. Structured review: evaluating the effectiveness of nurse case managers in improving health outcomes in three major chronic diseases. *J Clin Nurs*. 2009;18(21):2978-92.

166. Ross S, Curry N, Goodwin N. *Case management: what it is and how it can best be implemented?* London: The Kings Fund; 2011.

167. Billings J, Dixon J, Mijanovich T, Wennberg D. Case finding for patients at risk of readmission to hospital: development of algorithm to identify high risk patients. *BMJ*. 2006;333(7563):327.

168. Lang A, Edwards N. *Safety in home care: broadening the patient safety agenda to include home care services.* Edmonton, AB: Canadian Patient Safety Institute (CPSI); 2006.

169. Johnson K. Adverse events among Winnipeg home care clients. *Healthc Q*. 2006;9(Sp):127-34.

170. Vincent CA, Coulter A. Patient safety: what about the patient? Q*ual Saf Health Care*. 2002;11:76-80.

171. Robinson A, Hohmann K, Rifkin JI, Topp D, Gilroy CM, Pickard JA, et al. Physician and public opinions on quality of health care and the problem of medical errors. *Arch Intern Med*. 2002;162(19):2186-90.

172. Pandhi N, Schumacher J, Flynn K, Smith M. Patients' perceptions of safety if interpersonal continuity of care were to be disrupted. *Health Expect*. 2008;11(4):400-8.

173. Cleopas A, Villaveces A, Charvet A, Bovier PA, Kolly V, Perneger TV. Patient assessments of a hypothetical medical error: effects of health outcome, disclosure, and staff responsiveness. *Qual Saf Health Care*. 2006;15(2):136-41.

174. Scott J, Dawson P, Jones D. Do older patients' perceptions of safety highlight barriers that could make their care safer during organisational care transfers? *BMJ Qual Saf*. 2012;21(2):112-7.

175. Elder NC, Jacobson CJ, Zink T, Hasse L. How experiencing preventable medical problems changed patients' interactions with primary health care. *Ann Fam Med*. 2005;3(6):537-44.

176. Evans SM, Berry JG, Smith BJ, Esterman A. Consumer perceptions of safety in hospitals. *BMC Public Health*. 2006;6:41.

177. Dean J, Hutchinson A, Escoto K, Lawson R. Using a multi-method, user centred, prospective hazard analysis to assess care quality and patient safety in a care pathway. *Health Serv Res*. 2007;7(1):89.

178. Ocloo JE. Harmed patients gaining voice: challenging dominant perspectives in the construction of medical harm and patient safety reforms. *Soc Sci Med*. 2010;71(3):510-6.

179. Longtin Y, Sax H, Leape L, Sheridan S, Donaldson L, Pittet D. Patient participation:current knowledge and applicability to patient safety. *Mayo Clin Proc*. 2010;85(1):53-62.

180. Keogh B. *Review into the quality of care and treatment provided by 14 hospital trusts in England: overview report.* London: NHS England; 2013.

181. The National Advisory Group. *A promise to learn – a commitment to act. Improving the safety of patients in England. National Advisory Group on the safety of patients in England.* 2013; Available at:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/226703/Berwick_Report.pdf; Accessed 10.03.2014.

182. Agoritsas T, Bovier P, Perneger T. Patient reports of undesirable events during hospitalization. *J Gen Intern Med* 2005;20:922--8.

183. Thomas EJ, Studdert DM, Burstin HR, Orav EJ, Zeena T, Williams EJ, et al. Incidence and types of adverse events and negligent care in Utah and Colorado. *Medical Care.* 2000;38(3):261-71.

184. Entwistle VA, McCaughan D, Watt IS, Birks Y, Hall J, Peat M, et al. Speaking up about safety concerns: multi-setting qualitative study of patients' views and experiences. *Qual Saf Health Care*. 2010;19(6):e33.

185. Rathert C, Huddleston N, Pak Y. Acute care patients discuss the patient role in patient safety. *Health Care Manage Rev.* 2011;36(2):134-44.

186. World Health Organisation. *Exploring patient participation in reducing health-care-related safety risks. World Health Organisation*; Available at:
http://www.euro.who.int/__data/assets/pdf_file/0010/185779/e96814.pdf, Accessed on: 31.10.2013; 2013.

187. Bergal LM, Schwarzkopf R, Walsh M, Tejwani NC. Patient participation in surgical site marking: can this be an additional tool to help avoid wrong-site surgery? *J Patient Saf*. 2010;6(4):221-5.

188. Romagnoli KM, Handler SM, Ligons FM, Hochheiser H. Home-care nurses' perceptions of unmet information needs and communication difficulties of older patients in the immediate post-hospital discharge period. *BMJ Qual Saf*. 2013;22(4):324-32.

189. Smith SB, Alexander JW. Nursing perception of patient transitions from hospitals to home with home health. *Prof Case Manag*. 2012;17(4):175-85.

190. Coleman EA. Falling through the cracks: challenges and opportunities for improving transitional care for persons with continuous complex care eeds. *J Am Geriatr Soc*. 2003;51(4):549-55.

191. van Walraven C, Bennett C, Jennings A, Austin PC, Forster AJ. Proportion of hospital readmissions deemed avoidable: a systematic review. *CMAJ*. 2011 April 19, 2011;183(7):E391-E402.

192. Hughes S, Ulasevish A, Weaver F, Henderson W, Manheim L, Kubal. J, et al. Impact of home care on hospital days: a meta analysis. Health Serv Res. 1997;32(4):415-32.

193. McGraw C, Drennan V, Humphrey C. Understanding risk and safety in home health care: the limits of generic frameworks. Qual Prim Care. 2008;16(4):239-48.

194. Donabedian A. Evaluating the Quality of Medical Care. *The Milbank Memorial Fund Quarterly*. 1966;44(3):166-206.

195. Donabedian A. The quality of care. How can it be assessed? *JAMA*. 1988;260:1743 - 8.

196. Rademakers J, Delnoij D, de Boer D. Structure, process or outcome: which contributes most to patients' overall assessment of healthcare quality? *BMJ Qual Saf*. 2011;20(4):326-31.

197. Sainfort F, Ramsay JD, Ferreira PL, Mezghani L. A first step in total quality management of nursing facility care: development of an empirical causal model of structure, process and outcome dimensions. *Am J Med Qual.* 1994;9(2):74-86.

198. Kunkel S, Rosenqvist U, Westerling R. The structure of quality systems is important to the process and outcome, an empirical study of 386 hospital departments in Sweden. B*MC Health Serv Res*. 2007;7(1):104.

199. Carayon P, Schoofs Hundt A, Karsh B-T, Gurses AP, Alvarado CJ, Smith M, et al. Work system design for patient safety: the SEIPS model. *Qual Saf Health Care*. 2006;15(suppl 1):i50-i8.

200. SjØLie H, Karlsson B, Kim HS. Crisis resolution and home treatment: structure, process, and outcome – a literature review. *J Psychiatr Ment Health Nurs*. 2010;17(10):881-92.

201. Doran DI, Sidani S, Keatings M, Doidge D. An empirical test of the Nursing Role Effectiveness Model. *J Adv Nurs*. 2002;38(1):29-39.

202. Sidani S, Irvine D. A conceptual framework for evaluating the nurse practitioner role in acute care settings. *J Adv Nurs*. 1999;30(1):58-66.

203. Irvine D, SIdani S, Porter H, O'Brien-Pallas L, Simpson B, McGillis Hall L, et al. Organizational factors influencing nurse practitioners' role implementation in acute care settings. *Can J Nurs Leadersh*. 2000;13(3):28-35.

204. Sidani S, Irvine D, Porter H, O'brien-Pallas L, Simpson B, McGillis Hall L, et al. Practice patterns of acute care nurse practitioners. *Can J Nurs Leadersh*. 2000;13(3):6-12.

205. Cummings GG, Fraser K, Tarlier DS. Implementing advanced nurse practitioner roles in acute care: an evaluation of organizational change. *J Nurs Administration*. 2003;33(3):139-45.

206. Maxwell E. Closing the gate before the horse bolts: a new approach to patient safety. In: The Health Foundation, editor. P*atient Safety Resource Centre*: Available at:

http://patientsafety.health.org.uk/blogs/2013/august/closing-gate-horse-bolts-new-approach-patient-safety; Accessed 11.03.2014; 2013.

207. Guba E, Lincoln Y. *Competing paradigms in qualitative research*. In: Denzin, Lincoln Y, editors. Handbook of qualitative research. USA: Sage Publishers; 1994.

208. Crotty M. *The foundations of social research: meaning and perspective in the research process*. London: Sage; 1998.

209. Collis J, Hussey R. *Business research: a practical guide for undergraduate and post gradaute students*. London: Palgrave MacMillan; 2003.

210. Bhaskar R. *A realist theory of science.* London: Verso; 2008.

211. Danermark B, Ekstrom M, Jakobsen L, Karlssom JC. *Explaining society - critical realism in the social sciences*. Oxford: Routledge; 2002.

212. Bunge M. Realism and antirealism in social science. *Theory and Decision.* 1993;35:207-35.

213. Creswell JW. *Research design: qualitative, quantitative and mixed method approaches* (3rd Ed.). California: Sage Publications Ltd; 2009.

214. Popay J. *'My health is alright, but I'm just tired all the time': women's experiences of ill health.* In Roberts, H. (eds) Women's Health Matters. London: Routledge; 1992.

215. Greene JC, Caraceli VJ, Graham WF. Toward a conceptual framework for mixed-method evaluation designs. *Educational Evauation and Policy Analysis.* 1989;11(3):255-74.

216. Johnson R, B., Onwuegbuzie AJ, Turnerm LA. Toward a defintion of mixed methods research. *Journal of Mixed Methods Research*. 2007;1(2):112-33.

217. Creswell JW, Fetters MD, Ivankova NV. Designing a mixed method study in primary care. *Ann Fam Med*. 2004;2(1):7-12.

218. Morse JM. Approaches to qualitative-quantitaive methodological triangulation. *Nursing Research.* 1991;40:120-3.

219. Reeves S, Kuper A, Hodges BD. Qualitative research methodologies: ethnography. *BMJ*. 2008 2008;337:q1020.

220. Glaser BG, Strauss AL. *The discovery of grounded theory: strategies for qualitative research.* London: Wiedenfield and Nicholson; 1967.

221. Frank A. The standpoint of the storyteller. *Qual Health Res*. 2000;10:354-65.

222. Simms K. *Paul Ricouer (Routledge critical thinking)*. London: Routledge; 2003.

223. Husserl E. Logical investigations Vol 2. New York: Humanities Press; 1970.

224. Zucker D. *How to do case study research. School of Nursing Faculty Publication Series, Paper 2.* 2009;Available at: http://scholarworks.umass.edu/nursing_faculty_pubs/2; Accessed 11.03.2014.

225. Stake R. *The art of case study research.* London: Sage Publications Ltd.; 1995.

226. Yin R. *Case study research - design and method* (2nd ed). Thousand Oaks, CA: Sage Publishing; 1994.

227. Yin RK. Enhancing the quality of case studies in health services research. *Health Serv Res*. 1999;35(5 pt 2):1209-24.

228. Patton MQ. Enchancing the quality and credibility of qualitative analysis. *Health Serv Res*. 1999;34:5 Part II:1189-208.

229. Sayer A. *Realism and social science*. London: Sage; 2000.

230. Easton G. Critical realism in case study research. I*ndustrial Marketing Management.* 2010;39(1):118-28.

231. Bowling A. *Research methods in health* (2nd ed.): Open University Press; 2002.

232. Holloway I. *Qualitative research in health care*. Maidenhead: Open University Press; 2005.

233. Powell RA, Single HM. Focus groups. *Int J Qual Health Care*. 1996;8(5):499-504.

234. Kitzinger J. Qualitative research: introducing focus groups. *BMJ*. 1995;311(299).

235. Fern EF. The use of focus groups for idea generation: the effects of group size, acquaintanceship, and moderator on response quantity and quality. *J Mark Res*. 1982;19:1-13.

236. Morgan DL. Focus groups. *Ann Rev Sociol*. 1996;22:129-52.

237. Lewis A. Group child interviews as a research tool. *Br Educ Res J*. 1992;18:413-21.

238. Habermans J, Shapiro JJ. K*nowledge and human interests*. Boston, MA: Beacon Press; 1972.

239. Charmaz K. *The grounded theory method: an explication and interpretation* In: Emerson, RM., (eds.) Contemporary Field Research: A Collection of Readings. Boston, MA: Little, Brown; 1983.

240. Reid K, Flowers P, Larkin M. Exploring lived xperience. *The Psychologist*. 2005;18:20-3.

241. Smith JA, Jarman M, Osborn M. *Doing interpretative analysis*. In : Murray, M., Chamberlain, K. (eds) Qualitative health psychology: theories and methods. London: Sage; 1999.

242. Osborn M. *Interpretative phenomenological analysis: an idiographic case-study approach.* 7th International Interpretative Phenomenological Analysis Conference, 12-13 September. 2005.

243. Ritchie J, Spencer L. Qualitative data analysis for applied policy research. In: Bryman, A., Burgess, R.G. *Analysing qualitative data*. London: Rouledge; 1994.

244. Mallinson S. Listening to respondents: a qualitative assessment of the Short-Form 36 Health Status Questionnaire. *Soc Sci Med.* 2002;54(1):11-21.

245. Donovan J, Little P, Mills N, Smith M, Brindle L, Jacoby A, et al. Improving design and conduct of randomised trials by embedding them in qualitative research: ProtecT (prostate testing for cancer and treatment) study. *BMJ*. 2002;325(7367):766-70.

246. Lock CA, Kaner E, Lamont S, Bond S. A qualitative study of nurses' attitudes and practices regarding brief alcohol intervention in primary health care. *J Adv Nurs*. 2002;39(4):333-42.

247. NVivo 10. NVivo qualitative data software: QSR International PTY Lt; 2012.

248. De Vaus DA. *Surveys in social research.* (5th ed.) Crows Nest, Australia: Allen and Unwin; 2002.

249. Sapsford R. *Survey reseach*. London: Sage Publications Ltd; 1999.

250. Fink A. *How to analyze survey data.* London: Sage Publications; 1995.

251. Hazard Munro B. *Statistical methods for health care research*. Phiadelphia. New York. Baltimore: Lippincott; 2001.

252. Trochim W, Donnelly J. *The research methods knowledge base*. (3rd ed.): Atomic Dog Publishing Inc; 2006.

253. Kumar R. *Research methodology: a step-by-step guide for beginners*. (3rd ed.). London: Sage Publications Ltd; 2011.

254. Dyson S, Brown B. *Social theory and applied health research*. Maidenhead, England: Open University Press; 2006.

255. Denzin NK. *The Research Act*. (3rd ed.). Englewood Cliffs, NJ: Prentice Hall; 1989.

256. Denzin N. *The Research act: a theoretical introduction to sociological method.*: New York: McGraw-Hill; 1978.

257. Rubin H, Rubin I. *Qualitative interviewing: the art of hearing data* (2nd ed.). London: Sage; 2005.

258. Parahoo K. Research on couples. *J Adv Nurs.* 2008;62(3):275-.

259. Taylor B, de Vocht H. Interviewing separeately or as couples? Considerations of auntenticity of method. *Qual Health Re*s. 2011;21(11):1576-87.

260. Guest G, Bunce A, Johnson L. How many interviews are enough? An experiment with data saturation and variability. *Field Methods*. 2006;18(1):59-82.

261. Robinson N. The use of focus group methodology - with selected samples from sexual health research. *J Adv Nurs.* 1999;29(4):905-13.

262. TypeOut. *Home*. Available at: www.typeout.co.uk; Accessed 13.02.2014.

263. The National Archives. *Data Protection Act, 1998*. Available at: http://www.legislation.gov.uk/ukpga/1998/29/contents; Accessed 10.03.2014.

264. Random.org. R*andom sequence generator.* Available at: http://www.random.org/sequences/; Accessed 10.03.2014.

265. Microsoft Office. *Excel.* Available at: http://office.microsoft.com/en-gb/excel/; Accessed 10.03.2014.

266. IBM Corp. Released 2012. IBM SPSS Statistics for Windows VA, NY: IBM Corp.

267. Holbrook A. Response order effects; In: Lavrakas, P.J Eds. *Encyclopedia of survey research methods*. Sage Publications Inc.2008.

268. Krosnich JA, Alwin DF. An evaluation of a cognitive theory of repsonse-order effects in survey measurement. *The Public Opinion Quarterly*. 1987;51(2):201-19.

269. Zaller J, Feldman S. A simple theory of the survey response: answering questions versus revealing preferences. *American Journal of Political Science*. 1992;36(3):579-616.

270. Vellas BJ, Wayne SJ, Romero LJ, Baumgartner RN, Garry PJ. Fear of falling and restriction of mobility in elderly fallers. *Age Ageing*. 1997;26(3):189-93.

271. Delbaere K, Close JCT, Brodaty H, Sachdev P, Lord SR. Determinants of disparities between perceived and physiological risk of falling among elderly people: cohort study. *BMJ.* 2010;341:c4165.

272. NHS Commissioning Board. *Commissioning for quality and innovation (CQUIN): 2013/14 guidance*. London: The Stationery Office; 2012.

273. Schnell-Hoehn KN, Naimark BJ, Tate RB. Determinants of self-care behaviors in community-dwelling patients with heart failure. *J Cardiovasc Nurs*. 2009;24(1):40-7.

274. Arbaje AI, Wolff JL, Yu Q, Powe NR, Anderson GF, Boult C. Postdischarge environmental and socioeconomic factors and the likelihood of early hospital readmission among community-dwelling medicare beneficiaries. *Gerontologist*. 2008;48(4):495-504.

275. Leidy NK. Functional status and the forward progress of merry-go-rounds: toward a coherent analytical framework. *Nursing Research*. 1994;43(4):196-202.

276. Mainz J. Defining and classifying clinical indicators for quality improvement. *Int J Qual Health Care*. 2003;15(6):523-30.

277. Rodríguez-Artalejo F, Guallar-Castillón P, Pascual C, Otero CM, Montes A, Garcia A, et al. Health-related quality of life as a predictor of hospital readmission and death among patients with heart failure. *Arch Intern Med*. 2005;165(11):1274-9.

278. Sargent P, Pickard S, Sheaff R, Boaden R. Patient and carer perceptions of case management for long-term conditions. *Health Soc Care Community*. 2007;15(6):511-9.

279. Cahir C, Bennett K, Teljeur C, Fahey T. Potentially inappropriate prescribing and adverse health outcomes in community dwelling older patients. Br J Clin Pharmacol. 2014;77(1):201-10.

280. Fillenbaum GG. Screening the elderly: a brief instrumental activities of daily living measure. *J Am Geriatr Soc*. 1985;33(10):698-706.

281. Jette A, Davies A, Cleary P, Calkins D, Rubenstein L, Fink A, et al. The functional status questionnaire. *J Gen Intern Med*. 1986;1(3):143-9.

282. Campbell AJ, Robertson MC, Grow SJL, Kerse NM, Sanderson GF, Jacobs RJ, et al. Randomised controlled trial of prevention of falls in people aged ≥75 with severe visual impairment: the VIP trial. *BMJ*. 2005;331(7520):817.

283. La Grow SJ, Robertson MC, Campbell AJ, Clarke GA, Kerse NM. Reducing hazard related falls in people 75 years and older with significant visual impairment: how did a successful program work? *Injury Prevention*. 2006;12(5):296-301.

284. Clemson L, Mackenzie L, Ballinger C, Close JCT, Cumming RG. Environmental interventions to prevent falls in community-dwelling older people: a meta-analysis of randomized trials. Journal of Aging and Health. 2008;20(8):954-71.

285. Lord SR, Menz HB, Sherrington C. Home environment risk factors for falls in older people and the efficacy of home modifications. Age Ageing. 2006;35(suppl 2):ii55-ii9.

286. Gershon RRM, Dailey M, Magda LA, Riley HEM, Conolly J, Silver A. Safety in the home healthcare sector: development of a new household safety checklist. *J Patient Saf*. 2012;8(2):51-9.

287. Gershon R, Pogorzelska M, Qureshi K, Stone P, Canton A, Samar S, et al. Home health care patients and safety hazards in the home: preliminary findings. In Agency for Healthcare Quality, Advances, *Patient Safety: New Directions and Alternative Approaches (vol 1, pp407-422)*. Rockville, MD: Agency for Healthcare Research and Quality2008.

288. Dunning J. Service users at risk as home care cuts shorten visits. *Community Care*. 05.09.2011.

289. McNicoll A. Patients at risk as 'unsafe' mental health services reach crisis point. *Community Care.* 16.10.2013.

290. Sky News. GP Plan To Bring In Out-Of-Hours Surgeries. *Sky News*. 01.10.2013.

291. Hemingway H, Nicholson A, Stafford M, Roberts R, Marmot M. The impact of socioeconomic status on health functioning as assessed by the SF-36 questionnaire: the Whitehall II Study. *Am J Public Health*. 1997;87(9):1484-90.

292. Agabiti N, Picciotto S, Cesaroni G, Bisanti L, Forastiere F, Onorati R, et al. The influence of socioeconomic status on utilization and outcomes of elective total hip replacement: a multicity population-based longitudinal study. *Int J Qual Health Care*. 2007;19(1):37-44.

293. Thomas EJ, Brennan TA. Incidence and types of preventable adverse events in elderly patients: population based review of medical records. *BMJ*. 2000;320(7237):741-4.

294. Field TS, Gurwitz JH, Harrold LR, Rothschild J, DeBellis KR, Seger AC, et al. Risk factors for adverse drug events among older adults in the ambulatory setting. *J Am Geriatr Soc*. 2004;52(8):1349-54.

295. McDowell SE, Coleman JJ, Ferner RE. Systematic review and meta-analysis of ethnic differences in risks of adverse reactions to drugs used in cardiovascular medicine. *BMJ*. 2006;332(7551):1177-81.

296. Whittingham K, Barnes S, Gardiner C. Tools to measure quality of life and carer burden in informal carers of heart failure patients: A narrative review. *Palliative Medicine*. 2013l;27(7):596-607.

297. Pattenden JF, Roberts H, Lewin RJP. Living with heart failure; patient and carer perspectives. *Eur J Cardiovasc Nurs*. 2007;6(4):273-9.

298. Annerstedt L, ElmstÅhl S, Ingvad B, Samuelsson S-M. An analysis of the caregiver's burden and the "breaking-point" when home care becomes inadequate. *Scand J Public Health*. 2000;28(1):23-31.

299. Aiken LH, Clarke SP, Sloane DM, Sochalski J, Silber JH. Hospital nurse staffing and patient mortality, nurse burnout, and job dissatisfaction. *JAMA*. 2002;288(16):1987-93.

300. Blegen MA, Goode CJ, Reed L. Nurse staffing and patient outcomes. *Nursing Research*. 1998;47(1):43-50.

301. Needleman J, Buerhaus P, Mattke S, Stewart M, Zelevinsky K. Nurse-staffing levels and the quality of care in hospitals. *N Engl J Med*. 2002;346(22):1715-22.

302. Lang A, Edwards N, Fleiszer A. Safety in home care: a broadened perspective of patient safety. *Int J Qual Health Care*. 2008;20(2):130-5.

303. Agency for Healthcare Research and Quality. *Selecting structure measures for clinical quality measurement*. Available at: http://www.qualitymeasures.ahrq.gov/tutorial/StructureMeasure.aspx ; Accessed 11.03.2014.

304. Agency for Healthcare Research and Quality. *Selecting process measures for clinical quality measurement*. Available at: http://www.qualitymeasures.ahrq.gov/tutorial/ProcessMeasure.aspx; Accessed 11.03.2014.

305. Luborsky MR, Rubinstein RL. Sampling in qualitative research: rationale, issues, and methods. *Res Aging*. 1995;17(1):89-113.

306. Smith J, Bekker H, Cheater F. Theoretical versus pragmatic design in qualitative research. *Nurse Researcher*. 2011;18(2):39-51.

307. Swallow V, Lambert H, Santacroce S, Macfadyen A. Fathers and mothers developing skills in managing children's long-term medical conditions: how do their qualitative accounts compare? *Child Care Health Dev*. 2011;37(4):512-23.

308. Boynton PM, Greenhalgh T. Selecting, designing, and developing your questionnaire. *BMJ*. 2004;328(7451):1312-5.

309. Robson C. *Real world research: a resource for social scientists and practitioner-researchers* (3rd ed.). West Sussex, UK: John Wiley & Sons; 2002.

310. Gov.UK. *Data protection*. Available at: https://www.gov.uk/data-protection/the-data-protection-act; Accessed 11.03.2011.

311. Faugier J, Sargeant M. Sampling hard to reach populations. *J Adv Nurs*. 1997;26(4):790-7.

312. Muhib FB, Lin LS, Stueve A, Miller RL, Ford WL, Johnson WD, et al. A venue-based method for sampling hard-to-reach populations. *Public Health Rep*. 2001;116(Suppl 1):216-22.

313. Kennedy WA, Laurier C, Malo J-L, Ghezzo H, L'archevêque J, Contandriopoulos A, et al. Does clinical trial selection restrict the ability to generalize use and cost of health services to "real life" subjects? *Int J Technol Assess Health Care*. 2003;19(01):8-16.

314. Ganguli M, Lytle ME, Reynolds MD, Dodge HH. Random versus volunteer selection for a community-based study. *J Gerontol A Biol Sco Med Sci*. 1998;53A(1):M39-M46.

315. Kaisera C, Jegera R, Wyrscha S, Schoeba L, Kustera GM, Busera P, et al. Selection bias of elderly patients with chronic angina referred for catheterization. Int J Cardiol. 2006;110(1):80-5.

316. Turazza. F.M., Franzosi MG. Is anticoagulation therapy underused in elderly patients with atrial fibrillation? Drugs Aging. 1997;10(3):174-84.

317. Bornehag C-G, Sundell J, Sigsgaard T, Janson S. Potential self-selection bias in a nested case-control study on indoor environmental factors and their association with asthma and allergic symptoms among pre-school children. *Scand J Public Health*. 2006;34(5):534-43.

318. Antman K, Amato D, Wood W, Carson J, Suit H, Proppe K, et al. Selection bias in clinical trials. *J Clin Oncol.* 1985;3(8):1142-7.

319. Golomb BA, Chan VT, Evans MA, Koperski S, White HL, Criqui MH. The older the better: are elderly study participants more non-representative? A cross-sectional analysis of clinical trial and observational study samples. *BMJ Open*. 2012;2(6).

320. Department of Health. *Self care - A real choice: self care suport - a practical option*. London: The Stationery Office; 2005.

321. Department of Health. *The expert patient: a new approach to chronic disease management for the 21st century.* London: The Stationery Office; 2001.

322. Crosby RA, Salazar LF, DiClemente RJ, Lang DL. Balancing rigor against the inherent limitations of investigating hard-to-reach populations. *Health Educ Res*. 2010;25(1):1-5.

323. Lang A. There's no place like home: research, practice and policy perspectives regarding safety in homecare. International *Journal for Quality in Health Care*. 2010 April 1, 2010;22(2):75-7.

324. Hermann RC, Palmer H, Leff S, Shwartz M, Provost S, Chan J, et al. Achieving consensus across diverse stakeholders on quality measures for mental healthcare. *Medical Care.* 2004;42(12):1246-53.

325. Stolberg HO, Norman G, Trop I. Randomized controlled trials. *American Journal of Roentgenology*. 2004;183(6):1539-44.

Appendices

Appendix 1: Study I REC approval

NHS

National Research Ethics Service

NRES Committee West Midlands - South Birmingham

Prospect House
Fishing Line Road
Enfield
Redditch
B97 6EW

Telephone: 01527 582532
Facsimile: 01527 582540

Chairman: **Dr S Bowman**
Co-ordinator: **Mrs Rosa Downing**

Date: 27 May 2011

Miss Sarahjane Jones
International Manufacturing Centre
IMC, WMG
University of Warwick
Coventry
CV4 7AL

Dear Miss Jones

Study title: **Identification of appropriate measures of safety in community care for patients with long term conditions being case managed.**

REC reference: **11/WM/0031**

Thank you for your letter of 18 May 2011, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

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

Ethical review of research sites

NHS sites

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

Non-NHS sites

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion

This Research Ethics Committee is an advisory committee to West Midlands Strategic Health Authority
The National Research Ethics Service (NRES) represents the NRES Directorate within the Research Ethics Committees in England

279

does not therefore apply to any non-NHS site at present. We will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

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

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

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Covering Letter		
Evidence of insurance or indemnity		09 August 2010
GP/Consultant Information Sheets	1	25 May 2011
Investigator CV		
Letter from Sponsor		
Other: CV Mairi Macintyre		
Other: Staff Questionnaire	1	27 January 2011
Other: Patient Eligibility Questionnaire	1	27 January 2011
Other: Letter from Sponsor [Warwick University]		02 February 2011
Other: Itemised Amendments List		
Participant Consent Form: Patient/Carer Consent Form	1	06 May 2011
Participant Consent Form: Staff Consent Form	1	06 May 2011
Participant Information Sheet: Staff Participant Information Sheet	2	18 May 2011
Participant Information Sheet: Patient Participant Information Sheet (CROYDON)	2	18 May 2011

This Research Ethics Committee is an advisory committee to West Midlands Strategic Health Authority
The National Research Ethics Service (NRES) represents the NRES Directorate within the Research Ethics Committees in England

280

Participant Information Sheet: Patient Participant Information Sheet (DUDLEY)	2	18 May 2011
Participant Information Sheet: Patient Participant Information Sheet (NOTTCITY)	2	18 May 2011
Participant Information Sheet: Carer Participant Information Sheet (CROYDON)	2	18 May 2011
Participant Information Sheet: Carer Participant Information Sheet (DUDLEY)	2	18 May 2011
Participant Information Sheet: Carer Participant Information Sheet (NOTTCITY)	2	18 May 2011
Protocol	v.1	13 November 2010
REC application		31 January 2011
Response to Request for Further Information		18 May 2011

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

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

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

    Notifying substantial amendments
    Adding new sites and investigators
    Progress and safety reports
    Notifying the end of the study
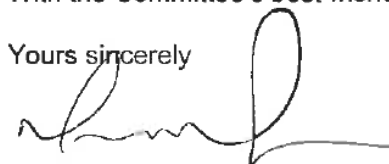
The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

11/WM/0031	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

Dr Simon Bowman
Chair

Email: rosa.downing@westmidlands.nhs.uk

Enclosures: "After ethical review – guidance for researchers"

Copy to: Dr Peter Hedges
               Director of Research Support Services
               Research Support Services
               University of Warwick
               University House
               Kirby Corner Road
               Coventry
               CV4 8UW

               Ms Christine Woolvern
               Clinical Governance
               Dudley Primary Care Trust
               4th Floor
               St John's House
               Union Street
               Dudley DY2 8PP

This Research Ethics Committee is an advisory committee to West Midlands Strategic Health Authority
The National Research Ethics Service (NRES) represents the NRES Directorate within the Research Ethics
Committees in England

282

Appendix 2: Staff information sheet

Staff Participant Information Sheet

Identification of appropriate measures of safety in community care for patients with long term conditions being case managed

We would like to invite you to take part in a research study. Before you decide, you need to understand why the research is being conducted and what it will involve should you choose to participate. Please take time to read the following information carefully and talk freely to others about the study if you wish.

Part 1 tells you the purpose of the study and what will happen to you if you agree to take part.

Part 2 gives you more detailed information about the conduct of the study.

Part 1: Purpose of study and your involvement.

What is the purpose of the study?

This study is in fulfilment of an educational doctoral research project. The principal research question being asked is; can we better measure safety in community care for patients with long term conditions being case managed? This will be answered through the principal research objective: the identification of measures as developed by staff, patients and carers.

Long term conditions such as asthma, diabetes and congestive heart failure need care that is continuous, supportive and proactive. Changes in 2005 to the care provision of patients with long term conditions has seen its delivery move from secondary to primary care, more specifically, into the community and into the patient's home. This new environment in which this care is received is highly varied between patients because of its personalised nature. The best outcome for the patient is to improve quality of life and extend it.

Quality of life refers to an individual's emotional, social and physical well-being. Quality of life is part of the bigger clinical picture in obtaining the best health outcomes for the patient. Safe care is also of great importance to patients, unsafe care occurs when a patient experiences harm; emotional, social and physical. Currently, safety incidents are reported after an incident has occurred and typically report physical harm only.

The aim of this study is to understand what safety means to patients, carers and healthcare professionals to identify items to measure and propose a new way of measuring safety based on a more holistic approach to measurement encompassing emotional, social and physical harm.

Part 1 will be questionnaires and focus groups. You will be asked to review a model of safety for your care pathway developed by the research team as well as discuss safety, and what you would like to see measured. Part 2 of the project will be a validation process using a variety of validation techniques.

Why have you been invited?

THE UNIVERSITY OF
WARWICK

EPSRC

Safety in Community Care for Patients with Long Term Conditions
Reference: ██████████████████

Version 2 Date: 18/05/2011

Quality of life refers to an individual's emotional, social and physical well-being. Quality of life is part of the bigger clinical picture in obtaining the best health outcomes for the patient. Safe care is also of great importance to patients, unsafe care occurs when a patient experiences harm; emotional, social and physical. Currently, safety incidents are reported after an incident has occurred and typically report physical harm only.

The aim of this study is to understand what safety means to patients, carers and healthcare professionals to identify items to measure and propose a new way of measuring safety.

Part 1 will be patient and carer interviews. This could include your carer should they wish to participate. You will be asked to review a model of safety for your care pathway developed by the research team as well as discuss safety, and what you would like to see measured. Part 2 of the project will be a validation process using a variety of validation techniques.

Why have you been invited?

You have been invited to take part because as a patient, you can offer a valuable perspective on the field we wish to study.

Do I have to take part?

It is up to you whether you take part or not. This information, which you may keep, is intended to provide you with all the information required for you to give informed consent. If you agree to take part, we will ask you to sign a consent form. You are free to withdraw from the study at any time, without giving a reason.

Your participation in this research will not affect the treatment you receive. Likewise, if you choose not to participate, you will not be discriminated against and your treatment will continue to be of the same quality. You are also free to stop the interview at any time.

You have been invited to take part because you have considerable knowledge and experience to contribute to the field in which we wish to study and we highly value your opinions on this topic.

Do I have to take part?

It is up to you whether you take part or not. This information, which you may keep, intends to provide you with all the information required for you to give informed consent. If you agree to take part, we will ask you to sign a consent form. You are free to withdraw from the study at any time, without giving a reason. There are no repercussions for not participating.

What will taking part in the study involve?

If you do decide to take part in study, you will be asked to provide up to 2.5 hours of your time as detailed below (please note you will either be invited into part 1 or part 2):

- ➤ Part 1: item generation
  - o Phase 1.1 - You will have two weeks to complete the questionnaire and return it to Sarahjane Jones who is the chief investigator detailed below. These questions require some deep thought and consideration. Please do not feel constrained by how much you can write. Write as much as you wish to. All questionnaires will be coded so that participants cannot be identified as all participation is anonymous.
  - o Phase 1.2 consists of a 90 minute focus group. This is an interactive group session where each participant's thoughts and feelings are shared between a group of like-minded individuals to debate a topic in mind. The focus group is to be a calm and welcoming environment in which to air opinions without fear of judgement or reprimands. You will be able to speak freely regarding the issue at hand and be fully involved in the generation of new ideas. This session will be video recorded for ease of transcription later but all data will be anonymised using the coding.
- ➤ Part 2: a one hour interview that will validate the items generated from part 1. Part of the interview will be the use of the tool developed and a review of its use regarding its design, content and delivery.

The focus groups will be run like workshops using flip chart paper to draw a consensus within the group of items to measure. This material will be analysed using content analysis. The focus groups and interviews will be video and tape recorded respectively to allow for transcription for research credibility and to allow transparency of findings. The recordings will be destroyed once transcription is complete, at the latest by September 2012. Your employer will not view any identifiable data.

Part 2: Detailed information.

Will taking part in the study be kept confidential?

Your personal details will be held in accordance with the Data Protection Act and will only be used by the research team to contact you regarding the project. The data generated from your participation will be

recorded and stored anonymously using coding. The personal details we hold on file for you will be stored confidentially and only be used to contact you regarding the research. The data collected is for use in an educational PhD thesis and further publications. After the PhD has been completed the thesis produced will be available in the public domain but will not contain identifiable data to the participants. Personal details obtained during the project will be destroyed upon completion of the study. Unidentifiable data will be kept and securely stored for up to 10 years after completion of the PhD. Everything that you contribute during your participation is confidential.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (see details below). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained upon request. Alternatively, you can contact the University's Academic Registrar; Michael Glover, 024675 22785.

What will happen to the results of the research study?

At the end of the study, a review will be compiled which you are welcome to receive. If this is the case, please let the researcher know.

The data collected is for use in an educational PhD thesis and further publications such as conferences and journals. After the PhD has been completed, the thesis produced will be available in the public domain but will not contain identifiable data to the participants.

Who is organising and funding the research?

The research is funded by the Engineering and Physical Sciences Research Council (EPSRC) through the University of Warwick to Sarahjane Jones for completion of a PhD.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by South Birmingham Research Ethics Committee.

Further information and contact details

If you require any further information about this research or wish to contact the researchers for any reason please do so using the following contact details for Sarahjane Jones

Sarahjane.Jones@warwick.ac.uk

WIMRC, University of Warwick, Coventry, CV4 7AL

07532 051543

Appendix 3: Staff consent form

STAFF CONSENT FORM

Title of Project: **Identification of appropriate measures of safety in community care for patients with long term conditions being case managed**

Identification Number for this study:

Name of Researcher: Miss Sarahjane Jones

Please initial box

1. I confirm that I have read and understood the information sheet dated 18/05/2011, version 2 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving reason up until 31st May 2012.

3. I understand that the data collected during the study will be used for a PhD thesis and future publication, that it will remain anonymous and be recorded and stored in accordance with the Data Protection Act. Only three people will have access to the data.

4. I understand that my participation will be video recorded and this will be destroyed upon transcription, to which I consent

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

6. I agree to take part in the above study

_____   _____   _____

Name of Participant   Date   Signature

_____   _____   _____

**Name of Person
Taking consent**   Date   Signature
When completed, 1 for participant; 1 for researcher site file

Appendix 4: Patient information sheet

Safety in Community Care for Patients with Long Term Conditions
Reference: ███████████████████████

Version 2 Date: 18/05/2011

Patient Participant Information Sheet

Identification of appropriate measures of safety in community care for patients with long term conditions being case managed

We would like to invite you to take part in a research study. Before you decide, you need to understand why the research is being conducted and what it will involve should you choose to participate. Please take time to read the following information carefully and talk freely to others about the study if you wish. A member of the research team will go through this information with you before you sign a consent form.

Part 1 tells you the purpose of the study and what will happen to you if you agree to take part.

Part 2 gives you more detailed information about the conduct of the study.

Part 1: Purpose of the study and your involvement.

What is the purpose of the study?

This study is in fulfilment of an educational doctoral research project. The principal research question being asked is; can we better measure safety in community care for patients with long term conditions being case managed? We want to know what you as a recipient of care would like to have measured in relation to safety.

Long term conditions such as asthma, diabetes and congestive heart failure need care that is continuous, supportive and proactive. Changes in 2005 to the care provision of patients with long term conditions has seen its delivery move from secondary to primary care, more specifically, into the community and into the patient's home. This new environment in which this care is received is highly varied between patients because of its personalised nature. The best outcome for the patient is to improve quality of life and extend it.

288

THE UNIVERSITY OF
WARWICK

EPSRC

Safety in Community Care for Patients with Long Term Conditions
Reference: ██████████████████████████████

Version 2 Date: 18/05/2011

Quality of life refers to an individual's emotional, social and physical well-being. Quality of life is part of the bigger clinical picture in obtaining the best health outcomes for the patient. Safe care is also of great importance to patients, unsafe care occurs when a patient experiences harm; emotional, social and physical. Currently, safety incidents are reported after an incident has occurred and typically report physical harm only.

The aim of this study is to understand what safety means to patients, carers and healthcare professionals to identify items to measure and propose a new way of measuring safety.

Part 1 will be patient and carer interviews. This could include your carer should they wish to participate. You will be asked to review a model of safety for your care pathway developed by the research team as well as discuss safety, and what you would like to see measured. Part 2 of the project will be a validation process using a variety of validation techniques.

Why have you been invited?

You have been invited to take part because as a patient, you can offer a valuable perspective on the field we wish to study.

Do I have to take part?

It is up to you whether you take part or not. This information, which you may keep, is intended to provide you with all the information required for you to give informed consent. If you agree to take part, we will ask you to sign a consent form. You are free to withdraw from the study at any time, without giving a reason.

Your participation in this research will not affect the treatment you receive. Likewise, if you choose not to participate, you will not be discriminated against and your treatment will continue to be of the same quality. You are also free to stop the interview at any time.

THE UNIVERSITY OF
WARWICK

EPSRC

Safety in Community Care for Patients with Long Term Conditions
Reference: ████████████████

Version 2 Date: 18/05/2011

What will taking part in the study involve?

If you do decide to take part in study, you will be asked to provide up to 1 hour of your time as detailed below (please note, if the response rate is high, you may not be selected to participate in either study but if selected, you will only be invited into part 1 or part 2):

> ➤ Part 1: a one hour interview to discuss what you personally consider important when measuring safety. This will help identify items which can be measured that are important to patients.
> ➤ Part 2: a one hour interview that will validate the data generated from part 1. Part of the interview will be the use of the measurement tool developed and a review of its use regarding its design, content and delivery.

The interviews will be conducted in your home or best place of convenience for you and will be tape recorded in order for the interview to be transcribed. The audio recording will be destroyed upon completion of the transcription.

Part 2: detailed information.

Will taking part in the study be kept confidential?

Your personal details will be held in accordance with the Data Protection Act and will only be used for the research team to contact you regarding the project. The data generated from your participation will be recorded and stored anonymously using coding. Data collected during the study may be looked at by individuals from regulatory authorities or from the NHS trust where is it relevant to your taking part in this research. The data collected is for use in an educational PhD thesis and further publications. After the PhD has been completed the thesis produced will be available in the public domain but will not contain identifiable data to the participants. Personal details obtained during the project will be destroyed upon completion of the study. Unidentifiable data will be kept and securely stored for up to 10 years after completion of the PhD.

THE UNIVERSITY OF

WARWICK

EPSRC

Safety in Community Care for Patients with Long Term Conditions
Reference: ███████████████████████████

Version 2 Date: 18/05/2011

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (see details below). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Further information is available from your local Patient Advice and Liaison Service: ████████████████████████████████████

Alternatively, you can contact the University's Academic Registrar; Michael Glover, 024675 22785

In the event of any unsafe practices being uncovered during your participation in the study, these will be reported to the clinical lead for long term conditions. They will then follow NHS protocol to deal with these issues accordingly.

What will happen to the results of the research study?

At the end of the study, a review will be compiled, which you are welcome to receive. If this is the case, please let the researcher know.

The data collected is for use in an educational PhD thesis and further publications such as conferences and journals. After the PhD has been completed, the thesis produced will be available in the public domain but will not contain identifiable data to the participants. What is said in the interviews will remain confidential and anonymous.

Who is organising and funding the research?

The research is funded by the Engineering and Physical Sciences Research Council (EPSRC) through the University of Warwick to Sarahjane Jones for completion of a PhD.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by South Birmingham

THE UNIVERSITY OF
WARWICK

Safety in Community Care for Patients with Long Term Conditions
Reference: ███████████████████████████
Research Ethics Committee.

EPSRC

Version 2 Date: 18/05/2011

Further information and contact details

If you require any further information about this research or wish to contact the researchers for any reason please do so using the following contact details

Sarahjane.Jones@warwick.ac.uk

Or

Miss Sarahjane Jones

WIMRC

University of Warwick

Coventry

CV4 7AL

07532 051543

Appendix 5: Carer information sheet

Carer Participant Information Sheet

Identification of appropriate measures of safety in community care for patients with long term conditions being case managed

We would like to invite you to take part in a research study. Before you decide, you need to understand why the research is being conducted and what it will involve should you choose to participate. Please take time to read the following information carefully and talk freely to others about the study if you wish. A member of the research team will go through this information with you before you sign a consent form.

Part 1 tells you the purpose of the study and what will happen to you if you agree to take part.

Part 2 gives you more detailed information about the conduct of the study.

Part 1: Purpose of study and your involvement.

What is the purpose of the study?

This study is in fulfilment of an educational doctoral research project. The principal research question being asked is; can we better measure safety in community care for patients with long term conditions being case managed? We want to know what you as a carer for someone in receipt of this care would like to have measured in relation to safety.

Long term conditions such as asthma, diabetes and congestive heart failure need care that is continuous, supportive and proactive. Changes in 2005 to the care provision of patients with long term conditions has seen its delivery move from secondary to primary care, more specifically, into the community and into the patient's home. This new environment in which this care is received is highly varied between patients because of its personalised nature. The best outcome for the patient is to improve quality of life and extend it.

Quality of life refers to an individual's emotional, social and physical well-being. Quality of life is part of the bigger clinical picture in obtaining the best health outcomes for the patient. Safe care is also of great importance to patients, unsafe care occurs when a patient experiences harm; emotional, social and physical. Currently, safety incidents are reported after an incident has occurred and typically report physical harm only.

The aim of this study is to understand what safety means to patients, carers and healthcare professionals to identify items to measure and propose a new way of measuring safety.

Part 1 will be patient and carer interviews. This could include your carer should they wish to participate. You will be asked to review a model of safety for your care pathway developed by the research team as well as discuss safety, and what you would like to see measured. Part 2 of the project will be a validation

293

THE UNIVERSITY OF
WARWICK

EPSRC

Safety in Community Care for Patients with Long Term Conditions
Reference: ████████████████████████
Version 2 Date: 18/05/2011

process using a variety of validation techniques.

Why have you been invited?

You have been invited to take part because as a carer, you have valuable experience of the field we wish to study.

Do I have to take part?

It is up to you whether you take part or not. This information, which you may keep, should provide you with all the information required for you to give informed consent. If you agree to take part, we will ask you to sign a consent form. You are free to withdraw from the study at any time, without giving a reason. Participation will not affect the care delivered to your relative.

What will taking part in the study involve?

If you do decide to take part in study, you will be asked to provide up to 1 hour of your time as detailed below (please note, if the response rate is high, you may not be selected to participate in either study but if selected you will only be invited into part 1 or part 2):

- ➢ Part 1: a one hour interview to discuss what you personally consider important when measuring safety. This will help identify items which can be measured that are important to patients.
- ➢ Part 2: a one hour interview that will validate the data generated from part 1. Part of the interview will be the use of the measurement tool developed and a review of its use regarding its design, content and delivery.

The interviews will be conducted in your home or best place of convenience for you and will be tape recorded in order for the interview to be transcribed. The audio recording will be destroyed upon completion of the transcription.

Part 2

Will taking part in the study be kept confidential?

Your personal details will be held in accordance with the Data Protection Act and will only be used for the research team to contact you regarding the project. The data generated from your participation will be recorded and stored anonymously using coding. Data collected during the study may be looked at by individuals from regulatory authorities or from the NHS trust where is it relevant to your taking part in this research. The data collected is for use in an educational PhD thesis and further publications. After the PhD has been completed the thesis produced will be available in the public domain but will not contain identifiable data to the participants. Personal details obtained during the project will be destroyed upon completion of the study. Unidentifiable data will be kept and securely stored for up to 10 years after completion of the PhD.

What if there is a problem?

THE UNIVERSITY OF
WARWICK

EPSRC

Safety in Community Care for Patients with Long Term Conditions
Reference: ███████████████████████   Version 2 Date: 18/05/2011

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (see details below). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Further information is available from your local Patient Advice and Liaison Service: ████████████████████████ ████████████ Alternatively, you can contact the University's Academic Registrar; Michael Glover, 024675 22785.

In the event of any unsafe practises being uncovered during your participation in the study, these will be reported to the clinical lead for long term conditions. They will then follow NHS protocol to deal with these issues accordingly.

What will happen to the results of the research study?

At the end of the study, a review will be compiled which you are welcome to receive. If this is the case, please let the researcher know.

The data collected is for use in an educational PhD thesis and further publications such as conferences and journals. After the PhD has been completed, the thesis produced will be available in the public domain but will not contain identifiable data to the participants. What is said in the interviews will remain confidential and anonymous.

Who is organising and funding the research?

The research is funded by the Engineering and Physical Sciences Research Council (EPSRC) through the University of Warwick to Sarahjane Jones for completion of a PhD.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by South Birmingham Research Ethics Committee.

Further information and contact details

If you require any further information about this research or wish to contact the researchers for any reason please do so using the following contact details

Sarahjane.Jones@warwick.ac.uk

Sarahjane Jones

WIMRC, University of Warwick

Coventry, CV4 7AL

07532 051543

Appendix 6: Patient eligibility questionnaire

Patient Eligibility Questionnaire

Identification of appropriate measures of safety in community care for patients with long term conditions being case managed.

This questionnaire aims to identify whether you would be interested in participating in some health service research or if indeed you are eligible. Please read the participant information sheet first and answer the questions below. Should you agree to partake and provide a contact telephone number; a researcher will be in touch with you within two weeks of receiving your questionnaire to discuss your potential involvement in the research further.

Question 1: Would you be willing to volunteer up to an hour of your time in a one-off interview for the purpose of this research?

Yes ☐ go to question 2

No ☐ please return the form to the address below in the self-addressed envelope

Question 2: Please provide the following contact details so we may contact you regarding your potential involvement in this research.

Full Name

_____

Address _____

_____

_____

_____

Telephone Number _____

Question 3: Please tell me...

Your Age _____

Your sex _____

Question 4: What health conditions do you have?

_____

_____

_____

_____

_____

_____

Question 5: How often do you receive care from the case management team?

_____

Thank you for taking the time to complete this questionnaire.

Please return the questionnaire in the self-addressed envelope provided or to

Miss Sarahjane Jones

WMG, University of Warwick

Coventry

CV4 7AL

Appendix 7: Patient and carer consent form

PATIENT/CARER CONSENT FORM

Title of Project: Identification of appropriate measures of safety in community care for patients with long term conditions being case managed

Identification Number for this study:

Name of Researcher: Miss Sarahjane Jones

Please initial box

1. I confirm that I have read and understood the information sheet dated 18/05/2011, version 2 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving reason up until 31st May 2012.

3. I understand that the data collected during the study will be used for a PhD thesis and future publication, that it will remain anonymous and be recorded and stored in accordance with the Data Protection Act. Only three people will have access to the data.

4. I understand that my participation will be audio recorded and this will be destroyed upon transcription, to which I consent

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

6. I agree to take part in the above study

_____   _____   _____
Name of Participant   Date   Signature

_____   _____   _____
Name of Person   Date   Signature
Taking consent
When completed, 1 for participant; 1 for researcher site file

298

Appendix 8: Sample chart (framework analysis)

Theme	CP001	CC001	DC002	DP002	DC003	DP003	DP005	DC DP004	DC001/DP006	NP001	NP005	NP006	NC001
Equipment	Originally I was going to make the bedroom down here, because this goes in to a bed, we brought this especially in case...so when they out that in [stair lift], that was a big help	The stairs have always been a problem, but then that's been overcome by the fact she's had a stair lift put in.	Well I know we had six or seven one time, and they've all got different things to do. Now, when one was, err, for the falls and the said you will need so and so and so. Well they brought her a big frame, but that was no good, and they couldn't get on with her. And as it did, err, a three wheeler, to walk with. And we've got that now. She uses it occasionally and when they finished up giving her a walking stick, the other doctor who'd done the leg said I asked him if I got her, err, a walking stick. He said I can get her a walking stick, he said but once I've got a walking	They've developed — they, they delivered us a three wheeler, like a pushchair or something. Three wheeler, there's a bag on the front and it's got brakes on, and so. Well they delivered they've got it if I want. And then a few weeks ago they delivered a stick. Well, I, I'm getting used to it but I'd rather hold [husband]'s arm or hand, you know. But erm, I've got it But whether I could get outside with a walking stick on my own, I don't think... because I've got this fear now I'm going to fall. And what happens if I fall? Because I had a bad fall,	Yes, well we've had two steps built for him so he can get up and down the steps.	the machinery that's provided now — well I think ...you know, if they took it off me, I would be extremely, extremely stressed	DP005: Um, with the the lady from Occupational Therapy, er she arranged for a half step to be put at the back door and that makes it a lot easier for me to get in and out of the house, so therefore that's safer for me. I: Okay. DP005: And she said, I said, "What can you do about a half step?" and she was able to arrange it, but I was thinking that if I've got a half step at the back door it would be helpful to get out into the garden, into the patio. I: Okay. DP005: Um, safer than it was before that, because it's an awkward step to get down. I: What does it prevent from happening? DP005: Falling	Carer: with equipment we've got to admit they've been very good because that extra rail, they did [wife] upstairs. They supplied her with those of these [commode] when she came out of hospital, one upstairs and one downstairs.	DC001: Well, alarms DP006: Alarm, telephones, DC001: Security locks? DP006: Security locks	NP001: But we've not been able to ... like at DAUGHTER1, not been able to get in and out of the bath to have a shower. Here I've got no bath. I: Um. You've got your walk in – NP001: And that was – I've got my walk in wet room. I: Yep, so that's all part of self-care. NP001: It's all part of looking after myself.	Oh, well, when I first came to have a look at the property when the council... then that social services were in touch on this matter and they came in and took one look and said, "Err, I'd like a shower, please." "Right," they said, "We're going to have this bath taken out that was in there and get you a new shower, get you a new shower." I use a scooter on the on the pathway on the ramp you see outside. Well, it wasn't quite, someone had not asked a disabled person you see, so it wasn't quite right so I mentioned, "Oh yes, we'll get that done." They widened the, widened the ramp there. And they put grab rails on the door, on the wall near the doors. Both near the back,	NP006: I've had most of the things; rails, grab rails on my doors; front and door. And they put my rails together up the garden at the back. I: Yeah, and on your stairs. NP006: And err, an extra banister up the stairs. So I have done what I can do, I think most. I did apply for a shower because I couldn't get in and out of the bath, but there was no help there, so I had to pay for that myself.	NC001: Yes. If I could only take her to the shops or somewhere. My daughter — well what she's trying to do now, she's got a ...see if the authorities can spare a mobility — what do they call them, these things you sit on. I: Like the wheelchair? NC001: Like a wheelchair, but she would ...she'd have a job on trying to move it you know. I: Yeah. NC001: On her own. My daughter said, well if ...if I had one I could push mum. I: Yeah. R: Now that would do her good. I: So she doesn't even have a wheelchair that she can go out in? NC001: No, she don't have one, yeah. If she could get

Appendix 9: Study II REC approval

NHS
Health Research Authority

National Research Ethics Service

NRES Committee West Midlands - South Birmingham

HRA NRES Centre Manchester
3rd Floor
Barlow House
4 Minshull Street
Manchester
M1 3DZ

Tel: 0161 625 7815
Fax: 0161 625 7299

23 May 2013

Miss Sarahjane Jones
International Manufacturing Centre
WMG, University of Warwick
Coventry
CV4 7AL

Dear Miss Jones

Study title:	**Identification of appropriate measures of safety in community care for patients with long term conditions being case managed.**
REC reference:	**11/WM/0031**
Amendment number:	**3**
Amendment date:	**06 May 2013**
IRAS project ID:	**58639**

- The amendment consists of a revised Questionnaire. In line with the committee's unfavourable opinion letter it has been piloted before being resubmitted.

Thank you for submitting the above amendment, which was received on 17 May 2013. It is noted that this is a modification of an amendment previously rejected by the Committee (our letter of 04 March 2013 refers).

The modified amendment has been considered on behalf of the Committee by the Chair.

Ethical opinion

I am pleased to confirm that the Committee has given a favourable ethical opinion of the modified amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved are:

Document	Version	Date
Questionnaire: S1p2.2 v.3 Survey	2	06 May 2013

| Participant Information Sheet: S1p2.2 v.3 | 3 | 22 April 2013 |
| Modified Amendment | 3 | 06 May 2013 |

R&D approval

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

Statement of compliance

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

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

| 11/WM/0031: | Please quote this number on all correspondence |

Yours sincerely

Signed on behalf of:
Professor Simon Bowman
Chair

E-mail: nrescommittee.westmidlands-southbirmingham@nhs.net

Copy to: Dr Peter Hedges – University of Warwick

                    Ms Priti Parmar - BBC CLRN RM&G Consortium office

Appendix 10: Participant information sheet – study II

Participant Information Sheet

Identification of appropriate measures of safety in community care for patients with long term conditions being case managed

We would like to invite you to take part in a research study. Before you decide, you need to understand why the research is being conducted and what it will involve should you choose to participate. Please take time to read the following information carefully and talk freely to others about the study if you wish.

Part 1 tells you the purpose of the study and what will happen to you if you agree to take part.

Part 2 gives you more detailed information about the conduct of the study.

Part 1: Purpose of the study and your involvement.

What is the purpose of the study?

This study is in fulfilment of an educational doctoral research project. The principal research question being asked is; can we better measure safety in community care for patients with long term conditions being case managed? The research has been conducted in two phases. Phase one of the research, which has been completed, explored the perspectives of safety from three key stakeholders. This phase, phase two, seeks to determine the level of agreement with the findings of phase one from a larger population.

Long term conditions such as asthma, diabetes and congestive heart failure need care that is continuous, supportive and proactive. Changes in 2005 to the care provision of patients with long term conditions has seen its delivery move from secondary to primary care, more specifically, into the community and into the patient's home. This new environment in which this care is received is highly varied between patients because of its personalised nature. The best outcome for the patient is to improve quality of life and extend it.

Quality of life refers to an individual's emotional, social and physical well-being. Quality of life is part of the bigger clinical picture in obtaining the best health outcomes for the patient. Safe care is also of great importance to patients, carers and staff, unsafe care occurs when a patient experiences harm; emotional, social and physical. Currently, safety incidents are reported after an incident has occurred and typically report physical harm only.

The aim of the overall study is to understand what safety means to patients, carers and healthcare professionals to propose a more appropriate way of measuring safety.

Why have you been invited?

You have been invited to take part because you have been identified as a key stakeholder; a patient, carer or staff member, and you can offer a valuable perspective on the field we wish to study.

Do I have to take part?

It is up to you whether you take part or not. This information, which you may keep, is intended to provide you with all the information required for you to give informed consent. You are free to withdraw from the study at any time, without giving a reason.

What will taking part in the study involve?

If you do decide to take part in study, you will be required to complete a survey, which is enclosed. It is anticipated that this will take no longer than 30 minutes to complete. Please be open and honest in your responses. Once complete, return the survey in the pre-paid envelope provided. Receipt of the completed survey is acknowledgement that you have read and understood this participant information sheet and have granted consent to participate.

Part 2: detailed information.

Will taking part in the study be kept confidential?

The study will not collect any personal details. The data generated from your participation will be recorded and stored anonymously using coding. Data collected during the study may be looked at by individuals from regulatory authorities or from the NHS trust where is it relevant to your taking part in this research. The data collected is for use in an educational PhD thesis and further publications. After the PhD has been completed, the thesis produced will be available in the public domain but will not contain identifiable data of the participants. Unidentifiable data will be kept and securely stored for up to 10 years after completion of the PhD.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (see details below). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure.

THE UNIVERSITY OF
WARWICK

EPSRC

Home Safe Home Survey

Research has been conducted, as part of a doctoral research project, which suggests that different stakeholders of care have different perspectives of safety when health care is delivered in the home and that these perspectives differ from when care is delivered in a hospital. The aim of this survey is to determine your level of agreement with the findings of the research project, what safety means to you and what importance you give to particular components of care. As a key stakeholder (a person with an interest in the success of care), your participation will help determine the representativeness of the findings and the extent of the differences between key stakeholders. Your participation will also contribute towards the development of a measurement framework which could be applied in future to measure and improve safety in home healthcare.

No personal data will be collected. As such, your responses will not be identifiable to you and the researcher will be unable to retrieve your data once it has been received. If you have any questions, please do not hesitate to contact the chief investigator on the details below. By returning the survey, it is assumed you have read the participant information sheet, meet the selection criteria given and provide inform consent to participate.

In order to ensure participants have the same basic understanding, a glossary table is included on key words. Please read these and familiarise yourself with them and refer back to them when necessary.

Word	Definition
Key stakeholder	A person with an interest or concern in something, particularly its success. This might include the patient, nursing staff, the GP, the pharmacy, carers etc.
Outcomes	The way things turn out; a consequence of an action. Four types of health outcomes: clinical, physical, psychological and social.
Clinical	A type of outcome related to the observation and treatment of patients e.g. blood glucose level
Social	A type of outcome related to activities in which people meet others for pleasure e.g. visiting friends and family
Psychological	A type of outcome related to the mental and emotional state of a person e.g. feeling happy or sad.
Physical	A type of outcome related to the function of the body e.g. being able to walk
Health	A state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity.

PLEASE NOTE THERE ARE QUESTIONS OVERLEAF

THE UNIVERSITY OF WARWICK

EPSRC

1. Which key stakeholder group do you belong to?   Patient ☐   Carer ☐   Staff ☐

2. If you are a patient, do you have an informal carer?   Yes ☐   No ☐

3. What is your gender?   Male ☐   Female ☐

4. What is your age? _____

5. What is your ethnic origin? _____

6. What is your nationality? _____

7. Which of the following definitions of safety most closely reflects your own view of safety in relation to your care in the home? Please tick **one** box only.

Option 1 – Safety is the meeting of complete care needs to generate positive clinical, physical, psychological and social outcomes and the reduction of risk of negative outcomes. Patient and carers can actively participate in efforts to be safe in addition to healthcare provider contributions.	☐
Option 2 – Safety is the prevention of harm through risk reduction and compliance with procedure or care plan. There is inherent risk in healthcare: it will not be harm free.	☐
Option 3 – Safety is the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum.	☐

8. Who do you think has the greatest responsibility for ensuring the safety of **patients**? Tick only 1

Patients ☐   Carers ☐   NHS staff ☐   NHS organisation ☐   Don't know ☐

Other: _____

9. Who do you think has the greatest responsibility for ensuring the safety of **carers**? Tick only 1

Patients ☐   Carers ☐   NHS staff ☐   NHS organisation ☐   Don't know ☐

Other: _____

10. Who do you think has the greatest responsibility for ensuring the safety of **NHS staff**? Tick only 1

Patients ☐   Carers ☐   NHS staff ☐   NHS organisation ☐   Don't know ☐

Other: _____

To what extent do you agree or disagree with each of the following statements?	Strongly Disagree	Disagree	Neither	Agree	Strongly Agree	Don't Know
11. The greater the number of patients that a single case manager is responsible for, the greater the risk to patients.	☐	☐	☐	☐	☐	☐
12. Patients who are self-funded are at greater risk of harm than those who are state-funded.	☐	☐	☐	☐	☐	☐
13. Adequate equipment provision reduces patient risk and improves safety (equipment such as such as zimmer frames, hand rails etc)	☐	☐	☐	☐	☐	☐
14. The availability of services is important for patient safety. For example the ambulance service, self-care classes and hospital clinics.	☐	☐	☐	☐	☐	☐
15. A 24 hour case management service would improve patient safety.	☐	☐	☐	☐	☐	☐
16. Specifically trained staff reduce risk to patients and increase positive patient outcomes.	☐	☐	☐	☐	☐	☐
17. Knowledge of available services is important for correct and suitable utilisation of services.	☐	☐	☐	☐	☐	☐
18. Having a less cluttered and tidy environment reduces patient risk and improves safety.	☐	☐	☐	☐	☐	☐
19. An environment in which communication between key stakeholders is encouraged can support patient safety.	☐	☐	☐	☐	☐	☐
20. Uncooperative carers and family members can negatively influence patient care, putting them at risk of poor outcomes.	☐	☐	☐	☐	☐	☐
21. Communication equipment such as care lines can reduce risk and improve patient safety.	☐	☐	☐	☐	☐	☐

22. Please comment freely on any other factors you believe contribute to patient safety in the home.

To what extent do you agree or disagree with each of the following statements?	Strongly Disagree	Disagree	Neither	Agree	Strongly Agree	Don't Know
23 Patients can be safer if they adhere to the care plan (maintain self care).	☐	☐	☐	☐	☐	☐
24. Patients can be safer if staff adhere to policy and procedure.	☐	☐	☐	☐	☐	☐
25. By managing medication effectively, patients can be safer.	☐	☐	☐	☐	☐	☐
26. Participating in social activities such as visiting friends generates better outcomes (physical, psychological and social).	☐	☐	☐	☐	☐	☐
27. Communication between key stakeholders is important in managing outcomes.	☐	☐	☐	☐	☐	☐
28. Communication between key stakeholders is important in ensuring patients remain safe.	☐	☐	☐	☐	☐	☐
29. It is important for patients to have a suitable diet.	☐	☐	☐	☐	☐	☐
30. It is important for patients to participate in exercise.	☐	☐	☐	☐	☐	☐
31. Accepting life with a chronic illness and making adjustments facilitates better outcomes.	☐	☐	☐	☐	☐	☐
32. The role of the case manager is to empower patients to deliver their own care more effectively.	☐	☐	☐	☐	☐	☐
33. Carers are an invaluable resource in managing patient outcomes and safety.	☐	☐	☐	☐	☐	☐

34. Please comment freely on any other actions you believe contribute to patient safety in the home.

35.   Listed below is a list of possible outcomes of care in relation to the case management programme. Please rank each of these outcomes in order of importance to you. Please rank the outcomes in order of importance, 1 being the most important, down to 15 being the least important. **Do not place the same number in more than one box.**

35.1: falls	
35.2: disease related outcomes	
35.3: pain	
35.4: ability to do housework	
35.5: feeding (bringing food to mouth) and eating (chewing and swallowing)	
35.6: hospital admission	
35.7: infection	
35.8: quality of life	
35.9: ability to communicate (using telephone or other forms of communication	
35.10: transportation within community	
35.11: Patient satisfaction	
35.12: Participation in social activities	
35.13: mobility	
35.14: depression	
35.15: negative emotional outcomes such as fear, vulnerability and paranoia	

36. Please comment freely on any other outcomes you consider important.

End of Survey

Please return this survey using the pre-paid envelop provided or to:

Miss Sarahjane Jones
WMG, University of Warwick
Coventry
CV4 7AL

THANK YOU!

Your participation is greatly appreciated. Should you have any further questions, please do not hesitate to contact the Chief Investigator: Sarahjane Jones on 07532051543

Further Information

If you would like to receive a report on the findings of the study then please leave your name and address below:

_____

_____

_____

_____

_____

_____

_____

_____

Appendix 12: Thematic framework

A priori theme	Theme	Sub-theme	Micro-theme
1: Definition of safety	1.1: Case management nurse	1.1.1: Unattainable nature of safety	
		1.1.2: Compliance with best practice	
	1.2: Patients and carers	1.1.3/1.2.1: Reduction of risk	
		1.2.2: Meeting of needs	
		1.2.3: Contribution of patients and carers	
2: Multiple key stakeholders	2.1: Patients		
	2.2: Informal carers		
	2.3: Organisations and their staff		
3: Structure	3.1: Equipment		
	3.2: Service		
	3.3: Environment		
	3.4: Financial Resources		
	3.5: Communication infrastructure		
	3.6: Patient characteristics		
	3.7: Carer characteristics		
	3.8: Operational conditions		
	3.9: Staff attitudes		
4: Process	4.1: Self-care and management	4.1.1: Medicating	4.1.1.1: Storage
			4.1.1.2: Prescription management
			4.1.1.3: Self-medicating
			4.1.1.4: Carer administration
		4.1.2: Adjusting to LTC	4.1.2.1: Reducing activities
			4.1.2.2: Changing role
			4.1.2.3: Changing behaviour
		4.1.3: Personal care	
		4.1.4: Home care	
		4.1.5: Diet management	
		4.1.6: Functional	

		mobility	
		4.1.7: Exercise	
	4.2: Clinical care of case manager		
	4.3: Communicating		
5: Outcomes	5.1: Adverse events		
	5.2: Clinical care sensitive outcomes		
	5.3: Functional health status		
	5.4: Psychosocial outcomes		

Appendix 13: Evidence of processes of self-care and management sub-themes

Sub-theme	Patient and carer quotes
Medicating	*"Well, first and foremost I suppose is making sure that she takes all her medication."* [CC001] *"I am managing all of my medication, I've got a lot of medication that I take."* [DP005]
Adjusting to LTC	*"Yes, yes. Erm, I do like to try and keep things clean, you know. Erm, and bless him, I mean *husband* does a lot, you know, but obviously it's not as you always want it is it? But no, I've had to let that go over my head now because there's nothing I can do about it, you know. And he does it, you know."* [CC001] *"The quality of life I have now is I can't work, which I did ... I did used to err like being a ... you know, bringing money into the house, being a breadwinner if you like. I found that important, but that's probably because of my age, I'm a bit old-fashioned like, you know what I mean. Like I say, I've never had pressure put on me off DC003 anyway, so."* [DP003] *"It stays … it has to adjust because if you cannot adjust you'll be like the dinosaur, die out very quickly. So I adjust to what's around me, namely my computer which I can use. I can walk a few steps, but not unaided. And err, otherwise mobility is the big problem. Not, my hearing, mobility."* [NP005]
Personal care	*"If he's well, I still have to go up with him now, but when he's really, really, really bad, he can't get in and out the bath so I have to help him in and out you know."* [DC003] *"So when I wash him and he turns round he has to hold onto a wall, because he couldn't just stand up on his own."* [DC001] *"She never asks me, umm there are times when she wants a little bit of adjustment with her earring, nonsensical things, but not for a woman. She wants to put her earrings on and that; she has difficulty fastening them etc. In fact I've had to do them this morning before she went out. But she's pretty independent and err she likes to do things herself. The same as she has a shower."* [NC001]

Home care	*"He, [CC001] erm, he does all the cooking, the cleaning."* (CC001)
	"I mean DP002 goes round with a duster but I wash, I cook, I make the bed, err – well, everything." (DC002)
	"I don't want anybody in to clean, I can clean myself. But in my own way." (NP001)
Diet management	*"Yes. As, as on the ball with the diabetes they can eat so much and you know, five a day and this that and the other, but her has these books from, from British Heart thing and they tell you what, err, what they can eat or whatever, what to keep off."* (DC002)
	"I've got into that now with this err, my chest being like it is, I probably have an interest because otherwise I've got to keep mucking about, but you know, recipes, oh look at this DC003, these are low calore recipes, a low fat recipe, things like that." (DP003)
Functional mobility	*"Well sometimes with his breath, he can't go to the toilet and everything and I have to go to the toilet and help him and things like that."* (DC003)
	"That is fairly recent since my wife died, and that's come from er, probably Social Services, and that's a help to me because needing a stick to walk around the house, it was difficult to carry anything, but with that trolley, come table, I can cope with carrying numerous at one time." (DP005)
	"Oh she most certainly does. Well I think ... I think she's depressed. In fact she said the other day, it's strange you bring that up, umm; she says I'm just absolutely fed up with being stuck in the house." (NC001)
Exercise	*"I did have one of them [trampoline] in the COPD classes and it was brilliant, you know, erm, I don't go on it, you go on it more than I do, don't you? But erm, I do try and do some exercises on it, but obviously I can't go mad on it, I can't go jumping up very high."* (CP001)
	"Well I've said to her, err, if we go to, not to shop, I says if, err, we go to, err, err, Merry Hill, we can walk round Merry Hill inside. I says and you can walk and exercise." (DC002)
	"And I did like to go swimming, but I don't go very often now. Yeah, I just forget these things. As I've got progressively worse, swimming got fired out, but I did have a thing off the government, the Labour government, so as I could go swimming for nothing." (DP003)

Appendix 14: CM nurse transcript – service knowledge

There's something sort of... as well with perceptions, isn't it? Because, um, and that can also be linked with care providers as well, perception that everyone out there in the ethos knows where services are and how to access services and how to use them, um, you know, because again, you'll have a situation where a daughter is looking after her father, struggling really on her knees and then trying to get services for the safety of both, both the patient but also for the carer, and yet the service providers are just handing out paper, so therefore, you know, to me it's... I don't want to say no, yes, but if you have money, oh, that means we can give you a paper, you can go and go out there and do your shopping yourself, but you have to know what you're going to shop, where you need to go and shop. It's not like you're going to go to Tesco and Sainsbury's, this is something completely different. So you give me a list and says 'here a shopping list, you can go and shop for many of these things', and from what I was getting from the carer is 'yes, I'm having these, I'm intelligent enough and able to read and understand, but how do I balance which is the best and which is the, you know, which is going to be suitable for me, how do I, I've never had this experience before so how do I gauge the service I'm going to receive from going outside to a private compared to a statutory organisation that used to provide a service?' So here's an element again one could say, I mean decisions and choice, how does someone way up who hasn't got that background getting in because if we're actually going to send papers out to patients and say here you are, these are all the patients, these are all you can look and you can get from here and there, and they go and make the wrong choices, the impact on that carer, on, on that person who's receiving the care can be quite significant because it could be deemed as I've failed to provide something that's suitable, to the point where they could actually become financially stripped because they're paying out for something they're not quite sure if this is the right amount or not. So again, it's, you know what I mean, providing care and supporting an individual who needs to be supported is looking at the whole picture, it's not just looking at one aspect, it's looking at the whole, the global picture, so with this situation is looking at the carer but it's also looking at the patient self as well and other extended family who seems to keep their distance cos sometime that has, you know what I mean, significant knock-on effect on the, um, the vision of care. And whose responsibilities, whose responsibility is it to actually help the carer who's a novice one would say in accessing care and the patient who is dependent on somebody to actually provide that service.

Appendix 15: Results for questions relating to structure (questions 11-21).

Question	Stakeholder	Strongly disagree	Disagree	Neither	Agree	Strongly Agree	Don't know
11. The greater the number of patients that a single case manager is responsible for, the greater the risk to patients.	patient	3%	6%	9%	44%	32%	6%
	carer	0%	0%	5%	37%	53%	5%
	CM nurse	0%	8%	21%	33%	33%	4.%
12. Patients who are self-funded are at greater risk of harm than those who are state-funded.	patient	9%	27%	15%	15%	9%	24%
	carer	6%	33%	0%	28%	17%	17%
	CM nurse	13%	25%	38%	13%	4%	8%
13. Adequate equipment provision reduces patient risk and improves safety (equipment such as such as zimmer frames, hand rails etc.	patient	0%	6%	6%	44%	29%	15%
	carer	0%	0%	0%	32%	68%	0%
	CM nurse	0%	4%	8%	54%	33%	0%
14. The availability of services is important for patient safety. For example the ambulance	patient	0%	0%	0%	37%	57%	6%
	carer	0%	0%	0%	37%	63%	0%

service, self-care classes and hospital clinics.	CM nurse	0%	0%	4%	67%	29%	0%
15. A 24 hour case management service would improve patient safety.	patient	0%	6%	6%	44%	29%	15%
	carer	0%	5%	5%	37%	42%	11%
	CM nurse	13%	57%	9%	13	4%	4%
16. Specifically trained staff reduce risk to patients and increase positive patient outcomes.	patient	0%	3%	0	47%	47%	3%
	carer	0%	0%	0%	477%	53%	0%
	CM nurse	0%	4%	4%	41%	46%	4%
17. Knowledge of available services is important for correct and suitable utilisation of services.	patient	0%	0%	6%	46%	46%	3%
	carer	0%	0%	0%	26%	68.%	5%
	CM nurse	0%	0%	0%	38%	63%	0%
18. Having a less cluttered and tidy environment reduces patient risk and improves safety.	patient	0%	0%	3%	49%	46%	3%
	carer	0%	0%	5.26%	26%	68%	0%
	CM nurse	0%	4%	0%	50%	46%	0%
19. An environment in which communication between key stakeholders is encouraged can	patient	0%	0%	6%	51%	4%	3%
	carer	0%	0%	5%	37%	58%	0%

support patient safety.	CM nurse	0%	0%	4%	33%	63%	0%
20. Uncooperative carers and family members can negatively influence patient care, putting them at risk of poor outcomes.	patient	0%	3%	6%	41%	50%	0%
	carer	0%	0%	5%	32%	63%	0%
	CM nurse	4%	0%	0%	58%	38%	0%
21. Communication equipment such as care lines can reduce risk and improve patient safety.	patient	0%	0%	8.57%	40%	43%	9%
	carer	0%	5%	0%	26%	68%	0%
	CM nurse	0%	8%	4%	42%	42%	4%