RISK MANAGEMENT SYSTEMS IN HEALTHCARE

PHD THESIS

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CONTENTS

Glossary of Terms

ALE	Auditors Local Evaluation
CEO	Chief Executive Officer
CNST	Clinical Negligence Scheme for Trusts
CQC	Care Quality Commission
DH	Department of Health
ERM	Enterprise Risk Management
FMEA	Failure Modes & Effects Analysis
GTT	Global Trigger Tool
HACCP	Hazard Analysis & Critical Control Points
HAZOP	Hazard & Operability Studies
HFEA	Human Fertilisation & Embryology Authority
HRA	Human Reliability Analysis
HRO	Highly Reliable Organisations
IHI	Institute for Healthcare Improvement
IOM	Institute of Medicine
JCAHO	Joint Commission of Accreditation of Health Care Organisations
NHS	National Health Service
NPSA	National Patient Safety Agency
OWAM	Organisation With a Memory
PRA	Probabilistic Risk Assessments
RCA	Root Cause Analysis
RPST	Risk Pooling Scheme for Trusts
THERP	Technique for Human Error Prediction
VSS	Vulnerable Systems Syndrome
WHO	World Health Organisation

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Abstract

Healthcare is recognised as a complex high risk industry that demands effective management of the risks presented. A total of 260 NHS Trusts were surveyed to identify the risk management arrangements in place. The results were analysed alongside three different sources of nationally published data (CQC, Monitor and NHSLA) to determine if certain organisational or system characteristics existed that would either predetermine risk performance or predispose the Trust to a higher or lower level of performance. The results successfully dispelled a number of preconceptions relating to the size and status of the Trust in determining the performance achieved. However what was evident was the influence that the Trust's culture and commitment to risk has on the safety and quality of services delivered. A second finding was the significant influence of central policy in the arrangements that organisations had in place from the presentation and content of risk strategy documents, criteria considered and executive leadership. The constraints of a national policy applied locally potentially limits the effectiveness of the processes in managing risk. It was concluded that whilst central policy may help in standardising how risk is managed current arrangements focus arrangements to narrowly. As a result the role of central policy makers should be to set principles that draw on and translate best practice from other high risk industries and encourage local health leaders to flex the approach to reflect local needs and priorities. This local flex should aim to integrate with other corporate programmes to ensure that risk is embedded in all decision making and the risk of the safety and quality of patients is considered alongside risks that may be perceived to be a higher priority such as operational targets and financial balance.

1. Introduction

This thesis aims to explore the role of risk management in healthcare. The focus of this research is on risk management practices and arrangements in NHS Trusts. This research is based on original data collection has been supplemented with national data sources to explore if there is a relationship between organisational and system characteristics and overall risk performance, predisposing Trusts to success or failure in the management of risk.

I will be using the introduction chapter to set the context for subsequent chapters. The introduction consists of four key sections:

- Scene setting through an introduction to risk management
- Problem overview drawing on the role of risk management in healthcare and perceived strengths and areas for development
- Research focus provides an overview of the research including objectives and the key questions I am seeking to answer
- An outline of the structure of the thesis structure that provides an overview of the content of subsequent chapters.

1.1 What is risk management? – an introduction

Risk Management is the process of defining and analysing risks and deciding on the appropriate course of action in order to minimise these risks whilst still achieving business goals (Harvard Business Review 2000). The Institute of Medicine (1999) adopts a more clinically biased view of risk management with a definition related to safety "safety is defined as freedom from accidental injury and does not reside in a person, device or department but emerges from the interaction of different parts of a system". Whilst the wider complexity of cause and effect is recognised (Reason 1990) the practice of embedding this in risk management in the NHS remains underdeveloped. This is demonstrated through the maturity of safety cultures (Kuhn & Youngberg 2002), tools used in incident investigations (Senders 2004) and the development of safe working practices from lessons learned (Wilf-Miron et al 2003). Healthcare organisations are recognised as lagging behind other high risk industries in the their capacity and capability to manage risk (Leape 2005)

A search on "risk management definition" via Google and Pro Quest identified a wide range

of potential definitions and references which suggests that agreeing a definition for risk management can be as complex as some of the systems in which it operates.

As an independent regulator in the UK, the Health & Safety Executive (HSE) defines risk management in terms of the identification of a hazard and the assessment of risk in the context of the task. The HSE (www.hse.gov.uk) provide the following definitions:

> a **hazard** is anything that may cause harm, such as chemicals, electricity, working from ladders, an open drawer, etc; and
>
> the **risk** is the chance, high or low, that somebody could be harmed by these and other hazards, together with an indication of how serious the harm could be

The assessment of risk is a core part of any risk management process. Successful risk management systems rely on the ability to predict outcomes reliably and with confidence. Such outcomes are not limited to harm (Weick and Sutcliffe 2007) but extend to performance and what drives organisations. Organisations that are preoccupied with a single priority or deliverable such as operational performance, financial savings, and increased production start to undermine their resilience and introduce or increase risk in other aspects of the business. Organisations exhibiting this behaviour are often described as suffering from vulnerable systems syndrome (Hollnagel et al 2001). Performance, outcomes and organisational priorities are all factors that should be considered as part of the risk assessment process irrespective of the direct or indirect nature (Hudson 2002). The level of detail of the assessment will vary depending on the tools that are used and its purpose.

1.2 Risk Management in High Risk Organisations

Risk management is a function that is applicable to all operations. The value of successful risk management is higher in industries and organisations where the risk of harm, loss or damage is or has the potential to be catastrophic (Hudson 2002). Such circumstances are often associated with high risk industries. Healthcare is often described as a high risk industry alongside aviation and oil and gas production (Leape 2005). Such organisations are characterised by high risk operating conditions where the outcomes have the potential to be catastrophic and fatal. The potential consequences require risk management is a core

part of how they operate and their overall performance (Hudson 2003). The achievement of exemplary safety performance by commercial airlines provides healthcare with an opportunity to learn from other high risk industries, offering insight to systems, behaviours and cultures and their value / contribution to managing risk. Kuhn and Youngberg (2002) recognises the evolutionary state of risk management in health, and the need and opportunities that exist to learn from past failures to aid future success.

1.3 The Importance and Relevance of Risk Management in Healthcare

In 2014/15 over 1.6 million adverse incidents were reported by healthcare organisations in England of these over 1.2 million occurred in acute / general hospitals (NRLS 2015). These incidents included patent accidents (314,314 incidents), incidents during the course of care and treatment being provided (385,528 incidents), incidents involving medication (175,459 incidents) and patient access, admission transfer and discharge (152,632 incidents). A number of studies have highlighted that reported figures represent the tip of the iceberg with many of the incidents being preventable (Brennan et al 1991), the concept of avoidable patient harm (Baker 2004), the opportunities to learn lessons (Barach & Small 2000) and that underreporting exists (IOM 1999).

Patient safety and the importance of a risk management function in healthcare has been recognised as a national an international priority in recent decades (IOM 1999, Leape 2005, Carroll & Rudolph 2006). This renewed priority status has been accompanied and driven by a number of initiatives, policies and mandated standards against which health services are regulated as well as acknowledging the underdevelopment of elements known to be critical to safety performance in other industries (Hofmann, Jacobs & Landy 1995). These drivers and the learning from other industries will be discussed in later chapters.

High performing systems are often described in relation to their resilience and reliability which helps to control potential vulnerabilities embedding in operational systems (Hollnagel & Woods 2006). The concept of vulnerable system syndrome has the potential to be more evident in commercially driven sectors where there is the potential to become preoccupied with activity targets, financial performance and optimising productivity (Gamble 2013). In the past decade, enhanced performance management in the NHS has increased the rigour and attention paid to the achievement of operational performance and improvement targets with

early signs of vulnerability evident in systems that pursue the targets without consideration to the increased or additional risks to be assessed (Weick & Sutcliffe 2007). To maintain the reliability of performance, including the operational delivery and effective management of risk, organisational systems need to align and integrate so that no single factor dominates to the detriment of other factors (HSE 2011). In healthcare, the independence of risk management and its lack of integration and profile in core business has resulted in other factors dominating decision making and introducing vulnerability to the system (Cagliano et al 2011).

1.4 Research Focus

Healthcare and the NHS are not deprived of approaches, models and systems to manage risk with a wide range to choose from. The further analysis of the tools and systems available alongside industry requirements continues to develop the understanding of characteristics of systems and expected levels of performance. What is clear is that there is an opportunity to transfer this learning to healthcare and use it to inform and develop how it manages risk. Whilst there are a number of risk assessment tools and risk management frameworks available to healthcare providers, a gap of the system is the absence of an integrated tool bring together and facilitating the comparison of clinical, non clinical, financial and organisational risks. This research aims to understand the strengths, weaknesses and opportunities to develop systems, the common characteristics of risk systems and organisations and how these impact on risk performance.

The focus of the research is on risk management systems in the NHS and aims to respond to the following three questions:

- Does risk management exist as a function in the NHS and what does this look like?
- Is it possible to measure the success of the systems and if so how?
- Do characteristics of either the organisation or system influence how a Trust performs?

In order to respond to these questions, the following research objectives have been set:

1. To identify common elements of risk assessment and management systems in use across the NHS

2. To analyse the impact or influence that characteristics of risk systems and of Trusts have on organisational performance
3. To determine if “risk information” is used within the organisation and the relationship between outcomes and organisational and other factors.
4. To review the influence of other approaches such as national initiatives and individual’s behaviour on risk management and in the achievement of a patient focussed service.

The response will draw upon the findings of original data collection involving the survey of 260 NHS Trusts, national data collections, regulatory outcomes across all NHS Trusts in England as well as an extensive literature review drawing on the experiences of international healthcare and other industries on the performance and content of risk management systems.

1.5 Thesis Structure

The research explores the activity and function of risk management that is evolving in its development and in its understanding in the NHS. Whilst some identify and describe particular elements of risk systems in healthcare as embryonic or evolving (Leape 2005) there is an emerging picture of common characteristics shared across Trusts as well as with other high risk industries in the processes and arrangements that are in place to manage risk. Carroll & Rudolph (2006), Sikka et al (2015) highlight the need to consider additional factors and criteria in the management of risk that may drive or influence successful high performance or equally prove to be a distraction to effective assessment and mitigation of risk.

The subsequent chapters look at current practice, considers what the literature says in terms of national and international practice of managing risk in healthcare, presents the findings of the data collection and analysis and presents the findings with a supporting discussion structured around the research objectives and ultimately answering the three key questions.

Chapter 2 is the detailed literature review that explores risk management systems, processes and arrangements in healthcare on a national and international scale. It considers the maturity and performance of systems judged by the factors influencing risk assessments and mitigating actions through learning from the risk management systems

and structures in high risk industries. Using the review of other industries measuring the success of risk management and aligning this to organisational characteristics is also identified.

Chapter 3 provides the concept analysis. This analysis reflects on the full breadth of the literature available and outlines the scope of the potential influencing factors and drivers of risk management systems in health care. The identification of key drivers and the insight that this offers has been translated into the next two chapters on methodology including the analytical approaches adopted and in the presentation of the findings.

Chapter 4 sets out the methodology of the proposal, data collection including a trial of the approach and the analytical approach adopted. Throughout the chapter a reference check to the objectives and the three questions is continually made.

Chapter 5 reports the results and findings through the use of qualitative and quantitative analysis. The results draw together the findings of the analysis, literature review and other possible outcomes or theories with the aim of providing insight to relationships, dependencies and characteristics.

Chapter 6 discusses the findings from chapter 5 and offers an evidence based view on what good looks like in relation to a risk management system in the NHS and also in demonstrated performance.

Chapter 7 reports upon the conclusions of the research including the potential for future research.

Chapter 2 - Literature Review

2.1 Introduction

In chapter 1 the complexity of risk management as a function and in its application and use in healthcare was identified. This complexity being contributed to by both the subject through its definition (HSE 1999) and scope and in its adoption in healthcare, in itself a complex and high risk industry (Reason et al 2001, Areh & Klazinga 2004). This chapter explores risk management systems, processes and arrangements in healthcare on a national and international scale. It considers the maturity and performance of systems judged by the factors influencing risk assessments and mitigating actions through learning from the risk management systems and structures in high risk industries.

2.2 Risk Management in High Risk Organisations

Risk management is a function that is applicable to all types of operations. The value of successful risk management is higher in industries and organisations where the risk of harm, loss or damage is or has the potential to be catastrophic (Hudson 2002). Such circumstances are often associated with high risk industries. Healthcare is often described as a high risk industry alongside aviation and oil and gas production (Leape 2005). Such organisations are characterised by high risk operating conditions where the outcomes have the potential to be catastrophic and fatal. The potential consequences require risk management is a core part of how they operate and their overall performance (Hudson 2003). The achievement of exemplary safety performance by commercial airlines provides healthcare with an opportunity to learn from other high risk industries, offering insight to systems, behaviours and cultures and their value / contribution to managing risk. Kuhn and Youngberg (2002) recognises the evolutionary state of risk management in health, and the need and opportunities that exist to learn from past failures to aid future success. In recent years healthcare systems have experienced significant changes from technological to normative ones all asking for increased efficiency in the face of increasingly complexity of hospital services (Cagliano et al 2011). Incidents and poor performance in the management of risk are costly (Reason 2000) hence the role and function of successful risk management has never been so relevant.

2.3 Risk Management in Healthcare

2.3.1 National Policy & Context

In the late 1990s, safety was recognised as a national and international priority in the delivery of healthcare (Battles & Lilford 2003). Similar commitments have previously been made with various safety initiatives introduced to national healthcare systems (Arah & Klazinga 2004),however this renewed commitment re launched risk management and questioned past practice, assumptions as well as introducing tolerance of risks to the debate (Power 2009). Experience over the preceding 20 years that contributed to this priority included an increase in the number of adverse incidents, the potential avoidability of patient harm and the presence of organisational tolerance (Barach & Small 2000). This priority status set the scene for a number of initiatives, strengthened controls and declarations for improving the safety of care through active risk management. Examples of this prioritisation included Institute of Healthcare Improvement's programme "Protecting 5 million lives from harm", the Department of Health's publication an "Organisation with A Memory", the WHO Safer Surgery Checklist and the identification of "never events" as part of the NHS National Reporting and Learning System (IHI 2004, DH 2000, WHO 2009).

In spite of a myriad of "improvement" initiatives, the practice of medicine remains vulnerable to error and injury with rates of harm and injury comparably higher for patients than other types of injury. Kohn, Corrigan and Donaldson (1999) define clinical risk as the probability that a patient is affected by an adverse event voluntarily or involuntarily caused by medical treatments. Kohn et al (1999) recognise that clinical risk is not solely due to medical activities directly impacting on patients but is reliant on a larger set of activities and professionals. Factors relating to the system, environment and the interplay of individuals within these systems are all relevant (Cagliano 2011). A number of models seek to understand why errors and failures occur and what needs to be done to achieve greater reliability (Gamble 2013). In healthcare this has resulted in duplication of initiatives and systems on safety, multiple definitions of what to do and what success looks like alongside a blindness to practice and behaviours that may be hindering the required improvement (Areh & Klazinga 2004).

This lack of clarity and consolidation of objectives and outcomes in healthcare is a potential barrier to achieving successful risk performance (Davies 2001). What is clear is that there is a wealth of information, expertise and experience to draw upon from within healthcare as

well as from other industries as foundations for risk management and safety improvement and in setting the context and environment in which care is delivered (Hickson et al 2007).

Reason (1990, 2000, 2001) identifies that fallibility exists within humans and systems providing the opportunity for adverse events and unintended consequences to occur. To date a culture of blame (Barach & Small 2000) has prevailed in healthcare incident reporting and investigation focussing on the unsafe acts of individuals rather than the performance of systems or other factors. The experience and lessons that can be learned from other sectors highlight that practices and professionals should be given equal consideration in the mitigation of risk as well as in the evolving state of risk management (Power 2004). The work of others such as Brennan et al (1991), Baker (2004), Carrol et al (2002), Leape et al (2002) all recognise that the complexity of healthcare systems is reflected in the potential criteria that may directly or indirectly contribute to system failures or foster conditions that may predispose individuals to making mistakes or performing unsafe acts. Organisational factors should be a focus of analysing clinical incidents (Vincent et al 2000) although if the outcome is to improve the quality of care received, risks need to be managed through earlier identification of potential failures rather than reacting to adverse events (Lawton & Parker 2002). In spite of a range of frameworks and tools available, prospective identification and analysis of risk is not a discipline that has gathered any significant momentum or adoption in healthcare unlike other high risk and high reliability industries (Gamble 2013, Carroll & Rudolph 2006).

The open use of data, information and intelligence has a key role to play in managing risk, targeting improvements, establishing a positive safety climate and maintaining public confidence (Mannion et al 2009, Gamble 2013). Davies (2004) stretches the thinking further with the inclusion of external pressures placed on healthcare from regulation, market forces and other forms of accountability as information to consider in risk performance. Halligan & Zecevic (2011) highlight the importance of safety and risk culture in healthcare safety improvement. In spite its importance and the relevance of other criteria the continued absence of a common set of definitions, dimensions and measures limits realisation of the intended benefits of initiatives (Philibert 2009) and inconsistent implementation (Areh & Klazinga 2004). The impact of poor use of information, the influence of external pressures inconsistency in the application and benefit delivery of initiatives was recognised during and as part of the recommendations of public inquiries in the NHS. The Francis Inquiry (2012) and the Kirkup Inquiry (2015) identified that opportunities had been missed through learning

from adverse events (incidents and complaints) and in recognising the role that external factors such as delivery of operational targets, pressure to achieve initiatives have on destabilising and increasing risk levels in organisations. Delivering the safety priority requires healthcare providers to look beyond the clinical environment and to consider wider influences (Kohn et al 1999). It is unlikely that healthcare can be error free (Hudson 2003) however lessons learned from other high risk industries that promote reliability (Philibert 2009) alongside better developed defences and controls (Carroll & Rudolph 2006) would strengthen local risk performance. Actions and initiatives to date have been generic and lack the local commitment needed to influence the frontline delivery of safe, quality services (White & Chao 2014).

2.3.2 Integrating Risk Management into Healthcare Delivery

The delivery of safe, quality care is complex (Leape 2005) and is increasingly complex with the drive for greater efficiencies and improvements (Cagliano 2011). The context in which care is delivered means that the provision of safe, quality care is not the only requirement on providers and that the quality of care competes alongside other operational priorities such as operational targets and financial balance (Sausman 2001). The significance of "competing priorities" is unclear. There is the perspective that suggests that it is within every Trusts capabilities to manage these priorities, a view based on the capability of some organisations to consistently outperform others (West 2001) whilst others may support a view that the pursuit of productive and financial indicators may act as blinkers to safety and quality priorities and introduce vulnerabilities to the system (Reason et al 2001)

The plethora of initiatives that have been prompted by the renewed priority status of safety and risk management could be described as creating a "bandwagon" (Edozien 2000) that potentially creates a burden rather than a benefit to the systems and providers delivering safe, quality care.

In a commitment to patient safety it is clear that there are multiple factors that directly and indirectly contribute to it. This widens the context and factors that impact on the achievement and delivery of safe, quality care. The breadth of these factors range from the national policy, political stakeholders, performance targets, financial balance, public reputation and confidence and safety and quality have sat uneasily alongside or as a tension in the absence of integration (Firth Couzens 2002). The reality is that these factors are all important and a way of working that delivers against all and at the same time manages the

risk is the goal that all healthcare providers should be aspiring to achieve. There is a tension between rhetoric and reality, the outcomes and expectations on NHS Trusts demands a greater alignment and integration of efficiencies, quality and safety of services (Arah & Klazinga 2004) whilst NHS central policy continues to maintain a separation of the systems for identifying, assessing and managing clinical, operational and financial risk whilst at the same time requiring outcomes to be integrated (DH 2015).

The challenge facing healthcare providers is how to deliver safe, quality care that is affordable, accessible and delivered within the resource envelope (DH 2015, Cagliano 2011). The growing agenda is challenged by the question of how to make healthcare safer whilst recognising and coordinating the myriad of direct and indirect factors in the NHS Operating environment. A common approach evident in guidance, policy and programmes is through standardisation and generic strategies (White & Chao 2014) for managing risk that have been evident in the clinical governance and safety programmes introduced to the NHS. Safety is concerned with the myriad ways in which a system can fail to function (Vincent et al 2014), understanding the role of organisational culture and individuals behaviours in safety and risk management requires further development (Smith 2004) as demonstrated in the absence of a common set of definitions, dimensions and measures (Halligan & Zecevic 2011). The wrong culture can act as a barrier to elements of risk management such as incident reporting (Lawton & Parker 2002) whilst the adoption of learning from other industries can help to deliver reliability in areas such as communication and patient hand offs (Philibert 2009). A culture of trust is seen by some (Firth-Cozens 2004) as the keystone of patient safety as well as organisational effectiveness, identifying a dependency between culture and leadership in an organisation and risk management and safety performance.

The lack of aligned and integrated systems to date may have limited progress, however a further policy mandating integration (DH 20115) provides further opportunity to optimise the potential benefits of integrated and alignment of operational service frameworks. This potentially provides the case for a financial risk such as the delivery of cost improvement programmes or financial balance (Cagliano 2011) to be compared against a patient receiving the incorrect operation, failure to achieve operational targets and a manual handling injury sustained by a member of staff. At present such risk comparison is neither common nor explicit in the safety approaches either used or endorsed by healthcare providers and regulators in the UK (Arah & Klazinga 2004). The desired outcome of this

integration and alignment of strategies is for an organisation whose processes are reliable, resilient and successful, delivering the required levels of performance.

2.3.3 Key publications and insight

The literature review has shown the priority that risk management and safety rhetoric in healthcare has been receiving in the last 20 years with a range of policies, initiatives and practices being referenced. Subsequent reviews continue to identify that the full benefit of the programmes has not been achieved and that this is due to a number of factors specific to the issue as well as generic to the implementation. Risk management and by extension quality in healthcare continues to evolve (Kuhn & Youngberg 2002). The opportunity to learn from the systems, processes and experiences of other industries is well documented and previously referenced with parallels drawn between safety initiatives from aviation such as the pilots pre flight checks and the introduction of the safer surgery checklist (WHO 2007). This learning is supplemented by the insight offered by a number of publications which have acted as milestones in the evolution and prioritisation of risk and safety in healthcare (Hudson 2003). Reviewing these publications provides an opportunity to identify the strengths of what has been delivered and the elements that need to continue to be developed so that further improvements can be made and the intended impact on safety achieved (Arah & Klazinga 2004).

2.3.3.1 Institute of Medicine – Crossing the Quality Chasm

The Institute of Medicine's report "To Err is Human; Building a Safer Health System" highlighted a commitment to making the delivery of healthcare safer through the building of safer systems and designing processes of care to ensure that patients are safe from accidental injury and the desired outcome is achieved. The report published in 2000 established the foundation of the safety and quality agenda in healthcare and set a ten year improvement strategy. Initially focused on US healthcare provision, healthcare systems across the world identified with the findings. The report included:

- A synthesised review of the wealth of literature and research linked to the quality of healthcare provided.
- Development of a communications strategy for raising the awareness of the general public and key stakeholders of quality of care concerns and opportunities for improvement.

- Articulation of a policy framework that will provide positive incentives to improve quality and foster accountability.
- Identification of characteristics and factors that enable or encourage providers, health care organisations, health plans and communities to continuously improve the quality of care.
- Development of a research agenda in areas of continued uncertainty.

Institute of Medicine (2000)

The scope of the report included errors in healthcare, adverse event reporting, understanding why incidents happen, expected performance in patient safety, the role of leadership and acknowledgement of accountability and the creation of safer systems, reflecting risk management in practice.

Building on the insight from the first report, IHI continued its message in two subsequent report focussing on patient safety and quality. The reports aimed to reinstate quality in health systems and align this with patient safety through reforms such as rules on the redesign of care, strengthening organisational change capacity and establishing new environments for care. The insight to change and improvements extends beyond clinical practice to the fundamentals and supporting systems that underpin services such as funding, IT infrastructure and workforce.

2.3.3.2 Department of Health's Organisation with a Memory (OWAM)

The identification of a role of managing risk in healthcare has been acknowledged at an international level since the early 1990s (Reason 1997) with a slower uptake in the UK than in other developed countries (Leape et al 2002).

"Organisation with a Memory (OWAM)" was first published by the DH in 2000 (DH 2001) and attempted to explain how adverse events are caused in healthcare organisations, why these events can never be entirely eliminated, but how organisations and healthcare systems as a whole can understand and learn from safety incidents and act to reduce risks and improve safety. Building a Safer NHS (DH 2001) was the DH's response to the growing priority surrounding patient safety and the direct and indirect causes of adverse incidents. These strategies were supported in the following decade by a myriad of initiatives from the National Patient Safety Agency (NPSA 2005), Patient Safety First (2009), the Department of Health

and regulators (Care Quality Commission 2009, Monitor 2009). The common link across the initiatives was the focus on outcomes specifically a 50% reduction in avoidable harm, prevention of incidents and learning to prevent a recurrence and recognising circumstances that predispose failure are not well recognised. Absent from the initiatives was the need to integrate and interface safety and risk with existing systems and clinical pathways (Leape 2005).

Progress against the findings and recommended actions such as accountability, public awareness and leadership is evident (Brennan et al 1991, West 2001, Sausman 2001, Davies 2004). Work by Cagliano (2011), Sikka et al (2015) continues to highlight that the factors that influence safety and quality of services, the significance of risks and the effectiveness of improvement strategies are not comprehensively understood or effectively translated from policy to practice. Arah & Klazinga (2004) concluded that in spite of the intended benefits of the safety approaches and initiatives published, in hindsight there were a number of foreseeable disadvantages, the number of initiatives, the lack of clarity and definition (ie too vague), the narrow focus, lack of awareness to external threats or forces and that the deliverables were too optimistic.

2.4. Learning from High Risk Organisations

2.4.1 Risk Management Frameworks

Successful frameworks are characterised by their systematic approach (Gamble 2013) to managing risk from the identification of the hazard, the understanding of the potential consequences and implications, the significance of secondary factors and the effectiveness of mitigating action. The frameworks can be complex not least due to the intricacy of other contributing or influential elements and should utilise available information to understand potential failures in systems (Vincent et al 2014). For the NHS, there is an opportunity to learn from other high risk organisations about the characteristics of a successful safety system (Hudson 2002). Characteristics of systems and behaviours that provide a foundation for effective risk management include (Hudson 2002, Battles & Lilford 2003):

2.4.2 Management Systems & Frameworks

The level of detail of the assessment will vary depending on the tools that are used and its purpose (Hudson 2002). The assessment tool adopted is influenced by a number of factors such as industry standards, central policy, organisational culture and the commitment to the

risk agenda. A review of practice in the NHS demonstrates the influence of national policy and the maturity of local safety cultures have on determining how assessments are completed, the depth of these assessments and the extent to which they reflect true cause and effect. In proactive situations where the assessment is as part of a commitment to safer systems and learning the assessment may adopt a quantitative methodology such as probabilistic risk assessments or draw on information such as human behaviours. At the opposite end of the scale are reactive assessments which may consider why something has happened. FMEA is a tool that has been adopted and is routinely used in aviation however the uptake in the NHS has been very limited being perceived as burdensome and cumbersome (Latino 2009).

There are a wealth of systems, generic and industry specific, advocating a systematic process for the management of risks. The status of the systems varies with individual frameworks commanding external verification and validation whilst others have been adopted by other sectors and are recognised as best practice within their specific industry. The following approaches have been selected as examples of techniques used in healthcare and more specifically in addition to common approaches to managing risk from industry.

The selection of risk management frameworks, tools and techniques available for organisations and industries to use is extensive and reflects the different situations, industries and types of risks that need to be identified, assessed and managed. The choice of framework can be influenced by a number of factors including organisational culture, the complexity of the task as well as external drivers such as national policy and regulatory oversight. The following frameworks, tools and approaches are examples of formalised systems aligned with regulation or industry standards, proactive risk assessment tools, incident investigation and error causation and techniques that look at individual elements such as safety culture assessments.

2.4.3 Formal Frameworks aligned to regulation and accreditation

2.4.3.1 HS(G)65 Successful Health & Safety Management

"Successful Health & Safety Management (HSG 65)" was prepared by the Health and Safety Executive's Accident Prevention Advisory Unit in 1991 as a practical guide for Board members and operational managers including health & safety professionals. The document outlined approach through which health and safety performance in their organisations could be improved. The system provides a clear message that organisations need to manage

health and safety with the same degree of expertise and to the same standards as other core business activities if an organisation is to achieve effective control of its risks and prevent harm to its staff or others that may be affected by their activities.

The guidance document details three main aims:

1. To describe the principles and management practices which provide the basis of effective health and safety management.
2. To set out the issues which need to be addressed
3. To establish a framework which can be used for developing improvement programmes, self audit or self assessment.

Health & Safety Commission (1997)

The key elements of the system are outlined in figure 2.1.

1. POLICY: *Effective health and safety policies set a clear direction for the organisation to follow.*

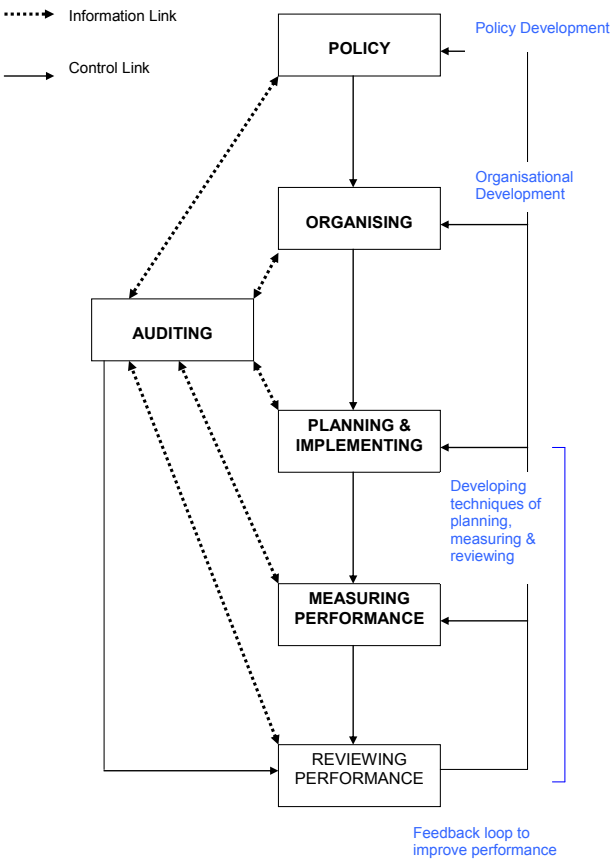
2. ORGANISING: An effective management structure and arrangements are in place for delivering the policy.

3. PLANNING: There is a planned and systematic approach to implementing the health and safety policy through an effective health & safety management system.

4. MEASURING PERFORMANCE: Performance is measured against agreed standards to reveal when and where improvement is needed.

4. *AUDITING & REVIEWING PERFORMANCE: The organisation learns from all relevant experience and applies the lessons*

Figure 2.1: Key elements of successful health & safety management. (HSE Books 1997)



The use of the five stage approach in the management of risk is reflected in HS(G) 65 Successful Health & Safety Management, BS 8800 and the AS/NZ 4360 standard on Risk Management whilst element such as assessment and monitoring are key components of Monitor's regulatory compliance framework. The five key stages are:

1. Identify the risk
2. Assess the significance of the risk
3. Identify and implement effective control measures and actions
4. Monitor the effectiveness of the controls in managing the risk
5. Review the system with a commitment to continual improvement

The framework is supplemented and strengthened by defined roles and responsibilities, and recognition of the influence of changes in normal operating conditions, circumstances on the management of risk. This prescription supports legislative requirement that sets a legal duty

and expectation of standards to be achieved in managing risk (McHale 2002) whilst in other examples it may be through best practice guidance.

2.4.3.2 AS/NZ Standard 4390 (1999): Risk Management

Risk Management is recognised as an integral part of good management practice. The Australian / New Zealand standard on Risk Management provides a set of principles and guidelines that can be generically applied across industry and different sectors. The standards are updated on a regular basis (every four years) to reflect changes and progress in thinking, technology and systems. The AS/NZ 4390:1999 was adopted by the NHS as an underpinning element to the national programme "Controls Assurance" - a set of standards covering areas of risk across healthcare which were subject to annual assessment and review via internal audit.

The AS/NZ standard provides a structured process and responds to the potential complexity of managing risk with a systematic, multifaceted approach. The five stage approach supports the systematic identification, assessment and action of risk as well as setting an expectation of continual improvement which builds on the monitor and review functions seen in other models. This commitment is a key feature in managing risk and hence minimising risk exposure. The standard provides a generic guide for the establishment and implementation of the risk management process. In 1999, the NHS adopted the AS/NZ standard for risk management as the approach to follow in managing risk in healthcare, equally its application is suitable for a wide range of activities, operations and industries.

The key stages of the risk management process are:

1.***Establish the context*:**

Establish the strategic, organisational and risk management context in which the rest of the process will take place. Criteria against which risk will be evaluated should be established and the structure of the analysis defined.

2. ***Identify risks***

Identify what, why and how things can arise as the basis for further analysis.

3. ***Analyse risks***

Determine the existing controls and analyse risks in terms of consequence and likelihood in the context of those controls. The analysis should consider the range of potential consequences and how likely those consequences are to occur. Consequence and likelihood may be combined to produce an estimated level of risk. The 5x5 matrix is used to assist with this calculation.

4. ***Evaluate risks***

Compare estimated levels of risk against the pre-established criteria. This enables risks to be ranked so as to identify management priorities. If the levels of risk established are low, then risks may fall into an acceptable category and treatment may not be required.

5. ***Treat Risks***

Accept and monitor low priority risks. For other risks, develop and implement specific management plan which includes consideration of funding.

6. ***Monitor & Review***

Monitor and review the performance of the risk management system and changes which might affect it.

7. ***Communicate and Consult***

Communicate and consult with internal and external stakeholders as appropriate at each stage of the risk management process and concerning the process as a whole.

Subsequent updates of the standard have identified interdependencies as well as an interface with broader organisational values, behaviours and functions. For example, risk is defined in terms of the effect of uncertainty on objectives;

- An effect is a deviation from the expected, positive and / or negative
- Objectives can have different aspects (financial, health and safety and environmental goals, and can apply at different levels such as strategic, organisation wide, project, product and process
- Risk if often characterised by reference to potential events and consequences or a combination of these

- Risk is often expressed in terms of a combination of the consequences or an event and the associated likelihood of occurrence.

(AS/NZS ISO 31000: 2009 Risk Management – Principles and Guidelines)

2.4.3.3 ISO 31000 (2009): Risk Management

ISO 31000 is one of a suite of standards published by the International Standards Organisation (ISO) against which organisations and systems can be accredited although this is not mandatory in their adoption. The purpose of ISO 31000:2009 is to provide a set of risk management standards that are not industry specific nor dependent on other systems but instead offer a best practice structure and guidance not only to risk management but also dependent operations

ISO 31000:2009 provides generic guidelines for the design, implementation and maintenance of risk management processes throughout an organization. The scope of this approach to risk management is to enable all strategic, management and operational tasks of an organization throughout projects, functions, and processes to be aligned to a common set of risk management objectives.

An element that sets ISO 31000 apart from other models is the definition of risk. The definition of "risk" is no longer "chance or probability of loss", but "the effect of uncertainty on objectives" ... thus causing the word "risk" to refer to positive possibilities as well as negative ones. This broader scope provides a shift in thinking that considers the interdependencies that exist between operational factors and successful risk management. Using and building on existing systems the focus of the framework has been on strengthening accountability, aligning objectives across disciplines and different sources of risk, embedding reporting mechanisms and establishing common risk criteria. The advantages of this system are that it not only reinforces the systematic approach of its sister standards and models but uses these as a foundation to then focus attention on other factors that learning has identified as important factors. Such attributes include leadership, commitment, corporate objective setting and planning, strategic policy implementation.

In addition to the core five stage model, ISO 31000:2009 supplements this with tactical tasks to manage the identified risk. This includes:

1. Avoiding the risk by deciding not to start or continue with the activity that gives rise to the risk

2. Accepting or increasing the risk in order to pursue an opportunity
3. Removing the risk source
4. Changing the likelihood
5. Changing the consequences
6. Sharing the risk with another party or parties (including contracts and risk financing)
7. Retaining the risk by informed decision

A review of recognised models from across regulation, accreditation, high performing high risk industries identifies four key tasks that are accepted as core to a structured approach to managing risk (HSE 1997, AS/NZ1999, ISO 2009).

1. Identification of the risk

A key aim of patient safety must be a focus on the sources of risks and hazards. For this purpose, the search needs to extend beyond care processes to enable organisational factors such as capabilities, performance targets, financial constraints, national policy to be examined for potential and actual risk factors. The complexity of the context of risk identification supports the need for a standardised approach to risk identification and comparison.

A review of a definition of risk assists with the search for such factors:

A risk is the "likelihood that a hazard will actually cause its adverse effects, together with a measure of the effect" (www.HSE.gov.uk).

The search can be further assisted by considering risk in the context of association and not simply causation. This link to association encourages the identification of latent factors, which although may not be a direct cause, have contributed to an incident or adverse outcome. The identification of latent risk factors allows all aspects of a system to be studied and the significance of elements understood. Such an understanding supports a proactive system of risk management as well as an overall reduction in risk. Beuzekom et al (2012) argues that proactively reducing latent risk factors that increase the risk of error by individuals will result in delivering safer care more quickly than taking measures directed, often reactively at specific individuals. Consistent with the objective of minimal patient harm, safety management in healthcare should be proactive rather than reactive. Latent risk factors can be found in error producing conditions (system or human error) for example poor design, unworkable procedures, shortfalls in training, inadequate staffing (skills and

competency may differ between rhetoric and operational practice). The recognition of latent risk factors within a risk system promotes openness, commitment and cognisance of risks and hazards facing an organisation. Carthey et al (2000) link such elements as defining characteristics of high reliability organisations whilst Beuzekom et al acknowledges the potential positive impact that this can have on fostering a safety culture and Rasmussen (2003) on improvements in safety performance.

2. Assessment of Significance

The assessment of the level of risk is potentially the most subjective aspect of the process requiring individuals to consider the likelihood of an event and also the potential consequences. Whilst this decision making process is often assisted by a number of tools, there remains the potential for over exaggeration both on occurrence and outcomes. A common oversight is for assessors to consider the risk before any controls are implemented. Unless the task or activity is new and innovative controls will be in place – it is the effectiveness and appropriateness of the controls that should be assessed and used to inform both likelihood of occurrence and potential outcome.

The use of adverse incident data provides a wealth of information on types of incidents occurring. Investigation of these incidents provides the information as to why it happened and how to improve the system, however this remains a reactive approach allowing harm, loss or damage to patients, staff and property to occur before action is taken. In the spirit of a system committed to improvement, the risk assessment process needs to be more proactive and comprehensive embracing human and system failures, their independent robustness and the interrelationships in risk management.

Rasmussen (2003) suggests three examples of human / system analysis that can be used to establish and support a proactive approach to risk identification and assessment:

1. Traditional Task Analysis and Human Reliability Estimation
2. Causal Analysis of Accidents after the fact
3. Design of reliable work conditions on modern socio-technical systems

3. Identified Risk Actions

The identification and assessment of risk should be followed by a risk treatment plan. Such plans can be an indicator of the acceptance and tolerance of the identified risk. Plans should be systematic in their application and be time limited with identified roles to complete the remedial work. The ability to measure the effectiveness of the actions is important not only as part of the monitoring and review mechanism but also as assurance the accuracy of risk identification and assessment.

4. Monitoring & review

The Institute of Medicine's report "To Err is Human" examines the safety performance of healthcare organisations and based on the performance has made a number of recommendations to minimise the risk of injury, ill health or harm from those requiring hospital treatment. Amongst the numerous recommendations is the declaration that healthcare organisations and professionals affiliated to them should aim to establish patient safety programmes committed to continual improvement. The IOM's recommendations for a safety programme expands on the role of risk assessment. It is this expanded definition that identifies how risk assessment may be more developed at an operational level in clinical terms than may be presumed when comparing traditional models.

The practice of progressing beyond stage 3 and reviewing the effectiveness of the action and setting a performance target has traditionally been linked to the management of health and safety and quality assurance and an increasingly recognised description of high reliability (Gamble 2013). However the use of these five stages provides a basic structure for the management of any type of risk identified. This framework is not exhaustive in the factors that need to be considered as elements of a process for managing risk. Factors such as communication, priorities, and schemes for the ownership of risk should also be considered and will be discussed later on in the chapter.

2.4.4 Proactive Approaches to Risk Identification & Assessment

2.4.4.1 National Patient Safety Agency : 7 Steps to Safety & Risk Assessment Programme

The National Patient Safety Agency (NPSA) was an Arms Length Body of the Department of Health up until 1 June 2012 when its functions were transferred to the NHS Commissioning Board (subsequently known as NHS England). The role of the

NPSA was to lead and contribute to improved, safe patient care by informing, supporting and influencing organisations and people working in the health sector. The functions of the NPSA continue with the National Reporting Learning System continuing to collect and collate incident data from across the NHS.

The National Patient Safety Agency (NPSA) published its first guide to achieving patient safety in 2004. The "7 Steps to Patient Safety" (NPSA 2004) aimed to avoid unintentional harm to patients by promoting patient safety at all levels of the health care system. The NPSA believed and promoted that risk is inherent to the delivery of healthcare and that these risks can be reduced by analysing and tackling the root causes of patient safety incidents. Such information is important in helping to prevent the same incidents from recurring. This concept of analysing and learning from incidents is promoted further through the National Reporting Learning System (NRLS) established by the Agency. The pioneering nature of the system meant that the system could be criticised and discussions over the consistency and quality of data detracted at times from the key messages and opportunities for learning.

The NPSA recognised that the delivery of patient safety is the result of several stages which when combined delivers continual improvements in safety. The approach adopted by the "7 Steps" echoes this concept of progress and improvement by providing a checklist to help outline and review performance in patient safety specifically, the steps are as follows:

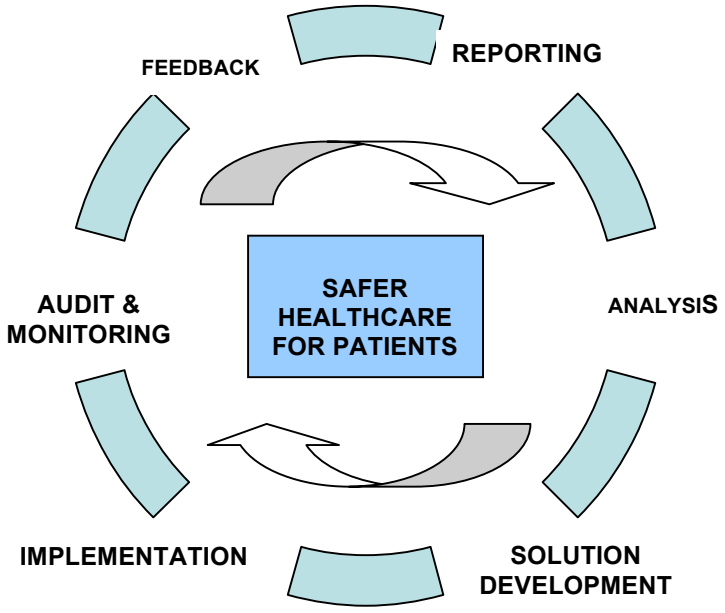
1. ***Build a safety culture***: create a culture that is open and fair
2. ***Lead and support your staff***: Establish a clear and strong focus on patient safety throughout your organisation.
3. ***Integrate your risk management activity***: Develop systems and processes to manage your risks and identify and assess things that could go wrong.
4. ***Promote reporting***: Ensure all staff can easily report incidents locally and nationally.
5. ***Involve and communicate with patients and the public***: Develop ways to communicate openly with and listen to patients.
6. ***Learn and share safety lessons*:** Encourage staff to use root cause analysis and to learn how and why incidents happen.
7. ***Implement systems to prevent harm***: Embed lessons through changes to practice, processes or systems.

National Patient Safety Agency (2004)

The principles of the “7 steps” echo the findings of incident investigations and public inquires with causal factors and contributory factors such as the influences of culture, communication, safe working systems and the ability to learn lessons from past incidents.

In conjunction with the “7 Steps” the NPSA also promote a “circle of safety” – a systematic process ensuring the constant cycle of progress and improvement in minimising risk. The “7 Steps” represents a framework for patient safety but not necessarily the wider risk agenda. Its use of familiar risk assessment tools and techniques under step 3 demonstrate its strong links with established risk management programmes in industry.

Figure 2.2: Circle of Safety (National Patient Safety Agency 2004)



The guidance provides another approach for healthcare organisations to adopt in their work to improve patient safety. A potential weakness of the “7 Steps programme” is its focus on patients and clinical activities compared with the operating context and non clinical activities of a functioning Trust. Risk Management in any organisation is multifaceted and hence approaches to assess and manage risks need to reflect all the risk factors and be selective. Changes to the national

operating environment of healthcare in the UK since 2005 with patient choice, payment by results and foundation trust status has meant that the delivery of care is multi dimensional and is significantly influenced by financial demands, performance requirements, national policies and patients needs.

The NPSA recognised the widening scope of risk assessment and risk management in healthcare, enhancing step three of the original "7 Steps" programme. The document sets out the NPSA's programme of work in risk assessment and describes approaches and suggests tools and techniques that can be applied. The NPSA programme recognises the need to identify, assess, analyse and manage all potential risks and that decisions made within an organisation and within practice should take into account potential risks that could directly or indirectly affect patient care. It is important to acknowledge the application of risk assessment and the need to analyse all potential risks. Risk is inherent in all aspects of healthcare including:

- Organisational strategy and business planning
- Financial planning
- Projects and service developments
- Purchasing
- Design of services
- Treatment and care delivery

National Patient Safety Agency (2006)

Assessing each of the elements is advised for which the NPSA suggest a range of assessment tools and techniques including Failure Mode and Effects Analysis (FMEA), Hazard Analysis and Critical Control Points (HACCP) and Probabilistic Risk Assessments(PRA). These tools are discussed in further detail later in the chapter as examples of techniques developed and used in other high risk industries.

2.4.4.2 Proactive Risk Assessment Techniques & Tools

A common element of risk management frameworks is the ability to identify potential hazards and assess their significance and subsequent level of risk within the context of the organisation, activity or event. Assessment tools and techniques commonly used in risk management include:

2.4.4.3 Failure Mode Effects Analysis

FMEA is a prospective process that identifies the failure effects associated with individual failures within a system. In these circumstances failure represents probabilistic deviation from intention and expectation (Tay et al. 2006). By analysing failure modes (human and system) of particular activities and the effects it is possible to map the error pathway.

Marx & Slonim (2003) outline the role of failure modes and effects analysis (FMEA) in the identification and assessment of risk and its application to patient safety in healthcare. The analysis is based on an underlying assumption that for every effect or outcome a set of causes must exist. FMEA helps to anticipate what can go wrong within a high risk health care process and to apply measures to prevent the error. The system of assessing risk can be further refined and made more robust when used in conjunction with fault trees, probabilistic risk assessment and root cause analysis. A complete proactive assessment is capable of identifying all the causal sets and the outcomes that could happen. FMEA and root cause analysis (RCA) could be described as the mantras of modern risk management. The two approaches represent a proactive and a reactive approach to the assessment and management of risk through the identification of causal factors in addition to revealing potential hazards and proposing mitigation measures. Day et al. (2006) describe FMEA as a performance improvement tool for clinical practice.

There are a number of advantages and disadvantages of using FMEA to detect potential defects. The strength of FMEA rests in its proactive and prospective analysis of potential failure effects either through initial detection or improved understanding. The analysis of a process enables a series of direct and indirect factors to be considered. In complex systems such as the delivery of patient care where a myriad of risk factors (causal, latent and other) can exist, such a process can provide a better informed view on the resilience or vulnerability of a particular pathway and the significance of identified gaps.

In spite of these strengths, FMEA does have weaknesses in its application and in the production of meaningful results (Marx & Slonim 2003). Due to the need to focus on individual processes and pathways, application tends to be locally focussed and can fail to recognise external forces, influencing factors and failures of complex systems. As the complexity of risk interactions increases the value of FMEA diminishes as it

cannot compare risk factors and their influence on each other in a positive or negative way. Alternative analysis techniques can be used to determine the impact of such interactions both proactively and reactively, for example probabilistic risk assessment and root cause analysis.

2.4.4.4 Probabilistic Risk Assessments

Probabilistic Risk Assessment (PRA) is a systematic and comprehensive methodology used to evaluate risks associated with complex activities and entities. Commonly used in high risk industries, PRA is characterised by the magnitude of the possible adverse consequence (ie the *severity*) and secondly the likelihood of occurrence of each consequence (ie *likelihood*).. A key input to this methodology is the expression of consequences and likelihood both numerically for example the number of people potentially injured and the probability of such occurrences over time.

Wreathall and Nemeth (2004) recognise the ability of PRA to systematically identify and review all of the factors that contribute to an event – system and human actions, their interactions and an understanding of the causes. PRA examines events that contribute to adverse outcomes through the use of event tree analysis and determines the likelihood of event occurrence through fault tree analysis. PRA has two aims:

1. To identify potential areas of significant risk and indicate how improvements can be made.
2. To quantify the overall risk from a potentially hazardous activity.

Wreathall & Nemeth (2004) acknowledge the roots of PRA in the nuclear industry. Applied to healthcare, the model supports a five stage approach to assessing risk:

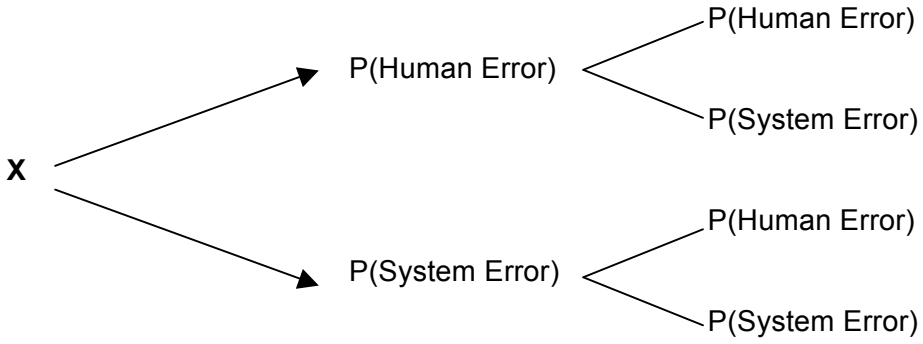
1. Identify the sources of potential hazard or adverse event
2. Identify the initiating events that could lead to this hazard / event
3. Establish the possible sequences that could follow from various initiating events (application of fault trees is beneficial to this stage)
4. Quantification of each event sequence considering:
    a. Frequency of the initiating event
    b. Probability of failure on demand of the relevant safety systems
5. Determine the overall risk of the incident / adverse event having considered the frequency of all possible accident sequences and consequences.

As an safety assessment tool, Probabilistic Risk Assessment combines the identification of potential causes of risk with a calculation of how likely is it that the event will occur ie its probability. This technique compliments analysis processes such as event tree analysis and fault tree analysis and considers a more in depth analysis to that provides by root cause analysis. Fault tree analysis and event tree analysis are extensions of their respective processes and provide a method of systems reliability / safety analysis that shows a logical description of the cumulative effects of faults within a system. A key strength of fault / event tree analysis is its ability to show cause and effect relations among events that culminate in a "top event".

2.4.4.5 Probability Trees

Probability trees enable tasks, systems human behaviour and the likelihood of error within an element of the task to mapped (Reason 1990). This mapping produces conditional probabilities that can be determined for every stage of the task and system. The probability Tress as shown in figure 2.3 represents a summary of the resilience of an action and accompanying controls. Identified gaps or concerns over the integrity of the defence mechanisms in particular human behaviour can be tested further through advanced human error techniques and fault trees.

Figure 2.3: Probability Tree



Operator Action Trees (OATs) focus on error factors once an accident or adverse event sequences have been triggered. These errors are described as "cognitive" errors which may materialise as mistakes, lapses or slips. It is possible to identify three main types of cognitive error:

1. Failure to perceive that an event has occurred
2. Failure to diagnose the nature of the event and identify remedial measures
3. Failure to implement appropriate responses correctly and in a timely manner

Operator action trees provide a structure for assessing operator failure modes independent of the procedures ie the human error element, its application is limited to single time reliability relationships rather than multiple errors over a time period.

2.4.4.6 Hazard and Operability Studies

Hazard and Operability Studies (HAZOP) is another proactive hazard analysis tool. HAZOP is a team based, systematic qualitative method to identify hazards which include deviations from design or intent, in process industries. The study begins with consideration as to the ways in which a process may deviate from the desired path, delivery of the desired outcomes and performance. IOM (2004) acknowledged the role of HAZOP identifying gaps in corporate frameworks such as contractual relationships and agreements. As with most processes and action plan is developed to eliminate or minimise deviations and their consequences.

Hazard analysis and critical control points (HACCP) also provides a systematic approach to the identification, assessment and control of hazards. The application of HACCP has traditionally been centred on food production and service however the existence of "critical points" in the manufacturing, distribution or delivery of any activity allows the principles to be shared. The HACCP approach is presented in seven steps:

1. *Conduct a hazard analysis preparing a list of steps in a process where significant hazards occur and identifying preventative measures.*
2. *Identify critical control points – steps at which controls can be applied to prevent, eliminate or reduce a safety hazard to acceptable levels.*
3. *Establish critical limits for preventative measures associated with each identified critical control point*
4. *Establish monitoring requirements for each critical control point and procedures to monitor results to adjust the process and maintain control.*
5. *Establish corrective actions to be taken when a critical limit deviation occurs*
6. *Establish procedures to verify on an ongoing basis that the HACCP system is working correctly*
7. *Establish record keeping procedures to document the HACCP system*

Institute of Medicine (2004)

A number of the steps in HACCP are familiar such as the identification of hazards, setting preventative measures and establishing monitoring mechanisms and are

evident in other assessment tools. HACCP introduces the additional elements of tolerability and assurance to the process for assessing and managing risk. These two elements are important to an organisation's risk profile as they confirm the level of risk and organisation is willing to take either in a controlled manner or latent form and the level of assurance Board members and stakeholders require on the effectiveness of control measures. The absence of these elements may result in an organisation acting beyond its safety parameters and therefore decreasing corporate resilience and creating vulnerable systems.

2.4.4.7 Human Reliability Analysis

The assessment and management of risk is not limited to system failures. Human Reliability Analysis (HRA) is an analysis tool which considers the specific role of human behaviour in error occurrence and adverse incidents. Used in conjunction with other assessment techniques such probabilistic risk assessments accident causation can be fully understood. The benefits of this technique rest with industries where systems of control may be robust however adverse events occur due to the unpredictable input from individual human beings. This approach is used in high risk industries such as Nuclear Power.

A number of techniques have been identified for predicting and analysing human error. This ability to predict assists with the overall calculation of reliability. Reason (1990) acknowledged the work of Schurman & Banks (1984), Hannaman, Spurgin and Lukic (1984), Senders, Moray and Smiley (1985) and Williams (1985) as cumulatively reviewing twenty seven models designed to predict the probability of human error. However one technique dominates, both in terms of criticism and use, the science of human reliability probabilities, this is THERP – Technique for Human Error Prediction (Reason 1990).

THERP is a technique which considers the actions of an individual in the same way as it would the success or failure of an element of a control system. The object of THERP is "to predict human error probabilities and to evaluate the degradation of a system caused by human errors alone". The execution of THERP resembles that of PRA, with four key steps:

1. Identify the system functions that may be influenced by human error
2. List and analyse the related human operations (this includes a detailed task analysis)

3. Estimate the relevant error probabilities using a combination of expert judgement and available data
4. Estimate the effects of human errors on the system failure events. This represents an integration of HRA and PRA.

The effectiveness of the analysis can be tested by implementing and removing controls and varying conditions that may impact on human behaviour and decision making. It is at this point that a detailed task analysis is essential.

2.4.5 Reactive Risk Management approaches (including incident reporting & investigation)

The literature review on risk management has consistently referenced the function and role of incident reporting , investigation and error causation and its contribution to successful risk management (Reason 1990, Leape 2001, DH 2005). The contribution made extends beyond knowing when things go wrong to understanding why the incident has occurred and supporting to learning to make the changes and improvements necessary to prevent a recurrence.

2.4.5.1 Adverse event reporting

In 2014/15, the NHS was reporting on average 400,000 incidents each quarter (NHS England 2015). A number of reviews including the Harvard Medical Study (Brennan et al 1991) and the Institute of Medicine's report "To Err is Human" concluded that approximately 50% of incidents (Neale et al 2001) that occur are avoidable. Using the statistics available that omit unreported incidents, there are significant opportunities to learn and improve the safety and the management of risks causing or contributing to these incidents. These conclusions offer insight on the relationship between incidents and the potential to manage them through safe systems and the influence of culture on reporting and behaviours when errors occur. This makes incident reporting a core part of any risk approach as a valuable intelligence resource.

Understanding why errors occur is essential in order to lower the rate of preventable adverse events. Gluck (2007) identified four components of medical care and human behaviour which contribute to the possibility of error; (1) Human fallibility; (2) Complexity; (3) System deficiencies; (4) Vulnerability of defensive barriers.

Adverse event reporting systems and the use of this data to real effect by Healthcare organisations remains embryonic in comparison with other industries such as the aviation and petrochemical (Barach & Small 2000) and as such the potential for further use of the information collected from actual and near miss incidents remains unexploited. Weatherall (2006), Reason (1990) identify that incident reporting is not the only attribute of a risk or safety management system. Other factors include top level commitment, just culture, learning culture, awareness, preparedness, flexibility and opacity. An additional dimension for healthcare to manage is the "human element" (Marx & Slonim 2003), that is the practitioner and patient relationship, the clinical decision making and professional judgements and the individual patient. In other industries such as aviation, the significance of humanness is reduced due to the interface between man and predictable machine or technology.

In addition to the focus on incidents, complaints and medical negligence litigation cases provide additional potential data sources and indicators of risk. The response to these events and the use of the information are aligned to the characteristics of risk management systems that is culture, commitment, openness and transparency in the potential for learning as examples.

The complexity of healthcare systems provides the opportunity for multiple and combinations of failures (Marx & Slonim 2003). It is unrealistic expectation to suggest that a zero incident rate can be achieved in healthcare, however improvements in patient safety and a greater understanding of how other industries have dealt with similar low frequency, high impact situations does provide a way forward. Healthcare had not yet fully embraced a systematic approach of analysing errors, the interactions and building lessons learned into systems (Marx & Slonim 2003). This underdevelopment is demonstrated through incident reporting guidance which has been mandated through individual Trusts' policies and whilst encouraged there is no mandatory reporting requirement at a national level (www.nrls.npsa.nhs.uk). Initiatives and requirements such as the reporting of "never events" continue to raise the profile, underreporting of incidents prevails and the associated development of culture, systems and organisational commitment to improve is slow to keep pace with the ideal of open and transparent reporting when errors occur.

2.4.5.2 Incident Investigation

The roots of risk management in healthcare lay in responding to incidents (Vincent et al 2004). Some critics may use this to describe the philosophy and culture of risk in healthcare as reactive. In the same way as incident reporting is recognised as a key part of effective risk management the investigation of incidents to understand what happened and why is equally important (Reason 1990, Weatherall 2006).

Root Cause Analysis is one tool that has gathered that has been promoted in healthcare (Latino 2009) to aid the identification of what happened, why it happened and what needs to change to prevent a reoccurrence. However uptake of the model and in true causes of incidents are dependent on a range of factors which are explored by other models such as accident causation and risk assessment processes (Vincent et al 2004).

2.4.5.3 Accident Causation Models

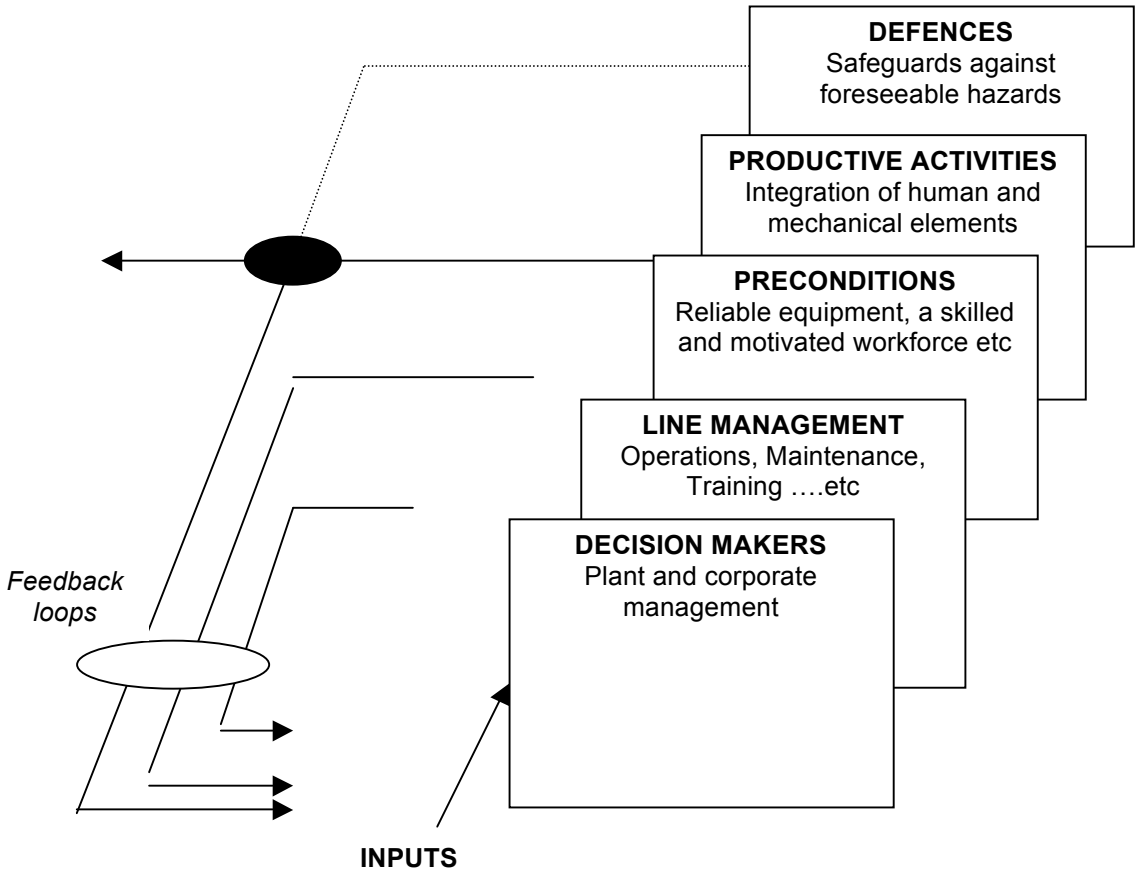
There are a number of models that seek to understand why incidents occur (Vincent et al 2004). Helmreich's accident causation model is a model focussed on error understanding and the identification of causal factors rather than error prediction. The model introduces the concept of error management which itself is a form of risk assessment (add reference). The identification of weaknesses and gaps within a system leave it predisposed to failure and hence the risk of an unwanted outcome. The process for identifying such gaps and a commitment to learn from adverse events is a key component of any framework (Faunce & Bolsin 2004).

To understand causation, Reason (1990) proposes three concepts that provide the foundation for understanding and using accident causation as a risk management tool.

- Basic Elements of Production

All systems whether complex or straight forward involve some for of production or delivery of an activity or service. Figure 2.4 identifies the basic elements of the system which includes decision makers, management, preconditions, productive activities and defences or barriers.

Figure 2.4: The Basic Elements of Production (Reason 1990)

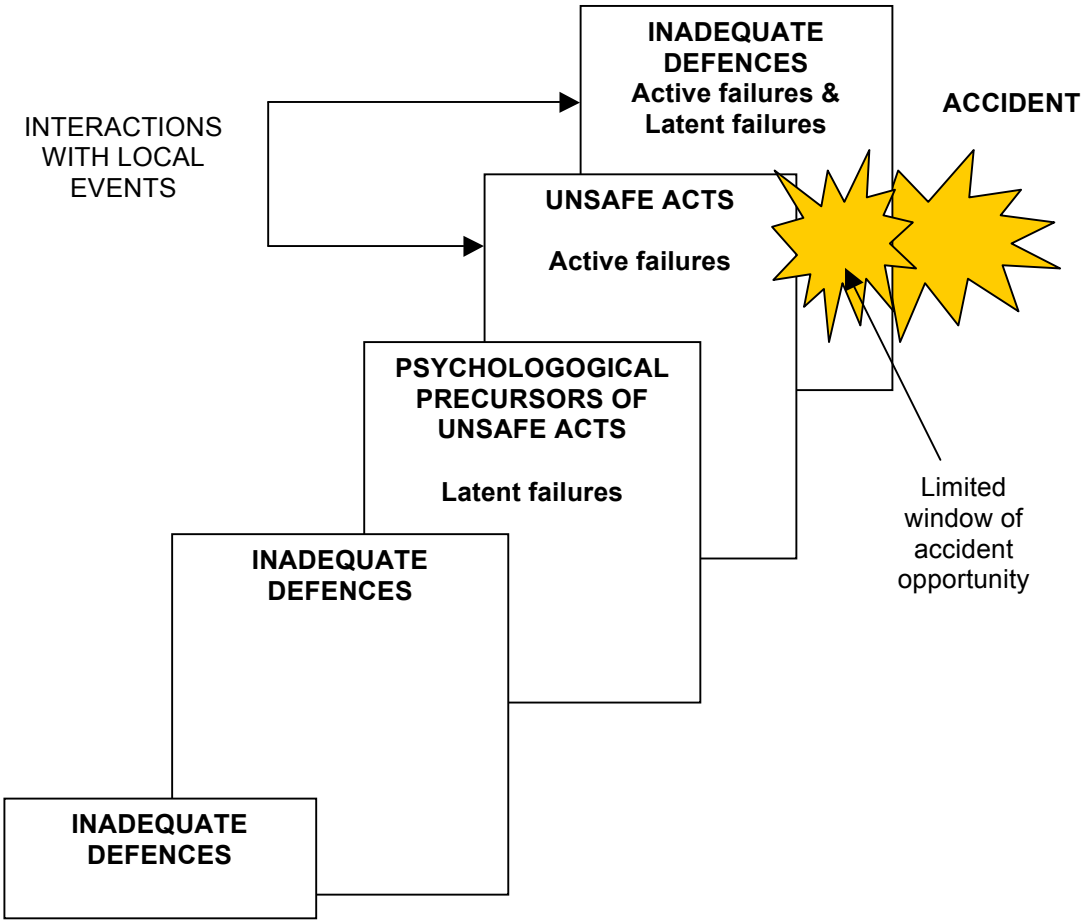


- Human Elements of Accident Causation

The very nature of human error demands understanding and mitigation. The reality is that the human contribution to systems means that accidents will occur. The likelihood and significance of this contribution is directly proportional to the level of involvement and the roles played. The presence of machinery or automation in systems proportionally reduces the risk as behaviour to a certain extent and consequently outcomes can be predicted. The human, human systems common in healthcare present the conditions for human error to occur.

Mitigation is achievable however this achievement is only possible if the system is strengthened to address gaps in control. Figure 2.5 maps the various human contributions to the breakdown of complex systems. Reason (1990) suggests that the primary systemic origins of latent failures are the fallible decisions taken by corporate decision makers. These are then transmitted via the intervening elements to the point where system defences may be breached.

Figure 2.5: Human contributions to the breakdown of complex systems.



A general overview of accident causation in systems reveals key contributory factors. Firstly the preconditions for unsafe acts; secondly contributory factor is the performance of an unsafe act in the presence of an identified hazard and thirdly the provision of opportunity.

- Error Management

In order to manage error it is necessary to understand how and why errors occur. The categorisation as error as either weaknesses or failures in human and system behaviour does provide a simple understanding of error occurrence and management. It is the preconditions of error that need to be understood ie the context of the risk or hazard.

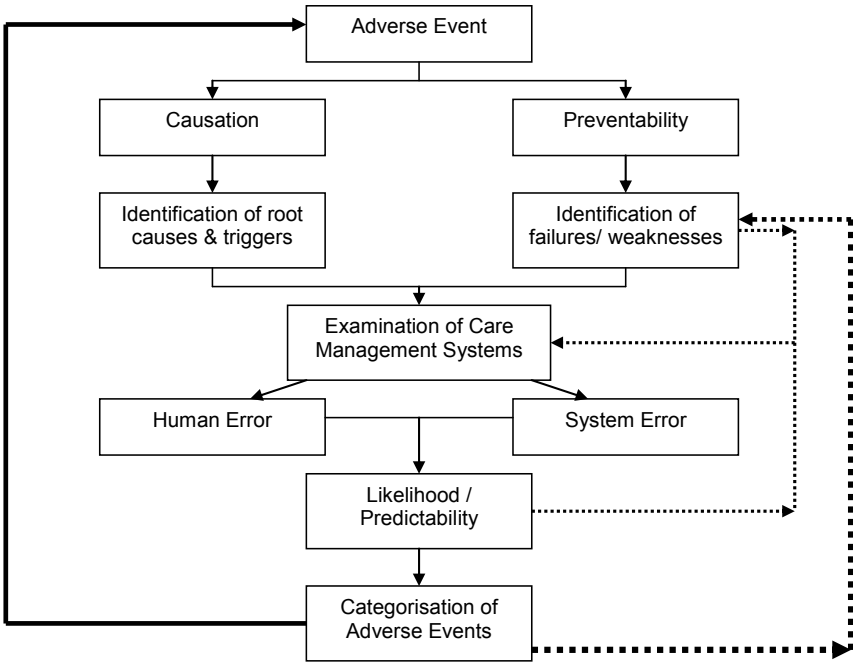
The reporting of adverse events, outcomes or errors provides a valuable insight into the systems in place, the likelihood of failure, the significance of the failings and the assurance that control measures are operational. The use of adverse incident

reports can also assist in prioritising treatment plans and risks resources to areas of greatest risk rather than favoured topics.

All too often incident management is perceived to focus on the negative ie what went wrong and why. The positive angle of managing incidents is to celebrate what went right and to identify opportunities for improvement through changes in practice and ensuring lessons are learned to prevent a reoccurrence. In order to learn from incidents it is important to analyse incidents and to detect the errors and weaknesses in the system such as the influence of human behaviour or the likelihood that through system design there is the opportunity for failure

A study of adverse events among hospital patients in Canada supported the notion that of adverse events reported a proportion were preventable hence reinforcing the findings of the Harvard Medical Practice Study (1991). Unlike previous studies Baker (2004) also identifies that some adverse events are unavoidable complications and consequences of healthcare. Application of this theory provides the link to the risk management principles including risk exposure, tolerability and acceptance. In the wider context the links to corporate governance arrangements become evident in terms of corporate responsibility. The emergence of such links needs to be recognised within a management programme. Baker (2004) recommends that in understanding adverse events, the system for treating the risk must consider causation and preventability in order to create safe systems of work. Figure 2.6 attempts to map this process and proposes a system of learning from adverse events and feeding this back into the risk system.

Figure 2.6: Feeding back lessons learned from adverse event reporting



Understanding the nature of error through the reporting of adverse events is important, however the reporting of incidents is itself a challenge. It is presumed that underreporting of adverse events in healthcare is a reality and maintained through the perceptions of healthcare professionals as real threats: retribution, litigation and malpractice, blame, professional suicide.

A key information source on risk management and performance is the use of adverse event data. Such events can include incidents, claims and complaints and be used to identify weaknesses within existing safety systems or organisational structures. The data collected can also be linked to the foundation stone of improvement with a commitment from organisations to learn lessons from adverse events and change practice as a result. Adverse events can include incidents, near misses, complaints, negligence claims and litigation.

2.4.6 Other forms of frameworks, assessment & tools

2.4.6.1 Safety culture

The role of a safety culture or climate has been widely recognised as a key factor in successful safety systems (Hudson 2002, Flin et al 2000). Healthcare in general and

the NHS specifically has suffered as a result of a blame culture related to adverse incidents, patient injury and unexpected outcomes. Organisational attitudes toward incidents have not developed at the same rate as medical negligence litigation perpetuating the sense of blame and human error compared to the contribution from systems, circumstances and corporate priorities. This sense of blame creates an anxiety about real and potential errors, subsequent reporting and investigation, in a community where individual professional opinion and decision making is a cornerstone of patient care. Healthcare leaders need to recognise the significance of this and the importance of establishing trust in the delivery of safe, quality care as well as when errors occur. This anxiety has the potential to be a barrier to risk management and its ongoing evolution of risk management is left unaddressed (Firth-Cozens 2002).

Westrum's model of safety cultures recognises different maturity levels within organisational cultures (Westrum 1984). At the lowest level a *pathological* culture is characterised by "who cares as long as we are not caught", followed by *reactive where* "safety is important , we do it a lot every time we have an accident" to mature cultures described as *proactive* where "we work on the problems we still find" and *generative* with safety embedded into the business done. The prevalence of incidents that are reported and go unreported in the NHS suggests that the culture is still in a formative and reactive stage.

Safety culture and attitudes are not limited to incident reporting and extend to proactive steps such as a visible and true commitment to safety and quality, investment in systems designed around safety, effective management of known risks through continued assessment and an openness to learning and improving performance.

2.4.7 Additional elements

2.4.7.1 Public Confidence in Healthcare

Commercial aviation recognises that there is a correlation between the trust of customers and safety performance. A parallel can be drawn with healthcare where the potential for harm demands a level of trust and confidence in how services are provided, the equipment used, the environment and the staff delivering it.

In the last decade public confidence and the credibility of healthcare providers and the NHS has been damaged. Adverse incidents and events resulting in fatal avoidable harm to patients and a number of public inquiries investigating systemic organisational failures have contributed to a loss of public confidence and a knock to the reputation of individual hospitals and services. This impact on confidence and reputation plays directly to the effectiveness of risk management systems and the ability of organisations to identify potential hazards and the commitment to mitigate the risk, improve safety and strengthen performance.

High risk organisations have responded to strengthening the public's trust and confidence in their ability to manage and successfully deliver high risk activities. For industries such as aviation and oil and gas production the additional incentive may also be financial in maintaining or attracting future investment. The added dimension of commercial competition introduces safety as a factor / dimension in defining market success. The limited influence of this within the NHS has the potential to create conditions of acceptance and tolerance of risk and incidents rather than striving for improvements in performance. Safety culture in healthcare has been described as reactive only responding to incidents and events when they happen rather than proactively seeking out hazards and risks.

The impact of poor risk management performance is not limited to the physical harm sustained, hidden costs such as lost of productivity, investigation time and implementation of remedial measures are well documented (Reason 1990). An inadequate response to patient harm or an inappropriate disclosure of information can alienate patients and damage professional reputations (McDonald et al 2010). When patients suffer harm most providers are ill prepared to respond. As part of the review of safety cultures in NHS the tendency to shame and blame has prevailed. This blame culture can also be accompanied by a silence from provider which creates mistrust and perpetuates feeling of a lack of openness and transparency. Such actions have commonly been linked to the rising rate of litigation (Galbraith 2006) as well as supplementing the evidence of a limited willingness to learn and improve from problems (Leape & Bates 1995).

Reputation and patient confidence are important factors in managing risk in healthcare. Confidence and trust varies across services along with perceptions of safety and tolerances of risk at key points in decision making and provision of care

(Cox 2013). The adoption of a systems approach to managing risk that helps to predict performance will encourage the required shit from a reactive culture to one that is open to learn and seeks system causes as well as human causes for why things go wrong (Firth-Couzens, Cording & Ginsburg 2003) and help to build and maintain public confidence in the quality and safety of care provided and that the organisation is a learning organisation and committed to improvement.

2.4.7.2 Risk Performance & priorities

The nature of the work undertaken by high risk organisations in industries such as aviation and healthcare demands strong risk performance. This performance can be demonstrated through a number of different routes as described in the literature, a proactive safety culture, the adoption of a systematic approach to managing risk, learning through adverse event reporting and a commitment to improvement. The achievement of this performance needs to be a priority (Battles & Lilford 2003) although not to the extent that it is pursued irrespective of cost exposing the organisation to vulnerability as achievements of targets dominate the delivery of a service (Hollnagel et al 2001).

Since the early 2000s quality and safety performance has been articulated through central policy objectives (Sutherland 2004) with national targets set to reduce types of incidents such as MRSA infections (DH 2005) or improve patient outcomes (NHS England 2014). Performance measures directly related to risk are limited with local commitments prioritised around national policy. There is little to demonstrate a direct link between organisational culture and performance (*add reference*) although insight provided through public inquiries and independent investigations have suggested links (Francis 2014).

Current healthcare systems have been shaped by national programmes, policies and priorities. An output of these developments has been the growth of regulation (Storch 2005) and the establishment of a number of organisations tasked with providing oversight to a number of different aspects of healthcare (McHale 2002) such as quality, safety, staff competencies and financial management .

There are a number of external agencies such as Monitor, the Care Quality Commission and the professional regulators tasked with providing opinion or regulation, mandatory or otherwise, within the healthcare industry. Nationally based

their views and recommendations infiltrate local service provision, however the driver behind the policy shift or initiative may over shadow the intended purpose and outcome with systems designed to meet requirements rather than deliver effective risk management (Shaw 2001). Faunce & Bolsin (2004) reviewed the role of external regulation of safety management systems and the value of such schemes post adverse events in which key causation could be attributed to gaps within controls not uncovered by the regulatory process. The reviews did highlight a lack of confidence in the system for identifying and managing risks or raising concerns although did demonstrate that national policy requirements had been met.

Risk and safety are outputs and hence the focus should be on the ability of a system to consistently deliver the required standard of care. High risk organisations including healthcare have no option but to function reliably if outcomes are to be as expected and intended predictable (Weick & Sutcliffe 2007). The answer, in part is in system design, however this not only needs to address and mitigate against significant single events but also be sufficiently robust to survive and respond the cumulative effects of multiple minor to moderate failings or even suggested gaps within a system. Corporate systems need to be capable of managing the unexpected to avoid disruptions to service and the spiral of decline associated with secondary factors such as financial losses, loss of reputation and a decline in public confidence
Healthcare is at a formative stage of the model with key elements developed to a greater or lesser extent however it is the relationship and interdependencies that require further understanding along with direct and indirect factors.

2.5. Common Characteristics

Risk management is widely recognised as a complex function (McNeil et al 2015) from its definition, the countless frameworks, systems and tools that are available for use as well as the influence that other aspects of organisations have on it such as culture, national policies, corporate performance (Cagliano et al 2011, Philibert 2009). The complexity of systems and the industries in which they are implemented add further dimensions that serve to shape and introduce priorities to the function (Gamble 2013, Ginsburg et al 2014). In the face of this variation, the literature review has identified a number of common elements that are present in the systems and frameworks reviewed as well as serving to highlight characteristics of risk management which may serve as early foundations of what is a “good” risk

management framework. Figure 2.7 provides a summary of the models that have been reviewed and the characteristics derived from their purpose and core deliverables. In summarising the risk characteristics six criteria have been identified. There is an emerging theme of the strengths and potential benefits of systems in providing a systematic approach, that identifies and assesses the significance of risk whilst criteria such as mitigating action, monitor and review and continual improvement appear to be less reliable as factors included or characterising the system.

Figure 2.7: System Characteristics of Risk Management Frameworks

Risk Management Systems & Models	**System Characteristics**					
	Systematic model	Identifies risk	Assessment of significance	Mitigating actions	Monitor & review	Continual improvement
AS/NZ Risk Management Standard	✓	✓	✓	✓	✓	✓
HSG (65) Health & Safety Management Systems	✓	✓	✓	✓	✓	✓
Failure Modes & Effects Analysis (FMEA)	✓	✓	✓	✓		
ISO 31000	✓	✓	✓	✓	✓	✓
Probabilistic Risk Assessments (PRA)	✓	✓	✓			
Human Reliability Analysis	✓	✓	✓			
Technique for Human Error Prediction	✓	✓	✓			
Root Cause Analysis	✓	✓	✓	✓		✓

The insight provided by this summary leads the research on to its next stage and looking at risk management systems and practices in the NHS, what drives it and the impact if any different parts of the system have on risk and organisational performance.

Chapter 3 – Concept analysis

In chapter 2 the literature review explored risk management systems and arrangements across high risk industries with a specific focus on how risk is managed in healthcare and the factors that influence. The review provided insight that contextualised risk management, its development, the characteristics of systems and frameworks and its relevance and its adoption by healthcare in particular the NHS. The output has identified a number of factors that influence and drive the way in which healthcare responds to risk management at a strategic and operational level.

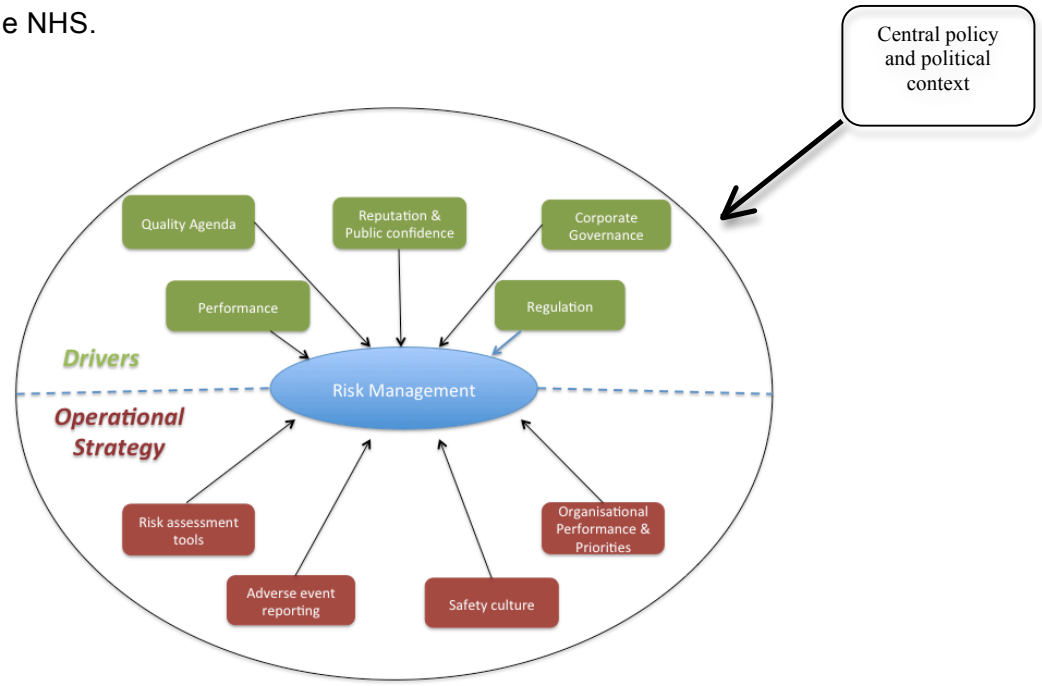
3.1 Contextualising risk management in healthcare

Risk management is an increasing discipline in healthcare, from patient centred risk assessments such as the risk of patients falling to a corporate strategy setting our the delivery of care that is safe and of a high quality as well as efficient and effective. This broad scope of risk management confirms that risk is inherent in everything that we do and it is the uncertainty that surround the issue (ie the risk) that requires management be it reactive or proactive.

Over the last 25 years, the role, insight and adoption of risk management in healthcare has gathered momentum. Examples include a library of guidance, strategies and performance improvement targets. On an international scale, a range of organisations have attempted to identify key features and characteristics of systems designed to ensure patient safety, the quality of service provision and provide an output where all associated risks are managed. The Institute of Medicine (IOM) raised the profile of the debate in the late 1990s with the publication "To Err is Human". The accompanying headline suggested that 98000 people per year in the US are killed in healthcare by avoidable incidents. The publication offered insight into the role that human behaviour plays in achieving safe, quality care alongside systems and processes such as incident reporting and risk assessment tools. The establishment of a safety culture or a just culture was seen as key development and an expansion of the ever growing list of potential characteristics of risk management in healthcare.

To Err is Human was the first publication in a trilogy from the Institute of Medicine and offered a view on the complexity of risk management by identifying characteristics of systems or processes. The complexity and characteristics identified by the IOM and others is equally reflected in the risk systems and landscape of the NHS and healthcare in the UK. Further studies on the way in which healthcare manages and responds to risk have identified a number of programmes, initiatives and features as well as potential drivers. Drawing on these studies figure 1 suggests a number of factors that either influence or are prevalent in the identification of risk, how it's managed and expectations. The factors can be broadly divided into two groups (1) operational drivers and (2) strategic drivers.

Figure 3.1: Strategic and Operational factors shaping the face of risk management in the NHS.



3.2 What drives and influences risk management?

3.2.1 Strategic Drivers

The grouping of strategic drivers reflects factors or requirements of risk management systems that have been prescribed through policy, national initiatives and key stakeholders. This is not an intended to be an exhaustive list although should reflect a list that can be easily identified with and resonates with leading publications.

3.2.1.1 Quality Agenda

Quality is a growing agenda incorporating the expectations and experiences of direct patient care, the standard to which care is delivered and a reflection of recognised best practice to work to or be regulated against. The World Health Organisation (2006) presented two main arguments for promoting a focus on quality in health systems, firstly that there is variation in the standards of healthcare delivered resulting in intended outcomes not being achieved; secondly investment needs to deliver the best results and respond to local priorities.

There are many definitions of quality used in relation to health care and health systems, and in other spheres of activity. One of these defines quality using six dimensions, (1) effective, (2) efficient, (3) accessible, (4) safe, (5) equitable and (6) acceptable ie patient centred. Behind each of these dimensions is a comprehensive programme of delivery promoting different inputs and outputs, language and priorities. These individual programmes provide an early indication of the potential complexity that exists in one element of a risk management system as well as the overlap and alignment with identified drivers such as performance through efficiency and effectiveness, risk overall via safety and avoidance of harm and access to services.

In recent years the scope and definition of quality has evolved to include quality improvement. This evolving scope shines a lens on the local context of quality and encompasses the efforts of everyone in making changes that will lead to better patient outcomes (health), better system performance (care) and better professional development (Bataldan & Davidoff 2007). Translating this further shines a spotlight on leadership, engagement with local service users and the general public, achievement of regulatory standards and the adoption of particular models of care.

The quality agenda is a growing and is increasingly seen as encompassing all aspects of patient care from the standard to which care is provided at the point of delivery, the adherence to national clinical standards, the safety of the care through to strategic leadership to where it should be provided from and how should be accessed. This all encompassing agenda provides strong links and dependencies with incident reporting and learning from where care has resulted in avoidable harm as well as with performance targets relating to activity volumes, expected clinical outcomes and the cost based on the national tariff of delivering the service.

3.2.1.2 Reputation & public confidence

Reputation and public confidence are key factors in risk management and in the mitigation of risk. High risk industries such as aviation and the nuclear demonstrated both aspects in their commercial operation. For aviation, maintaining a good public reputation based on service, efficiency, safety and cost, a number of which are factors identified under the quality agenda, is key to commercial success. The nuclear industry needs to demonstrate a positive reputation that it has the capacity and capability to manage the risks associated with industry to act as subject experts and give the public confidence on a risk that is beyond their immediate control. The reputation of healthcare providers in the UK has been hit by a number of high profile cases in recent years for example the high death rates at Mid Staffordshire Hospitals, paediatric mortality rates at Bristol Royal Infirmary and maternity service failures at University Hospitals of Morecambe Bay. As each incident brings its own headlines there are commitments of learning and improvement to prevent a reoccurrence. Such statements aim to rebuild public confidence, show healthcare as learning from mistakes to improve and that incidents highlighting risks in delivering care can be managed.

Reputation of the sector, of hospitals and of individuals can all influence the confidence of patients and the public. In managing the reputation it is necessary to consider factors that may impact on them, positively or negatively, as well as those that may impact of public and patient confidence. Factors identified includes:

- Delivery against expected performance targets
- Failure to meet patient expectations
- Adverse clinical outcomes
- Turnover of staff – unstable workforce
- Financial management and control
- Access to services
- Responding to local population needs

There is a synergy between the factors affecting an organisation's reputation or impacting on patient confidence and in the factors and overall drivers of risk management at an operational and strategic level. Parallels can be drawn between factor and its contribution to enhancing public confidence and reputation or in managing risk for example the act and outcomes of incident reporting in patient choice and access to services that meet expected performance levels meeting the

required standards of safety, quality and operational delivery.

3.2.1.3. Corporate Governance

Governance is a term used to encompasses all aspects of how an organisation functions. It extends from the composition of the Executive Board, committee structures, the provision of oversight and assurance of operational delivery and adherence to internal controls. In the late 1990s, clinical governance had become an integral part of the NHS, commissioners and providers. Previous cases within the sector and in other industries highlighted the potential insight that patient engagement can have on the quality of frontline services, in the management of risk and harm and in the learning to improve services and build public confidence. Simply asking how well a function is working or if the outputs were as intended would start to validate activities. The driver of clinical governance has set standards and expectations that have translated the principles of corporate governance to the clinical setting.

Focusing on healthcare, the significance of the role that governance has to play in health was reflected in the Health Act 1999. Section 18 states, "it is the duty of each Health Authority, Primary Care Trusts and NHS Trust to put and keep in place arrangements for the purpose of monitoring and improving the quality of healthcare which it provides to individuals." The 1999 act sets out the requirements under a broad heading of quality that sets an expectation that care is delivered safely and effectively. This statement again starts to draw parallels with the quality agenda and contributes to the complexity of the picture that is evolving that describes risk management. The legislative requirement not only sets an expectation of standard and delivery by an organisation but also is a further demonstration that recognises that risk management and its associated factors are multi dimensional.

Under the banner of clinical governance banner, the legal requirements are translated into practice, clinical services and patient experiences. Leadership and responsibility is identified through specific roles and responsibilities for monitoring the quality of clinical practice. Overall it identifies the Chief Executive that as the Accountable Officer, placing the responsibilities for quality, operational activity and financial probity / control alongside each other and with one individual.

The scope of clinical governance overlaps with a number of risk management drivers

(strategic and operational) as well as the nuances of the activities that sit behind them for example the quality agenda and the clinical governance responsibilities aligned to this that consider clinical effectiveness, optimizing care and a culture that learns from adverse events. A key achievement and characteristics of governance is the ability to place to place the duties assigned to the Chief Executive as Accountable Office on an equal platform. It is at the deployment stage that the tensions emerge and the reality of compromises and balancing competing priorities are the key deliverables.

3.2.1.4 Performance

The quality of care delivered to patients and service users is under significant scrutiny following several high-profile inquiries, such as the Francis Inquiry. At the same time, the NHS faces a number of profound challenges, such as severe spending constraints, organisational changes and increasing levels of chronic disease in an ageing population.

In the 2000s, governments in the UK, particularly in England, developed a system of governance that set a structure with expectations on performance alongside a regime of accountability. One of the drivers behind the targets and performance regime is one of improvement and the delivery of expected standards. Prescribed performance regimes attract debates on their merits and demerits, across the NHS one of the greatest areas of debate has been around benchmarking and its use in the identification and dissemination of best practice or as an introduction of static performance standard.

Benchmarking is one of the private sector-grown "managerialist" tools whose application and significance is rapidly increasing in the UK public sector. Despite its prevalence, the nature (competitive or comparative), the process (based on indicators or ideas) and the outcomes (standards or "best practice") of benchmarking in public services remain unclear. For the health service, the debate remains open with supporters describing performance targets and tools as the approach to achieve for best practice and improvement whilst critics may view the targets as underpinning judgments. There is a group that straddles both camps and that is those that see performance frameworks as an "indicator" and are inquisitive to investigate what lies behind a figure. Performance frameworks are often one dimensional and fail to take

into account multiple variables for example a purist could view the non achievement of a 4 hour target in A&E as a failure and judge accordingly in terms of poor performance and inability to deliver to required standards. Whilst clinical evidence may support that 4 hours is the optimum wait for clinical effectiveness, if a further wait to ensure either access to additional diagnostic services and skills requires an additional 2 hours can this constitute a failure if the patient outcomes have been enhanced by access to the right services at the right time. This scenario highlights a potential relationship and tension between performance and the quality of care and the complexity of managing the individual and combined risks.

Whilst benchmarking is a recognised performance tool, there is also a role for the independent stakeholders and institutions to provide an authorative view and insight on the quality and safety of care. In the NHS there are a number of national audits and returns that are used to benchmark that equally offer monitoring and independent scrutiny against key indicators with the aim of highlighting areas of improvement and measuring improvement. In the face of the shared goal of improvement is the absence of an agreement of how to measure and the representative indicators of quality and safety improvements. For example the Quality Check a collaboration between the Health Foundation and the Nuffield Trust currently track almost 300 indicators of quality across Health & Social Care, the Care Quality Commission regularly review data sets in excess of 200 indicators. Whilst there may be similarities the absence of a common set invites debates, speculation and challenge as well as adding further complexity to an already complex landscape.

3.2.1.5. Regulation

The regulation of healthcare in the UK is made up of a number of different bodies as well as a larger group of stakeholders. The regulation of healthcare provides oversight of standards and promotes accountability across there key areas (1) service providers, (2) healthcare professionals and (3) healthcare products including medicines, with each aspect led by a different regulatory body. The complexity of multiple owners has been widely recognised and the effectiveness of relationships and cross boundary working, including the sharing of information identified as offering opportunities for strengthening. Such criticism was evident in the findings of the Francis Inquiry with subsequent inquiries and incidents suggesting that further learning and improvement opportunities exist. The purpose of regulation and the role of regulatory bodies is subject to continual scrutiny however there is consensus

that core to the function is an act of holding to account that required standards are met and more recently that performance improves.

Whilst a number of the regulatory bodies are independent of the Department of Health in statute, there is a close working relationship via sponsor teams and publically accountable bodies. The existence of regulation and independent regulatory bodies can also be traced back to the introduction of clinical governance as well as the strengthening of practice in a post inquiry learning environment. In one aspect this adds to the growing complexity of the risk management landscape and agenda whilst also aligning and establishing a relationship across the other strategic drivers identified.

3.2.2 Operational Drivers

The grouping and description of operational drivers aims to identify tactical elements of managing risk, these are elements that are visible as part of day to day delivery, systems and processes. In the review of the strategic drivers the potential areas of overlap and dependencies were evident, for example between the quality agenda and public confidence. Whilst identifying the overlap and potential for duplication, the complexity that exists due to multiple definitions, the absence of a consistent or standardized approaches and the presence of tension and conflicting priorities was also noted.

3.2.2.1 Risk assessment Tools

Risk assessment is a process of identifying the hazard and assessing it in the context of a process, activity, system or behaviour. A risk assessment considers the likelihood of the hazard occurring and its significance that may be in terms of harm, damage, loss and financial cost as examples. Following identification of the hazard subsequent stages may expand the process to incorporate the assessment of different scenarios, “what ifs” as well as identify mitigation measures and a commitment to monitoring and reviewing the risk.

Risk assessment is one part of a risk management system however as frameworks evolve the language of risk assessment and risk management can be used interchangeably. In general risk assessment is used to describe the process of hazard identification, assessment of its significance and the mitigating risk action.

Risk management generally has a broader scope that extends to monitoring and review processes, risk improvement targets and cultures.

The term risk assessment is commonly used in health in the delivery of care as well as in the functioning of an organisation. Whilst the term may be common, the processes and systems supporting its application in the clinical, operational and corporate settings vary. There are a number of tools and techniques to assess risk ranging from a structured model, to predictive models and those that draw on past performance. These techniques will be discussed in more detail in chapter 3. In the absence of a single approach to assessing risk in healthcare attempts have been made through the introduction of specific guidance and initiatives, each offering a slight variation and adaptation of previous tools, the absence of a single approach not only introduces complexity and possible confusion but also makes risk comparison, prioritisation and comprehensive assessment a challenge.

The Controls Assurance programme introduced by the Department of Health that ran throughout the early 2000s adopted the 5x5 matrix used in the AS/NZ Risk Management Standard. The matrix adopted the traditional equation of risk = likelihood x consequences, with criteria scored on each axis on a 1 to 5 defined scale. The result was a risk score and rating that was categorized according to the level of risk.

Table 3.1: 5x5 Risk Assessment Matrix (Risk Rating; extreme, high, medium, low)

Likelihood	Consequences				
	Insignificant	Minor	Moderate	Major	Severe
Almost certain	M	H	H	E	E
Likely	M	M	H	H	E
Possible	L	M	M	H	E
Unlikely	L	M	M	M	H
Rare	L	L	M	M	H

Table 3.2: 5x5 Risk Assessment Matrix (Risk Score)

Likelihood →	1	2	3	4	5
Consequence score ↓	Rare	Unlikely	Possible	Likely	Almost certain
5 Catastrophic	5	10	15	20	25
4 Major	4	8	12	16	20
3 Moderate	3	6	9	12	15
2 Minor	2	4	6	8	10
1 Negligible	1	2	3	4	5

As with previous initiatives and attempts to improve how risk is managed in health, the controls assurance programme was superseded by a number of products, programmes and bodies. New products, tools and approaches emerged not least authored by the National Patient Safety Agency and continued the development of a further set of tools for identifying and managing risk. The improvements in the understanding of risk through the application of common tools to financial, clinical and operational risk was lost .

3.2.2.2 Adverse Event Reporting

Adverse incident reporting is structured approach to recording the events when things go wrong. Incident reporting has a strong affiliation with risk management, in the identification, assessment and monitoring of risk. The value of reporting is well recognised across the literature and whilst helping to actively manage the risk also provides an additional insight of learning and improving to prevent re occurrence.

The function of incident reporting captures information on the types of incidents that occur, their prevalence and impact as well as the potential to analyse them to learn lessons, make changes and improve systems. The aim is to strengthen prevention to be more proactive in the management risk compared to a solely reactive approach. This approach is well recognised in other industries in particular high risk industries where operational risks are high and any incidents are likely to have a catastrophic and potentially fatal consequences. Learning from incidents has focused on designing safe systems and processes. “Error free” is often used to describe mechanical or automated systems. In healthcare, humans both as operators of a system and the source of the activity are a constant risk that requires understanding and management. Understanding what behaviours may lead to or contribute to error within a system is important. These errors either human or system highlight risks that require management as well as an insight through investigations and understanding causes of incidents the behaviour, culture and additional drivers that may have been identified. From a patient’s perspective understanding the possible risk factors that they may pose such as co morbidities and procedure related complication rates. These factors are all relevant in understanding why adverse events occur and in learning and prevent repeat occurrences.

In the NHS there is no mandatory requirement for reporting for adverse incidents.

The National Reporting and Learning System (NRLS) is a central reporting function hosted by NHS England. NRLS is a voluntary scheme for reporting patient safety incidents, and therefore does not provide the definitive number of patient safety incidents occurring in the NHS, only those that have been reported via NRLS.

The insight and intelligence offered through incident reports extends beyond the individual incident or adverse event. Reporting rates have been used as an indicator or organisational culture and safety however a low or high rate does not translate into a safe or unsafe organisation, instead it may highlight a culture of openness, learning and transparency. Experience in other industries has shown that as an organisation's reporting culture matures, staff become more likely to report incidents. Therefore, an increase in incident reporting should not be taken as an indication of worsening patient safety, but rather as an increasing level of awareness of safety issues amongst healthcare professionals and a more open and transparent culture across the organisation.

Certain types of incidents can also be used to establish a safety culture for example "never events". These are a nationally compiled list of incidents that should never happen. The events are characterised by defined actions accompanied by prescribed checks and controls that if followed should deliver the intended outcome. An example of this is the never event of wrong site surgery and the application of the safety surgery checklist which sets key checks to be performed to prevent incorrect surgery. From a culture perspective this sets a tolerance for incidents and a focus on incidents where the circumstances are such that an incident could have been prevented.

3.2.2.3 Safety Cultures

The introduction of culture as a part of operational risk management is potentially referenced most frequently in connection to adverse incident reporting. Safety culture is described as an integrated pattern of individual and organisational behaviour that continuously seeks to minimize patient harm arising from the processes of care delivery.

There is a considerable amount of literature on what is culture, what defines and influences it. There have been numerous terms used to describe and set the tone for

safety culture, including fair blame, just or no blame. Reason (1990) suggests four critical elements of an effective safety culture: reporting, just, flexible and learning culture. A characteristic of culture and also a common theme of the terminology is the promotion of accountability for incidents alongside the context of what has happened. A strategy for a safety culture needs to embrace two key elements, firstly it needs to promote a system that encourages reporting when things go wrong in which individuals feel free from blame, humiliation or retaliation. Secondly, the culture and system needs to be open and equally applied and adopted.

Culture is not solely defined by incident reporting. A successful safety culture embraces all aspects of organisational beliefs, values and behaviours and applies these. Culture may be set by leadership with clear expectations on what to do and the standards to deliver to alongside accountability for actions. This shared view recognises the risks and errors in healthcare but continues to reinforce on a regular basis what is required. This shared view extends to all staff hence it is essential that knowledge and skills are an essential foundation for safe practices so thinking at a recruitment stage of what an organisation needs to ensure it delivers is a characteristic of a maturing safety culture.

Building a strong safety culture is a long term commitment . Having set foundation stones, ongoing maturing of a culture needs to build and respond to what is happening and how the organisation is learning and responding. Analysing performance data and data on incidents and near misses is one element, understanding and being open to what has happened and learning is another example.

The significance of culture and the role it has to play in risk management and as a factor of other programmes should not be underestimated. At a superficial level culture has strong links with incident reporting and encouraging learning from these events whilst the openness displayed through learning and the commitment to improvement aligns with the quality agenda and developing public confidence.

3.2.2.4 Organisational Performance & Priorities

Organisational performance in the NHS has tended to be measured and reported on using three categories (1) finance, (2) operational activity and (3) safety or quality of care. Across all categories there are a range of qualitative and quantitative

indicators that are used to demonstrate performance, priorities and improvement. The outputs can take many different forms such as an annual report (eg Quality Account or Governance Statement) to a performance scorecard and be used to engage with stakeholders, demonstrate the attainment of national standards and promote public confidence and support of the services provided.

Over the last 15 years, the NHS has had a rigid commitment to operational performance and priorities, with delivery prescribed through a number of operational and business frameworks. These frameworks have been used to form the basis of commissioning requirements and delivery expectations with performance often aligned to a Trust's income and financial position. An example of this is "Payment by Results", an outcome based payment scheme against fixed tariffs for service delivery monitored by the Department of Health. Expectations are set locally in terms of delivery expectations relating to volumes of activity and expected outcomes. These outcomes will be informed and based around national guidelines and previous benchmarking of outcome data. The scheme pays against completed activity as defined in the contract, however it does not take into account where activity or outcomes fall short or outside the expected standards for example prolonged length of stay due to medical complications related to treatment, additional treatment in response to avoidable harm or readmissions within 30 days of discharge. In these circumstances Trusts may be subject to a financial penalty. This dependency with finance is a strong driver in ensuring that the expected levels of delivery are achieved and in dominating organisational priorities.

In addition to the volume of activity, the timeliness of activity defined through hard, quantitative targets, is also a key characteristic of performance management and has been a key measure of patient access to care and treatment. The origins of "timeliness" targets can be tracked to the treatment of cancer and the impact of timely referrals, diagnosis and treatment on the quality of care and patient outcomes. The positive impact that rigid response and access targets had on cancer outcomes encouraged the wider application of time sensitive targets to Referral to Treatment (RTT) in 18 weeks; a maximum 4 hour wait in A&E to be seen and a decision made to admit, treat and discharge. The intended driver behind these targets has been one of improvement to the quality and safety of care that patients receive however critics highlight a tension and risk that exists if the priority of achieving operational targets dominates. To secure the financial income, Trusts need to deliver activity

commitments. The continued pressure on tariffs, delivering services at cost or potentially loss result in tight financial margins where even the smallest deviance from plan can create a deficit. With expectations growing, services are put under increasing pressure to deliver more often with the same or less resource. Facilities, equipment and staff suffer fatigue and errors occur which incur penalties that add further pressure to an already stretched resource model and introduce vulnerabilities.

The significance of the dependency between finance and operational activity may dominate performance reporting and the determination of priorities, however there is an equal wealth of safety and quality indicators support the efficient and effective delivery of safe services. NHS England coordinate a suite of patient safety indicators that covers national standards, safe staffing, infection control and cleanliness, open and honest reporting, patient clinical risk assessments eg vte, pressure ulcers, patient falls. The indicators support the comparison and benchmarking of hospitals as described in the context of strategic drivers however locally may be used by prospective patients in choosing the hospital or service to access.

3.3 Summary

Risk management has the potential to be a complex function. As a simple model it offers a systematic approach to hazard identification, assessment of risk, mitigation and improvement actions and a process of monitoring and review. Applied to high risk organisation, this structured approach remains visible although is added to with additional factors that add further complexity.

This review of risk management in healthcare has highlighted the potential complexities challenging the function. From a strategic and an operational perspective there is an absence of a standardized approach, from definition through to methodology for the assessment and management of risk. The plethora of guidance, initiatives and factors that have guided the development of risk in healthcare, however have failed to achieve a consistent approach or clarity in terms of a single all encompassing definition of risk, responsibility for risk or the ability to compare and ensure equal assessment of risks in particular financial and performance risks against quality of services.

The strategic drivers highlight that the factors that influence how risk is managed, assessed, tolerated and mitigated are not exclusively local operational decisions and highlights the influence of policy, reputation and performance targets have on deciding what is the priority to manage, how it should be managed and what does good performance look like. The steer from these drivers has the potential to introduce additional risk, issues and factors for consideration as the management of risk in one area may add or introduce risk elsewhere. These dependencies and interdependencies may not be explicit however are added dimension that required consideration and inclusion in mitigating or improvement actions adding to the complexity of the subject.

The analysis of the drivers, strategic and operational, has revealed that effective risk management is not solely a reactive process, with elements of the risk assessment process, the logic underpinning performance targets and the learning presented from adverse events all offering a proactive and prospective lens through which to view risk and critically promote continual improvement as part of the process. Whilst the identification and contribution of factors to managing risk is evident, the scale and significance of this contribution or the added value of one factor against another factor is less clear. The literature review has highlighted that this value may be demonstrated through a range of measures from the identification of the core component parts of the risk assessment through to operational performance such as the number of claims paid or regulatory compliance achieved.

Chapter 4 sets out the methodology for testing these elements and responding to the original questions:

- Does risk management exist as a function in the NHS and what does this look like?
- Is it possible to measure the success of the systems and if so how?
- Do characteristics of either the organisation or system influence how a Trust performs?

Chapter 4 – Methodology

4.1 Background

Healthcare and the NHS are not deprived of approaches, models and systems to manage risk with a wide range to choose from as described in chapter 2. Whilst there are a number of risk assessment tools and risk management frameworks available to healthcare providers, the literature review did identify a consistent theme of risk systems and the limited integration with other risk systems and the core operational management of Trusts.

A review of literature on risk management in healthcare has identified that in addition to multiple approaches being available, systems in healthcare are less mature than risk management systems in other high risk industries. Whilst rhetoric may suggest that there are differences and opportunities to learn from the risk management approaches adopted by other high risk industries, it is important that the reality of risk management in healthcare, systems, scope, performance and effectiveness is established. The absence of a standardised approach to managing risk in healthcare and across organisations is evident on a national and international scale. Whilst key principles are commonly advocated, the development of robust frameworks, central to organisational activities is less than consistent (DH 2000, Khojania et al 2002, NPSA 2006, CQC 2010, Monitor 2013).

This research aims to understand the strengths, weaknesses and opportunities that exist to develop risk systems in place in NHS Trusts in England. In addition it will aim to develop the understanding of the drivers of risk management in the NHS, identification of common characteristics adopted approaches and the impact that this collectively has on the performance of organisations.

This chapter sets out the research method for identifying, collecting and analysing the empirical data. The research method adopted is a combination of both qualitative and quantitative approaches to data collection and analyses. The focus of the research and the data collection is on risk management systems in the NHS and aims to respond to the three questions previously identified in chapter 1:

- Does risk management exist as a function in the NHS and what does this look like?

- Is it possible to measure the success of the systems and if so how?
- Do characteristics of either the organisation or system influence how a Trust performs?

To answer these questions, I have used the findings of the literature review and the concept analysis to set the following research objectives:

1. To identify common elements of risk assessment and management systems in use across the NHS
2. To analyse the impact or influence that characteristics of risk systems and of Trusts have on organisational performance
3. To determine if "risk information" is used within the organisation and the relationship between outcomes and organisational and other factors.
4. To review the influence of other approaches such as national initiatives and individual's behaviour on risk management and in the achievement of a patient focused service.

The response will draw upon the findings of original data collection involving the survey of 260 NHS Trusts and the provision of Trust Risk Management Strategies, the use of national data collections such as the number of claims paid by the NHS Litigation Authority and regulatory outcomes from the Care Quality Commission and Monitor across all NHS Trusts in England as well as an extensive literature review drawing on the experiences of international healthcare and other industries on the performance and content of risk management systems.

Table 4.1: Summary of data collection and analytical approach adopted

Data Source	Time Period	Data	Type of Data
Survey	2005	Survey of 260 NHS Trusts	Qualitative
NHS Directory (Procurement)	2005	Data aligned to organisational characteristics including employees and financial turnover	Quantitative
Care Quality Commission	2012	Regulatory outcomes against outcomes 4 & 16 Essential Standards	Quantitative
Monitor	2012	Breaches in authorisation of NHS Foundation Trusts	Quantitative
NHSLA	2005 & 2012	Total number and value of clinical negligence claims made and paid annually by the NHSLA 2005/06 - 11/12	Quantitative

4.2 Research Proposal & Ethical Approval

Prior to commencing the data collection, a key criterion for the effectiveness of the methodology was the planning and preparation of the research.

A proposal focusing on the collection of data was prepared and submitted to the Local Research & Ethics Committee in 2005. The proposal included a summary of the original research proposal, details on the scope of the data collection and an outline of the methodology to be used for data collection. Whilst the initial scope of the research falls outside the requirements of ethics approval, the research did involve direct data collection from NHS Trusts and other healthcare related organisations. In the interest of openness and transparency and in promoting best practice, an application outlining the proposal was submitted to the Chair of the Local Research Ethics Committee and confirmation was received that approval was not required.

4.3 Definitions of Risk Management Systems

The literature review highlighted the different approaches, definitions and understanding of risk management in general and specifically in relation to healthcare. As part of this research it has been important to define the scope of risk management in terms of what it means and risk management systems, what processes are included. For the purposes of this research the scope is defined as:

1. The function of *risk management* is defined as, Clinical risks (including patient safety), non clinical risks (including heath & safety, occupational health) corporate risks (including organisational issues, performance management and financial management).
2. *Risk management systems and processes* include, Risk identification, risk assessment, treatment options, monitoring and review and will incorporate risks associated with all aspects of healthcare.

4.4 Data Collection

4.4.1 The Approach to Data Collection

In chapter 1, I set out three high level questions for the research to respond to:

1. Does risk management exist as a function in the NHS and what does this look like?
2. Is it possible to measure the success of the systems and if so how?
3. Do characteristics of either the organisation or system influence how a Trust performs?

In chapters 2 and 3 I identified some of the complexities and drivers that exist in managing risk in a healthcare setting. This insight assisted in detailing the role of risk management in high risk industries, its application and adoption in healthcare and the strategic and operational drivers that shape the risk management function. Using the literature review to identify the core components of a system, it was evident that the detail required to investigate risk management arrangements in use in the NHS Trusts did not exist in a central collated format. The absence of a central data source supported the need for original data collection.

The focus of the data collection in 2005 would be the collation of qualitative data identifying and detailing the arrangements, content and oversight of risk management arrangements in NHS Trusts in England. In collaboration with my academic supervisor we discussed a number of approaches that could be used, these included face to face interviews with a series of structured and open ended questions, identification and testing of a series of models over a defined time period and a survey approach. The approach that was selected and formed the basis of the 2005 data collection was the development of a survey with structured questions and the opportunity to provide supplementary information through open ended questions and the voluntarily provision of relevant Trust documents. The selection of the final approach was predicated on the logistics of co-ordinating data collection across a cohort of 260 Trusts; the achievement of a sufficient data to analyse and draw conclusions from; the observed evolving state of risk management approaches and definitions from the literature review and the need to establish an operational baseline of risk management function to accompany central policy. The factors described supported the decision to adopt a survey approach. This involved the design of a bespoke survey with questions structured to capture responses against the common themes emerging from both literature and rhetoric as well as organisational specific information such as the executive leadership given to risk management and a copy of the local risk management strategy.

A survey encompassing qualitative and quantitative questions was designed. The survey comprised of 19 questions covering the breadth of risk management and organisational data. To assess the value of the survey and the information captured, a pilot study was conducted prior to its distribution to the 260 Trusts.

Data collection for this research has included a primary data collection through direct surveying of NHS Trusts, data requests to regulators using Freedom of Information requests as well as use of information and intelligence resources in the public domain. The data was collected in two stages. The first collection was in 2005 with a questionnaire distributed to 260 NHS Trusts in England.

4.4.2 2005 Survey Design

The primary source of data collection was through the distribution of a two page survey distributed to 260 NHS Trusts in England. The Trusts were identified through the NHS Directory (procurement). The survey contained in appendix 1, consisted of 19 questions on the organisational and risk management processes adopted and implemented within the individual Trusts. The basis of the questions was informed by the literature review and more specifically the key findings following a review of the databases (Medline & Proquest). This review used the terms “risk, healthcare”, “risk management in healthcare”, “clinical safety” and “clinical quality & risk”.

In completing the questionnaire respondents were provided with instructions on each question, this included options of single and multiple responses to the questions as well as free text on open ended questions. As part of the survey and specifically question B1, Trusts were asked to provide a copy of the Trust’s documented risk management strategy. This document has been a requirement under NHS LA CNST assessments (NHSLA 2012) as well as in DH policies and safety initiatives (CQC 2010, DH 2008)

For questions where the responses were structured with single or multiple options the information was collated in a data base identifiable by individual Trusts.

4.4.3 Testing & Evaluation of Survey Design

The proposed methodology was reviewed and approved by the academic supervisor of the research. This review consisted of two distinct stages; part one involved the development of a survey for distribution; part two tested the survey prior to its full distribution to 260 NHS Trusts.

To support the effectiveness and validity of the final survey, the survey was trialled prior to its distribution by five NHS Trusts. The pilot included acute Trusts, a Mental Health & Shared Services Trust, a Primary Care Trust and an Ambulance Trust, a

sample that represented each sector that could be included in the final distribution. The participating Trusts were members of a local peer review group through which practice and research was regularly shared, reviewed and tested.

As part of the pilot, feedback was received both on the logistics of the full distribution of the survey and on the survey questions. The feedback included some specific references as well some general themes such as:

- Lack of clarification of the scope of the survey as language used did not align with most recent central policy or common national programmes.
- Parity in application across all sectors and types of Trusts, this was a specific observation from the PCT who identified that the function was commonly a shared function with another Trust.
- Phrasing of the questions assumed a technical expertise in risk management, which did not align with the intended target audience.

As a result of the feedback received a number of changes were made to the survey. These included:

- Changes to the phrasing of questions specifically clarification through the rewording of key questions relating to the risk management documents and risk assessment criteria.
- Clarity on what was included in the scope of risk management noting that within the pilot sample, variation in the interpretation of the scope was evident.
- Confirmation of the rationale and consistency of using the Chief Executive and Accountable Officer as the intended recipient of the survey.
- Noting that risk management arrangements in PCT included in the pilot sample did not align with arrangements of other Trusts with risk policies and oversight provided from a “host” organisation.

The changes made to the survey following the pilot did not significantly change the survey, with the integrity of the logic behind each question intact and aligned to its foundation established in the literature review and concept analysis. A copy of the final survey is provided in Appendix 2.

It is important to note that the Trusts that participated in the pilot were also included in the final distribution of the survey with the amended survey sent to the Trust Chief

Executive in line with the other Trusts included in the sample size of 260 organisations.

4.4.4 Survey Distribution

The sample for the survey distribution in 2005 identified using "The National NHS Trust Procurement Directory 2004/05". The directory is a national directory identifying NHS Trusts by region and also by type. Each entry includes key contact details within the Trust. This information is updated on an annual basis by each Trust. For the purpose of the distribution of the survey the Trust contact was the Chief Executive. The Chief Executive was identified as the recipient of the survey in their role as Accountable Officer. This role is one that is that is highlighted in legislation, and also as a duty in operational management in the NHS in the Department of Health publication "Board Assurance" and updated in the guidance supporting the Annual Governance Statement (DH 2012). The full distribution list for the survey is contained in appendix 1.

A postal survey accompanied by a covering letter and return envelope were sent to the Chief Executive of the each of the identified 260 trusts. The accompanying letter outlined the context of the research to the recipient and requested their participation in the research. The information provided included instructions on the completion of the questionnaire and a request for a copy of the Trust's Risk Management Strategy to be provided with the completed survey. Both the completion of the survey and the provision of a copy of the documented strategy were voluntary.

To achieve a satisfactory response rate that would be considered as a reflective sample of practice in healthcare and hence enable conclusions to be drawn, the survey was distributed four times over a 10 month period. The timeline for the distribution of the survey is shown in table 4.1 and sees the first round of survey distribution starting in August 2005. All surveys had previously been numbered using a unique numbering that identified each Trust. This numbering allowed all completed surveys to be tracked and the subsequent distribution of surveys targeted at non respondents.

Table 4.1: Distribution of Survey

Distribution of Survey	Date of Distribution
Round 1	August 2005
Round 2	December 2005
Round 3	February 2006
Round 4	June 2006

The method of distribution remained consistent throughout each round of the distribution. However in round 4 the distribution was supplemented by a telephone call and follow up emails to the Trusts who had not responded. This approach did not have a significant impact on improving the response rate with only one survey returned from fifty Trusts contacted.

4.4.5 Survey Distribution 2005

A total of 260 Trusts in England were sent a copy of the questionnaire. The distribution included all Acute, Mental Health and Ambulance Trusts as well as identified providers of risk management services by other Trusts. Given this complexity and the results from the piloting of the survey that identified a multitude of options for the provision of risk management in Primary Care Trusts (PCTs), this Trust group was excluded.

The data collection has excluded NHS Trusts in Wales, Scotland and Northern Ireland due to the promotion of local risk management programmes and specific initiatives. An initial decision to exclude Scotland was made due to the existence of an established system for risk management and claims management through Clinical Negligence and Other Risks Indemnity Scheme (CNORIS). This system has the support of all Trusts across NHS Scotland. As the data collection has progressed a similar system is being implemented across Wales with the support of the National Welsh Assembly. It was concluded that the inclusion of these regions and the recognition of the regional initiatives and programmes would skew the results. The existence of regional programmes is recognised and examined in the literature review and will be drawn upon to analyse the results and identify the key elements of a risk system.

4.4.6 Collation of the Completed Surveys

All returned surveys were recorded and collated using an excel database. The database was developed using an excel spreadsheet recording the individual responses. To maintain objectivity throughout the analysis of the data and in the collation of the results, all entries have been inputted using the individual codes assigned to each of the Trusts at the time of initial distribution. Responses were collated as appropriate including yes, no and partial in addition to specific details such as individuals with defined risk responsibilities and tools used in the completion of risk assessments.

4.4.7 Collation of Risk Management Strategies

The provision of the risk management strategies was requested alongside the survey, the objective was to analyse these separately to identify any similarities, common themes or distinct features of the strategy documents. To assist with this the documents were logged separately and a matrix drafted to identify criteria, format and content as each strategy was reviewed. The criteria used to map and unpack the strategies would refine as the detail and content of the strategies emerged. In the first phase of mapping a number of broad headlines were identified that mapped to headlines highlighted as part of the literature review and had informed the design of the survey. These were:

- Identification of risk including a definition of risk and the approach adopted
- Roles and responsibilities
- Systems and processes for the identification, assessment and mitigation of risk and aligned programmes
- Commitment to risk management (purpose, improvement and integration in business)
- Measurement and reporting on risk performance

Whilst the headlines were broad, a checklist or more prescriptive approach had been avoided so that local arrangements could be explored without the constraint of preconceptions. The request for the Risk Management strategies aimed to provide richness and supplement the information provided in the completed survey as well as provide further detail on local conditions and systems for managing risk including the measurement and monitoring of risk. The importance of risk management arrangements flexing and replicating local conditions was identified as part of the

literature review as a feature that develops organisational resilience and reliability (Gamble 2013, Hollnagel & Woods 2006).

4.4.8 Supplementary Data Collection 2012 – Regulatory Performance & Claims Management

A second round of data collection was completed in 2012 that accessed information held by national agencies. The aim of this data collection was to provide context to insight offered through the surveys on the impact of risk management arrangements on a Trust's performance. Specific, tailored requests were made to the NHS Litigation Authority and to the Care Quality Commission and Monitor as independent regulators of all NHS Trusts and Foundation Trusts respectively. The original request was made under the Freedom of Information Act (2000), however as information that is already in the public domain I was directed to the relevant reports on the individual websites.

Table 4.3: Details of 2012 data collection

Data Source	Time Period	Data
Care Quality Commission	2012	Regulatory outcomes against outcomes 4 & 16 Essential Standards
Monitor	2012	Breaches in authorisation of NHS Foundation Trusts
NHSLA	2012	Total number and value of clinical negligence claims made and paid annually by the NHSLA 2005/06 - 11/12

The aim of this additional data collection was to respond to questions 2 and 3:
Question 2: *Is it possible to measure the success of the systems and if so how?*
Question 3: Do characteristics of either the organisation or system influence how a Trust performs?)

These questions consider the value of characteristics identified under question 1 and if they are significant by examining the impact on organisational performance.

This second round of data collection focused on three key sources of data.
1. Care Quality Commission - Compliance data and details of registration conditions for all NHS Trusts registered with the Care Quality Commission (Health & Social Care Act 2008 (Regulated Activities) Regulations 2010 and the Care Quality Commission (Registration) Regulations 2010*

Outcome 4: Care and Welfare

Regulation 9 of the Health & Social Care Act 2008 (Regulated Activities) Regulations 2010 state:

This is translated into a outcome reflected what patients can expect to experience as well as establishing an understanding with providers.

People who use services can expect to experience effective, safe and appropriate care, treatment and support that meets their needs and protects their rights. As a result providers will reduce the risk of people receiving unsafe or inappropriate care, treatment and support by:

- assessing the needs of people who use services
- planning and delivering care, treatment and support so that people are safe, their welfare is protected and their needs are met
- taking account of published research and guidance
- making reasonable adjustments to reflect people's needs, values and diversity
- having arrangements for dealing with foreseeable emergencies

Subsequent prompts to assist with the delivery of this standard highlights the need to identify risks and say how these will be managed and reviewed.

Outcome 16: Monitoring the Quality of services

Regulation 10 of the Health & Social Care Act 2008 (Regulated Activities) Regulations 2010 state:

The registered person must protect service users, and others who may be at risk, against the risks of inappropriate or unsafe care and treatment by means of the effective operation of systems designed to enable the registered person to:

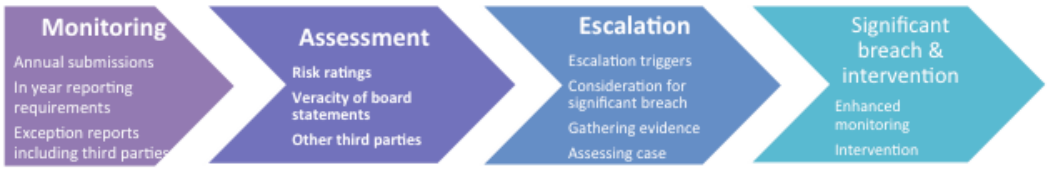
a. Regularly assess and monitor the quality of the services provided in the carrying on of the regulated activity against the requirement set out in the regulations; and
b. Identify, assess and manage risks relating to the health, welfare and safety of service users and others who may be at risk from the carrying on of the regulated activity.

CQC (2010)

*2. Monitor - Identification of NHS Foundation Trusts * found to be in Breach of their authorisation as termed by Monitor and its operating framework (*authorised and operating as FTs in November 2012)*

Monitor regulates Foundation Trusts against a set regime consisting of four stages; monitoring; risk assessment; escalation; significant breach and intervention. Figure 3.4a shows the stepped process.

Figure 3.4a: Monitor's Regulatory Regime (Compliance Framework 2012)



The scope of the assurance required by boards' demands a comprehensive system, which is subsequently declared against and regulated through the Compliance Framework. This declaration is summarised by three key areas:

1. *Clinical Quality* – Monitor requires that the board of each foundation trust certify in its annual pan that to the best of its knowledge and using its own processes that it is satisfied that effective arrangements are in place. This satisfaction is supported by metrics from the Health care Commission and any further relevant metrics. The aim of this is to deliver assurance to the board.
2. *Service Performance* – Boards must be satisfied that plans are in place to ensure (1) ongoing compliance with all existing national core standards and targets and (2) prospective compliance with known national targets due to come into force going forwards.
3. *Exception and ad-hoc reports* – Performance and risk management systems of an NHS foundation trust indicate that there is a significant risk that it will not meet a current or future national core standard or target or is at risk of failing to put in place effective arrangements for the purpose of monitoring and continually improving the quality of healthcare provided.

Performance against these three areas is determined via risk ratings which are informed by a regular monitoring programme, focussed assessments based on key deliverables linking back to core performance metrics. The aim is to clarify how

clinical quality and service performance issues are considered to be elements of the risk and performance management dimension of corporate governance in healthcare.

The governance risk rating which also includes the outcomes of an assessment of risks, quantified using a 5 x 5 matrix similar to that used in the AS/NZ 4390 standard, reports on a Green, Amber or Red rating. The framework and implementation strategy used by Monitor has a strong risk base and uses deviations in expected performance and organisational responsibility and accountability arrangements to identify, analyse and provide assurance on the key criteria .

The *Compliance Framework* outlines Monitor's risk-based approach to regulating NHS foundation trusts. This regulation is supported by internal mechanisms including an annual assessment on service performance, quality of care and other risk activities. Assessments previously required by Monitor as part of the initial application for Foundation Trust status have been quantified using the 5x5 matrix, a variation of that provided in the Australian / New Zealand standards. The supporting sourcebook (Monitor 2006) prescribes the assessment criteria. In the event that "significant failings" are identified, Monitor will assess the significance in light of any action the board is taking to resolve the issue or any relevant previous monitoring or intervention. The identified failings have the potential to act as triggers and change the risk profile of an organisation.

3. NHS Litigation Authority - Claims received and paid as part of the NHS LA Clinical Negligence Scheme for Trusts.

The NHS Litigation Authority (NHSLA) operates an indemnity scheme for clinical negligence and non clinical claims. The scheme is voluntary and all NHS Trusts are eligible to join the programme. It is noted that other insurance schemes do exist although proportionally the NHSLA has the largest share of NHS Trusts. The NHSLA acknowledges that clinical and non clinical risks manifest themselves with different outputs and implications and as such operate separate schemes and assessment processes to determine the standards of risk systems through the application of three levels (Level 1 - policy; Level 2 - practice; Level 3 - performance).

The Clinical Negligence Scheme for Trusts handles all clinical negligence claims

against member NHS bodies where the incident in question took place on or after 1 April 1995 (or when the body joined the scheme, if that is later). The costs of the scheme are met by membership contributions. The projected claim costs are assessed in advance each year by professional actuaries. Contributions are then calculated to meet the total forecast expenditure for that year. Individual member contribution levels are influenced by a range of factors, including the type of trust, the specialties it provides and the number of "whole time equivalent" clinical staff it employs. Discounts are available to those trusts which achieve the relevant NHS LA risk management standards and to those with a good claims history. When a claim is made against a member of CNST, the NHS body remains the legal defendant. However, the NHS LA takes over full responsibility for handling the claim and meeting the associated costs.

4.5 Data Collation

All surveys were numbered prior to distribution to allow tracking of respondents. The numbers were also used to anonymise data whilst retaining traceability should original data need to be checked as well as ensuring that trends are based on analysis and not pre existing views on the Trust.

The survey data was collated along with the national regulatory performance and claims management data on an excel spreadsheet. This collation allowed all information to be centrally collected and used as baseline data for the analysis and presentation of findings.

4.6 Data Quality

4.6.1 Tracking Trusts Between 2005 and 2012

Inevitable changes in Trust status, name and existence have occurred since 2005. A full mapping exercise was completed, mapping the original cohort of 260 Trusts through to 2012. To assist with this mapping exercise a number of different reference points were used including Trust data, website information, Strategic Health Authority (SHA) strategy documents as well as historical documents and national returns. Aligning the claims data to the new organisations was also necessary and was managed on an individual Trusts basis, mapping Trusts and organisational changes and combining the claims data. Where it was not possible to align organisations the Trusts were omitted from the data set. The alignment of

regulatory performance was not affected by this process given the data collection in 2012.

4.6.2 Multiple Indicators Describing a Single Variable

Collation of the data identified the potential for multiple indicators to be used as a descriptor of a single variable. This was evident in organisational characteristics and specifically the size of a Trust. Data available for Trusts related to the number of employees as well as financial turnover. Both indicators individually describe size however in terms of the relationship and subsequent correlation needed to be established to determine if one indicator should be preferred over the other or the impact that the use of one of the indictors would have in determining or influencing the findings. In this example correlation determined a strong relationship between the two indicators with a ranked correlation coefficient of 0.86 concluding that either indicator could be used as the data source for the variable relating to the size of an organisation.

4.6.3 Independent & Dependent Variables

To aid the analysis of the collected data, the indicators have been collated and aligned to the research objectives. The collation also confirmed the data as dependent or independent variables as part of the comparison undertaken along with the size of the data set as this in itself was found to vary according to responses received. A summary of this collation is provided in table 4.2.

Table 4.2: Data Collation – Dependent & Independent Variables and Analysis completed.

Source	Indicator	Analysis	Dependent Variable	Independent Variable	Objective Alignment
2005 Survey	Summary of responses from 2005 survey categorized by Trust and Region	Qualitative	Not applicable	Not applicable	1. To identify common elements of risk assessment and management systems in use across the NHS 2. To investigate the existence of a divide in the approaches and management of in NHS Trusts.
2005 Survey	Summary of Executive roles with lead responsibilities for risk management	Qualitative	Not applicable	Not applicable	1. To identify common elements of risk assessment and management systems in use across the NHS 2. To investigate the existence of a divide in the approaches and management of in NHS Trusts.
2005 Survey	Summary of positive responses to the existence of a Risk Management Strategy categorised by type of Trust and by Region	Qualitative	Not applicable	Not applicable	1. To identify common elements of risk assessment and management systems in use across the NHS 2. To investigate the existence of a divide in the approaches and management of in NHS Trusts.
2005 Survey	Summary of positive responses to the existence of a documented process for assessing risk by type of Trust and by Region.	Qualitative	Not applicable	Not applicable	1. To identify common elements of risk assessment and management systems in use across the NHS
2005 Survey	Risk Assessment Criteria – Summary by Region	Qualitative	Not applicable	Not applicable	1. To identify common elements of risk assessment and management systems in use across the NHS
2005 Survey	Correlation coefficient calculation between two variables "the total number of employees" and the "annual financial turnover" of the Trust.	Qualitative	Financial Turnover	Number of employees	3. To analayse the impact or influence that charcteristics of risk systems and of Trusts have on organisational performance
2012 Data collection (NHSLA)	Correlation calculation using two variables, "the total number of claims paid by Trust by the NHSLA" and "the size of the Trust (based on financial turnover £ million.	Spearmans ranked correlation coefficient	Financial Turnover	Total number of claims	3. To analayse the impact or influence that charcteristics of risk systems and of Trusts have on organisational performance
2012 Data Collection & 2005 Survey Data	Regression analysis to "adverse event" data (incorporating the total number of claims paid and regulatory non compliance) against the variable of Trust size (financial turnover £ million).	Regression Analysis	Financial Turnover	Adverse event data	3. To analayse the impact or influence that charcteristics of risk systems and of Trusts have on organisational performance
2012 Data Collection (NHSLA) & 2005 Survey Data	Stage 2 of the application of regression analysis to the total number of claims paid (under NHSLA scheme) against the variable of Trust size (financial turnover £ million).	Regression Analysis	Financial Turnover	Total number of claims	3. To analayse the impact or influence that charcteristics of risk systems and of Trusts have on organisational performance
2012 Data Collection (CQC & Monitor) & 2005 Survey Data	Application of regression analysis to identified regulatory non compliance against the variable of Trust size (financial turnover £ million)	Regression Analysis	Financial Turnover	Regulatory non compliance	3. To analayse the impact or influence that charcteristics of risk systems and of Trusts have on organisational performance
2012 Data Collection (CQC) & 2005 Survey Data	Expected and Observed values of Trust Regulatory performance measured by CQC compliance and the size of the Trust based on the number of locations.	Chi Squared test	Number of Trust locations	CQC compliance	3. To analayse the impact or influence that charcteristics of risk systems and of Trusts have on organisational performance
2012 Data Collection (Monitor) & 2005 Survey Data	Expected and Observed values of Foundation Trusts regulatory performance measured by breaches in authorisation and the size of the Trust based on the number of locations.	Chi Squared test	Number of Trust locations	Monitor Compliance (Breaches in authorisation)	3. To analayse the impact or influence that charcteristics of risk systems and of Trusts have on organisational performance
2012 Data collection (NHSLA)	Calculated correlation between two variables "the total value of claims paid in 2011/12" and "the total number of claims paid in 2011/12" in all NHS Trusts covered by the NHS Litigation Authority.	Spearmans ranked correlation coefficient	Total number of CNST claims	Total value of CNST claims	3. To analayse the impact or influence that charcteristics of risk systems and of Trusts have on organisational performance
2012 Data collection (NHSLA)	Linear regression line applied to the variables of size of the Trust (Financial turnover) and the total number of claims paid.	Spearmans ranked correlation coefficient	Financial Turnover	Total number of claims	3. To analayse the impact or influence that charcteristics of risk systems and of Trusts have on organisational performance
2012 Data collection (NHSLA)	Calculated correlation and linear trendline of variables "total number of claims paid by the NHSLA" and "the total number of employees" in Foundation Trusts	Spearmans ranked correlation coefficient	Number of employees	Total number of claims	3. To analayse the impact or influence that charcteristics of risk systems and of Trusts have on organisational performance
2012 Data collection (NHSLA)	Total number of claims paid between 2005/06 and 2011/12 and the number of Trust locations	Spearmans ranked correlation coefficient	Number of locations	Total number of claims	3. To analayse the impact or influence that charcteristics of risk systems and of Trusts have on organisational performance
2012 Data collection (NHSLA)	CNST claims reported to the NHSLA between 2008/09 and 2011/12	Qualitative	Time period (years)	Total number of claims	4. To determine if "risk information" is used within the organisation and the relationship between outcomes and organisational and other factors.
2012 Data collection (NHSLA)	Total number of CNST claims received by NHSLA grouped by Strategic Health Authority between 2008/09 and 2011/12	Qualitative	Not applicable	Not applicable	4. To determine if "risk information" is used within the organisation and the relationship between outcomes and organisational and other factors. 5. To review the influence of other approaches such as national initiatives and individual's behaviour on risk management and in the achievement of a patient focussed service.
2012 Data collection (CQC & Monitor)	Expected and Observed values of Foundation Trusts in breach of authorisation and their corresponding regulatory performance under the CQC's Essential Standards.	Chi Squared test	Regulatory Performance	Regulatory Performance	5. To review the influence of other approaches such as national initiatives and individual's behaviour on risk management and in the achievement of a patient focussed service.

4.7 Statistical Analysis

The identification and completion of statistical analysis has been driven by the initial objectives and the early findings of the analysis. Table 4.3 details the dependent and independent variables and the size of the individual data sets.

Using the data collected analysis has been completed to establish a baseline on risk management arrangements across the surveyed Trusts, this includes qualitative analysis and commentary on:

- *Response rate*: reported overall, by region and by Trust category, this aims to set a baseline in terms of the spread of responses as well as demonstrating a

representative group from the respondents of the original distribution list. The respondents in addition to be representative of Trust category and geographical spread also underpin the data collected from the main body of the questionnaire.

- *Inclusion and omission of identified risk assessment criteria:* in their responses Trusts were asked to identify from a list factors what would be considered and assessed as part of a risk assessment. The list was developed using the literature review and recognised risk assessment practice across high risk industries with a focus on healthcare for clinical elements. The factors were also grouped by clinical and management process factors to assist in identifying priorities and focus. The grouping and collation of criteria has assisted with making observations and commentary around criteria most and least likely to be considered as part of a risk assessment by NHS Trusts. The results of this collation were used as an independent variable in correlation with variables of Trust size and the number of claims made under the NHSLA scheme.
- *Collation of risk management strategies* including a three stage mapping process to identify common themes and headlines. The risk management strategies were reviewed individually and the content collated under broad headings informed by the literature review. Following this initial review and the collation of the findings using the headings, it was possible to refine the groupings further and supplement with categories that reflected the emerging content. This mapping, collation and refinement of groupings were repeated three times.

The qualitative analysis and presentation of findings aims to provide the insight to relationships to investigate further through the proposed quantitative analysis. In lien with the objectives the quantitative analysis aims to test the presence of relationships, the significance of these in terms of the way they may or may not influence performance and the role of specific organisational characteristics as predictive indicators of risk performance or in pre determining the performance that could be achieved.

Quantitative analysis was applied to the data collected in 2012 that included regulatory performance against standards monitored by CQC and Monitor and

outcome data defined by the number of clinical negligence claims made and paid under the NHSLA Clinical Negligence Scheme for Trusts.

The data collected was analysed using principles of comparative analysis including:

- Correlation coefficients: to determine the level of correlation between identified variables. This has been used as the first stage of analysis to determine the type of relationship that exists between Trust characteristics such as size and performance, measured through regulatory outcomes or claims made.
- P – values: to provide commentary on the significance of the correlation as a predictive indicator. The p value has been used to confirm the statistical significance of the relationship and the level of confidence that can be taken from the result as a finding and in informing the conclusions and recommendations.
- Regression analysis: to investigate the strength and type of linear relationship between identified variables and provision of additional commentary on the significance as part of the risk management process.
- Chi squared test: continuing the theme of relationships between variables, the chi squared test has been used to test the relationship between variables from the perspective of observed values ie the results of the data collected and the expected values ie based on the relationship what you may have anticipated or "expected". This test was also accompanied by a p value again to confirm the statistical significance of the result and its application to subsequent findings.

The qualitative and quantitative approached adopted have supported the development of a comprehensive view based on the data available. This view starts with a foundation made up of risk management arrangements in the NHS, the content and common themes from practical application, performance based on national assessments. The analysis and techniques used have then used this foundation to test, monitor and explore the relationships that exist between variables. These variables reflect organisational characteristics, performance and interdependencies within these groupings. In the event that relationships are identified the significance of these has been tested to determine if these could be considered as predictive or not. During the course of the analysis, statistical lines of

enquiry and the deployment of further analysis will remain fluid and responsive to the results obtained.

In chapter 5 I will present the findings of the research. The presentation of these findings will draw on the data collected, analysis undertaken and further investigations completed. The results will also be accompanied by a narrative that presents the analytical findings as well as providing some further interpretation that links this to the literature review as well as other results.

Chapter 5 – Results & Findings

5.1 Introduction

In chapters 1 to 4 there has been an evolving picture of risk management as a function and its role in healthcare. These chapters have provided a valuable insight on its status, current practice and policy and the potential opportunities that may exist in learning from risk management practices in other high risk industries.

In chapter 4, the methodology used this insight to confirm the three questions to answer. Alongside the questions, I have explained how a combination of qualitative and quantitative approaches of data collection would be used to develop an understanding of risk management processes and practices in the NHS. These approaches involved direct data collection as well accessing nationally published data. In chapter 5, the data and the relevant findings have been presented in the context of answering the three questions posed in chapter 1:

Question 1: Does risk management exist as a function in the NHS and what does this look like?

Question 2: Is it possible to measure the success of the systems and if so how?

Question 3: Do characteristics of either the organisation or system influence how a Trust performs?

5.2 Data Collection

As described in section 4.4 there were two periods of data collection. The first in 2005 used a bespoke survey designed to collect information directly from 260 NHS Trusts on local risk management arrangements. The second data collection was in 2012 and used nationally collected data collated and published by national bodies (Monitor, Care Quality Commission & NHS Litigation Authority).

Table 5.1 provides a summary of the data collected in 2005 and 2012. Over 7000 individual data items have been collected, collated and analysed. In addition, this information has also been supplemented by 29 risk management strategies provided by NHS Trusts as part of the 2005 survey. Table 5.1 provides a summary of the data as well as the context of its collection, the aim of the analysis and the analytical approach adopted.

Table 5.1: Summary of data collection and analytical approach adopted

Data Source	Time Period	Data	Type of Data	Aim of Analysis	Analytical Approach
Survey	2005	Survey of 260 NHS Trusts	Qualitative	To identify what a risk management function and arrangements look like in the NHS	Presentation of empirical data
NHS Directory (Procurement)	2005	Data aligned to organisational characteristics including employees and financial turnover	Quantitative	To identify the relationship that exists between organisational characteristics and identified performance variables.	Correlation Coefficients Chi Squared Test
Care Quality Commission	2012	Regulatory outcomes against outcomes 4 & 16 Essential Standards	Quantitative	To determine if organisational risk management arrangements and characteristics of Trusts have an impact on regulatory performance using compliance with outcomes 4 & 16 as performance measures	Correlation Coefficients Linear Regression Chi Squared Test
Monitor	2012	Breaches in authorisation of NHS Foundation Trusts	Quantitative	To determine if organisational risk management arrangements and characteristics of Foundation Trusts have an impact on regulatory performance using breaches in authorisation as performance measures.	Correlation Coefficients Linear Regression Chi Squared Test
NHSLA	2005 & 2012	Total number and value of clinical negligence claims made and paid annually by the NHSLA 2005/06 - 11/12	Quantitative	To determine if organisational risk management arrangements and characteristics of Trusts have an impact on performance using the number of claims made and paid by the NHSLA as an indicator of safety performance.	Correlation Coefficients Linear Regression

The 7000 data items have been collected and collated at a Trust level with Trusts then grouped in the four regions (North, East & Midlands, South & London). This grouping is consistent with regional NHS operating boundaries as used in the NHS Directory. Table 5.2 to 5.4 provide an overview of the information collected.

Table 5.2: Summary of 2005 Survey Data collated by region

Region	Number of Trusts in region	Number of respondents	Total annual turnover 2005/06 (£'000)	Average Trust Turnover in region 2005/06 (£'000)
North	79	33	7,538,608	95,425
Eastern & Midlands	70	50	5,704,956	81,499
London	41	25	3,402,116	82,978
South	70	48	6,911,270	98,732

In Table 5.2 there is variation in the information presented on the number of Trusts, the size of the Trusts and the number of respondents across the four regions. This variation is to be expected and relates to the different types of Trusts, the different sizes and make up of Trusts including geographical distribution, multiple locations and activity (type and volume) undertaken. Over the course of the 2005 and 2012 data collections the sample profile (for example by Trust, region) remained consistent with less than 3% variation, equivalent to 7 Trusts moving between regions or merging with neighbouring organisations. Where changes were noted these were tracked along with the relevant organisational information.

As mentioned earlier in this chapter a further data collection was completed in 2012, drawing on the data held by national bodies on the performance of NHS Trusts. The definition of performance and hence measures adopted a proactive and reactive perspective. The proactive perspective encompassed regulation as the performance measure of risk management through the attainment of standards set and regulated through legislation by the Care Quality Commission for all NHS Trusts and by Monitor for Foundation Trusts (table 5.3). Performance has also been considered from a reactive outcome perspective using litigation claims made and paid (table 5.4).

Table 5.3: Summary of regulatory performance (collated 2012) by region

Region	Number of Trusts in region	Number of Trusts assessed as compliant against CQC Outcome 4	Number of Trusts assessed as compliant against CQC Outcome 16	Number of Foundation Trusts in region	Number of Foundation Trusts assessed in breach of authorisation	Total number of claims paid 2005/06
North	79	70	54	34	10	1816
Eastern & Midlands	70	56	57	24	14	1363
London	41	33	34	20	1	703
South	70	66	66	17	7	1156

The data in table 5.3 shows a high number of Trusts demonstrating compliance with regulatory standards set by the CQC and / or Monitor. The figures shown in table 5.3 are based on nationally published data and were not reliant on response rates from the 2005 survey hence the sample size was larger than the previously referenced 2005 survey response rate.

Table 5.4: Summary of NHSLA CNST claims against regional Trust data (collated 2012)

Region	Number of Trusts in region	Total number of claims paid 2005/06 to 2011/12	Total number of claims paid 2005/06	Total annual turnover 2005/06 (£'000)	Ratio of CNST claims to Trust Turnover (2005/06)
North	79	11570	1816	7,538,608	1:£49,000
Eastern & Midlands	70	2750	1363	5,704,956	1:£61,000
London	41	4501	703	3,402,116	1:£127,000
South	70	7700	1156	6,911,270	1:£78,000

Table 5.3 included the total number of claims paid in 2005/06. Table 5.4 provides further context to these claims based on the Trusts, the size of Trusts based on financial turnover, region and the ratio of claims to Trust Turnover. The results for London region indicate a higher financial turnover to each claim paid. One possible explanation for this variation is the higher number of teaching and specialist Trusts in London which typically have a higher financial turnover compared to acute Trusts outside of London.

Tables 5.2 to 5.4 do indicate a level of variation across regions. In Table 5.2, response rates across the four regions ranged from 42% in the North to 71% in

Eastern & Midlands. In chapter 4 I described the four rounds of survey distribution, providing all Trusts and all regions with equal opportunity to respond to the survey. The difference in the response rates does not appear to have had a significant impact on later results. Other data presented in table 5.3 provides further context to the NHS landscape and operating conditions of Trusts within the regions such as the number of foundation trusts within regions and also the average financial turnover per Trust. Whilst variation is evident it is spread across the regions and is potentially reflective of the complexity of Trusts (sector, services delivered, size, geographical location, number of employees) recognised by Khun & Youngberg (2002) and others in the literature review.

Table 5.3 sets the scene of regulatory compliance as defined by the judgements made by the Care Quality Commission (all NHS Trusts) and Monitor (Foundation Trusts only). The data also reflects claims data (Clinical Negligence Scheme for Trusts) as reported nationally by the NHS Litigation Authority. There is a shared theme and level of compliance across the regions with the Care Quality Commission. In reviewing Foundation Trusts alone, variation was evident with London reporting the lowest proportion of breaches in authorisations at Foundation Trusts in the region whilst in the East & Midlands regions 58% of foundation trusts had been identified as in breach of their authorisation conditions by Monitor. Interestingly it is East & Midlands region which also has the lowest proportion of authorised Foundation Trusts across the four regions. Given the conditions that need to be met locally and the higher rates of breaches there is the possibility of local factors within the region playing a contributory factor in this level of performance. The validity of this would need to be tested further to confirm the significance.

Table 5.4 explores the claims data further beyond the total number of claims made. In order to draw comparisons between the different size of Trusts, services delivered and the sectors, the results have been presented as a ratio of claim to financial turnover. In column 5, the difference between Trusts in the North and in London is clear with Trusts in the North region receiving approximately three times the number of claims compared to London Trusts. The literature review identified that adverse events including incidents, complaints and claims are affected directly and indirectly by a number of factors. Halligan & Zecevic (2011) identified the role that organisational culture plays in higher and lower rates of events. The lower number of claims in the East & Midlands region as with a higher number of breaches in

authorisation in Foundation Trusts suggests that other issues may be influencing performance such as culture or the experience of learning from incidents.

The absence of consistent variation in a single region across the core data aligns with the wider published research on organisational performance and factors that may influence risk management performance such as communication, leadership and performance drivers / targets. Whilst there is no reference to location as a factor, geography cannot be excluded as an inherent factor that can influence an organisation's performance. I completed an initial review of NHS Trusts whose performance was below standard as defined under the Health & Social Care Act 2008 or struggled to maintain standards identified a number of Trusts that shared a common characteristic. These Trusts were geographically isolated, coastal locations although distributed across regions.

The general findings presented were to be expected as the nature of the data collection and the analysis completed was not targeted at specific factors or the significance of these factors. There was a general theme of high levels of compliance to be expected less than 2 years post registration however what this does do is conceal the factors that may be underpinning non compliance in individual Trusts. Such practice may provide opportunities for learning and improvement in other Trusts and the promotion of a culture of anticipation of risk rather than reactive risk management.

In reviewing the performance results at a regional level high and low performing Trusts across all regions have been concealed through the averaging of performance. What cannot be ignored is the anecdotal evidence that suggests that certain factors do exist that act as integral challenges and constraints to a Trust's performance, initial attainment and maintenance of standards to the capacity and capability to improve. Some of these factors will be explored later on in this chapter however further targeted data collection and analysis may be necessary to determine the true level of influence and attribution.

5.3 Findings from the 2005 Survey

A total of 260 NHS Trusts were surveyed using the questionnaire detailed in the methodology and in appendix 2. 158 Trusts responded to the survey representing a

61% response rate. Absent from the respondents were any Primary Care Trusts which had been excluded from the sample prior to the final distribution based on the potential for different arrangements to exist in PCTs. The difference in arrangements was identified in the piloting of the survey. As previously highlighted in the methodology, at the time of the survey Risk management as a function was often provided by a host organisation. Based on the nil response PCTs as a category of Trust was excluded from further analysis to avoid future results being skewed.
Table 5.5 shows a distribution of the survey responses by type of Trust and also region.

Table 5.5: Summary of responses from 2005 survey categorized by Trust and Region

Type of Trust	Region				
	North	East & Midlands	South	London	Total
Acute	16	28	27	19	90
Mental Health	7	13	8	4	32
Ambulance	7	6	10	1	24
Foundation Trust *(as at 2005)	1	2	2	2	7
Other	2	1	2	2	7
Responses	33	50	49	28	158
Trusts Surveyed	79	70	70	41	260
Response Rate (%)	**42**	**71**	**70**	**68**	**61**

*To note this figure denotes the number of Foundation Trusts (FTs) in 2005 and differs to the figure reported in table 5.3 which denotes the number of FTs in 2012.

The next four sections detail the findings of the survey based around the themes of documented policy (risk management strategy) and processes (risk assessment process), executive accountability and responsibility and the influence of a range of organisational characteristics on Trust performance.

5.3.1 Risk Management Strategy

As part of the survey, Trusts were asked two specific questions in relation to a documented risk management strategy. The background to the survey question and the requested copy of the strategy was based on the documented standards and requirement for a strategy. The requirement for Trusts to have a documented Risk Management strategy is well documented through the CNST level 1 standards through to a clinical strategy forming part of Monitor's assessment framework for foundation trust authorisation.

In the 2005 survey all Trusts were asked the question “Does the organisation have a documented Trust wide Risk Management Strategy?” with options of yes or no as responses. Where Trusts responded positively a copy of the strategy was requested however this was optional. A total of 154 out of the 156 responding Trusts reported having a risk management strategy. The two Trusts that responded negatively are unrelated in characteristics and performance, one Trust a Mental Health Trust in South region was assessed as compliant by both CQC and Monitor and had a relatively low number of claims made. The second Trusts was an Ambulance Trust in the north region and was again assessed as compliant by the CQC however had a history of CNST claims.

As part of the survey a copy of the risk management strategy was also requested however only 29 (19%) Trusts provided a copy. There was variation in the documents provided by Trusts, these included executive summaries to the complete framework (up to 100 pages long). The variation strongly supports the existence of different approaches and the absence of standardised formats and frameworks for risk management in healthcare ranging from the content of the strategy, criteria included in a risk assessment and overall management responsibility and accountability at Board level.

A qualitative review of the Risk Management strategies focused on the content of the documents including definitions of risk, scope of risk management and local arrangements for risk management. This review identified a number of key themes.

Tables 5.6a-c map the identification of common elements and the consolidation of the headlines to five key themes relating to the content and practice of risk management in NHS Trusts. Table 5.6a provides an initial summary of the headlines emerging from the sample of risk management strategies provided. These headlines were identified from a review of the content and structure of the documents and the identification of similarities and common themes across the 29 documents.

Table 5.6a: Common headlines emerging from the sample of Risk Management strategies

Identified Headlines from Risk Management Strategies	Number of Trusts
Reference to NHSLA CNST standards in the introduction	29
Reference to national policy and drivers such as Never Events, NRLS, NPSA and clinical governance	20
Definitions of risk are generic and align to national standards	20
Responsibility for RM identified as part of everyone's role in the Trust with no specific reference or detail provided of what to do	20
Strategies presented in a very structured / checklist format	25
Links made to incident reporting policy and process	20
Process and systems dominate the content of the strategies	25
Improvement targets are identified and there is a commitment to learning and continual improvement	3
Recording risk and management actions in risk registers, learning logs or on data bases are identified tasks, limited reference to how the information is proactively used.	27
Context of risk management and how well the Trust is performing not referenced	21
Attainment of NHSLA level referenced as a performance indicator	25
Mechanism for monitoring and review identified for policies but not content	25
Detail and content of the strategy varied identifying the differences of the use of the document	3
Limited reference to dependencies and interdependencies with other functions of the Trust - some acknowledgement but no process	3
Document did not act as a "how to guide" although the existence of this was not always evident or useful	17
Acknowledgement that strategy needs to be part of the way services are delivered	13
Human factors not identified as part of the process	13
Organisational culture or safety climate not referenced (different to commitment)	15
Lack of personalisation or local context to personalise the strategy to the provider	13
Processes described are focused in clinical settings but are not clinical risk assessments such as those for falls or pressure ulcers	23
No Board level role dedicated to Risk management - appears as an add on to already large portfolios	29
Responsibility for risk is not well defined	12
RM responsibility at Board level identified as one of the duties for the named ED with no reference to time allocation or resource input	19
Relationship with other Board posts with defined responsibilities for potential influencing factors not referenced.	24
No reference to actual or proposed plans to integrate or how risk factors across an organisation are brought together and considered.	24

A further review of the headlines identified in table 5.6a highlighted a number of potential and emerging themes. The headlines were grouped together under identified themes. These themes and the groupings are presented in table 5.6b.

Table 5.6b: Consolidation of the common headlines to emerging themes

Identified Headlines from Risk Management Strategies	Number of Trusts	Summary of Findings	Number of Trusts
Reference to NHSLA CNST standards in the introduction	29	Reference to national policy, initiative and / or standards	29
Reference to national policy and drivers such as Never Events, NRLS, NPSA and clinical governance	20		
Definitions of risk are generic and align to national standards	20	Evidence or specific reference to approaches and tools adopted from national policy	20
Responsibility for RM identified as part of everyone's role in the Trust with no specific reference or detail provided of what to do	20	Structure of strategy in line with headings / criteria from national standards or policy - not personalised to the Trust	25
Strategies presented in a very structured / checklist format	25	Criteria for consideration as part of the RA process limited to set criteria	25
Links made to incident reporting policy and process	20		
Process and systems dominate the content of the strategies	25	Other factors such as performance, financial and operations not reference for specific consideration as either potential influencing factors (direct or indirect) or as context.	21
Improvement targets are identified and there is a commitment to learning and continual improvement	3		
Recording risk and management actions in risk registers, learning logs or on data bases are identified tasks, limited reference to how the information is proactively used.	27	Tolerance and acceptance of risk not fully defined	18
Context of risk management and how well the Trust is performing not referenced	21		
Attainment of NHSLA level referenced as a performance indicator	25	Strong reference to a process or structured systems ie Identification of hazard, assessment of risk, add to risk register, monitor and review period	27
Mechanism for monitoring and review identified for policies but not content	25		
Detail and content of the strategy varied identifying the differences of the use of the document	3	Limited or no reference to other types of risk or systems that the strategy should interface with.	20
Limited reference to dependencies and interdependencies with other functions of the Trust - some acknowledgement but no process	3	Reporting on risk provides little insight to context such as operational or financial performance	20
Document did not act as a "how to guide" although the existence of this was not always evident or useful	17	Reference to supporting documents	3
Acknowledgement that strategy needs to be part of the way services are delivered	13		
Human factors not identified as part of the process	13	Limited or no reference to the different types of failures and understanding why this happens ie human and system error or risk	13
Organisational culture or safety climate not referenced (different to commitment)	15	Reference to "learning" focused on learning logs not active learning and sharing of findings	23
Lack of personalisation or local context to personalise the strategy to the provider	13		
Processes described are focused in clinical settings but are not clinical risk assessments such as those for falls or pressure ulcers	23	Strategy guidance is not explicit that other criteria may need to be considered ie not an exhaustive list	25
No Board level role dedicated to Risk management - appears as an add on to already large portfolios	29	Roles and responsibilities identified from the Chief Executive as Accountable Officer and to the ED lead.	23
Responsibility for risk is not well defined	12		
RM responsibility at Board level identified as one of the duties for the named ED with no reference to time allocation or resource input	19		
Relationship with other Board posts with defined responsibilities for potential influencing factors not referenced.	24		
No reference to actual or proposed plans to integrate or how risk factors across an organisation are brought together and considered.	24		

From the initial identification through the continued refinement of the emerging headlines and shared content of the risk management strategies the aim has been to

identify a number of shared themes across the strategies that offer insight on the content, value and arrangements for risk management in NHS Trusts. Table 5.6c presents the final stage of refining the findings and the identification of five common themes.

Table 5.6c: Consolidation of Findings to key themes emerging from the Risk Management Strategies

Summary of Findings	Number of Trusts	Shared Themes
Reference to national policy, initiative and / or standards	29	Structure and content of RM strategy driven by national policy, initiatives and standards
Evidence or specific reference to approaches and tools adopted from national policy	20	
Structure of strategy in line with headings / criteria from national standards or policy - not personalised to the Trust	25	
Criteria for consideration as part of the RA process limited to set criteria	25	
Other factors such as performance, financial and operations not reference for specific consideration as either potential influencing factors (direct or indirect) or as context.	21	Strong focus on process and not reflecting the purpose or intended impact of risk management or interdependencies with other systems and parts of the organisation
Tolerance and acceptance of risk not fully defined	18	
Strong reference to a process or structured systems ie Identification of hazard, assessment of risk, add to risk register, monitor and review period	27	
Limited or no reference to other types of risk or systems that the strategy should interface with.	20	Evidence of separate systems that do not appear to be joined up or show any plans for an integrated model of service delivery.
Reporting on risk provides little insight to context such as operational or financial performance	20	
Reference to supporting documents	3	
Limited or no reference to the different types of failures and understanding why this happens ie human and system error or risk	13	Assessment criteria not comprehensive or inclusive for all potential factors that may influence the risk
Reference to "learning" focused on learning logs not active learning and sharing of findings	23	
Strategy guidance is not explicit that other criteria may need to be considered ie not an exhaustive list	25	
Roles and responsibilities identified from the Chief Executive as Accountable Officer and to the ED lead.	23	Board level commitment to Risk Management defined although as an add on with no additional resource or protected time (eg MD - clinical sessions / week) or focus eg Finance Director and Chief Operating Officer.

Collation of these themes across the sample of 29 documents provided highlighted five headlines. These are:

1. Structure and content of RM strategy driven by national policy, initiatives and standards
2. Assessment criteria not comprehensive or inclusive for all potential factors that may influence the risk
3. Strong focus on process and not reflecting the purpose or intended impact of risk management or interdependencies with other systems and parts of the organisation
4. Board level commitment to Risk Management defined although as an add on with no additional resource or protected time (eg Medical Director - clinical sessions / week) or focus eg Finance Director and Chief Operating Officer
5. Evidence of separate systems that do not appear to be joined up or show any plans for an integrated model of service delivery.

In addition to identifying themes and similarities between the risk management strategies provided, the return rate and headlines has provided further insight on the behaviour and culture of Trusts and the potential drivers of risk arrangements in NHS Trusts.

In chapter 3 a number of operational drivers were identified strategically in determining and shaping policy and tactically shaping local policies and processes. Cagliano et al (2011) recognised the systematic approach taken to managing risk in healthcare alongside the drivers and tensions of delivering against national initiatives and targets. These two themes were evident in the strategies as well as characterising the local arrangements for risk for example documented strategies structured in a checklist style to meet the requirements and standards of national programmes whilst consideration of local conditions or a commitment to continual improvement was notably absent in over two thirds of the documents. In chapter 2 factors were identified as drivers of the development and direction of risk management in healthcare, one of these was the political driver of national policy. This review of the strategies supports the significant role that national policy and programmes have in not only determining the recognition and adoption of the function but also the content of documents and processes which appear to be written to meet these requirements rather than using them as a framework for local application.

In addition to the content of risk management processes, the sample of strategies provided a level of insight to the culture of organisations overall and / or in relation to risk management. From the responding Trusts, 127 Trusts opted to participate in the survey, feeling comfortable to respond to questions, the results of which would be anonymised however did not want to support their responses with evidence of their practical delivery and performance in response to managing risk. The reasons for this are unknown however may suggest a lack of confidence in the processes described to effectively manage risk, a potential level of commitment to having a process to meet external requirements and an lack of openness and transparency to Trust operations and activities. The results would need to be analysed further and additional information collected in order to comment further on this however it does provide the opportunity for additional research in the future. From the Trusts that did respond, 29 Trusts geographically spread across England and the sectors, the documents and analysis highlighted the significant influence of national policy in how and what is included in risk management. The lack of transparency was also evident not least in the "fit" of risk management with other organisational activities, policies and processes.

5.3.2 Documented Risk Assessment Processes

A similar pattern to that seen in the responses of the existence of a risk management strategy is seen in the responses to "Does the organisation have a documented process for assessing risk?." Only two Trusts responded negatively to this question from the 156 responding Trusts. The Mental Health Trust that responded negatively to a documented risk management strategy also responded negatively to the existence of a documented risk assessment process. The second negative response was made by an acute Trust in the London region. The Trust is a single site Trust with less than 4000 employees and has a history of non compliant assessments by the Care Quality Commission as well as a history of a high number of claims year on year from 2005/06 to 2011/12.

The strong positive response is again a reflection of the influence of national policy. In 1999, the Department of Health implemented "Controls Assurance", a mandatory national programme for NHS bodies comprising of standards aligned to a common set of 18 risks in healthcare. The standards build on the findings of the Turnbull Report by setting out good practice in terms of controls to manage the associated

risk. The foundation of the risk based framework was based on the AS/NZ Risk Management standard discussed in chapter 3. The framework adopted and promoted the use of a 5x5 matrix for risk (Table 3.1 in chapter 3), an approach that was commonly referenced in the 154 responses provided. Further elements of the AS/NZ standard and their presence in Trust processes was evident in the criteria considered and included in risk assessments, presented later in this chapter. Risk assessments appear to share the checklist characteristics that were evident with the risk management strategies, this will be explored as part of the analysis of the criteria and the impact on performance.

5.3.3 Risk Assessment Criteria

The survey results identified the inclusion of certain factors in a Trust's risk assessment process, in particular that are most and least likely to be included in a Trust's risk assessment process based on core elements drawn from practices in high risk industries. Table 5.7 shows the percentage of respondents that positively identified the individual criteria as elements considered as part of a risk assessment. The results have been grouped by the percentage of positive responses and the results RAG (Red, Amber, Green) rated. The responses have been converted into an overall percentage based on positive responses identifying the criteria and the number of respondents in the survey. The data has been collated for analysis into four bands; less than 70%, 70-79%, 80-89% and over 90%. These bandings could be seen as arbitrary in the absence of statistical analysis although represent an attempt to initially identify and filter the results on common and less common criteria of a risk assessment process. This builds on the principles of Delphi statistical technique in forecasting through the use of repeated questions and the collation of responses.

Table 5.7: Risk Assessment Criteria – Summary by Region

	Risk Assessment Criteria															
	Hazard Identification	Control Measures	Assessment of Significance	Training	Risk Treatment Actions	Monitoring	Timescales for action	Reference to guidance, standards & legislation	Responsibilities	Assurance	Communication of risks (internal)	Identification of Secondary Factors	Risk Improvement Targets	Emergency Conditions	Communication of risk (External)	Assessment of Tolerability
North	97%	97%	91%	88%	88%	94%	91%	94%	85%	97%	82%	73%	79%	70%	67%	61%
Eastern & Midlands	96%	94%	88%	90%	92%	88%	92%	88%	90%	78%	78%	66%	82%	72%	64%	62%
London	96%	92%	92%	92%	80%	88%	72%	88%	88%	84%	76%	60%	48%	68%	60%	48%
South	93%	91%	89%	84%	89%	87%	84%	80%	76%	78%	67%	71%	53%	56%	64%	69%
Overall	95%	93%	90%	89%	88%	87%	86%	86%	84%	83%	75%	68%	68%	66%	65%	62%

An observation from the results is the existence of two distinct trends, the criteria most likely to be included in a risk assessment and the criteria least likely to be included in a risk assessment. Variation was also noted across the regions. The responses clearly identify the criteria at either end of the range of criteria for possible inclusion and omission from the assessment process. Three criteria were identified as being included in over 90% of risk assessments; these were, hazard identification (95%), assessment of significance (90%) and control measures (93%). Five criteria were identified as least likely to be included in a risk assessment; these were, identification of secondary factors (68%), assessment of tolerability (62%), external communication of risks (65%), emergency conditions (66%) and risk improvement targets (68%).

These results assist in identifying and proposing possible criteria for a risk assessment process and also the consideration given to management and process issues compared to contextual elements and factors which may need to be considered in identifying and assessing risk. However to determine if such criteria are representative, regional responses were considered and a consistent theme of common and shared criteria identified which are included and/ or considered as part of a risk assessment.

The same analysis was completed for each of the four regions to determine if there were any distinct differences in the individual responses. The results did identify variation in criteria included in risk assessments across regions. A number of observations were made which would benefit from further investigation and understanding of the context and prevalence of criteria compared to other regions.

North region - variation was noted to other regions in two criteria: Monitoring and Assurance. Both criteria received positive responses for inclusion in a risk assessment with 94% and 97% of respondents identifying inclusion of the factors compared to the other regions where consistency ranged between 78 and 88% of respondents.

Eastern & Midlands region - variation noted with two criteria were identified as frequently included in risk assessments; Risk Treatment Actions and Timescales for actions. The two criteria are linked and reflect a commitment to improvement through time limited actions. However the region's responses indicate that the monitoring of such actions or the risk is not a strength, with only 78% of respondents considering monitoring as part of a risk assessment.

London region - one criteria, training, appeared to be stronger, based on classifications, for the London region although not significantly different when compared with the actual figures. The criteria that showed the least consideration was risk improvement targets with 48% of respondents including it in a risk assessment.

South region showed further variation. The total number of responses support the core criteria identified nationally although criteria least likely to be included is expanded beyond the external communication of risk include internal communication of risk and consideration to emergency conditions. As with London, Risk Improvement Targets remained a low scorer with 53% of respondents including it in a risk assessment.

Out of all the regions, South region identified on average lower positive responses across the criteria. With strengths and preferences of individual criteria by all regions, this has the potential to be explored further to understand what this may mean in terms of different cultures and behaviours within regions and if this variation extends to other elements of risk performance.

In section 5.3.1 the analysis of the sample of Risk Management strategies provided a brief insight into the drivers and influencing factors to risk management as a function as well as the criteria and stages considered as part of a risk assessment process. The significance of national policy was clear and could be described as dominating the documents, structure, content and use. A similar theme potentially carries forward to the risk assessment process with risk assessment seen as an exercise to complete and log rather than in realising the benefits of improved performance.

As table 5.7 shows, the criteria most likely to feature in a risk assessment are hazard identification, control measures to mitigate the risk and an assessment of significance to determine the level of the risk. These common features extend beyond healthcare to other industries as well as being recognised as key steps in risk management frameworks outlined in chapter 3. The strength of these criteria is in the systematic approach and commitment that they offer and also the suggested reliance on system and process based activities. The activities confirm that a task is completed and its completion is likely to be documented. Looking at how other criteria perform in particular elements such as communication and improvement targets, the criteria do not feature as strongly. One possible explanation of this is the purpose and value assigned to risk management factors (direct and contributory) in

NHS Trusts. The results suggest a function that is transactional in nature ie its structured following a clear pathway to achieve a given output. Such characteristics mean that the adoption of an approach based on national policy fits well, the ability to introduce local criteria is limited and the value is limited as there is little integration with local systems, other risks or it being reflective of the real risks and challenges that are presented to Trusts.

The absence of processes reflecting local conditions may also be symptomatic of the maturity of risk management as a function in healthcare and the confidence of providers to understand and achieve the benefits of good risk management. Hollnagel & Woods (2006) highlight the importance of resilience in the design of systems incorporating a sensitivity to local conditions as well as listening to employees in relation what works well and where the opportunities for improvement exist. The absence of this has the potential alongside the pursuit of performance driven by targets to introduce vulnerability to operational practice and organisational performance. There are opportunities to reflect and learn from other high risk organisations on the value that is given to risk management in systems and processes as well as in the culture and behaviour of organisations and the workforce with the criteria that is included in a risk assessment.

There is an emerging picture in the results of the risk assessment criteria considered by NHS Trusts that is process focused, considers a limited set of criteria. Based on incident and claims data, the risk assessments are not sufficiently comprehensive to consider all possible factors or reflect the complexity of healthcare. Learning from incidents, errors and avoidable harm provide a lens on factors that contribute to risk but also the effectiveness of controls. The priority assigned to improvement demonstrates a lack of learning or a commitment to putting actions in place to prevent a reoccurrence. This reactive approach has previously been flagged as common in healthcare compared to the proactive approach that anticipates and prevents unintended outcomes in other high risk industries. Clear gaps exist in a lack of a clear definition of risk, unclear parameters and levels of tolerance, a lack of commitment to change or improvement although again documenting what needs to be done through learning logs and change registers. Hofmann, Jacobs & Landy (1995) recognise that safety and risk performance is strengthened by looking at a broader set of criteria than the common process steps of hazard identification, assessment of significance and control measures with criteria currently least likely to be considered a strong feature. An example of this is demonstrated in the findings of

the Francis Inquiry (2012) that highlighted the contribution that poor communication and sharing of information made to increasing the level of risk that patients were exposed to at the Mid Staffordshire Hospitals NHS Foundation Trust. Haywood & Farmer (1988) confirm that a risk assessment model needs to consider multiple elements for it to not only be effective but also for the organisation to demonstrate strong safety performance. Irrespective of the setting or industry a balance in the criteria considered as part of the process, be it system, human or task orientated, is essential.

The results continue to add to the emerging picture of a function shaped by national policy and a generic set of requirements that once applied fail to adequately reflect the complexities of healthcare and adapt to the local conditions and factors that may influence performance. However documented risk systems (strategies and risk assessment processes) alone do not produce successful safety performance. As part of the importance of culture, leadership to risk is critical in setting the standards of what is acceptable, providing a commitment to improving and leading a culture where individual roles are clear about their contribution and responsibility for risk management and the behaviours required for optimum safety performance (Barrett et al 2009).

Culture, incorporating leadership, behaviours and defined roles has been identified as a factor and a driver in risk management in chapters 2 and 3. The extent to which culture is a direct or indirect contributory factor in risk performance will continue to be explored throughout the results.

5.3.4 Executive Responsibility

The survey collected information on the executive leads for risk management across the cohort of Trusts. As highlighted in the review of risk management strategies, executive leadership for risk management was an emerging theme that was common across the sample of strategies analysed. The results identified a number of executive roles and job titles with responsibility for risk management, these included statutory and non statutory executive positions.

A total of 139 Trusts identified the executive lead for risk management as part of their survey response. Table 5.8 shows the breakdown of roles by region and overall. A total of six roles were identified along with an “other” category that was used to

capture job titles not falling within the “executive” category or were individual Director roles not repeated by other respondents. The results identified the role of Chief Nurse (also referred to as the Director of Nursing) as dominating the executive lead role accountable for risk management with 44% of Trusts assigning the executive lead to this role, followed by the Medical Director leading risk in 15 % of Trusts and the Chief Executive in 12% of Trusts. A fourth grouping of “others” was also prominent with the second highest response rate (22%). This group consisted of bespoke roles and titles to organisations that did not correlate with other responses, for example Director of Governance and Turnaround Director. It was not clear if these roles were “Executive Director” roles and Board members.

Table 5.8: Summary of Executive roles with lead responsibilities for risk management

Executive Lead role	Chief Executive		Medical Director		Director of Nursing / Chief Nurse		Chief Operating Officer		Director of Finance		Director of HR		Other	
Region	Number in lead role	% of region	Number in lead role	% of region	Number in lead role	% of region	Number in lead role	% of region	Number in lead role	% of region	Number in lead role	% of region	Number in lead role	% of region
North	3	9%	10	31%	9	28%	0	0%	1	3%	1	3%	8	26%
Eastern & Midlands	6	13%	4	9%	27	59%	0	0%	3	7%	0	0	6	13%
London	4	17%	2	9%	8	35%	0	0%	2	9%	0	0%	7	30%
South	4	9%	6	13%	21	46%	2	4%	0	0%	2	4%	11	24%
Overall	17	12%	22	15%	65	44%	2	1%	6	4%	3	2%	32	22%

The prevalence of the three identified executive roles was compared against other indicators of the risk system and organisational characteristics. A specific aspect of the role considered was the potential influence of the diversity of executive portfolios. However, the multiple functions and diversity of portfolios, in particular of the Chief Nurse role had been expected to be a factor in performance, in spite of the positive relationship the correlation was weak (correlation coefficient =0.2) and the breadth of a portfolio was not found to be a significant influencing factor on a Trust’s risk performance with a p value greater than 0.1 ($p>0.1$).

Hofmann, Jacobs & Landy (1995) recognise that senior and executive leadership of risk is an important factor in successful safety management in particular for leading strong performance in the face of competing priorities. The sample of strategies highlighted defined roles for senior management and a recognition that risk management was the responsibility of all staff, the lack of detail defining the expected contribution including behaviours (Barrett et al 2009) from all staff acts as a barrier to embedding risk management and safety performance into the culture of an organisation. Sikka et al (2015) support this finding extending the importance of role definition beyond senior leaders to others to foster positive safety behaviours locally.

The absence of a dedicated role at executive level in NHS Trusts may in itself not be significant however it is perhaps reflective of the true commitment and priority that is afforded risk management compared with other corporate functions such as finance or operational delivery each of which have dedicated Executive Director roles. However what is potentially an influencing factor on performance is the addition of this key function, its embryonic state well recognised (Khun & Youngberg 2006) to the role of the Chief Nurse and possibly one of the largest and more complex portfolios. As a result capacity for development is limited with certain risks around staffing levels and medicines management potentially creating conflict of interest for a single role. The disadvantages of this portfolio allocation and executive leadership are evident in the Trusts where performance is a struggle, to achieve and maintain. From 2011, the Care Quality Commission used its legal power to "investigate" under section 48 of the Health & Social Care Act 2008. This power is reserved for the most serious cases of systemic failure and concerns relating to the quality of care and was conducted in just four NHS Trusts. Having identified the Trusts I have been able to identify a common feature shared by the organisations that is the management arrangements for risk management. In all cases the executive leadership and board level responsibility was for risk including safety and quality of care was all held within a single portfolio led by the Chief Nurse. It could be suggested that the demands on any lead role in a Trust struggling to achieve the required standards needs to be focused on a core deliverable not spread across a diverse programme of responsibilities.

5.3.5 Summary Findings based on Risk Management Arrangements and the Characteristics of Trusts

As I conclude the presentation of the Trust results based on characteristics of the system, there a number of emerging themes evident in the findings:

- Strong confirmation through documented frameworks and processes that NHS Trusts have a risk management function
- Lack of openness and transparency amongst NHS Trusts in sharing risk management practices which may be an indicator of confidence or a reflection on the extent to which it is embedded
- Risk assessment criteria appears to be focused on systems and processes aligned to the keys steps of common risk models rather than the factors that could improve or strengthen safety performance

- Organisational behaviour and commitment to risk management often defined as a “safety culture” is a key factor based on learning from other industries but is notably absent from NHS practice
- The rhetoric of risk management is a key driver and influencer of local policies and processes irrespective of its meaningfulness in practice.
- Executive leadership of risk management is dominated by the Chief Nurse role as an addition to an already extensive portfolio, the impact of which is unknown although is recognised as a common feature of struggling Trusts.

The next section builds on the insight to risk management arrangements and practices and uses it to determine how this impacts on performance with characteristics inherent in a Trust’s make up predisposing it to success or failure.

5.4 Findings from the 2012 Data Collection

The 2012 data collection builds on the 2005 survey data by exploring the context and impact of local arrangements and organisational characteristics on Trust performance independently assessed through national programmes. Tables 5.3 and 5.4 detail the empirical results on collective Trust performance against regulatory standards (published by Monitor and the CQC) and clinical negligence claims data (published by NHS LA).

Using the combined evidence base provided by the 2005 and 2012 data collections, analysis has then been undertaken to investigate if any relationship exists between organisational factors (including policies and processes) and the performance of organisations.

This line of enquiry has been identified through learning from other high risk organisations (Gamble 2013) where factors such as operational and financial performance are prioritised over the management of risk. This prioritisation along with over standardisation of processes and procedures have been diagnosed as introducing vulnerability to the system. In addition to being a source of vulnerability (Hollnagel et al 2006) there is the also the concept that the adoption of standard operating frameworks assists in building reliability and resilience into activities delivering higher quality and stronger performance. For the purposes of this research, the analysis will examine the relationship between variables and determine

the extent of their influence on performance in assisting and enhancing performance or potentially limiting it.

5.4.1. Organisational Characteristics & Systems

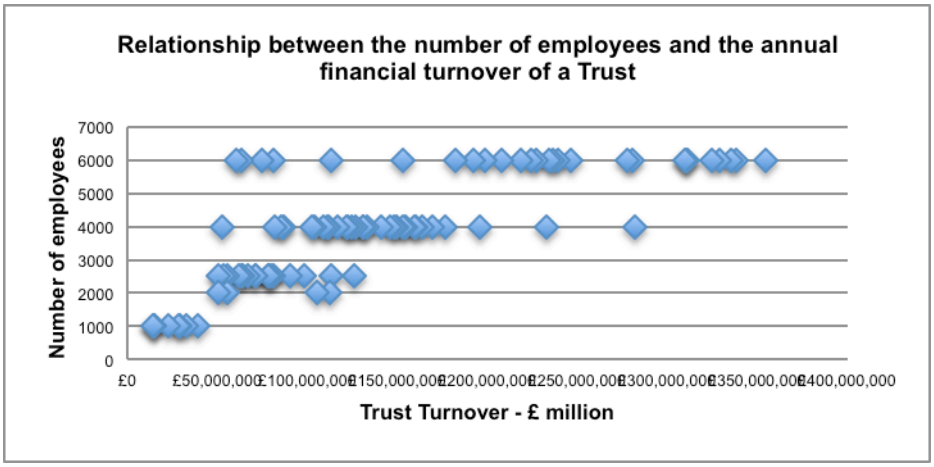
The scope of organisational factors and context considers the size of the Trust (number of employees and financial turnover), number of locations, executive leadership and risk assessment criteria. The relationship between a number of variables has been explored to determine if individual or collective organisational characteritics can be used to inform the risk management arrangements of Trusts as well as the relaionship between certain organisational factors and other variables aligned to claims management and regulatory performance.

- **Size of the Trust**

The data collection has identified a number of variables that could be used as an indicator of the size of the Trust. To establish the robustness of the variables and to identify a potential proxy that can be consistently used in the analysis two variables have been considered; the total number of employees in a Trust and the annual financial turnover of the Trust (£million). The data on the number of employees was collected as part of the 2005 survey of Trusts hence analysis of employee data was limited to respondent Trusts. Trusts were requested to provide data in bandings of employees (up to 1000, up to 2000, up to 2500, up to 4000 and up to 6000). Data on the annual financial turnover of Trusts was taken from the NHS Directory and based on annual submissions made by individual Trusts and represented all 260 Trusts in the sample not just the 156 respondents.

The two data sources were collated and ranked. Spearman's ranked correlation was applied and a correlation coefficient of 0.86 calculated. This result indicates a positive relationship and strong correlation between the two variables of size – the total number of employees and the annual financial turnover. The correlation is significant with a calculated p value of $p<0.01$. The strong, positive correlation between the two variables allow for either the total number of employees or the annual financial turnover to be used as valid indicators of size. For further analysis financial turnover will be used as the indicator for size.

Figure 5.1: Relationship between two variables "the total number of employees" and the "annual financial turnover" of the Trust.



- **System Characteristics**

In section 5.3 I examined the existence of key risk documents as part of risk management arrangements in NHS Trusts. The existence of a documented risk strategy and a documented risk assessment process as required by a range of national initiatives and programmes provided a strong positive finding with only two Trusts responding to each question negatively. The strength of this finding alone provided little insight into the influence and impact that this has on performance. A focussed review on the negative responses also failed to provide any additional insight on the impact of the absence of the strategy and risk assessment documents on a Trust's performance. Further evaluation and qualitative analysis of the sample of risk management strategies provided by the respondents identified common themes between the strategies. Due to the voluntary nature of providing the strategies the sample size (29 Trusts) was too small to confirm the impact on performance however the themes and key findings from the literature review suggest that the content of Risk Management Strategies is strongly influenced and aligned to the requirements of national initiatives and programmes rather than being focussed and flexed to enhancing local performance. However the detail provided across the 154 respondents on the content of risk assessment process did permit further analysis. The results of tis analysis is described later in this chapter.

- **Risk Assessment Criteria & Trust Size**

In table 5.7 I looked at and identified the criteria most and least likely to be considered and included as part of a risk assessment. To understand this context of the criteria further and possible influencing factors analysis was completed to determine if there was any correlation between the size of the Trust and the number

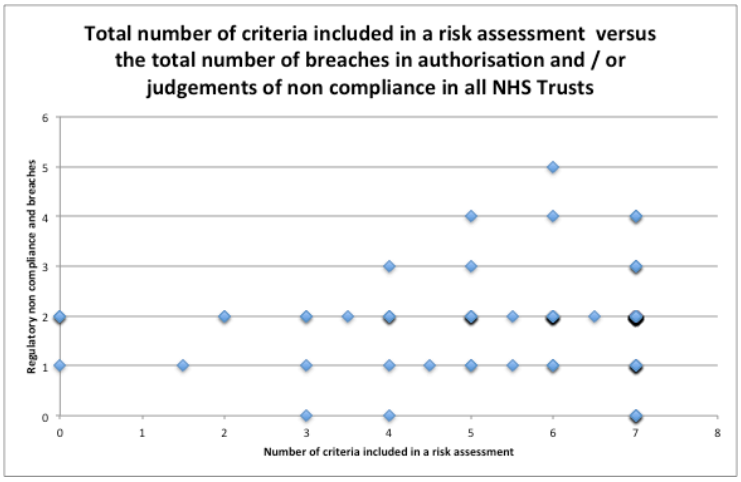
of criteria commonly considered as part of a risk assessment. Using a ranked correlation a correlation coefficient of 0.08 was calculating confirming that there is no correlation between the size of the Trust and the number of criteria included in the risk assessment process. Trusts with the highest annual financial turnover were found to consider all 16 criteria whilst at the same time there were examples of Trusts with substantially lower turnovers that considered all 16 risk assessment criteria. It was observed that between 5 and 8 criteria were commonly considered by Trusts irrespective of size. This compliments the findings in table 5.7 that indicated that over 85% of respondents considered a selected 8 criteria or less in the risk assessment process.

- **Risk Assessment Criteria and Regulatory Performance**

In the correlation analysis described in the previous paragraph we confirmed that there was no relationship between the number of risk assessment criteria identified as part of the risk assessment process and the size of the Trust (£million turnover) however as shown by table 5.7, there is a clear preference for the criteria that Trusts use as part of a risk assessment and therefore a reasonable question to ask about the relationship between the risk assessment criteria and performance. The impact of the number of risk assessment criteria selected and the Trust's regulatory performance was investigated. Correlation analysis was initially completed to determine if a relationship exists, further analysis would be applied if a positive correlation was identified.

A correlation coefficient of 0.06 was calculated for the "total number of criteria included in a risk assessment" (dependent variable) and the "total number of regulatory breaches and judgements of non compliance" (independent variable). Figure 5.2 shows the two variables.

Figure 5.2: "Total number of criteria included in a risk assessment" versus the "number of breaches in authorisation and / or judgements of non compliance" in all NHS Trusts.



A correlation coefficient of 0.06 is positive however it is not sufficiently strong with a p value more than 0.05 ($p>0.05$) to identify a causal relationship. The analysis was repeated for Foundation Trusts to determine if this could be an influencing factor on Trust performance. A similar pattern was identified with a correlation coefficient of 0.05 for this group of Trusts and a p value of more than 0.05 which again is not significant. In spite of the statistical insignificance of these results, the findings add further insight to the emerging picture and suggestion that the content of documented processes such as risk management strategies and risk assessment processes need to be driven by and be sensitive to other factors reflecting local business needs that support and work towards strong safety performance.

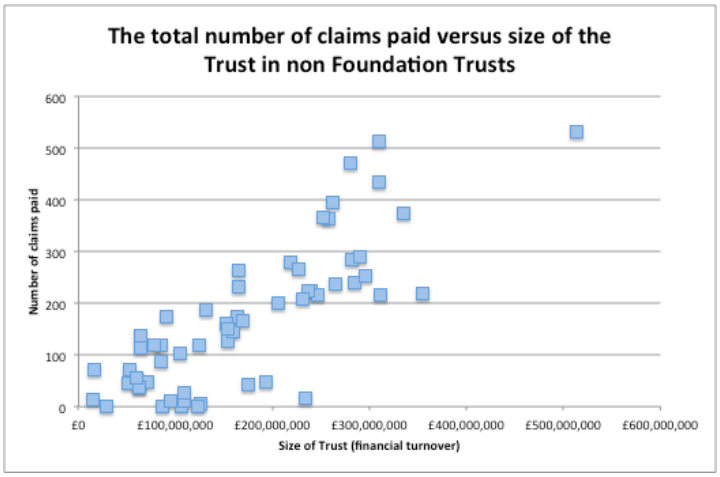
Cagliano et al (2011) highlighted the influence that national policy has on shaping local policies to an extent that the pursuit of the national agenda overshadows local needs. Whilst such policy is often designed and implemented to deliver identified benefits there are notable disadvantages that may be indirectly realised for example the fatigue of organisations and systems through continued assessment against checklist and external requirements (Ginsburg et al 2004). In spite of this there are a number of common elements that constitute core requirements of a risk management system and process irrespective of the industry, sector or source of risk (Flin et al 2000). This core set of requirements and the potential basis of a model are reflected in the findings presented in table 5.7 and include hazard identification, control measures and the assessment of significance.

However the content of the systems is not the only factor that has the potential to influence, positively or negatively, the risk and safety performance of organisations. The following section looks at the influence of variables inherent in the make up organisations and the role that these may or may not play in pre determining, enhancing or acting as a barrier to risk management. The significance of these factors such as size based on financial turnover or geography is unknown although as the literature (Mick at al 1994) as well as anecdotal feedback has suggested that larger organisations have found their size to potentially act as a constraint to the achievement of required standards and performance.

- **Number of Claims and the Size of the Trust**

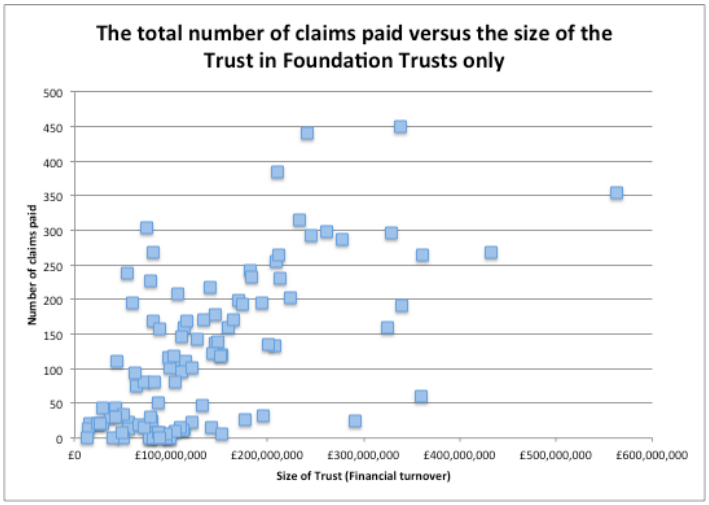
The number of claims paid under the NHSLA scheme have been used as an alternative indicator of performance against which organisational factors and characteristics can be tested. Two variables were analysed, "the total number of claims paid by Trust by the NHSLA" (aggregate of claims 2005/06 – 2011/12 – *independent variable*) and "the size of the Trust" (based on financial turnover £ million – *dependent variable*). Due to the data sources used ie nationally published data, it was possible to include all NHS Trusts in the analysis and not only the respondent Trusts. The information is presented in figures 5.3a and 5.3b. The data was separated into two groups to reflect Foundation and non Foundation Trusts. For each set of data the data was ranked using Spearman's ranking and a correlation coefficient calculated. The aim of the approach was to determine if there was correlation and the significance of this in terms of establishing a relationship between the size of the Trust and the number of claims paid. A Spearman's ranked correlation of 0.71 was calculated for non Foundation Trusts identifying a strong, positive correlation between Trust size and the number of claims paid. The result is significant with $p < 0.05$ indicating the larger the Trust the higher the number of claims paid under the NHSLA scheme. As figure 5.3a shows and as indicated by a strong but not absolute correlation there are smaller Trusts that do record a high number of claims paid. These exceptions tend to represent acute organisations providing specialist services focussed on a single core activity or service for example specialist Trusts providing cancer or orthopaedic services.

Figure 5.3a: Calculated Correlation between the variables "the total number of claims paid by Trust by the NHSLA" and "the financial turnover of the Trust (based on financial turnover £ million)" in non Foundation Trusts



The analysis was repeated for Foundation Trusts only (Figure 5.3b). The results replicated the findings of non Foundation Trusts with the identification of a positive relationship demonstrated by a correlation coefficient of 0.61 which was a significant result with a p value of less than 0.05 ($p<0.05$) confirming that there is a strong relationship between the size of the Foundation Trust and the number of claims paid.

Figure 5.3b: Calculated Correlation between the variables "the total number of claims paid by Trust by the NHSLA" and "the financial turnover of the Trust (based on financial turnover £ million)" in Foundation Trusts

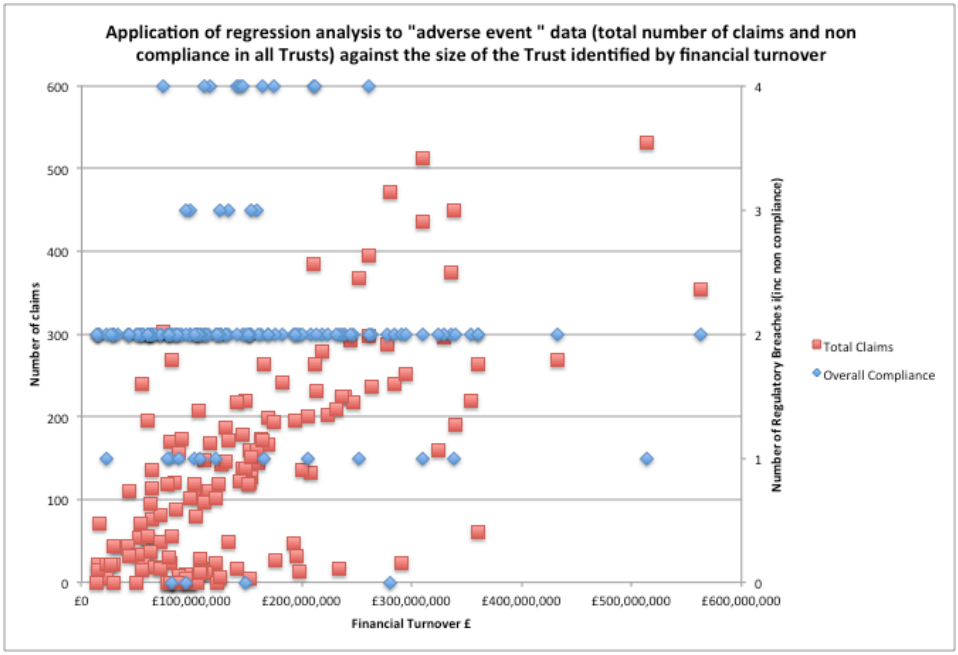


Based on the strong, positive correlation between the two variables ("the total number of claims paid by Trust by the NHSLA" and "the size of the Trust" (based on financial turnover £ million) the scatter plot indicates a linear pattern. To understand

the significance of this pattern and the relationship between the two variables, regression analysis has been applied. The decision to apply regression analysis is based on the strong positive correlation already identified (correlation coefficient = 0.7) and the observed linear pattern on the scatter plot.

The regression analysis has been approached in three stages in order to determine the significance of individual variables. The first stage of the analysis considers the significance of the relationship between regulatory non compliance / claims ie an indicator that unintended standards of care or services have been delivered against the size of the Trust. For future reference this will be referred to as "adverse event" data. The use of the variables in this way aligns with a perception from practice and within the literature review that it is more difficult for larger Trusts defined either by turnover, locations or the complexity of services offered to achieve and deliver care that meets the requirements of the myriad of quality, safety and operational standards (Love et al 2008,). Figure 5.4a sets out the "adverse event" data against the financial turnover of all Trusts. The trend line has been applied and confirms the linear pattern previously identified. Application of regression analysis provides a calculated R value of 0.38. This indicates a significant between "adverse events" and the size of the Trust.

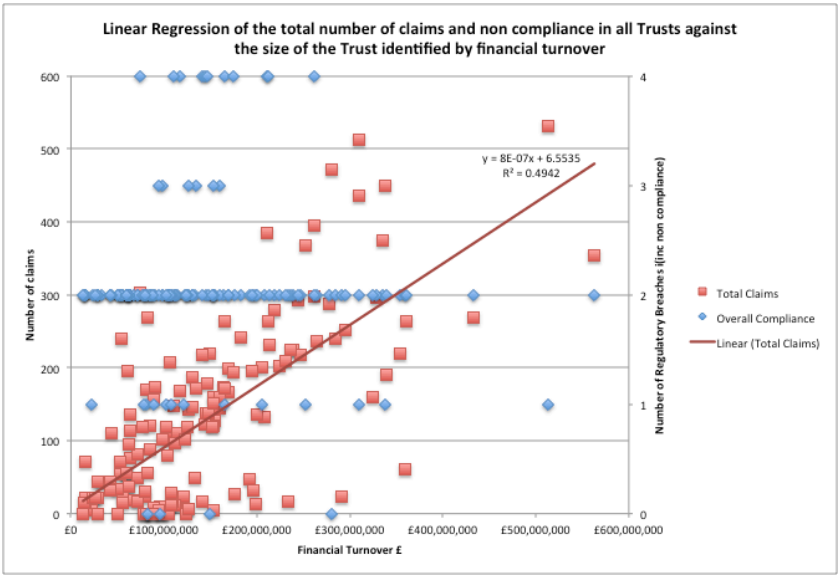
Figure 5.4a: Stage 1 of the application of regression analysis to "adverse event" data (incorporating the total number of claims paid and regulatory non compliance) against the variable of Trust size (financial turnover £ million).



However, the application of the trend line in figure 5.4b, has provided a further line of inquiry that raises a question in relation to the variables and if the significance of their contribution in equal. The adverse event data was separated out to establish the independent data sources and variables of (1) the total number of claims paid under the NHSLA scheme and (2) identified regulatory non compliance. The regression analysis was repeated for each data source alongside the variable of the size of the Trust. The results of this analysis are displayed in figures 5.4b and 5.4c.

Figure 5.4b shows the findings using financial turnover as the indicator of size did produce a stronger linear trend line with R^2=0.49. It is not a definitive indicator in predicting the number of claims paid although as the linear regression trend line shows a value of 0.49 it is sufficient to acknowledge that a relationship exists between the two variables. Calculating a p value as an indicator of significance shows that the relationship of the variables "annual financial turnover" and "the total number of claims" and "non compliance with the CQC Essential Standards" is significant with $p<0.05$.

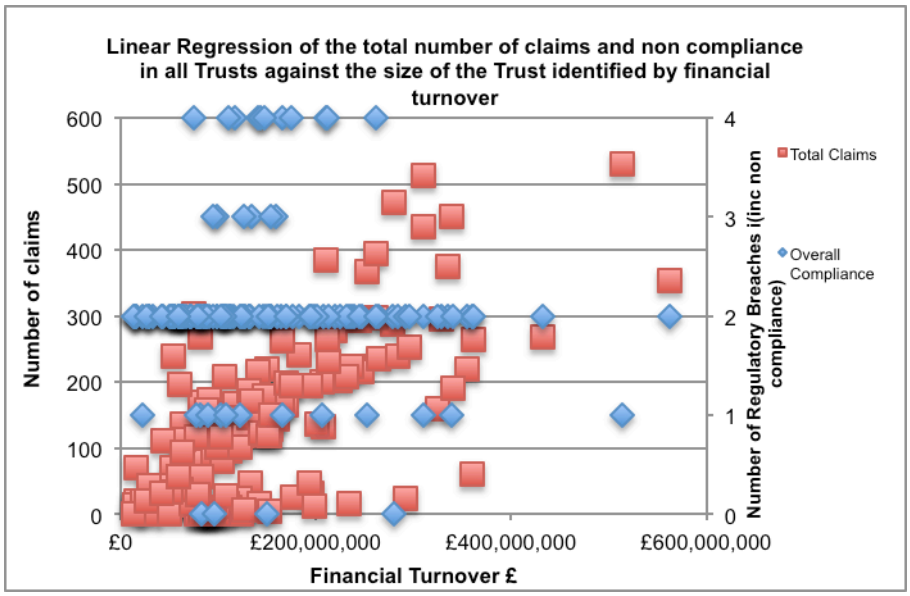
Figure 5.4b: Stage 2 of the application of regression analysis to the total number of claims paid (under NHSLA scheme) against the variable of Trust size (financial turnover £ million).



The analysis was repeated again for the second variable previously included in the "adverse event" data. Figure 5.4c shows the final stage of the analysis application with the plotting of variables of regulatory non compliance and the size of the Trust. The trend line added to the scatter plot confirms that in spite of a previously

moderate positive correlation of 0.49, the relationship is not significant. This confirms the previous findings in figure 5.4b that the linear relationship only exists between the number of claims paid and the size of the Trust.

Figure 5.4c: Application of regression analysis to identified regulatory non compliance against the variable of Trust size (financial turnover £ million)



The findings have identified an emerging theme relating to the size of the Trust and its significance in influencing risk performance. In reviewing the size of the Trust, two indicators were originally considered, the number of employees and financial turnover. To further strengthen the understanding of this factor a third indicator of size has been considered largely prompted by the work of Mick et al (1994) on the geography of hospitals and the impact on performance. This third indicator of size exists from the data collected in the 2005 survey and relates to the number of locations in a Trust. There are a number of limitations to the use of this data as a primary indicator of size not least due to the myriad of factors influencing the number of locations and the absence of a standardized profile for example an NHS location must have a certain number of employees, beds, income or turnover, activity or services. In reality the variation exists as much within Trusts themselves as in the sector and across different types of Trusts. Sites may also only act as hosts to services such as community services with the care or activity being delivered elsewhere such as in a patients home. In spite of these limitations the relationship between the number of claims paid and the number of locations of a Trust was considered.

Initial analysis of the relationship between the number of claims paid and the number of locations in a Trust was undertaken. The relationship identified was not a linear relationship hence logistic analysis was pursued. Table 5.9 shows the application of Chi squared test to investigate the relationship between regulatory compliance and non compliance and the number of locations to all Trusts. A p value of 0.33 was calculated which indicated that the relationship was not statistically significant ($p>0.05$).

Table 5.9: Expected and Observed values of Trust Regulatory performance measured by CQC compliance and the size of the Trust based on the number of locations.

Observed Values (all Trusts)	Compliant	Non compliant	Total
Trusts with 1 site	27	3	30
Trusts with more than 1 site	86	18	104
Total	113	21	134

Expected Values (all Trusts)	Compliant	Non compliant	Total
Trusts with 1 site	25.3	4.7	30
Trusts with more than 1 site	87.7	16.3	104
Total	113	21	134

The analysis was repeated for Foundation Trusts only. As an organisational characteristic it is important to determine if this is a factor that influences performance in any way. Table 5.10 shows the observed and expected values for Foundation Trusts. A p value of 0.26 was calculated. This result reflects that already reported for all Trusts and again in not statistically significant ($p>0.05$), confirming that irrespective of Trust status there is no statistically significant relationship between the number of claims paid per Trust and the number of locations in the Trust.

Table 5.10: Expected and Observed values of Foundation Trusts regulatory performance measured by breaches in authorisation and the size of the Trust based on the number of locations.

Observed Values (FT only)	Breach in authorisation	No Breach in authorisation	Total
Trusts with 1 site	7	17	24
Trusts with more than 1 site	10	46	56
Total	17	63	80

Expected Values (FT only)	Breach in authorisation	No Breach in authorisation	Total
Trusts with 1 site	5.1	18.9	24
Trusts with more than 1 site	11.9	44.1	56
Total	17	63	80

Although these findings relating to the size of the Trust and its impact on performance are not statistically significant, they are relevant in responding to the perception that the size of a Trust is a predetermining factor in the performance (quality, financial and operational) of a Trust. Anecdotal evidence across the sector suggests it is more difficult for larger Trusts as either single site or multi site organisations to achieve the same standards and performance beyond risk management compared to that achieved by smaller Trusts. The results and the relationship shown in figures 5.4 a-c and 5.5 shows that this is not the case. Whilst the size of a Trust remains a factor it is not a factor that can be used to predict and predetermine performance suggesting that other factors may and do have a role in how well a Trust performs in achieving and maintaining standards of quality and safety and overall operational success.

- **Claims Management Performance – a holistic view**

Having considered the relationship between claims and other variables linked to organisational characteristics, the results have also considered the claims performance of Trusts over a 6 year period. The purpose of this focus is to identify any patterns either in claims reporting or in the Trusts reporting higher number of claims made and paid. In order to identify the latter Trusts that met one or more of the following criteria were initially identified as outliers. The criteria included the top 5 highest number of reported claims, a number of claims double the national annual average and a frequency to the a high report number. This data was anonymised to avoid any bias. This focus has identified a number of Trusts who appear as frequent outliers ie they present with a higher number of claims compared with other Trusts in the sample. These Trusts are represented in figures 5.6 a – f by the letters A to O. The reason for looking at the claims data in this way is to determine if there are any common organisational characteristics shared between Trusts with a high number of claims that could be investigated for their potential impact on risk performance. Over the 6 year period, four Trusts were identified as having a total number of claims significantly higher claims made than the national average, a higher number of claims when compared with their peers and also at a frequency that occurred for more than half of the time period ie 3 years or more.

Figure 5.6a: Total number of NHSLA claims presented by Trust in 2006/07

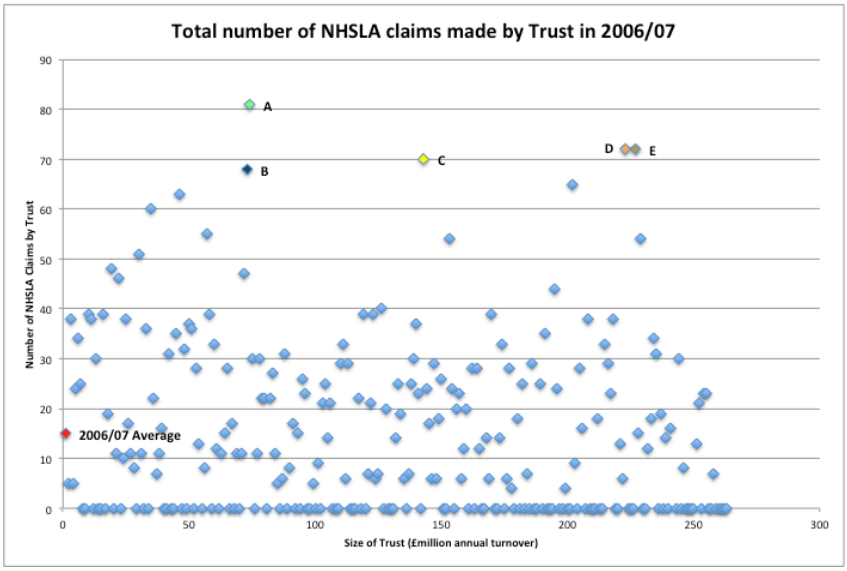


Figure 5.6b: Total number of NHSLA claims presented by Trust in 2007/08

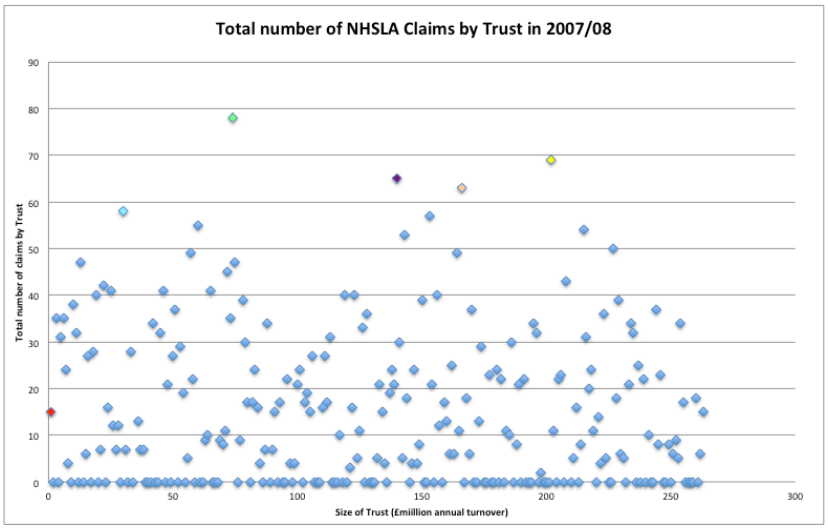


Figure 5.6c: Total number of NHSLA claims presented by Trust in 2008/09

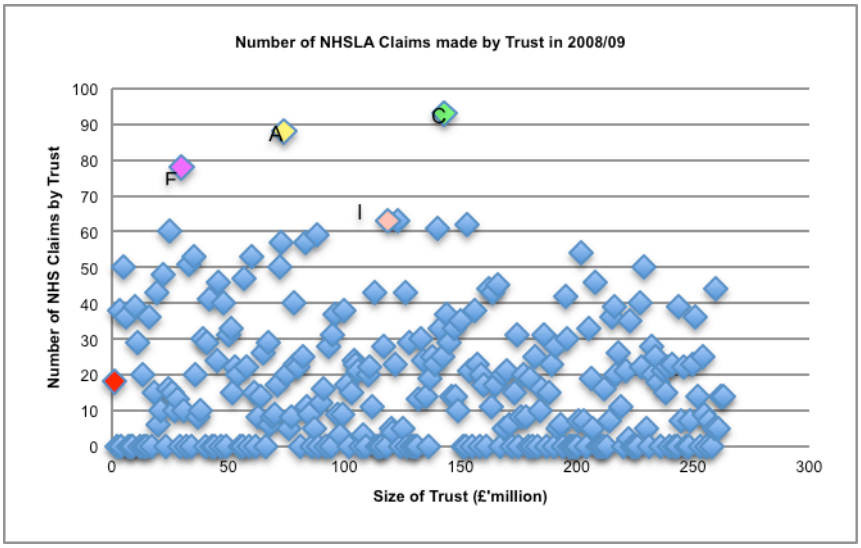


Figure 5.6d: Total number of NHSLA claims presented by Trust in 2009/10

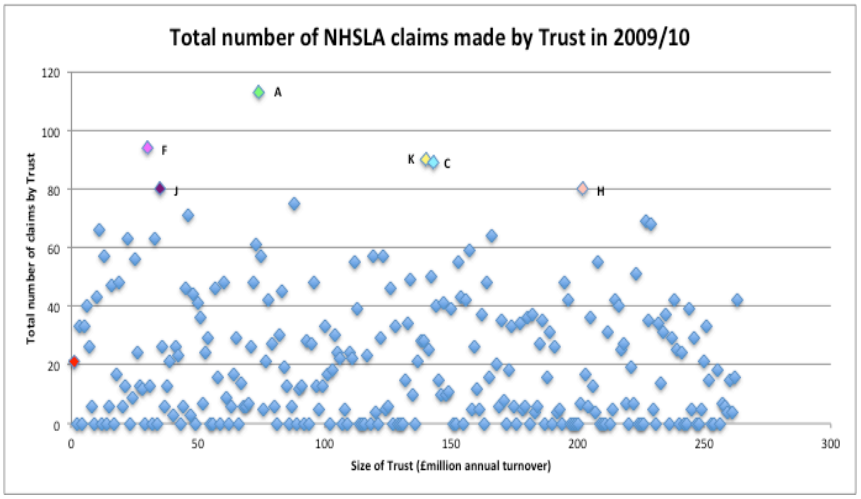


Figure 5.6e: Total number of NHSLA claims presented by Trust in 2010/11

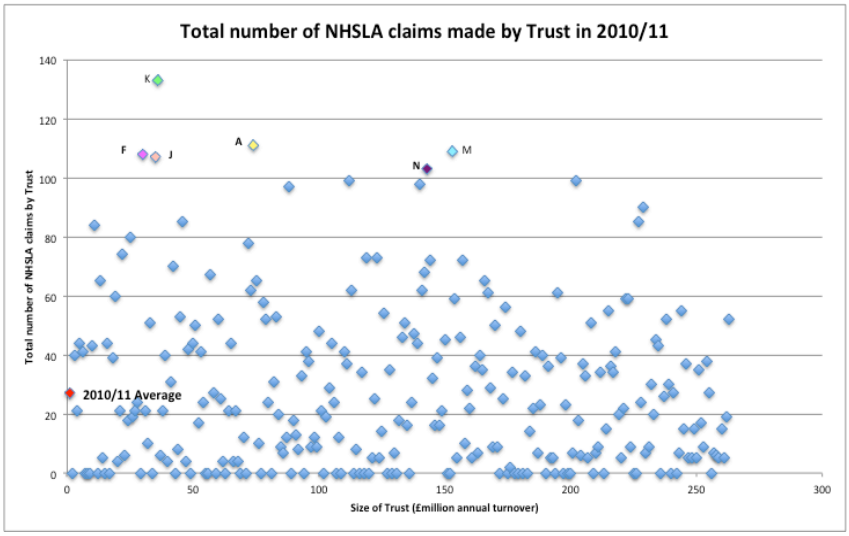
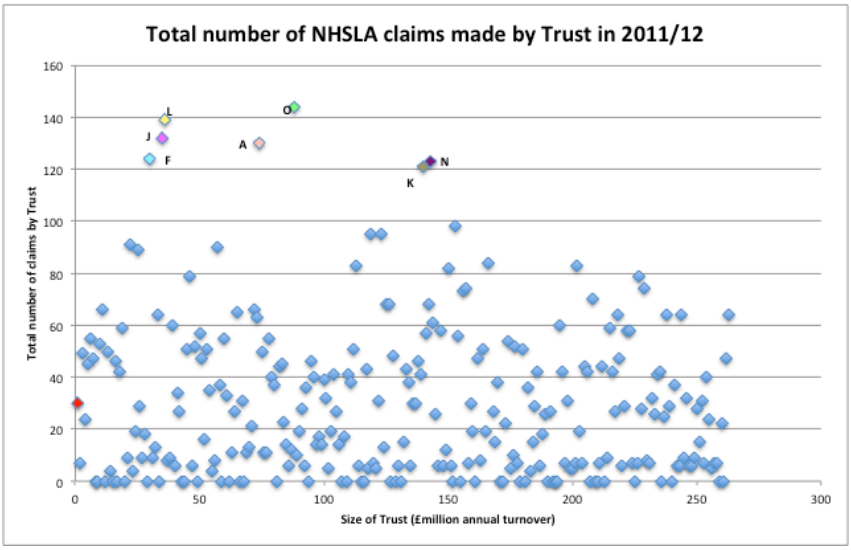


Figure 5.6f: Total number of NHSLA claims presented by Trust in 2011/12



Trust A consistently had a high number of claims made throughout the 6 year period and reported the highest number of claims made in four out of the six years. This high number of claims aligns with the national trend of an increasing number of claims over the period. The three other Trusts reporting a similar pattern of high claims over the period are Trust C, Trust F and Trust K. Trust F reported the second highest number of claims over the period with a high number of claims made in 5 out of the 6 years. These Trusts share a number of common factors such as a smaller Trust, the range of services delivered, non Foundation Trusts, no previous conditions imposed at the time of registration under the HSCA 2008. In addition to the similarities, the Trusts also share a history as Trusts that have struggled to achieve maintain and improve on operational, financial and quality performance. There are also distinct differences in the Trusts with the absence of a shared geography, Trust A is city based whilst Trust F is in a coastal location; the neighbouring Trusts to Trust A are acknowledged as high performing organisations based on national indicators (DH 2011).

The review of the data in this way suggests that other organisational factors other than the size of the Trust can influence the risk performance of an organisation. This again confirms the role of multiple strategic and operational drivers of risk management as introduced in section 3.1 of the concept analysis chapter.

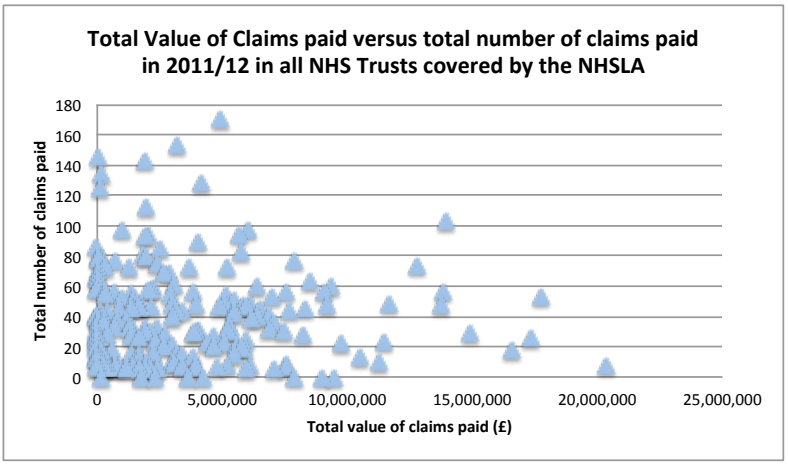
- **Claims Management – the financial value of claims**

Having established a relationship exists between the size of the Trust and the number of claims paid, the next stage of investigation and analysis seeks to

investigate the validity of the performance measure of the number of claims paid used in figures 5.3 a and b as well as the relationship that exists between the number of claims paid and the value. This second point seeks to understand if a similar relationship exists between the higher number of claims in smaller Trusts due to the specialist nature of services and hence if claims are low in volume but high in value.

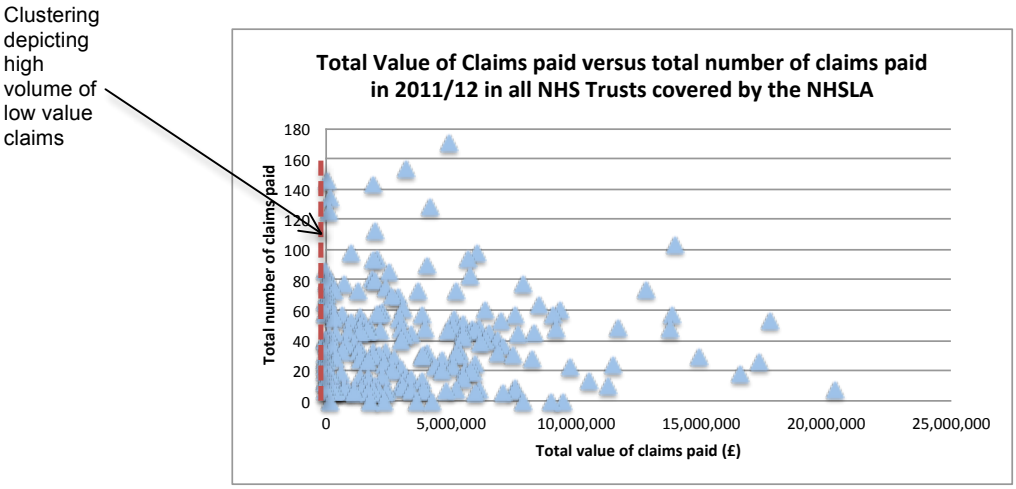
Initial analysis sought to determine if a relationship existed between the number of claims and the value of the claims. The data for 2011/12 was selected as the last published data set for claims made and paid under the NHSLA scheme in 2012. Data was used from 209 Trusts that could be mapped against the original sample of 260 Trusts. The difference in numbers is explained by changes in organisations over the period including Trust mergers and non reported information suggesting that an alternative scheme to that offered by NHSLA had been adopted by some Trusts. Figure 5.6a plots the correlation of two variables, firstly "the total value of the claims" *(dependent variable)* and a second variable of "the total number of claims paid" *(independent variable)*. The correlation coefficient was calculated at 0.03. The result confirms a positive relationship however the very low value combined with a calculated p value greater than 0.1 ($p > 0.1$) confirms the correlation and relationship is not significant. These results confirm that there is no direct correlation or significance between the total number of claims and the total value of claims paid. One possible factor in this is the high value attached to some individual claims. This reflects the inherent risks associated with key service types such as specialist surgery and novel treatments.

Figure 5.6a: Calculated correlation between two variables "the total value of claims paid in 2011/12" and "the total number of claims paid in 2011/12" in all NHS Trusts covered by the NHS Litigation Authority.



A further review of the number of claims paid and their value provides further insight into claims management and the risk behaviour of organisations. The scatterplot in figure 5.6b shows clustering in the total number of claims paid that depicts a theme of a high volume of low value claims under the NHSLA insurance scheme. The number of claims that a Trust receives has already been identified as being influenced by a number of factors some of which are within but also beyond the organisation's control. A potential influencing factor here relates to culture and organisational behaviour in setting a risk appetite around the level of risk that can be tolerated, accepted and defended in terms of evidence of systems (Sikka et al 2015).

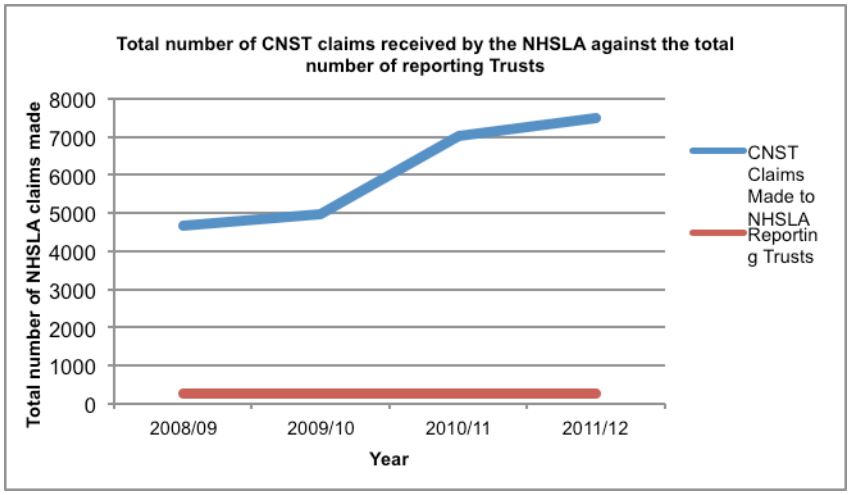
Figure 5.6b: Calculated correlation between two variables "the total value of claims paid in 2011/12" and "the total number of claims paid in 2011/12" in all NHS Trusts covered by the NHS Litigation Authority.



- **Claims Management Reporting Patterns across Strategic Health Authorities**

Looking at national patterns of claims reporting and payment, consideration was given to the potential for regional variations from the Trusts; variation between Trusts and regional reporting was identified in the responses to the 2005 survey. To determine the significance of the claims data it is important to consider its context and also any regional or national variations either in trends or practice. Figure 5.7 shows a year on year increase between 2008/09 and 2011/12 in the number of claims received by the NHSLA. To note, the number of total number of Trusts has remained constant and there was a small regional in the number of Trusts in each SHA.

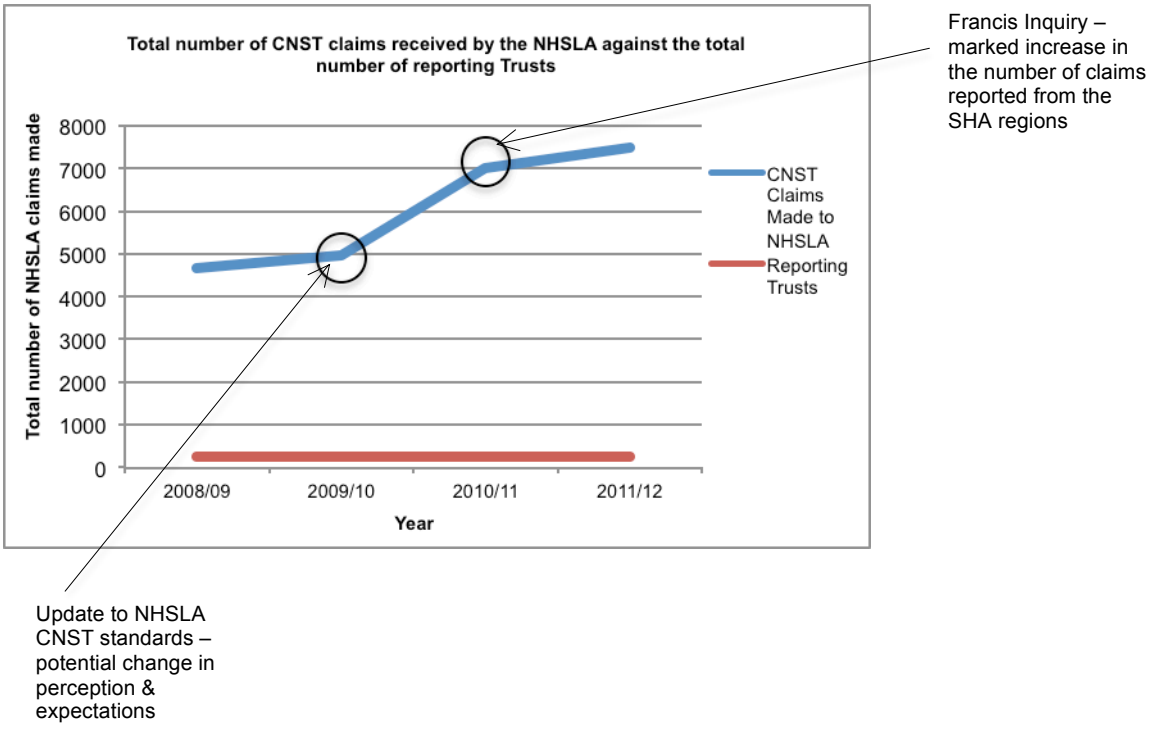
Figure 5.7: CNST claims reported to the NHSLA between 2008/09 and 2011/12



At a regional level, represented by Strategic Health Authorities, the reporting trend is again reflective of the national picture of year on year increases, with the highest proportional increases (2000 claims) between 2009/10 and 2010/11. It is important to note that over the same period the total number of Trusts remained constant with variations limited to no more than a +/- variance of 2 (Trusts) across the regions.

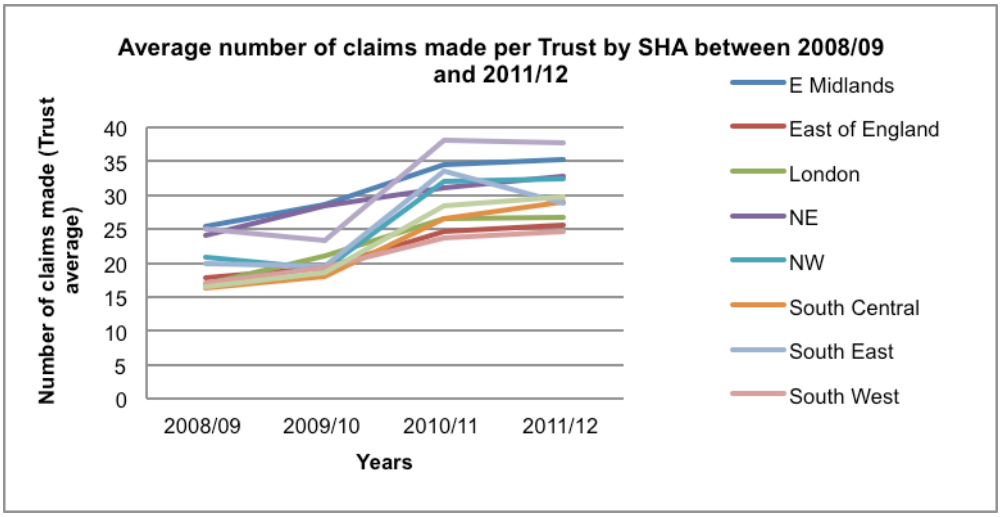
Noticeable in figure 5.7a and highlighted 5.7b are stepped changes in the number of reported claims. The step is marked on both occasions suggesting events.

Figure 5.7b: NHSLA reported claims – changes in performance 2008/09 – 2011/12



In order to determine if claims management and reporting practices are consistent across regions, the number of claims per Strategic Health Authority have been examined as an average across the number of Trusts in the SHA. Figure 5.8 provides details of the average number of claims made by Trust by former Strategic Health Authority.

Figure 5.8: Average number of CNST claims made per Trust grouped by former Strategic Health Authority between 2008/09 and 2011/12.



The claims data presented in figure 5.8 shows variation in the activity of claims made and paid. An average number of the claims made per Trust (unit) has been calculated across each of the SHA regions to support cross region comparison. It is evident from the claims data that there is variation across the SHAs. Yorkshire and Humberside and East Midlands consistently report a higher average number of claims proportion of claims in the region over the four year period whereas East of England, South Central and the South West have consistently reported a lower number of claims being made.

An explanation to this variation needs to consider the influence of factors beyond the reporting of adverse events as indicators and drivers of risk management performance. As discussed in chapter 3 there are a number of strategic and operational factors influencing risk management arrangements and practice for example national policy, leadership, culture and performance management. Carroll

& Rudolph (2006) highlight the importance of these factors in contributing to the design of high reliability healthcare organisations. By extension these factors can also be applied to the effectiveness of systems to manage adverse events. Hickson et al (2007) highlighted the existence of regional variation in the management of medical malpractice.

- **Application of Further Analysis to the Impact of Organisational Characteristics to the risk performance of NHS Trusts.**

The findings so far have considered the role that organisational characteristics have to play as predictors in performance. During the course of the results chapter and analysis I have considered the status of foundation and non foundation Trusts as a an organisational characteristic that has the potential to influence performance. A Department of Health policy commitment reported that all NHS Trusts in England would need to achieve Foundation Trust status by 31 March 2015. Oversight of the authorisation of a Trust to Foundation Trust status would be provided by Monitor with the achievement of FT status representing the achievement of standards rewarded by operational autonomy within defined limits in relation to financial and operational performance. As an organisational characteristic the significance of FT status and its impact on risk performance has been tested. In order to investigate if the performance of Foundation Trusts as a precursor to higher performance in the safety and quality of services a Chi Squared test has been applied to Foundation Trusts authorised up to 2012 and non Foundation Trusts.

Tables 5.11 and 5.12 show the observed and expected values for Foundation and non Foundation Trusts and their respective regulatory performance. For Foundation Trusts this performance includes the variables of compliance with the CQC's Essential Standards Trusts and the variable identified breach of authorisation and not in breach of authorisation under Monitor's Compliance Framework.

Table 5.11: Expected and Observed values of Foundation Trusts in breach of authorisation and their corresponding regulatory performance under the CQC's Essential Standards.

Observed values (FTs only)	Outcome 16 Compliance	Outcome 16 Non compliance	Total
Breach in authorisation	14	4	18
No Breach in authorisation	93	1	94
Total	107	5	112

Expected values (FTs only)	Outcome 16 Compliance	Outcome 16 Non compliance	Total
Breach in authorisation	17.2	0.8	18
No Breach in authorisation	89.9	4.1	94
Total	107	5	112

Using table 5.11, a Chi Squared value was calculated at 0.000065 and using a 99% confidence interval, the p value was calculated at less than 0.05 ($p<0.01$) and therefore was statistically significant. This means that a Trust's Foundation Trust (FT) status does predispose it to the delivery of services of a higher quality or to a standard judged as being more likely to meet regulatory standards.

The chi squared test was repeated for non Foundation Trusts (Table 5.12) using the variables of compliance with CQC's Essential Standards (Outcomes 4 and 16) and non compliance with CQC's Essential Standards (Outcomes 4 and 16). The application of the chi squared statistical test identified a similar result to that calculated for Foundation Trusts ie a relationship exists between compliance and non compliance between the two outcomes. The significance of this relationship however was not as strong as the relationship that exists in Foundation Trusts and compliance and breach in authorisation. A p value of 0.046 was calculated which was considered significant at a 95% confidence ($p<0.05$).

Table 5.12: Expected and Observed values of non Foundation Trusts and their corresponding regulatory performance under the CQC's Essential Standards (Outcomes 4 and 16).

Observed values	Compliant Outcome 16	Non Compliant Outcome 16	Total
Compliant Outcome 4	216	10	226
Non Compliant Outcome 4	20	12	32
Total	236	22	258

Expected values	Compliant Outcome 16	Non Compliant Outcome 16	Total
Compliant Outcome 4	206.7	19.3	226
Non Compliant Outcome 4	29.3	2.7	32
Total	236	22	258

In the context of operational delivery at a Trust level this means that if a Trust is assessed as non compliant in one outcome there is a strong possibility that a similar

level of performance can be expected in the other outcome. Outcome 4 sets the standards for the delivery of care and the welfare of patients incorporating safety and quality within the expectations of all aspects of service delivery. Outcome 16 sets out the expectations for monitoring and oversight of care delivery incorporating aspects of required governance arrangements, incident reporting and culture aspects such as learning. The practical relationship between the two standards is undeniable with one outcome (outcome 4) setting the standards for operational delivery and the other outcome (outcome 16) providing the arrangements for ensuring that the standards are delivered and improvements made through a culture of learning and changes triggered through adverse event reporting.

This finding and relationship aligns with a core component of risk management models implemented within high risk industries. A stage in the process that "monitors" and "reviews" if the preceding steps of risk identification, assessment and implementation of controls have been effective (HSE 1996). This function is a notable gap in the core criteria and processes used by NHS Trusts to manage risks as highlighted in tables 5.6a-c and table 5.7. The significance and value of a step in the process that monitors and reviews the effectiveness of the preceding steps is widely recognised. The value is multi factorial incorporating elements of understanding of harm incurred when care is not delivered as intended (Reason 1990, Vincent et al 2000), barriers to achieving intended performance (Lawton & Parker 2002) and the benefit of specific features of safety practice and interventions (Taylor et al 2011). At a strategic level the function of monitoring and review is a common feature of risk management models often aligning with a broader cultural commitment to continual improvement (AS/NZ standards 1999) continuation of the quest to for optimum reliability and resilience through the design of systems and processes (Carroll & Rudolph 2006, Hollnagel & Woods 2016, Gamble 2013) as well as the ongoing maintenance of safety standards (Vincent et al 2014).

Vincent et al (2014) identify the importance of measurement and monitoring in healthcare. As we are aware from the work already presented the focus and prioritisation of measurement has been driven through the significance applied to performance (delivery and reporting) within NHS Trusts. The value of a monitoring function will only be realised if it is accompanied by shifts in national policy to embed risk management as a function and as a pre requisite of high performance, there is a culture commitment to that is open to using proactively the results of monitoring to

improve operational delivery and overall performance and the function importantly exists as a real entity and not as a characteristic of a checklist.

5.5 Summary of Collective Findings

The combined analysis of the 2005 and 2012 results has provided an insight to risk management arrangements in NHS Trusts and the performance of these organisations based on the outcomes of independent regulation and nationally compiled clinical negligence claims data. The findings when summarised provide the following headlines:

- The risk management performance of Trust is influenced by a number of factors consistent with the findings of the literature review and the drivers identified under the concept analysis however the significance of individual factors such as culture and leadership was not definitive.
- On investigation it was possible to define if a relationship exists between certain organisational characteristics such as the size of a Trust, the status of the Trust and other operational factors such as Executive responsibility for risk management the significance of factors varied.
- The relationship between Foundation Trusts in breach of authorisation and non compliant performance under the Essential Standards was assessed as statistically significant. A similar relationship was identified in non Foundation Trusts relating to non compliance in different outcomes of the CQC's Essential Standards. Whilst the statistical significance was not quite as strong this does confirm a pattern of performance in Trusts where non compliance or breaches predispose the organisation to non compliant performance in other areas.
- Anecdotal evidence has suggested that it is more difficult for larger Trusts to achieve and maintain standards of care as defined by nationally set requirements. The analysis undertaken confirmed that size if not a definitive factor in determining a Trust's performance (regulatory or claims management). This trend continued through the testing of three different indicators of size the most relevant to influencing performance is possibly the number of locations. This relationship was again found to not be statistically significant in either Foundation or non Foundation Trusts.
- Adopting a focus on NHSLA claims to identify any common characteristics across Trusts with high rates of Claims paid identified the absence of

common criteria preventing the development of a profile although did identify a relatively small group of Trusts (15 out of 260) that consistently reported the highest number of claims on more than one occasion over a 6 year period.

These findings start to challenge and cast doubt on the assumptions of higher rates of compliance and higher standards in the quality of care are found in Foundation Trusts due to their FT status and authorisation and smaller Trusts. As a national, political initiative it is further evidence that supports the emerging pattern that systems, policies and processes are designed to meet rhetoric, national targets and other initiatives compared with enhancing the quality and safety of the services and care experienced and delivered. When compared to the drivers in other high risk organisation such a model could be described in the context of Hollnagel's model of diagnosing vulnerable systems syndrome (Hollnagel & Woods 2006).

Hollnagel & Woods (2006) and Reason et al (2001) flagged the pursuit of performance targets and prioritising their achievement over the quality of the product as introducing vulnerability to an organisation's performance. The pursuit of Foundation Trust status and authorisation by organisations has been identified as potentially contributing to serious failures in the quality and safety of care provided in individual Trusts (Francis 2012, Kirkup 2015). Whilst the conceived benefits support the delivery of high quality and successful risk performance as seen in high risk organisations (Gamble 2013), the reality has witnessed the display of traits aligned to vulnerability and risk ie the pursuit of targets, over standardisation of procedures and a focus on delivering to a national agenda divorced from local needs.

In conclusion the results and the findings of the subsequent analysis have provided sufficient insight to risk management as a function in the NHS to provide a summary of what is in place:

National policy – a defined national programme establishing central policy and prescribed standards for healthcare organisations to implement and adopt. The standards are cross cutting of service types as well as oversight bodies although interdependencies are not fully integrated.

Documented Systems and processes – risk management arrangements are supported through documented processes promoting a concept of standardised

practices to identify risks, assess the significance and implement mitigating actions. Documentation reviewed included the Trust Risk Management Strategy and content and criteria considered as part of the Risk Assessment process. The documentation was reflective of the prescription from central policy and with implementation adopting a checklist approach for inclusion. The limited consideration given to operational application of the policies and overall purpose of the process was evident in the core criteria most likely to be considered (hazard identification, assessment of risk and control measures) and least likely to be part of the process (identification of secondary factors, risk improvement targets, emergency preparedness, communication and assessment of tolerability)

Roles and responsibilities – leadership to the risk management function is recognised as an important factor in ensuring risk is embedded in the delivery of an organisation's activities. Executive leadership has been well documented with consistency across Trusts in the nomination of the Chief Nurse as the Executive lead for risk. This leadership role is frequently one of many functions and corporate responsibilities held by the nominated lead.

Performance – the measurement and monitoring of risk performance through safety, quality or other measures is not prominent in the Trust's risk management arrangements. It was evident that there is an established culture of performance reporting for operational and financial risks such as Referral to Treatment Times (RTT) or financial overspend, with a premise of judgement and consequences rather than improvement. Risk reporting and in particular improvement targets were less likely to be considered as criteria of a risk assessment. In spite of this the benefits of a performance improvement programmes related to healthcare risk have proved to be positive in enhancing patient experience, supporting changes in practice and reducing risk. A myth buster identified within identified arrangements in terms of performance was the impact of organisational characteristics such as size, geography and financial turnover as predictors of safety performance.

This final stage of analysis completes the findings and insight offered through the analysis of the survey and the review of national data sets.

Chapter 6 – Discussion

6.1 Introduction

The focus of the research has been developing an understanding of risk management as a function in the NHS. This focus has provided an informed view that establishes a baseline of risk management arrangements in place in NHS Trusts and the role that these factors have on influencing, positively or negatively, organisational performance. The research and data collection has also considered if certain characteristics of a Trust predispose the organisation to either additional risk or a certain level of performance. The collective insight delivered through this work has supported a number of observations to be made with varying degrees of confidence, from definitive viewpoints to emerging themes requiring further investigation.

In chapter 1 I set out a number of questions underpinned by more detailed aims, which I was seeking to answer through the research approach and findings. In chapter 2, the literature review looked at risk management practices in healthcare as well as in other high risk industries to understand the work that has already been undertaken and the opportunities for learning from other sectors. This work informed chapter 3 and the concept analysis that proposed the existence of multiple drivers at a strategic and operational level that impact on the way risk is managed in healthcare and specifically in the NHS. This wealth of background information had already identified some potential themes that would be tested through the methodology described in chapter 4 and the findings presented in chapter 5 along with a view on the significance of factors and relationships.

In this chapter I will be bringing together the information and insight gained from the preceding chapters and using this combined intelligence to discuss the questions that have driven this research previously set out in chapters 1 and 4.

- Does risk management exist as a function in the NHS and what does this look like?
- Is it possible to measure the success of the systems and if so how
- Do characteristics of either the organisation or system influence how a Trust performs?

In discussing the possible and actual responses to these questions, drawing on the contextual learning from the wider healthcare sector, risk management practices in industry and the performance of high risk organisations I will be sharing some additional potential lines of enquiry that have been identified and may benefit from further investigation.

6.2 Does risk management exist as a function in the NHS and what does this look like?

Objective 1: To identify common elements of risk assessment and risk management systems in use across the NHS

Objective 2: To investigate the existence of a divide in the approaches and management of risk in NS Trust

Risk management as a function exists in the provision of healthcare and is evident in NHS Trusts in England. This statement is supported by the findings presented in chapter 5 that confirm the existence of systems, policies and processes, identifies a number of common and characteristics of how risk management works and starts to suggest how risk management is used within the organisation.

Over the last 30 years there have been a number of examples of risk practices (identification, management and monitoring) being introduced to clinical practice and the delivery of care to patients (Karsh et al 2006). The results of the survey of 260 NHS Trusts confirmed that the function of risk management is recognised by NHS Trusts. This was demonstrated by the confirmed existence of policies, systems and processes as well as specific arrangements and responsibilities for the management of risk. What was evident from the information collated is that the description of the function, the role of the function and what drives it differs from that seen and operated in other high risk industries (Carroll & Rudolph 2006) such as corporate context, culture and a commitment to improve. This difference and the influence of key drivers are discussed further in the following paragraphs.

6.2.1 The Influence of National and Central Policy

National programmes and policy that promote risk management provide a clear demonstration and represent a commitment to the function and its adoption. The policy position on risk management for the NHS is largely prescriptive and promotes a myriad of standards, requirements and best practice published from within the NHS

as well as by regulatory and oversight bodies (The Care Act 2015). In addition these requirements have also been informed by experience and a series of high profile, catastrophic and isolated cases (Ritchie 1999, Francis 2013, Kirkup 2015) not least reinforced by a common theme that harm incurred whilst delivering care is largely avoidable (IHI 2000). Avoidability assumes a level of integration of systems, risks and a complex environment working together. The practical experience is different and results in an approach full of complexity and interdependencies which are delivered with varying degrees of success and results in fragmentation being evident between systems that manage different types of risk such as operational, clinical and financial.

Risk management arrangements in both high risk and high reliability organisations are visibly integrated within core business activities and represent a way of working (Carthey et al 2001) that sets out what is required, how it should be done and why it is relevant. Such an approach actively manages the risks of over standardisation of processes, the lack of sensitivity to local conditions and feedback from operations, and a culture of learning to support continual improvement (Carroll & Rudolph 2006). As has been evident from the literature review these risks can present and introduce vulnerability to an organisation in particular if combined with the pursuit of targets such as operational delivery and financial performance (Cagliano et al 2011).

The development of national initiatives and central policy appear to have ignored these warnings and introduced frameworks and a culture of prescribed practice and action. This has contributed to the disabling of local needs and requirements being reflected in the approach as Trusts perceive any alternative approach to that proposed as unacceptable. Whilst this may not have been the intended impact it is the unintended consequence of a standardised approach. The influence of local conditions and requirements in healthcare should not be underestimated and represents a stark contrast to other high risk industries. Unlike in aviation where there is a high level of similarity between aircraft irrespective of the external branding, there is no “standard” acute hospital. The absence of a standard setting or product means that the need to consider local operating conditions and the impact of local factors is increased. As Belascu & Horobet (2011) note, risk management needs to be developed beyond a rules based approach and reflect local elements of an organisation. The contrast in activities between high risk industries limits the direct translation of safety practice from aviation and limits the effectiveness of

standardisation however does allow for principles of risk management and safety practice to be shared (Hudson 2003)

The standardization of a function across an industry with an estimated annual operating budget in excess of £116 billion (NHS England 2016) aims to deliver consistency not only from the providers' perspective but also from the perspective of patients and the public. The function needs to set not only the "how" but also the "why". The IHI through its trilogy of publications in the early 2000s (IHI 2000, 2001, 2004) balanced the impact of a central, national directive and local delivery through the focus on the intended outcomes. This approached avoided a checklist approach that confirms that a strategy document exists or that mandatory training has been completed however does not address or evaluate if it has delivered the intended outcome or impact. Instead the approach focuses on deliverables either through a quantified target or a supporting rationale including an outcome such as the value of a task, activity or step in a process. Cagilano et al (2011) recognise the benefits of this prescriptive approach as key part of a programme of delivery. Across the literature either through the lens' of high reliability organisations, the development of resilience within systems to cope with normal and abnormal conditions or in the identification and / or establishment of vulnerability within operational practices of systems, functions and activities driven by prescription, performance targets etc, can by default introduce additional risks to the process rather than their intended purpose of mitigation and strengthening the safety of the environment.

6.2.2 Documented processes

The confirmed existence of a risk management strategy and risk assessment was overwhelmingly positive with only three responding Trusts providing a negative response. It is possible that this result is indicative of the impact of national policy that relies on documentation, such as strategies, risk assessment processes and arrangements to demonstrate the existence of a function and its effectiveness. The need for a documented risk assessment process is yet another requirement which has been supplemented by a preferred tool again promoted via national policy (DH 2000).

The extent to which national prescription is replicated in practice was evident in the arrangements identified at a Trust level. The similarities between individual Trust strategies that were geographically dispersed, delivered different services in

incomparable operating environments were undeniable. As described in tables 5.6 a,b,c, there were a number of common headlines from the Risk Strategies that were provided by respondent Trusts. The documents as presented were similar not only in content but also in the presentation giving a sense that the documents had been constructed using a template or proforma that acted as a checklist of contents and structure. This observation aligns with the emphasis that Trusts apportion to meeting external requirements and standards irrespective of the local context or impact. Whilst some healthcare organisations have viewed the role of regulation as a burden (Nieva & Sorra 2003), other negative implications have included the pursuit of certain performance levels irrespective of cost or additional risk and a culture that does not embrace reliability and resilience (Love at al 2008)

As the content of risk management documentation is reviewed the results extend the insight to the impact that prescription has on the function as it moves from national to a Trust level. The prescription through national models of thinking, delivery and standards does have an impact on implementation with possible constraints including:

- Agreement of a single and meaningful definition of risk (Reason 1990)
- Flexing arrangements to local risks and conditions (Eastaugh 2000)
- Interface of risk policies with other risk, organisational and corporate structures (Alexander et al 2006)
- Local ownership and leadership of risk that provides clarity of the local risk appetite and establishes a positive Trust safety culture (Kentel & Aral 2007)
- Effective team working (Barrett et al 2009)

This finding and the insight supported by subsequent analysis of the national data sets is further evidence of the significance of central policy and political initiatives on risk, its arrangements and the priority given to different types of risk – safety, operational or financial.

Whilst high risk organisations are characterised by the need to standardise, an awareness and flex to local conditions and needs is equally important (Latino 2009). This absence of local flex and awareness of local conditions is again reflective in the risk assessment process and the criteria considered. The dominance of a framework and tool previously promoted through the Department of Health initiative Controls Assurance (DH 2001) continues to be prevalent although lacks the local flex of

context, local conditions and secondary risk factors that may capture elements such as culture, pressure achieve certain targets or cooperating constraints such as staff shortages and financial deficits; all of which are risks continually challenging the NHS.

6.2.3 Culture

"Culture" is a phrase that has been commonly referenced in the description of successful safety performance in high risk industries. Attributes commonly associated within a safety culture relate to systems, behaviours, environments and leadership. Critically a take away message from the literature reviewed relates to doing the right thing not just in the task but also about when systems are not working. Ginsburg et al (2014) reflected on the culture in healthcare as seen through one of the many safety culture assessments promoted. The perception of a ticked checklist is again evident with culture being reflected through assessments rather than actions, changes to behaviours or the leadership that sets risk management as a priority.

As identified in other high risk industries (BP US Refineries Independent Safety Review Panel 2007) and a theme that has emerged as a possible explanation to risk performance during this research is that of culture and leadership. Individual NHS Trusts are staffed and led by local teams that may reflect regional demographics and provide a local dynamic to the delivery of services. Such dynamic may set the thresholds for the recruitment and retention of staff, reflect local values and behaviours as well as set the appetite for changes and improvements aligned with the management of risk. The literature is explicit about the importance of individuals understanding what their role and responsibilities are in managing risk (Sausman 2001).

At a Trust level roles and responsibilities for core duties are well defined with risk being "everyone's responsibility". Such a statement can equate to a lack of accountability and ownership with assumptions made that if it is everyone that takes responsibility. The virtual checklist of national policy adopts this approach although does identify the importance of executive leadership. In practice, this commitment is frequently fulfilled by the Chief Nurse as a responsibility within an often already overcommitted portfolio. It is the absence of a dedicated role to risk management or an aligned discipline such as safety or quality which provides one of the most

significant indicators on the true commitment and priority that the function is given and its integration in to core business activities. Functions such as operational delivery and financial performance in NHS Trusts have dedicated Board level posts (Monitor 2013) representing, leading and reporting on the delivery of the function. This dedicated resource is potentially reflective of the priority given to the other functions through mandatory performance targets such as the Referral to Treatment Time (RTT) and financial balance and cost improvement programmes. The absence of a dedicated role has been seen as promoting the function as cross cutting and part of all senior roles (DH 2004). In practice the function and its purpose is potentially compromised as "risk management" is an additional responsibility without a resource.

It is not only the absence of a dedicated role where there is a gap in the organisational commitment to risk management. Risk management in spite of national programmes encouraging integration remains a stand alone function with limited practical integration at a Trust level or in operational delivery. Whilst some steps have been taken to reference risk through other systems, the review of the risk management strategies confirmed the lack of alignment with other corporate programmes or the broader consideration of risk beyond the immediate issue being assessed. Whilst this was the observation from a relatively small sample (8% of Trusts), it is another possible indication of the significance of national guidance as a driver to what risk management arrangements look like and their application at a local Trust level.

The definition of roles and responsibilities is closely aligned to the findings defining culture and board commitment. Leadership of risk and at the most senior level sets the expectations for risk and safety not only in terms of policy but also the expected levels of performance (Love et al 2008).

6.2.4 Risk Management Models & Frameworks in the NHS

The risk management model in use in the NHS consists of a number of principles seen in both high risk industries and in general risk management models. The NPSA's publications "7 steps to patient safety (NPSA 2004) and the Circle of Safety (2006) reflect aspects of the HSE's HS(G) 65 model on successful safety management through a systematic approach that provides a feedback loop for continual improvement. A notable gap in the model and supporting frameworks

adopted in the lack of integration of other types of risk or a co-ordination of programmes to ensure delivery to a common goal.

This gap is made more relevant by the level of prescription from central policy which limits, whether intended or not, the inclusion of arrangements, dependencies and consideration of local risk priorities. The adherence to central policy is also seen to limit deviance reflecting local conditions or taking into account the prevalence of individual organisational risks. One possible reason for this is the national steer provided to risk management as a function and the arrangements. The detail of policy or the method of implementation such as the NHSLA standards encourages the adoption of the arrangements and reproduction in local systems and processes. The risks associated with this prescription include a function that fails to operationally manage risk, a culture that is falsely assured that risk is being managed as completion of the strategic checklist is represented of the function and an operating context that has the potential to establish an environment in which risks, operational and strategic can flourish. Overall the policy and strategic assessment of risk is responding to the questions that have been set rather than those that need to be asked. This has been particularly evident in promotion of safety culture through culture assessments (Ginsburg et al 2014).

Risk management as a function in the NHS is heavily influenced by external factors, which are considered by some to burdensome, and a potential barrier to the delivery of safe, quality care. External factors that influence the function, its existence, purpose and operational implementation include political rhetoric, individual high profile incidents and central initiatives. The impact and extent to which this is considered as a burden and potential hindrance to successful safety importance is only truly acknowledged retrospectively following adverse incidents and the subsequent learning. The recommendations from public inquiries following failings at Trusts including Mid Staffordshire Hospital (Francis 2012) and the University Hospitals of Morecambe Bay (Kirkup 2015) highlight the myriad of factors including the influence of external factors including policy, acceptance of risk and performance reporting as contributory factors when things go wrong. The main risk for central policy to balance is ensuring the synergy between concept and the output of operational delivery with the intended benefits being realized.

Given the commitment of learning from adverse incidents occur (Leape et al 2002), it may have been reasonable to think that the documented processes of risk strategies and risk assessment processes would reflect this in their purpose, content and be visible as part of their implementation. However in spite of numerous headlines, reported clinical incidents, claims and complaints documenting avoidable harm and the more formal public inquiry following systemic failure of a healthcare provider, learning lessons and affecting changes to prevent a reoccurrence continues to require improvement (Barach & Small 2000). Latino (2009) continues to highlight the opportunities that exist to optimise safety assessments in healthcare with the adoption of proactive tools that anticipate failure (e.g. Failure Modes and Effects Analysis) alongside reactive tools (e.g. Root Cause Analysis). Tools alone are not sufficient and hence the model needs to be accompanied by a culture that promotes safety and risk and leadership that sets the expectations for safety and acceptance of risk.

A number of observers may consider this a harsh critique of risk management in NHS Trusts however the context and examples provided in the earlier paragraphs support this statement and start to set out the case that recognises the current arrangements for risk management, identifies the impact of key drivers and the potential benefits and constraints of the model(s) in place.

6.2.6 Learning from other Industries

Risk management is a core specialist function in high risk industries. The need to actively manage risk, to embed it within the work activities and processes is seen as a pre requisite for reliability, resilience and successful risk and safety performance (Hollnagel & Woods 2006). In addition to enhanced performance through a focus on resilience and reliability of systems and processes, Love at al (2008) highlight that a risk management model needs to multifactorial (Love et al 2008) responding to different types of risk, influencing factors and dependencies with other corporate programmes. Raju et al (2002) highlight the alignment with financial and quality performance. The learning between risk models extends beyond performance measurement to include the basics of hazard identification, assessment of significance and importantly the corporate tolerance to the risk perspective. This last factor is important in setting the context for safety cultures through safe environments, listening to frontline staff and using them to inform safety controls as well as moving towards a work practice based on the anticipation and prevention of

risk and not the reactive reporting. Such factors are not commonly associated with risk management systems in the NHS nor the wider healthcare however is reflected in the aspiration of policy makers.

The development of the capacity and capability to anticipate is broader than an assessment tool. The tools and models described in chapter 2 have the potential to provide a foundation for this shift to a more proactive approach to risk management through the open identification of the potential hazards, failures and their impact and in assessing the likelihood of the event. The approach makes use of risk information gathered such as incidents reported in addition to leading a commitment to learning and continuous improvement.

6.3 Is it possible to measure the success of the systems and if so how?

For industries where the potential implications of not managing risk are catastrophic, serious injury and possible death, there is a need to measure the effectiveness of systems as a safety net, in reducing errors, in improving systems and in strengthening their ability to anticipate and not solely react to risk. One measure of success of an organisation is its ability to manage risk from identification through to mitigation and monitoring (Power 2004). Increasingly the business environment in high risk industries such as nuclear power, aviation and energy production increasingly talk in terms of reliability with the aim of the sector and company being known as a high reliability organisation. Gamble (2013) identified 5 traits of high reliability organisations that should be hardwired into a business, these included a sensitivity to operations, systems and processes; a reluctance to accept simplified explanations to problems; a preoccupation with failure; deference to expertise and corporate resilience. Such traits aim respond to the expectations and value of shareholders. Love et al (2008) offer an alternative perspective, which is based on the critical considerations of healthcare leaders where performance measures are financially focused and include operating profit margin. The findings also highlighted consideration of non-financial indicators such as physician and employee satisfaction, hospital-acquired infection rates, surgical site infection rates, inpatient mortality, infection control outcomes, and medication error rates.

The operation of the NHS as a public service demands public accountability and the demonstration of continual improvements often demonstrated through political

commitments. Since the 1990s, performance measures at all levels have been a key feature of the management of healthcare provision by NHS Trusts. The focus of the indicators may shift, although ultimately they should support the delivery of high quality, effective healthcare recognised by both services users and providers of the care (Love et al 2008). Such measures have been used by commissioners to set the standard of the quality, safety, cost and activity of services provided. Measures set by oversight bodies such as the former Strategic Health Authorities and NHS England have aligned to the delivery of headlines of quality and effective care and at a national level measures have focused on the timeliness of operational delivery, its cost effectiveness and to a lesser extent the quality of care provided.

Performance measures as indicators of success, continual improvement or areas to target resources were not identified as a strong feature of risk management arrangements in the NHS. As part of the generic models for risk management (HSE 1997, NPSA 2004, ISO 2009) the common characteristic committing to continual improvement was evident through feedback as well as defined step of monitoring and review. As part of the review of risk assessment processes the criteria least likely to be considered by NHS Trusts included the setting of risk improvement targets and processes that incorporated the monitoring and review of risk, the impact of mitigating action and the ongoing tolerance. Vincent et al (2004) highlight the importance of measurement and monitoring of safety in healthcare not only as a source of improvement but more importantly maintaining standards and not allowing risk and concerns to increase.

The absence of such measures may be partially explained by the scene set nationally where central policy acts as a driver to what happens locally. Historically the risks associated with MRSA bacteraemia cases were well documented. In 2004, the Department of Health launched a commitment to reduce MRSA bacteraemia cases by 50% by 2008 and Clostridium Difficile cases by 30% by 2010/11. Evidence based clinical practice suggested that these cases were avoidable and it was a tolerance that had established at all levels of the NHS from point of care through to the oversight and commissioning that continued to accept the reporting of these incidents and harm to patients. This commitment and setting of reduction targets challenged the preceding culture and prompted attention, action and avoidance of these cases. At the end of the 5 year period cases of avoidable hospital acquired infection had significantly reduced. The key factor here is the influence of national

targets with the 5 year strategy led to a perceptible change in trust leadership on infections and responding to infection rates (NAO 2011) as well as operational changes in policy and practice.

The absence of key performance measures, improvement targets, a commitment to increased reliability from risk assessment practice and also standard operating processes suggests that the journey for learning is still ongoing. The understanding of risk management needs to be developed beyond checklists or national standards to local needs, priorities and context within day to day delivery of health care. Farrow (2015) describes how quality & safety performance is influenced by a range of factors including organisational design and structure. Policy makers will be just one influencing factor others may include leadership (NAO 2011), culture (West 2001), risk appetite and tolerance (Kentel & Arah 2007). The learning to take away is that risk management is not one dimensional and hence in a complex sector such as healthcare the model needs to multi factorial, focused on improvement and have a locally driven purpose.

6.4 Do characteristics of either the organisation or system influence how a Trust performs?

Objective 3: To analyse the impact or influence that characteristics of risk systems and Trusts have on organisational performance

Objective 4: To determine if "risk information" is used within the organisation and the relationship between outcomes and other organisational factors

Objective 5: To review the influence of other approaches such as national initiatives and individual's behaviours on risk management and in the achievement of a patient focused service.

Healthcare and the provision of high quality, safe care is recognised as complex (Leape 2005). This complexity transfers to the systems and arrangements that organisations have in place to deliver on a day to day basis but also as part of a wider system and operating landscape. Central to this delivery is the patient and the expectations that they have on the services provided – access, responsiveness, quality and safety (CQC 2013).

The analysis that has been undertaken and the data that has been collected does demonstrate variation in the way in which Trusts manage risk and the success with which they do it. The source of this variation may be explained by the type of Trust,

activity undertaken and demographics incorporating health conditions of the local population. In addition the research has also attempted to understand if there are factors that are inherent to an organisation that pre determine performance irrespective of the outputs. Such factors may be characteristics of the organisation such as size, financial turnover, geography as well as system content and criteria.

The findings presented in chapter 5 have informed the presentation of a high level framework incorporating organisational factors and characteristics and the influence that these have on performance. These findings have proven insightful in dispelling myths that exist around predictors and pre requisites for effective risk management performance and in identifying factors that may assist or enhance a Trust's performance.

6.4.1 Factors to enhance and strengthen risk performance in NHS Trusts

All Trusts have the potential to achieve successful performance in the management of individual risks or in the attainment of nationally set targets, standards or requirements. As Cagliano et al (2011) and the research findings have identified there are a myriad of factors that have the potential to influence performance, some of these were identified in chapter 3 in figure 3.1 and include a mix of strategic and operational factors. It is potentially these factors that ultimately influence an organisation in terms of what it does, how it does and how well, rather than factors inherent to the Trust such as size, location, geography and status. It is these last factors that have often been referenced by organisations at all levels of the NHS hierarchy in explaining strong and not so strong performance. However whilst the indirect influence of these factors as contributory factors to organisational performance is evident their individual significance does vary.

A number of possible indirect factors were identified through the review of the data, information and findings. These included culture, leadership, and unintended consequences of national programmes that continue the curiosity of risk management arrangements in the NHS compared to other high risk organisations. The common finding that joins these factors together is the possible immaturity of risk in the NHS in comparison to other industries and in particular sectors where getting it wrong has catastrophic consequences. These factors are visible in aviation, nuclear energy and oil and gas production and are key features due to the learning from past incidents. The independent safety review panel that investigated the BP Texas City oil refinery fire accident in 2005 that resulted in the death of 15

employees, injury to over 170 members of staff and significant economic losses identified serious concerns relating to the corporate safety culture. These concerns related to the effectiveness of the BP North America's corporate safety oversight of its refining facilities and a safety culture that may have tolerated serious and longstanding deviations from good safety practice. The final report made a number of recommendations identifying shortfalls in existing systems and the opportunity for improvements in relation to safety leadership, safety culture, clearly defined expectations and accountability for safety, Board monitoring and becoming an Industry leader (BP US Refineries Independent Safety Review Panel 2007). These recommendations and learning points are as relevant in safety and risk management in the NHS in developing systems and enhancing performance.

6.4.2 Organisational Characteristics

The results presented in chapter 5 confirmed the variation that exists in the risk management arrangements adopted by NHS Trusts. This variation was evident in the systems and frameworks adopted, the different executive leadership models applied to risk management by individual Trusts and the impact and influence of other organisational characteristics. The relationship that exists between these factors needs to be understood individually and collectively.

i. Size of the NHS Trust

NHS Trusts have been described or referred to as complex organisations (Leape 2005). Such descriptions often follow periods of adversity, unexpected outcomes or poor performance. The size of an organisation, a process or an activity could be considered to be a factor that influences and determines overall performance and outcomes in quality, safety or financial performance.

The results showed that when indicators of size were considered alongside variables of regulatory performance and claims management, the impact of size was not statistically significant. This challenges the perception and evidence that may be presented by Trusts to explain performance that falls below expected standards. Although size was not statistically significant in determining performance, the relationship with claims management was stronger than that with regulatory performance. This difference is not unexpected and the trend in litigation could be influenced in part by a number of factors such as service type and clinical activity as well as size of the organisation and its ability to monitor the quality of care. Terziovski

& Samson (1999) qualified their understanding of the impact of size on quality performance through the ability to influence practice through behaviours or systems. Again this supports the earlier thinking on culture and performance.

The dismissal that the size of the Trust does not influence performance should be approached with caution. The relationship was not statistically significant it was not the absence of an influence. Data relating to two indicators of size was collected and examined as part of this research; financial turnover and the total number of number of employees represent macro indicators and are supported by multiple meso indicators that have the potential to impact on the quality of care being delivered. For example relating to staffing; staffing levels, recruitment and retention of staff, vacancies, skill mix, patient to staff ward based staffing ratios are all elements relating to workforce that are known to impact on the quality of care delivered. From a financial perspective, whilst turnover may be the most appropriate indicator of size, other elements that may impact on quality include cost improvement programmes and their delivery. As with the size of an organisation, close links are drawn between financial improvement targets and cost reductions and the quality of the services delivered. Whilst again there are examples of the detrimental impact that fiscal policies have on patient experiences and clinical outcomes, there will also be examples of where financial pressures and the need for savings have not impacted on the quality of care provision. This reintroduces the concept of systems designed for other priorities other than the intended outcomes and the risk to Trusts of vulnerable systems syndrome, testing and revealing organisational priorities, commitment and culture.

In understanding the impact on the quality and safety of care provided, “can a Trust be too big?”. The results have already highlighted both positive and negative responses to this, for example with the correlation between size and regulatory performance as well as the total number of claims reported and paid. If there is an optimum size of an organisation, proportionally is there a scale that relates to the quality of service provision and the impact on patients. Bojke et al (2001) ask the question “is bigger better for primary care groups and trusts?” Their findings are summarised by the following observations:

- The size of the organisation is one of the factors affecting performance not determining it.

- There is no evidence that increases in the size of organisations (primary or secondary care) will automatically generate substantial improvements in overall performance or economies of scale
- Optimal size varies substantially for different functions
- Organisational structures can be used to achieve the different optimal sizes for various functions

It is clear that local conditions are influential on structures and arrangements for managing risk as has been seen through risk assessment criteria and executive leadership. In addition, policy priorities are also seen as influential factors, which again supports the links with vulnerable system syndrome already referenced. These two aspects were not specifically explored as part of this research however the observations made as part of the results analysis has raised this a future area of study.

A related aspect to size may be that of culture which has a strong alignment with leadership, values and organisational behaviours. This relationship provides a link back to the design and content of risk management strategies and frameworks including leadership. Culture is inevitably influenced by values and behaviours to create a "way" of doing things. It is possible to apply this cultural thinking to leadership and the impact or significance that the backgrounds of leaders have on risk performance and standards of quality and safety, priorities and tolerances.

Hollnagel et al (2006) shares the concept of Vulnerable System Syndrome where organisations are focused on finance and activity targets above all else hence attacking and putting the resilience of a function or organisation under pressure. Shared responsibility for risk as well as for finance or operational performance has the potential to compromise the system further. Independent and objective oversight of the individual functions is lost and inevitably the higher priority wins. The lack of integration of systems equally supports the delivery of the perceived highest priority such as a financial bottom line or the delivery of a national or a delivery target, as cause and effect and hence true costs and consequences of decisions or focus of resources is not identified.

Whilst this research was explicit in its scope focusing on risk management, it is interesting to note the emerging practical reconciliation of quality and safety along

side financial risk given the challenges inherent in NHS service delivery of savings. This potentially creates an operating tension from the extent to which risks are identified, assessed, tolerated and mitigated through to executive leadership and corporate priorities.

ii. Foundation and Non Foundation Trust status

In reviewing the Trusts, the difference between Foundation and non Foundation Trust status was considered. The achievement of Foundation Trust status was been seen as a display of robust governance arrangements, strong financial controls and operational performance (Monitor 2013). As part of the assessment process Trusts have been seen to redesign, add to and strengthen their internal systems to meet the required standards and performance. The authorisation process is a challenging process, the decision to explore any potential differences was two fold; firstly in order for Trusts to be authorised as Foundation Trusts the internal systems, structures and functionality in areas such as governance, financial management and operational performance are assessed and forensically analysed. In practice Trusts can be seen to redesign, add to and strengthen such systems in order to become analysed. Such changes and strengthening of systems may be expected to enhance performance however may also detract from operational delivery running in parallel.

In reviewing and comparing the results and outcomes for Foundation and non Foundation Trusts, there was no significant difference or variation between the two groups in characteristics of the Trust such as size, claims management performance and regulatory outcomes or in the themes emerging from risk management arrangements. It was noted that Foundations Trusts identified in breach of authorisation were less likely to go on to be non compliant in the next CQC inspection again suggesting the role of culture in improving and delivering the required standards of care.

The result of no discernable difference between Foundation and non Foundation Trusts was unexpected due to the requirements on risk and governance systems in the application and authorisation of Trusts by Monitor. The absence of any significant difference poses a number of possible questions and possible explanations such as, the rigor of assessment in testing the true performance of systems and governance arrangements supporting the delivery of quality care; systems and governance architecture may be designed to satisfy assessment

purposes and not a sustainable operating model; prescriptive systems and requirements such as those set out in the authorisation and subsequent operating framework by Monitor fail to deliver notable improvements in the operational delivery of healthcare. The absence of variation poses a potential counter to the requirement of all NHS Trusts becoming Foundation Trusts, a counter indirectly supported by failure to deliver all aspirants Trusts to Foundation status by 31 March 2014 deadline.

6.4.3 Regulatory Performance & Risk Management Systems

A review of regulatory performance identified a number of broad themes and relationships between difference data sets to allow consideration and commentary to be made around organisational characteristics and the influence on risk performance and also as potential predictive indicators. Faunce and Bolsin (2004) found regulation did not always identify shortfalls in an organisation's performance or in attaining the required standards. The analysis of the regulatory performance data for outcomes 4 and 16 of the essential standards did confirm a relationship between assessments. For example if a Trust was assessed as compliant with outcome 4 relating to the care and welfare of patients there was a string likelihood that the organisation would also be compliant with outcome 16 which assessed monitoring of these standards. The same was true for non-compliance. Irrespective of the statistical significance this result aligns with the general expectations as a Board member, Commissioner, Regulator or indeed a patient. However, the absence of a perfect correlation does highlight the potential for other factors to influence these outcomes.

Leadership has already been noted as being as important factors that influences the risk management function (BP Safety Review Panel 2007, Love et al 2008). However for the purposes of regulatory performance it was not something that was observed through the results. Executive leadership for risk management had been dominated by the Chief Nurse role however in relation to regulatory non compliance this was shared with executive colleagues in particular the Chief Executive and Medical Director. There is a relationship that cannot be ignored and that is the role of the Chief Nurse and executive responsibilities held in organisations that have experienced significant failings in the standards of care. This is an area that requires further investigation as although the role is a common factor the diversity of the portfolio, breadth and functions may also be a factor and may an insight on

governance and the maintenance of openness and transparency in decision making and reporting (internally and externally).

In terms of indicators of the quality and safety of care that be used to inform and assure a Trust on the quality of services being delivered, there are a number of different indicators and outcomes that can be used. The drivers behind this range of metrics may in fact influence the final outcome and any potential bias in terms of reporting or proposing a certain level of performance. For example, a national review of mortality rates and indicators in early 2013 identified 14 NHS Trusts as possible outliers in performance. Agreement on the "list" was not universal with regulators, academic institutions and information teams suggesting alternatives from their own lists that did not feature in what became known as the "Keogh Trusts". Mortality is commonly used as an indicator of the quality and safety of clinical care however there is a lack of consensus in the measure – crude mortality rates, standardised mortality rates, risk adjusted mortality rates or a combination to triangulate the overall view. Jarman, Pieter and Jones (2010) compared a hospital standardised mortality ratio against a risk-adjusted model as a tool for Dutch hospitals to assess their quality of care, illustrating the variety of models, approaches and measures for mortality.

In July 2013, a further 18 Trusts were identified by the Care Quality Commission. A mix of Trusts displaying a range of high and moderate risks across a range of indicators of safety and quality. A third "list" potentially exists using and testing the characteristics that have emerged through the research. As part of the results and as a test of the emerging findings, the following characteristics were identified for each programme, as shown in table 6.1.

Table 6.1: Summary of Trust characteristics displayed in nationally collated lists of "risky" Trusts.

Keogh Trusts (Mortality outliers) 14 Trusts	CQC's Chief Inspector of Hospitals 18 Trusts	List of Trusts emerging from research 15 Trusts
Equal split of FTs and non FTs	Prevalence of non FTs	Prevalance of non FTs
Compliance in outcomes 4 and 16 of the Essential Standards	Theme of compliance across outcomes 4 and 16 of the Essential Standards	Theme of compliance across outcomes 4 and 16 of the Essential Standards
Observed breaches in authorisation although only one registration condition	No breaches in authorisation and only one Trust with a condition at registration	Identified breach in authorisation with Monitor and condition at registraion
Increasing trend of claims reported	Mix of steady and increasing numbers of claims reported	Increasing trend of claims reported (year on year and above national average)
Content of risk assessents focus on core criteria (not complex)	Complex risk assessment processes with high number of criteria being considered, although monitoring and review function is limited	Complex process of risk assessment with high number of criteria being considered. Review programme and processes highlighted as present by the Trust
Trusts tended to be multi site and relatively smaller turnovers	Mix of multi and single site Trusts with average number of employees at 4000	Trusts tend to be larger in overall size (staff and turnover) with multiple sites

As the findings of table 6.1 identify there is limited correlation in the characteristics of the Trusts appearing on each “list”. This in itself is suggestive of the challenges facing the identification of predictive indicators of shortfalls in quality and safety and an ultimate indicator of quality and safety.

Healthcare relies upon a complex series of interactions between systems, practitioners and patients with each of the interactions containing its own intrinsic rate of failure. Terziovski & Samson (1999) recognise the difficulties in reconciling patient experiences with evidence based information and data. Anecdotal reports in the media are common from members of the public, past patients and current service users when services are threatened with closure due to safety or quality issues. Whilst there may be a requirement of a risk management system to be proactive in the anticipation and identification of risk, the use of predictive indictors may only be a partial answer and must be considered along side additional undetermined factors reflective of the wider system, such as geographical context, local demographics, performance across the health economy, patient experience and public perception. The design and performance of health systems may be badged as being in the public interest however as the results have shown there are alternative drivers including policy and politics that prevail overriding the logic and desire of clinicians for patient centred care.

Monitor and the Care Quality Commission operate different models and approaches to regulation. In April 2016 the regulatory landscape change again with Monitor merging with NHS Trust Development Authority (TDA) to form NHS Improvement. This potential streamlining of regulation around a common purpose of “improvement” supports an emerging theme from the results and compliance with standards monitored by the CQC and Monitor. It was also noted that Trusts identified in breach of their authorisation were less likely to then be found non compliant by the Care Quality Commission. Whilst not a predictor, this is an interesting characteristic which may provide grounds to assess the impact of regulatory intervention (irrespective of source) on the overall performance of a Trust and its behaviours. There is a potential caveat to this suggestion in as much as is the performance and recovery of the Trust is influenced by the intervention of a single regulator however if the scrutiny is provided by a multiple regulators is the same benefit experienced.

The aim of any regulatory model should be to minimize the burden on the provider and deliver efficiency and effectiveness through its regulatory approach (Adil 2008). The findings have presented a clear view on the significant influence that central policy has on local systems as well as the lack of integration between the various models that providers are assessed under. This complexity presents a danger of providers responding to rhetoric instead of operational needs and improvements. The findings of the review of risk assessment criteria are broadly supportive of this notion with criteria being predominantly system based with potentially less attention being assigned to the consideration of clinical aspects of a system. Given the core business is clinical and the setting is healthcare, the context for risks is limited or not considered at all. The HSE in its guidance around the management of health & safety (HSE 1998) identifies one of the first steps of a risk system as "establishing context".

In addition to Trusts responding to regulatory requirements in the design and content of systems as seen in the content of risk management frameworks, there is the potential for this profile to be extended to what and how an organisation prioritises – characteristics of vulnerability systems syndrome. Whilst this is a simplified analogy, the findings flag a potential correlation not only with a negative impact on quality but also a positive influence on organisational behaviours, risk performance and a commitment to improvement. The research identified that Trusts found in breach of their authorisation by Monitor were less likely to subsequently be found non compliant by the CQC suggesting that the impact of interventions such as formal regulatory notices (Monitor 2013, Care Act 2015) acted as a lever for improvement not only against the original breach but also improving quality standards and organisational behaviours.

6.4.4 Claims Management and Risk Management Frameworks

Runciman et al (2003) state that while people understand that disastrous outcomes can result from avoidable failures in health care delivery, most people believe that these outcomes are isolated events. Such incidents including those that progress and are addressed through litigation offer an insight into errors and an opportunity to learn lessons to inform safe system design in healthcare. Reason (1990) promotes the importance of understanding incidents, adverse events and unexpected outcomes and the causes behind them in order to prevent a repeat of events. As a result, claims as a data source have the potential to be used positively as part of an

improvement strategy to enhance the quality of care. In addition an organisation's response to claims may assist in identifying its culture and commitment to quality, safety and learning from such events in addition to identifying drivers and priorities in the delivery of care.

Vincent et al (2000) highlight the importance of investigating and analysing clinical incidents, encouraging learning and changes in practice from individual incidents as well as themes and trends. The analysis of the risk assessment criteria and the increasing trend in the total number of claims made both directly and indirectly support the absence of learning or at least learning that results in change and improvement in the NHS. The risk assessment criteria did not routinely consider secondary factors in the assessment of risk nor did it commitment to improvement targets as part of effective mitigating action. The gap in monitoring and review stage of the process has already been noted however this is relevant for claims management as it fails to monitor trends and themes in the claims made which may change the overall assessment of risk, tolerance and action taken. In the context of emerging trends, a small number of Trusts were identified for frequent high levels of claims reporting over a 6-year period. Two Trusts in particular displayed higher rates than the other Trusts as well as demonstrating variable regulatory performance. As indicators of poor performance the true cause of this performance may lie elsewhere such as culture and leadership as indicated by the absence of learning. Whilst claims data and its possible relationship with organisational performance is not definitive as a predictor it continues to add value (Phillips et al 2004) to the effectiveness of risk management arrangements. This value is added through its proactive use in improving future systems through learning and strengthening systems and changing behaviours.

The role of culture, leadership and behaviours continues as a strong theme and influencing factor in risk management. Culture is a key factor in how healthcare organisations manage risks to the safety and quality of care provided and responds to information that may be indicators of risk or failures in systems and processes. Reports of negligence create a defensive atmosphere compared to the openness and candour to aid learning and promote improvement. Hence the culture element developed as part of the overall risk management framework is key. The culture has a tendency to focus on carelessness or omission of an individual and apportion blame rather than look at the broader system issues as either root causes or

contributory factors. In the absence of a systematic approach, other factors, behaviours and priorities have the ability to influence (Cagliano et al 2011).

6.5 The Model Organisation & Operating Environment

The research findings have provided a view and insight to the existing strengths and opportunities to strengthen risk management in healthcare and in particular in the NHS. Drawing on these findings it is possible to make the following recommendations in terms of strategic and operational drivers. Using the drivers identified in chapter 3 (figure 3.1) as a framework:

6.5.1 Strategic Drivers

Central policy and political context is a strong influencing factor which at times is at risk of overwhelming the function and shifting the emphasis of delivery from effective management of the risk to the fulfilment of policy requirements. The prescribed approach replicates characteristics of arrangements in other high risk organisations however the over simplification through standardization of strategies, risk assessment tools and a culture that promotes checklists at the expense of consideration of local conditions is at risk of introducing vulnerability and further risk to the system. A balance needs to be achieved that presents a framework to work within that recognises and rewards local application with performance measured through both outcomes and inputs. This subsequent measurement could form the basis of regulation which seeks to regulate the entirety of the function represented through the what, the how and how well.

From a *performance* perspective the relationship to date has been to measure for judgement. Learning from other industries, other models such as those subject to independent accreditation, and also as a key feature of a safety culture, the purpose of performance measurement of risk should be to support improvement. Industries successful in managing risk establish continual improvement targets that stretch performance to enhance outputs, increase reliability and reduce error. Over the last decade there are examples of this both in strategy and practice set out by the Institute of Healthcare Improvement and the Department of Health however the perceived threat of financial penalties in an environment of increasing deficit provides a difficult scorecard to balance and deference to performance as priority. The move

in 2016/17 to the development of Sustainability and Transformation plans may assist in achieving this balance or the start of a realigned journey.

Risk management in healthcare is complex and is increasingly referenced and encompassed in the *quality* and safety of health care delivery. The breadth of this scope demands an understanding of the dependencies between risk, quality and safety and the operational and corporate delivery of providing services. As the findings indicated risk as a function is often a standalone programme, lacking integration with other corporate systems such as operational efficiency delivery and financial balance. In industries such as aviation, effective risk management is integrated into "business as usual" operations with decisions considering safety and the quality of a service alongside the delivery of the activity and its financial viability. To strengthen risk management as a function in healthcare further integration with all corporate and operational activities is necessary to ensure that the delivery of certain areas of performance is not at the expense of others. This integration needs to exist beyond the page of a policy and to a "way of working".

Love et al (2008) flagged the importance of being able to demonstrate accountability in the use of resources and the outcomes achieved. Comparisons with industries such as aviation and energy production are helpful in drawing similarities in the scale of consequences but potentially less so in parallels of safeguarding reputation and maintaining public confidence in the services and providers of services. The key difference is that in other industries it is assumed that the customer has choice of an alternative supplier. However in healthcare whilst choice may exist it may not be accessible or an option to all. The maintenance of public confidence is critical and as such protection of a sense of purpose and outcome for the service user should not be forgotten. The initiatives reviewed during the period of this research recognised the value of patient experience and responded to it with a further programme where the interface with risk was not explicit.

The case of integration is an area that is critical to managing risk and achieving sustainable performance. This is reflected in the new Sustainability and Transformation Plans – STPs (DH 2015) underdevelopment across the commissioning areas of NHS England. These plans aim to provide an integrated plan for the operational delivery of the Forward View, a five strategy for the delivery

of health and social care that considers in equal measure the resource envelope, operational performance and the quality of services.

6.5.2 Operational Drivers

A number of operational drivers were identified, conceptually and operationally, that highlighted some of the practical priorities and challenges facing the successful implementation of risk management in Trusts.

The development and delivery of *risk assessment tools* that present consistency at a strategic level and allow local flex to incorporate local conditions and circumstances is important. As identified by Gamble (2013) over simplification and standardisation of processes whilst achieving a common way of working can also introduce additional risks to a system. Adopting a tool that reflects national requirements as well as local conditions is key to successful management but also in terms of recognising dependencies with other local corporate programmes and a local way of how things are done the nuances of which may not be reflected in a generic policy. Such nuances may include culture, leadership as well as elements of risk appetite and tolerability.

Adverse event reporting is a first step and indicator of an unexpected and unwanted event. Reporting rates are influenced by a number of factors, which are directly or indirectly influenced by policy, performance and local behaviours. In line with the ethos of performance measurement incidence of adverse events (incidents, complaints and claims) should be used as levers for improvement rather than punitive. The events provide a valuable intelligence resource for learning and strengthening practice and performance (Leape 2002) that can be used to enhance reliability and resilience of systems and organisations.

The role of *safety culture* has been an emerging theme through the findings, the significance of which would benefit from further investigation. However as an interdependency that cuts across what is done, how and who does it and how well it is done, the contribution of culture and with it leadership would benefit from further investigation and analysis. There is the potential for organisational culture in relation to risk and more widely to be a latent factor in performance.

Organisational performance and priorities are strongly influenced by the current rhetoric. Strategically the drivers behind policy changes and national initiatives have

been developed in isolation to the practical application. As such dependencies and the consequences of the policy, intended or otherwise, may not have been full appraised. In order to achieve robust risk management that is demonstrated through the successful management and mitigation of risk, performance measurement and reporting should be multifactorial. For example the reporting of organisational performance through a corporate index that takes into account financial, operational and safety performance and provides leaders of organisations with an insight on their position on a performance scale made up of integrated measures and a single index.

6.5 Successful Risk Management in Healthcare

The collective view provided by this research has highlighted a number of characteristics and behaviours that have been used in other industries to strengthen risk management. Working from a position that opportunities still exist for the arrangements in healthcare and in particular the NHS to mature, the following represents a view on characteristics of a future model and approach. The framework should:

Strategically:

- Set out an agreed definition of risk, the purpose of risk management and the scope of its application. The detail needs to balance prescription for consistency and foster a local drive for ownership.
- Be inclusive in its application and consideration of different sources and types of risk present in a healthcare environment
- Provide a systematic approach to the context, identification, assessment, mitigation and monitoring of risk whilst ensuring an overall commitment to continual improvement
- Represent a core set of nationally agreed requirements which on implementation are supported by locally developed arrangements, systems and processes
- Embed risk management as core to the delivery of safe, quality healthcare across the NHS reflected in the appointment of a dedicated Board level position in all Trusts
- Align national standards and possible oversight of healthcare to reduce the burden, bureaucracy and differences in expected levels of performance to enable a focus on achievement, improvement or holding to account.

- Promotes a culture that promotes learning, improvement and change that engages senior leaders and operational delivery equally
- Integrate risk management into business deliverables and strategic planning

Operationally:

- Prioritise safety of its staff, patients and its ability to deliver high quality care
- Be aligned to the local setting with national principles translated to local conditions, arrangements and priorities as appropriate
- Agree a local appetite for risk and seek to continually improve on it, acting as a local and national leader
- Design policies and processes that support "getting it right" removing barriers between competing priorities and promoting an integrated approach
- Be supported by a culture that promotes safety performance and successful management of risk alongside performance measures as part of a high performing organisation.
- Provide clarity to all staff avoiding generis statements on their roles and responsibilities in effective risk management.
- Seek to continually improve through learning from cases of avoidable harm, themes and trends from corporate data and from listening to its workforce not only on what to improve but how to do it.

Learning and improvement are important attributes of a successful risk management system. In considering a future model it is essential that the function continues to evolve to reflect its industry in which it is embedded, the lessons to be learned that will continue to present from incidents, complaints, patient experiences and claims and the new models of care and service delivery that continue to demonstrate the innovative trait of healthcare. Over the next 5 years the delivery of healthcare and the access to services will undergo significant change (DH 2015) and as such risks will be present. The pressure is on the function not only identify them irrespective of source or presentation but to find ways to minimise the risk of harm, loss, and unintended consequences to the patient, the business or the service.

The direction going forward reflects a number of characteristics. The future needs to ensure that nationally and locally safety and the quality of care received by patients remains the highest priority. To achieve this and in the face practical constraints such as funding, change is essential. The level of change spans behaviours through

to models of care however is characterised by the need for sustainability at all levels; from concept and central policy, through to operational delivery and a commitment to delivering safe, quality care within the financial envelope provided.

Successful risk management is something to be defined. A key learning point through this research has been that the systems and arrangements in high risk industries are not directly transferable. Successful risk management for healthcare would need to be defined and could take the structure of performance against improvement targets, an indicator of patient experience potentially drawing on the role of the "customer" or as and integrated index that brings together financial, operational and safety to provide a corporate score. The merits of different approaches to measurement requires further exploration and should interface with the STP proposals and 5 year strategy.

6.6 Limitations & Constraints

Over the course of the different stages of the research from design to data collection through to analysis I have encountered certain limitations that have constrained the final outputs.

6.6.1 Operating Landscape

In the last 10 years the operating environment and landscape of healthcare its delivery by NHS Trust, its oversight by Strategic Health Authorities and regulation has evolved. In practice there have been changes to individual Trusts through mergers, expanding scope of services provided, changes to regional boundaries and the introduction of new oversight arrangements including performance monitoring and regulation. These last two points as examples are relevant as the changes resulted in the introduction of new additional bodies and organisations to the healthcare environment. The role of the relationship and stakeholder management is a critical one.

This ever changing landscape of context, stakeholders and purpose has been a key risk to manage to ensure the work remains valid and relevant. The risk has been actively managed through the tracking of changes to individual organisations, additional data collections that take into account the changes in the 2010-2012 period and a continual update and refresh of standards to reflect learning through

policy changes as well as ensuring that comparable periods and standards are consistent.

6.6.2 Time periods

A potential limitation to the research was the protracted time period over which data was collected, analysed and presented. The data was collected in two separate phases, which presented a risk that data related to organisational performance would not be directly comparable to the 2005 data set due to organisational changes. This risk was mitigated by the tracking of changes to Trusts in the original 2005 distribution list and then in the 2012 data collection. Where changes were identified the data was also tracked.

6.6.3 Inconsistency in the Sector

A key finding from the literature review and observation from the review of risk management arrangements in the NHS was the inconsistency that exists. This inconsistency is displayed in regional variations in performance, criteria considered as key to a risk assessment process and executive responsibility. Accompanying this inconsistency was a strong degree of commonality between local arrangements and national policy. Although the variation noted could have been viewed as a limitation to the research it instead provided evidence and a key finding that the lack of local flex and amendment to central policy relating to risk management when implemented by Trusts. The absence of a shared and common definition of risk management that did not distinguish between sources of risk was also recognised. The conclusion of the discussion chapter has recommended the development of a common definition for risk and risk management for use in the NHS that does not distinguish between sources of risks and aids integration.

6.6 Summary

Healthcare is a complex industry and as such the management of risk to support the delivery of safe, quality care is also complex. The multiple drivers and factors that influence how risk is managed adds to the complexity whilst not always adding value or having a positive impact. In the course of this research I have attempted to identify the current arrangements for managing risk, provide a view on performance measurement and also the extent to which factors inherent in an organisation and the sector influence and possibly predetermine performance. During the research

the operating environment of the NHS and healthcare provision in England has changed at a national level with the introduction of regulators and stakeholders to the oversight of quality and safety whilst at the same time the loss of some key players. In spite of these changes which have aimed to strengthen the management of risk learning and adopting safety practices from other industries it is possible to conclude that risk management as a function in the NHS is different to that seen in high risk industries.

National initiatives and central policy are a significant influence on what is considered risk, how risk is managed and what local arrangements look like. The influence of local risk management practices is an important factor that would benefit from further investigation as it is largely invisible to standards and requirements set nationally. Such local conditions do not relate to the organisation's profile or status but reflect the softer elements of leadership, behaviours, commitment, roles and responsibilities and integration with local programmes. The findings of the research have constantly hinted that it is elements such as these that influence and underpins successful risk and safety performance. This finding challenges what has been assumed or given as anecdotal evidence that there are conditions and characteristics inherent to the organisation that predetermine its performance. In summary successful risk performance is not achieved through a single action but through the combined relationship and interdependencies that exist and drive complex systems. As such effective risk management must be part of core business rather than a separate entity.

Chapter 7 – Conclusion

Vincent (2001) recognises the key role of risk management in healthcare in enhancing patient safety and delivering safe clinical services. However it is evident that safeguarding the safety of patients is more complex than the clinical competencies of healthcare professionals and requires consideration to the wider factors that may influence and act as risks to the safety and quality of care. In addition to influencing the patient's experience at point of care, national directives, performance targets and similar drivers also influence the content of systems and processes.

The results highlighted a number of findings in response to the questions and objectives set. In the first instance, risk management is a recognised function in NHS Trusts with a significant part of arrangements, approaches and requirements defined by central policy and national initiatives. Variation was identified in the content of risk management systems within NHS Trusts. Using this variation it was possible to identify common elements and attributes of systems such as the existence of a strategy and a risk assessment process however the detail of its content including individual risk criteria considered highlighted further differences but also possible characteristics of organisational culture and priorities. The significance of these characteristics when compared against other variables such as regulatory performance or claims management provided further insight into the influence of initiatives and risk factors on the overall effectiveness of the system and risk management capabilities.

The research identified a number of themes as well as the possible existence of findings that support the identification of characteristics of other high-risk industries that could be applied to NHS and broader healthcare delivery. The themes from both sets of data collection and subsequent analysis included:

- Performance against regulatory standards and requirements is not determined by the size of a Trust.
- The characteristics of a Trusts such as size, geographical spread and multiple locations do affect the number of claims reported and paid however are not predictors of performance.

- The status of a Trust as a Foundation or non Foundations Trust did not determine overall risk and quality performance.
- Executive leadership responsibility for risk management is often seen as part of a portfolio and is dominated by three roles, Chief Executive, Medical Director and Director of Nursing.
- Criteria considered as part of a risk assessment favours management processes compared to clinical factors with a limited number of criteria that could be considered as "core" to a risk assessment.
- Variations exist across regions and risk systems in terms of performance and also practice and the ability to identify common elements of a system.
- Few "true indicators" exist to support predictive modelling in relation to regulatory performance or in the effectiveness of risk management systems.
- Successful risk management supporting the delivery of high quality, safe care is dependent on multiple factors that extend beyond systems, processes and standards and are influenced by local conditions such as Trust leadership, culture and behaviour.

These findings and the wider results when tracked back to respond to the original objectives concluded the following against each objective and key questions:

Question 1: Does risk management exist as a function in the NHS and what does this look like?

Common elements do exist in risk management systems and frameworks. The existence of a documented risk management strategy and risk assessment prevailed across 98.7% of Trusts. In addition to confirmation of documents, the content of risk assessments also highlighted a number of common elements in the criteria most likely to be included (>90% of respondents) such as hazard identification and least likely (<70% of respondents) to be included such as risk improvement targets. In addition to the common elements there were a number of observations including 44% of Trusts assigning lead responsibility at Board level for risk to the Director of Nursing.

As a high risk industry it was evident that the NHS through central policy and national initiatives has tried to replicate approaches characterising risk management arrangements in other industries. Examples of this include the standardisation of operating procedures, arrangements for the oversight of risk and the way in which

risks are assessed. Although the rhetoric is correct, the translation has resulted in the adoption of the prescribed rather than the application of the standards to suit and reflect local needs, conditions and priorities. This structure not only impacts on the effectiveness of the approaches adopted but also limits the ability for systems and programmes to be truly integrated . This lack of integration not only challenges the profile of risk as a core function but also results in compromises and other activities being prioritised ahead of safety and quality of care. Such challenges are evident in operational and financial performance in spite of the hidden costs both financially and operationally associated with the poor management of risk.

The lack of integration was further highlighted in the results of the review of the Risk Management Strategies provided. The absence of any reference, dependency or association with other programmes was significant. However it was the absence of a clear commitment to risk and detailing of expectations from tolerance, appetite and responsibility for risk that highlighted the absence of a strong safety culture. This gap confirmed that not only are systems not integrated in relation to risk however the organisational behaviours are also not a strong feature of the Trust's culture.

Question 2: Is it possible to measure the success of the systems and if so how?

The literature review highlighted that systems and performance can be influenced by multiple factors. The results confirmed that organisational characteristics can influence performance however it is not a direct causal relationship hence any measures need to reflect local conditions. However as the survey results confirmed the monitoring and review of risk including mitigating action and the use of improvement measures or targets is not a common feature of processes. On the basis of the information collected and findings measurement of risk should encompass:

- A clear purpose set locally and reflective of local priorities and risks identified
- A balanced set of measures reflecting the efficiency of the systems and processes (standards that consider the optimum use of resources for delivery, risk control and assurance); effectiveness (to support the delivery of the intended outcome and impact) and economics (integrates systems to provide value for money).
- A commitment from local leaders that measurement of risk is for improvement and not judgement

- A set of measures that are meaningful to stakeholders, this includes commissioners, patients and staff. The measures should be clearly defined be accompanied by expected levels of performance that ideally stretch the organisation to eliminate risk
- A demonstration of learning, improvement and increasing shift towards the anticipation and prevention of risk and not solely reactive.

The ability to identify and manage risk relies on effective measurement to understand not only overall performance but opportunities to strengthen and develop systems for incremental improvement at key stages of the process. As a result measurement and improvement are closely aligned to organisational culture and leadership which set the tone for what can be achieved.

Question 3: Do characteristics of either the organisation or system influence how a Trust performs?

On commencing the research I had expected the findings of the research and analysis to support the identification of a Trust profile that could be associated with strong risk performance and a "safe" organisation. Whilst the results did confirm that certain characteristics of a Trust could influence performance there was no single factor that performance could be attributed to. The findings did help to dispel a number of preconceptions such as it was more difficult for larger Trusts to comply with required standards and that Foundation Trusts are perceived to be higher performing organisations. In the 260Trusts reviewed there were exceptions to these statements hence the ability to use characteristics either of an organisation or through performance as predictive indicators is potentially limited.

Although there was no significant different between the performance of Foundation and non Foundation Trusts, there was indirect evidence of risk information being used in Foundation Trusts that are found in breach of authorisation. Subsequent breaches were followed by compliance with the CQC's assessments suggesting that the use of information in the initial assessment was used to improve standards overall. Whilst not a specific analytical result, the use of information does align with an organisation's safety culture and a commitment to improve. This represents a further area of study alongside the broader topic of culture in NHS Trusts.

It was evident that national policy and initiatives have previously influenced the design and development of systems. The prevalence of management criteria in the risk assessment process could be suggestive of a response to external requirements compared to local conditions. The impact of rising claims again is possibly explained through a lack of learning and changes to local practices and policy suggesting a degree of disconnect between policy and practice and the drivers behind both. Organisational culture in particular resilience and reliable design, flags the pursuit of targets and priorities not aligned to local objectives as introducing potential vulnerability rather than rigour to the system.

At present there are divisions in the approaches used by NHS Trusts in managing identified risks based on the risk issue, its origin and the perception of individuals and organisations to mitigation. Systems currently in use display signs of vulnerability with safety overshadowed by a focus on performance. Whilst such systems may not have been consciously designed in that way, risk management needs to be a core element of all corporate functions. The achievement of this integration can driven be by internal actions of leadership, a positive safety culture and external actions which respect and support a balance of safety, quality and operational performance in the delivery of health care. From the perspective of central policy and ongoing national programmes the prescription needs to focus on achieving consistency and whilst the application needs to embrace local priorities, conditions and risks.

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