Examining the application of STAMP in the analysis of patient safety incidents

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Examining the application of STAMP in the analysis of patient safety incidents

by

Aneurin Canham

Doctoral Thesis

Submitted in partial fulfilment of the requirements for the award of Doctor of Philosophy of Loughborough University

September 2018

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Abstract

This thesis examines the application of Systems-Theoretic Accident Model and Processes (STAMP) in healthcare and the analysis of patient safety incidents.

Healthcare organisations have a responsibility for the safety of the patients they are treating. This includes the avoidance of unintended or unexpected harm to people during the provision of care. Patient safety incidents, that is adverse events where patients are harmed, are investigated and analysed as accidents are in other safety-critical industries, to gain an understanding of failure and to generate recommendations to prevent similar incidents occurring in the future. However, there is some dissatisfaction with the current quality of incident analysis in healthcare.

There is dissatisfaction with the recommendations that are generated from healthcare incident analysis which are felt to produce weak and ineffective remedial actions, often including retraining of individuals and small policy change. Issues with current practice have been linked to the use of Root Cause Analysis (RCA), an analysis method that often results in the understanding of an accident as being the result of a linear chain of events. This type of simple linear approach has been the target of criticism in safety science research and is not felt to be effective in the analysis of incidents in complex systems, such as healthcare.

Research in accident analysis methods has developed from a focus on technical failure and individual human actions to consideration of the interactions between people, technology and the organisation. Accident analysis methods have been developed that guide investigations to consideration of the whole system and interactions between system components. These system approaches are judged to be superior to simple linear approaches by the research community, however, they are not currently used in healthcare incident investigation practice.

The systems approach of STAMP is felt to be a promising method for the improvement of healthcare incident analysis. STAMP strongly embodies the
concepts of systems theory and analyses human decision-making. The application of STAMP in healthcare was investigated through three case studies, which applied STAMP in:

1. The analysis of the large-scale organisational failure at Mid-Staffordshire NHS Trust between 2005-2009.
2. The analysis of a common small-scale hospital-based medication prescription error.
3. The analysis of patient suicide in the community-based services of a Mental Health Trust.

The effectiveness of the STAMP applications was evaluated with feedback from healthcare stakeholders on the usability and utility of STAMP and discussion of the STAMP applications against criteria for accident analysis models and methods.

Healthcare stakeholders were generally positive about the utility of STAMP, finding it to provide a system view and guide consideration of interactions between system components. They also felt it would help them generate recommendations and were positive about the future application of STAMP in healthcare. However, many felt it to be a complicated method that would need specialist expertise to apply. The STAMP applications demonstrated the ability of STAMP to consider the whole system and guide an analysis to the generation of recommendations for system measures to prevent future incidents.

From the findings of the research, recommendations are made to improve STAMP and to assist future applications of STAMP in healthcare. The research also discusses the other factors that influence incident analysis beyond that of the analytical approach used and how these need to be considered to maximise the effectiveness of STAMP.
Statement of originality

The author (Aneurin Canham) is solely responsible for the work submitted in this thesis. The work presented in this thesis was funded by Loughborough University, with additional financial support from Carlton Hayes Mental Health Charity for Study 3 (Chapter 6).

Neither the submission nor the original work contained therein has been submitted to this or any other institution for a degree.
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Mum, Dad, Dan, Alex, Noah and Thomas, for being a home.

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<td>A&amp;E</td>
<td>Accident and Emergency department</td>
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<td>AEB</td>
<td>Accident Evolution and Barrier Model</td>
</tr>
<tr>
<td>ATSB</td>
<td>Australian Transport Safety Bureau Model</td>
</tr>
<tr>
<td>BTA</td>
<td>Bow-Tie Analysis</td>
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<tr>
<td>CAST</td>
<td>Causal Analysis using System Theory</td>
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<tr>
<td>CCG</td>
<td>Clinical Commissioning Group</td>
</tr>
<tr>
<td>CQC</td>
<td>Care Quality Commission</td>
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<tr>
<td>DH</td>
<td>Department of Health</td>
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<tr>
<td>DSN</td>
<td>Diabetes Specialist Nurse</td>
</tr>
<tr>
<td>EMAHSN</td>
<td>East Midlands Academic Health Science Network</td>
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<tr>
<td>FRAM</td>
<td>Functional Resonance Analysis Method</td>
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<tr>
<td>FMEA</td>
<td>Failure Modes and Effects Analysis</td>
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<tr>
<td>FMECA</td>
<td>Failure Mode Effects and Criticality Analysis</td>
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<tr>
<td>GP</td>
<td>General Practitioner</td>
</tr>
<tr>
<td>HCC</td>
<td>Healthcare Commission</td>
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<tr>
<td>HEAPS</td>
<td>Human Error and Patient Safety incident analysis tool</td>
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<tr>
<td>HFACS</td>
<td>Human Factors Analysis and Classification System</td>
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<tr>
<td>HFE</td>
<td>Human Factors and Ergonomics</td>
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<tr>
<td>HPA</td>
<td>Health Protection Agency</td>
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<td>HRA</td>
<td>Health Research Authority</td>
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<td>HSE</td>
<td>Health and Safety Executive</td>
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HSIB – Healthcare Safety Investigation Branch

IRAS – Integrated Research Application System

LIIPS – Leicestershire Improvement, Innovation and Patient Safety Unit

MIT – Massachusetts Institute of Technology

NDM – Naturalistic Decision Making

NHS - National Health Service

NICE – National Institute for Health and Care Excellence

NPSA – National Patient Safety Agency

PCT - Primary Care Trust

PPG - Patient Participation Group

PPI - Patient and Public Involvement

RCA – Root Cause Analysis

RCS – Royal College of Surgeons

RCT – Randomised Controlled Trial

RMF – Risk Management Framework

SCM – Swiss Cheese Model

SCS – Safety Control Structure

SEIPS – Systems Engineering Initiative for Patient Safety model

SHA - Strategic Health Authority

STAMP – Systems-Theoretic Accident Model and Processes
Chapter 1 - Introduction

1.1 The research problem

In the year 2000, reports from the UK’s Department of Health (Department of Health, 2000) and the USA’s Institute of Medicine (Institute of Medicine, 2000) attracted much attention to the issue of patient safety in healthcare. In the UK’s NHS hospitals it was estimated that adverse events causing harm to patients occur in around 10% of admissions, costing around £2 billion a year in additional hospital stays (Department of Health, 2000). Both reports discuss the importance of building up knowledge and learning through the effective investigation and analysis of adverse events, which can be used to develop remedial actions for safety improvement.

In the present day (2018), concerns have been raised about the effectiveness of current practice regarding the investigation and analysis of healthcare adverse events in both the UK and USA. Issues around the quality of investigations and their resulting ineffective recommendations, which often focus on retraining frontline staff and small policy change, have been linked to both practical and theoretical limitations. Investigations are undertaken by clinical professionals who lack the time and safety expertise for comprehensive investigation (Peerally et al., 2016; Trbovich and Shojania, 2017). Theoretical concerns regard the prominent use of the Root Cause Analysis (RCA) technique which is limited by its reductionist nature (Wu, Lipshutz and Pronovost, 2008; Kellogg et al., 2016; Peerally et al., 2016; Trbovich and Shojania, 2017).

Potential pitfalls in incident or accident investigation and analysis have been known to the safety research community for some time. Accident investigation is used in other safety critical industries, such as aviation, nuclear and rail, to learn from failure and create action plans to avoid future occurrence (Salmon et al. 2011). With these safety critical industries in mind, there have been continual research efforts to improve safety knowledge and investigation and analysis methods. This knowledge should be of benefit to healthcare in their
learning from adverse events and development of effective safety improvements.

When studying past events, the objectivity of an investigation can be compromised by psychological bias. One bias, the hindsight bias, occurs due to the investigator having knowledge of the outcome of an event and working backwards to try to understand how this event occurred (Woods and Cook, 1999). The knowledge of outcome gives rise to the tendency for those making judgements of past events to overestimate the how foreseeable an outcome would be to those involved at the time of the event (who would not have knowledge of outcome) (Fischhoff, 1975; Woods and Cook, 1999). Further to this, there is an outcome bias, where a negative outcome, as in an adverse event such as a patient suicide, can influence the judgement of the processes and decisions linked to that outcome. Research has shown that those with knowledge of a negative outcome, judge the process, decision or action linked to that outcome more severely (Woods and Cook, 1999).

Accident analysis is shaped by explanations of cause, with an investigation normally stopped when an investigator is satisfied with the identification of causes and the explanation of an accident (Rasmussen, 1990). This satisfaction is based on an investigator’s subjective stop-rules which are influenced by their background knowledge and practical considerations, reasons for stopping include: the inability to follow a causal path due to missing information; a familiar abnormal event is found to be a reasonable explanation; or, a cure is available (Rasmussen, 1990). Investigations can be open to the influence of organisational culture and an analyst’s own self-interest (Dien, Dechy and Guillaume, 2012). Investigation outcomes may be influenced by organisational hierarchy, with efforts made to protect the organisational image and the role of senior managers (Dien, Dechy and Guillaume, 2012).

These pitfalls can lead investigations towards a narrow focus on human error and the actions of those closest to an incident, the frontline workers (Woods and Cook, 1999). However, research in safety argues that accidents in complex systems, such as healthcare, are rarely singularly caused by the actions of individual workers (Perrow, 1984; Rasmussen, 1990; Reason, 1995).
Rather than explaining accidents as simply resulting from errors of frontline workers, knowledge from safety research guides us to view them as a symptom of deeper system problems. Furthermore, frontline workers are viewed as the creators of safety with their adaptations and actions often diverting potential accidents before they happen (Woods and Cook, 2002; Hollnagel, 2014).

Research on accident causality has fed into the development of models and methods to guide investigations and analyses to be more systematic and objective. Accident causation models underpin approaches to accident investigation and influence how data are collected, how causal factors are identified and how an accident is explained (Leveson, 2004; Lundberg, Rollenhagen and Hollnagel, 2009). Some accident models, such as the Domino Model (Heinrich, 1931), view accidents as the result of a simple linear chain of events. These models may work well for simple systems and failures of physical components, but are not thought to be sufficient for the investigation of accidents in complex systems (Leveson, 2004). A different type of accident causation model has been developed for large, complex systems, with their multiple interactions between people, technology, policy and different organisational levels (Leveson, 2004). These systemic accident analysis methods and causation models, based on systems-theory, attempt to expand investigations beyond proximate events and use hierarchical system modelling to assist in the identification of organisational and structural deficiencies (Rasmussen and Svedung, 2000; Leveson, 2004). However, there is a gap between the systemic methods most recently developed in safety research and their adoption in industry incident investigation practices (Underwood, 2013).

In healthcare, the flawed adverse event (accident) investigation practices rely heavily on RCA (Wu, Lipshutz and Pronovost, 2008; Kellogg et al., 2016; Peerally et al., 2016). RCA is based on a simple event chain accident causation model (Hollnagel, 2004) and may not be the most suitable technique for analysing accidents in healthcare systems. There is reason to believe that the adoption of a systems approach could be of benefit to healthcare. However, healthcare has had limited exposure to systems-theory based approaches to
accident analysis and there is little evidence of their application in the UK. Furthermore, there is limited understanding of how a systems approach could be integrated into healthcare accident analysis given the practical limitations of current practice. This is the area this research aims to address and provides the motivation for the studies that form this thesis.

1.2 Systemic accident analysis and the focus on STAMP
There are three main systemic accident analysis methods that have been identified, regularly used and cited in safety literature (Salmon et al., 2011; Underwood and Waterson, 2012; Underwood, 2013), those being: AcciMap (Rasmussen and Svedung, 2000); Functional Resonance Analysis Method (FRAM) (Hollnagel, 2004, 2012); and Systems-Theoretic Accident Modelling and Processes (STAMP) (Leveson, 2004, 2012).

Both AcciMap and STAMP model systems in node-link diagrams (Ware, 2013) as hierarchical structures that represent different levels of a sociotechnical system. In AcciMap the causal factors of an accident are identified at the different levels of the hierarchy and represented as the nodes, with the factors linked to their effects to illustrate how one factor influenced the other (Branford, Naikar and Hopkins, 2009), an illustrative example is provided in Figure 1. This causal linkage shows similarities with event chain methods, which are criticised for the subjectivity in identifying the causal links between events (Leveson, 2004). Hollnagel has previously noted a similarity between AcciMap, the Domino Model and RCA in their focus on causal factors (Hollnagel, 2012) and this is a potential limitation of AcciMap. Furthermore, it has been suggested that while the levels of the hierarchy facilitate the analysis and graphical representation, the levels constrain the analysis by limiting it to these levels, which are perhaps not generally applicable to all work systems (Hollnagel, 2012). This thesis seeks to improve the analytical approach to patient safety incident investigation and analysis, which currently involves RCA, due to AcciMap’s focus on causal factors, it is felt that it may not be optimal for providing a different perspective to incident analysis than provided in current practice.
The developer of AcciMap, Jens Rasmussen, also developed the Risk Management Framework (RMF) and ActorMap (Rasmussen, 1997; Rasmussen and Svedung, 2000), with an example shown in Figure 2. The RMF views risk management as a control problem, with accidents and incidents seen as resulting from the loss of control of a hazardous physical process capable of injuring people or damaging property (Rasmussen, 1997). The RMF models the sociotechnical system involved in risk management and the multiple levels of decision-making including politicians, managers and work planners involved in the control of safety by the use of laws, rules and instructions (Rasmussen, 1997). Rather than focussing on an event chain, the model represents the actions decision-makers take to control safety (down arrows) and the information they receive from the lower system levels to inform them of the status of the work system (up arrows). AcciMap can be used in conjunction with the RMF (Waterson and Jenkins, 2010) but it is often used
alone and AcciMap method guidance describes AcciMap as a stand-alone method (Branford, Naikar and Hopkins, 2009).

Figure 2 The socio-technical system involved in risk management, adapted from Rasmussen 1997

STAMP, developed by Nancy Leveson, builds on the ideas behind the RMF. Noting some limitations of the RMF, the development of STAMP sought to emphasise system development processes alongside operations and components of control beyond information flow. Furthermore, the developer aimed to provide a classification of specific factors involved in accidents (Leveson, 2004).

In analysing an accident, STAMP explains accidents as the result of inadequate enforcement of safety-related constraints. STAMP models the control structure (see Figure 3) in place to enforce safety constraints on system development and system operation. Work systems are viewed as interrelated components that are kept in dynamic equilibrium by control-feedback loops.
The control structure model includes the controllers in the system, those being the individuals, groups and technology that can influence the behaviour and status of the system (Leveson, 2012). These controllers are represented as nodes, with the links between the nodes representing the control-feedback loops. The down arrows represent a reference channel and the control actions taken to enforce safety constraints on the system level below. The up arrows represent a measuring channel and the feedback of information on the status of the lower system level that is returned so the controller can adapt its behaviour and control actions if necessary (Leveson, 2004, 2012, 2015). The operating process in the bottom right corner of Figure 3 shows a model of decision-making, this accommodates the need to consider the role that human decisions and the interactions among decisions by multiple, interacting decision makers play in accidents (Leveson, 2004).

**Figure 3 Generic STAMP control structure model, adapted from Leveson 2012**

STAMP benefits from considering and modelling the control-feedback connections between system components, rather than causal links between...
events. STAMP also clearly embodies systems theory concepts (Underwood and Waterson, 2014), but it may have a limitation in its usability characteristics and practitioners have previously reported difficulties in using STAMP (Underwood, Waterson and Braithwaite, 2016). It should be mentioned that AcciMap may benefit from greater usability, but this author feels that STAMP has more potential to provide a different perspective to patient safety incidents, by shifting focus away from causal links. STAMP also further benefits from giving more emphasis to system development alongside system operation.

FRAM is another option as a systemic approach to accident analysis. It is an interesting approach, quite distinct from AcciMap and STAMP in that it does not include a hierarchical model of a sociotechnical system and is more focussed on performance variability. When used in accident analysis, FRAM is said to consider what should have gone right, but did not, rather than focussing on what went wrong (Hollnagel, 2012). The developer of FRAM, Erik Hollnagel, criticises both AcciMap and STAMP, stating that the methods are limited by their reliance on a system model or model of an accident. Hollnagel suggests the models place an a priori interpretive structure on the accident event, which means the value of the results are dependent on the correctness of the model. Although the model improves the efficiency of the approach, simplified models may contain incorrect assumptions (Hollnagel, 2012). It is true that for system models to be usable they need to provide some simplification of reality and assumptions are made, however system models provide useful tools for the communication of results and ideas (Hettinger et al., 2015). FRAM does use some graphical descriptions of its results, but the graphical element is relatively unstructured and Hollnagel considers FRAM a method not a model, contrasting the approach with STAMP and AcciMap. The main problem this author had with FRAM when considering the use of the method was the difficulty in understanding the approach. There was also a lack of example applications to guide understanding at the time of this research. These difficulties meant FRAM was not given further consideration for use.

In summary, STAMP is chosen as the focus of this research for several reasons, namely: its theoretical underpinning in systems theory and clear embodiment of systems theory concepts (Underwood and Waterson, 2014);
its movement away from identifying causal links between events; its structured
consideration of human decision-making (Leveson, 2012), a critical
component in the operation of healthcare systems; and the availability of
method guidance (Leveson, 2012) and example applications (Leveson et al.,
2016; Pawlicki et al., 2016; Raman et al., 2016).

1.3 Research aims and objectives
This research aims to further the current understanding of the application of
STAMP to healthcare incident analysis by meeting the following objectives:

- To describe the known issues in healthcare incident analysis current
  practice.
- To evaluate the application of STAMP to healthcare incident analysis
  with healthcare stakeholder input.
- To examine the effectiveness of the approach and issues regarding its
  adoption.

1.4 Research questions
With the stated research aims and objectives in mind the following research
questions will be addressed:

- How do healthcare stakeholders perceive the usability and utility of
  STAMP in application to healthcare incident analysis?
- How effective is STAMP in healthcare incident analysis?
  - Can STAMP be used in the analysis of different types of
    healthcare incident?
  - Can STAMP be used in the analysis of individual incidents and
    the aggregated analysis of multiple incident data sets?

1.5 Research scope
With the research undertaken in England, it is focussed on the UK’s National
Health Service (NHS) healthcare system. STAMP is applied to incidents, or
adverse events, within the NHS.

The NHS is a huge organisation employing over 1.5 million people (NHS
Choices, 2016) with a budget of around £123.5 billion for 2017/18 (Department
of Health, 2015). The government is responsible for healthcare in the UK, with the NHS funded by taxation and free at the point of use for all UK residents (NHS Choices, 2016), with the NHS in England dealing with over one million patients every 36 hours (NHS Choices, 2016).

The NHS has a responsibility for the safety of the patients they are treating and define patient safety as the avoidance of unintended or unexpected harm to people during the provision of health care (NHS Improvement, no date). NHS organisations are advised to record incidents relating to patient safety so learning can take place to reduce the risk of similar incidents occurring again, the NHS National Reporting and Learning System receives over two million reports each year (NHS Improvement, 2017).

1.5.1 Terminology
Within safety literature, and NHS patient safety practice and documentation, the terms accident, incident and adverse event are all used to refer to events where something has gone wrong. Definitions of these terms can differ greatly between industries and disciplines. Leveson (Leveson 2012, p. 181) has given a definition of an accident as: ‘an undesired or unplanned event that results in a loss of human life or human injury, property damage, environmental pollution, mission loss, etc.’ The Leveson definition is used within this thesis for accident, incident and encompasses other terms for patient safety incidents such as adverse event.

1.6 Thesis structure
The thesis structure is shown in Figure 4. The thesis is comprised of eight chapters which are summarised below:

Chapter 1 - This chapter gives an overview of the thesis. Introducing the research problem, the research aims, objectives and questions, and the structure of the thesis.

Chapter 2 - The second chapter presents a review of the background literature most relevant to the thesis. This includes literature on accident investigation, accident analysis methods and issues in healthcare incident investigation.
Chapter 3 - This chapter describes the research approach, research design, methodology and ethical approval process for this research. Case study procedures are detailed, including the criteria for evaluating STAMP applications.

Chapter 4 - This chapter presents the first case study applying STAMP in healthcare. The case study begins with an interview study investigating the issues with current practice healthcare incident investigation. Following this, STAMP is applied to the large-scale failings at Mid-Staffordshire NHS Trust and its hospital between 2005 and 2009. The reports from the public inquiry into the events are used as data for the analysis. This is combined with interviews and a workshop with healthcare stakeholders to gain insight into their perceptions of the usability and utility of STAMP.

Chapter 5 – Following on from Case Study 1, this chapter presents the second case study which examines the application of STAMP to a small-scale hospital-based medication incident. STAMP is applied with input from the healthcare stakeholders involved in the original RCA-based investigation. Building on from Case Study 1 the stakeholders’ perceptions of STAMP are collected.

Chapter 6 - In this chapter the third case study is presented. STAMP is applied in the analysis of 41 suicide incidents of community care patients from one Mental Health Trust. The findings from the STAMP analysis are contrasted with findings from interviews with 20 community-based mental health professionals on how their practice creates safety in suicide prevention.

Chapter 7 – This chapter discusses the findings of the research and performs a cross-case analysis. The themes from the case studies are presented, the application of STAMP is evaluated, analytical generalisations made and limitations to the research considered.

Chapter 8 - This chapter summarises the main findings and presents the conclusions of the research. The contribution to knowledge is presented and the potential for future research is discussed.
Chapter 1
Introduction

Chapter 2
Background literature

Chapter 3
Research approach

Chapter 4
Case Study 1: Application of STAMP to a large-scale hospital-based incident

Chapter 5
Case Study 2: Application of STAMP to a small-scale hospital-based incident

Chapter 6
Case Study 3: Application of STAMP to community-based healthcare incidents

Chapter 7
Discussion

Chapter 8
Conclusions and future work

Figure 4 Outline of thesis
Chapter 2 - Background literature

2.1 Introduction
To work towards the aims and objectives of this research, a first consideration is what has been done before and the background literature to the research and research problem. This chapter presents a literature review that sets the scene of how issues in healthcare incident analysis relate to the wider accident analysis literature and how analytical techniques developed in safety research may be able to improve incident investigation in healthcare. The review introduces literature on accident analysis in safety critical industries and the current state of incident investigation in healthcare. Moving towards ways to improve healthcare incident analysis, attention is given to the systemic accident analysis techniques most highly valued in safety science research. The final sections of the review focus on the application of the systemic accident analysis approach of STAMP in healthcare.

2.2 Identification of literature
The area of interest for this review, in accident analysis, is a large topic within Human Factors and Ergonomics (HFE) and safety literature (Salmon et al., 2011). The size of the topic does not lend itself well to a systematic search of literature, at least for the initial purpose of the review. The author’s education in HFE and background reading around the topic area gives an awareness of key literature and authors, such as Jens Rasmussen, James Reason, Erik Hollnagel and Nancy Leveson. This knowledge was used as a starting point for identifying literature for the review.

Previous work has reviewed accident causation models (Hollnagel, 2004; Underwood, 2013) and when new accident analysis methods are introduced they tend to be presented with a critique of other methods (Rasmussen and Svedung, 2000; Leveson, 2004, 2012; Hollnagel, 2012). Rather than duplicate previous work, this review uses this literature to give an overview of accident causation models and analysis methods as an introduction into the research within this thesis. Similarly, there are numerous textbooks on accident
investigation (Johnson, 2003; Salmon et al., 2011) and these are used to give an overview of the area. Research in accident analysis has tended to focus on developing and refining theories on accident causation and the development of methods for accident analysis (Woodcock, 1995). But considerations of bias and other factors influencing the outcome of accident investigations are also important (Woodcock, 1995) and these are also considered within the review.

The latter parts of this review concern the application of STAMP in healthcare and a literature search is used to identify relevant articles. The strategy used here includes the search of a resource provided by the STAMP community at the Massachusetts Institute of Technology (MIT) (http://sunnyday.mit.edu/STAMP-publications-sorted.pdf), electronic databases (Scopus, ScienceDirect and PubMed) and web search engines (Google, Google Scholar) with multiple search terms and following reference trails provided by identified literature. The review is limited to English language literature.

2.3 Learning from accidents

Several reasons have been given for studying past events (Benson, 1972), for accident analysis, the reasoning would fit with the aim of developing systematic knowledge about the world to improve our ability to predict and control (Benson, 1972; Fischhoff, 1980). Accident analysis is motivated by the future prevention of accidents, which requires that we understand how they happen so we can improve our ability to effectively guard against them (Hollnagel, 2004). Prior to considering this analysis of accidents, it is first necessary to explain what literature in the area considers an accident to be.

Hollnagel (2004) discusses the origin of the word accident, noting that dictionary definitions include reference to unpredictability, lack of human intention and loss or injury. The term accident can also be used to refer to an event, the outcome of an event, or the possible cause (Hollnagel, 2004). Hollnagel (2004) uses the term to refer to the event, not outcome or cause and defines an accident as ‘a short, sudden, and unexpected event or occurrence that results in an unwanted and undesirable outcome’ (Hollnagel 2004, p. 5). The event or occurrence must be the result of human activity, either directly or
indirectly (Hollnagel, 2004). Leveson (2012) uses a similar definition, noting that definitions of basic terms can differ between disciplines and industries, she provides a definition that reflects usage in system safety, defining an accident as: ‘An undesired or unplanned event that results in a loss, including loss of human life or human injury, property damage, environmental pollution, mission loss, etc.’ (Leveson 2012, p. 181). These definitions of an accident encompass failures of many forms and degrees of severity, and a range of phenomena referred to in safety research and practice, including incidents and adverse events (Hollnagel, 2004).

From the definitions alone, it is obvious why there is a desire to prevent accidents and prevention of accidents is of great concern when failure in an organisation’s activity has the potential for catastrophic consequences. This is the case in so-called safety critical industries such as nuclear, rail, aviation, shipping, oil and gas, and healthcare. People using and coming into contact with these services place trust in the organisations providing the service to prevent accidents and maintain safety (Johnson, 2003). There are numerous examples of accidents in these industries with consequences in loss of human life, financial cost and damage to an organisation’s reputation. To use just two examples to illustrate the cost of accidents: The capsizing of a ferry off the coast of Zeebrugge in 1987 involving failure in the closure of the ship’s water tight bow doors, was reported to result in 192 people drowning and millions of pounds in cost to the organisation that owned the ferry (Hopkins, 1999); The 1984 toxic gas leak from a chemical plant in Bhopal in India killed at least 2000 people, injured over 200,000 and resulted in a settlement of $470 million to be paid to victims (Hopkins, 1999).

Organisations have a responsibility to prevent accidents that could result from their activities, along with being bound by regulations, organisations in safety-critical industries employ safety management systems to control and manage safety (Johnson, 2003). These systems include accident reporting mechanisms that aim to reduce the frequency of accidents and mitigate their consequences through learning from the analysis of the accidents reported (Johnson, 2003). There is a recognition that it may be unrealistic to prevent all accidents (Hollnagel, 2004), however it is recommended that organisations
learn as much as possible from accidents when they occur (Reason, 2008). As a process, accident analysis is much like other research and investigative endeavours, Salmon et al. (2011) summarise a generic accident analysis procedure as shown in Figure 5. The process includes a search for data on an accident, the use of methods to analyse this data and the generation of recommendations to prevent future accidents.

The quality of the accident analysis process is important in maximising learning from accidents and the prevention of future accidents. This includes how data on the accident is collected, the analysis methods available (Salmon et al., 2011) and how people and organisations react to accidents. The quality of an accident investigation can be affected by both the analysts and the influences on them, and the analytical approach taken, with numerous works discussing how these factors influence investigation outcome (e.g. Lundberg et al. 2010; Rasmussen 1990; Woods & Cook 1999; Dien et al. 2012).

2.4 The current state of incident analysis in healthcare
At the time of writing, several recent papers have reported on a dissatisfaction in current practices in healthcare incident analysis in both the UK (Peerally et al., 2016) and USA (Kellogg et al., 2016; Trbovich and Shojania, 2017). Incident investigations are said to focus on individuals rather than organisational factors (Vincent, Taylor-Adams and Chapman, 2000) commonly resulting in poorly designed and ineffective remedial actions, which often focus on staff retraining and changes in policy (Wu, Lipshutz and Pronovost, 2008; Kellogg et al., 2016; Peerally et al., 2016). This ineffectiveness has been linked to the limitations in the choice of analyst and analytical approach. Investigations are generally undertaken by busy clinical staff, who lack safety expertise, as a side task to their main work activities.
(Peerally et al., 2016) and these analysts are guided by a flawed reductionist approach in the root cause analysis technique (Peerally et al., 2016; Trbovich and Shojania, 2017). This criticism of current practice in healthcare incident analysis touches upon concerns well known to HFE and safety science research on accident analysis.

2.5 Accident analysis and bias
Woodcock (1995) has written on bias in accident analysis and highlights the significance of analysts themselves, in that regardless of the actual processes of an accident, it is the causes identified by the analyst that determine the generation of recommendations. Accident analysis is shaped by causal explanations and causal attribution (Rasmussen, 1990; Hollnagel, 2004; Leveson, 2012), with humans having an almost innate desire to determine cause when faced with an accident (Hollnagel, 2004). This desire is linked to a human motivation to relieve anxiety, with a feeling of power given through tracing an unknown back to a known (Nietzsche, 1990; Hollnagel, 2004).

Although the motivation for finding an explanation for an accident may be high, the process of assessing an event after the fact gives rise to complications. When backtracking from an accident effect, people trace back searching for facts related to the accident from which they can explain why it has happened and to determine its cause (Hollnagel, 2004).

Researchers have described difficulties in this causal analysis and efforts in understanding past events by following a chain from effect to cause. The search for cause might be influenced by certain types of bias, derived from both motivations and common cognitive phenomena (Woodcock, 1995). Rasmussen suggests that the search for cause is terminated when an analyst is satisfied that they have an explanation for the accident (Rasmussen, 1990). This satisfaction and resulting termination is influenced by an analyst’s pragmatic and subjective stop-rules, which are dependent on their frame of reference, their familiarity with the context and the analysis aim (whether to explain an accident, allocate responsibility or to make system improvements) (Rasmussen, 1990). It is said there are typical reasons for investigations to be stopped including: the causal path can no longer be followed because
information is missing; a familiar, abnormal event is found to be a reasonable explanation; or, a cure is available (Rasmussen, 1990). There is a tendency for the analyst to see what they expect to find and a sensitivity to the topics discussed in their professional community (Rasmussen, 1990). Lundberg et al. (2010) describe some sources of bias in accident analysis as being well known, referencing Chris Johnson’s handbook on incident and accident reporting (Johnson, 2003), they summarise the following types of bias:

- Author bias, a reluctance to accept findings from investigations undertaken by others.
- Confirmation bias, a tendency to seek to confirm previously held beliefs about cause.
- Frequency bias, occurring when analysts regularly observe certain causal factors, a tendency to classify causes into common categories irrespective as to whether those causes applied to the incident.
- Recognition bias, arising when analysts have a limited vocabulary of causal factors. An analyst may attempt to make an incident fit to one of those factors, potentially disregarding the complexity of the incident circumstances.
- Political bias, where those with a high status can unduly influence investigation outcome.
- Sponsor bias, where the desire to protect the image of the investigated or investigatory organisation influences the investigation.
- Professional bias, where the analyst is drawn to identifying incident causes that are acceptable to their colleagues. (Johnson, 2003; Lundberg, Rollenhagen and Hollnagel, 2010)

The phenomena of hindsight and outcome bias are also identified in the literature as potentially influencing accident investigation (Woods and Cook, 1999; Dekker, 2006). Hindsight bias is well-documented in psychology literature (Woods and Cook, 1999) and refers to the effect of knowledge of accident outcome on an analyst’s judgement. With hindsight, having the accident to look back upon enables the analyst to judge the sequence of events leading up to a known negative outcome, giving them more information than the people involved in the accident had at the time. This more complete
knowledge gives rise to the tendency to overestimate the predictability or foreseeability of that outcome to those involved in the processes prior to the accident (Fischhoff, 2003; Woods & Cook, 1999). Further to this, there is an outcome bias, where a negative outcome, as there is in an accident, can influence the judgement of the processes and decisions linked to that outcome. Research has shown that those with knowledge of a negative outcome, judge the process, decision or action linked to that outcome more severely (Woods and Cook, 1999).

In the description of cognitive phenomena, such as hindsight and outcome bias, the safety literature often references works in experimental psychology. As it is useful to give an understanding of the research that gave rise to considerations of analyst bias this literature is discussed in Appendix 1. For clarity and flow, the following sections only consider work that is directly related to accident analysis.

2.5.1 Bias and influencing factors in accident investigation

There is a lack of literature directly examining bias in accident investigation and few empirical studies have been found. Seven experimental works were identified (summarised in Table 1) and two interview-based studies with accident investigators (summarised in Table 2), but most works in this area are theoretical discussions of the issues. The empirical studies are reviewed following a summary of the theoretical discussion in the area.

As briefly introduced in section 2.5, Rasmussen (1990) has discussed the issue of ambiguous and implicit stop-rules that determine when a causal search stops and define an analyst’s causal explanations. Within this discussion, Rasmussen proposes that an analyst will focus on what they consider to be abnormal, searching backwards through a chain of events and attempting to explain all conditions through discovery of events or acts that they find abnormal (Rasmussen, 1990).

This identification of abnormality can be a big factor in an analysis but is dependent on an analyst’s familiarity with the accident context, with the analyst interpreting events by consulting precomputed schemas and frames of
reference (Kahneman and Miller, 1986; Rasmussen, 1990; Woodcock, 1995). In the case of accidents, the analyst will also be making comparisons with mentally constructed representations. Kahneman and Miller (1986) have developed theory on the use of norms in human interpretation of events and causality. They say that experienced events are interpreted in a rich context of remembered past experiences and constructed representations of what could have been, might have been, or should have been (Kahneman and Miller, 1986). In the case of examining events leading up to serious accidents, events may be compared to counterfactual alternatives that are constructed ad-hoc, rather than retrieved from past experience (Kahneman and Miller, 1986). Events will be considered abnormal if they don’t meet the expectations of an analyst and they are able to retrieve or construct alternatives for what should have been (Kahneman and Miller, 1986). This gives some indication of how the thinking of an analyst can mould an accident investigation.

It is thought that an analyst’s frame of reference can affect the full process of an accident investigation, not only the interpretation of information, but also the search for possible causes (Woodcock, 1995). For efficiency, an accident investigation will require the formulation of initial informal ideas on causality to guide the gathering of relevant evidence and information (Johnson, 2003). The ideal is for this process to continue in an iterative loop, whereby understanding gained by the evidence informs the analyst who can then update their original beliefs on the causes of the accident (Johnson, 2003). However, this ideal can be limited by an individual’s interpretation of cause and its dependency on their subjective frame of reference (Johnson, 2003). In turn, an analyst’s frame of reference can be restricted by their initial view of the accident and lead the analyst to seek evidence that supports this view (Johnson, 2003). Different analysts may bring different frames of reference to the search for cause and the interpretation of an accident (Woodcock, 1995; Woodcock et al., 2005). Identification of cause can depend on what the analyst has learned previously (Woods et al., 2010), discussions and trends in the analyst’s professional community (Rasmussen, 1990), and there is evidence from experimental work of analyst background affecting accident interpretation (Svenson, Lekberg and Johansson, 1999).
2.5.1.1 Experiments examining analyst bias

Seven studies involving experiment-based investigations into analyst bias and influencing factors were identified and are summarised in Table 1. The limited number of relevant studies may be due to the difficulties in investigating real world accident investigations in a controlled manner. Indeed, a number of the identified studies use students as participants, rather than trained accident investigators, and only examine the interpretation and analysis component of an investigation, missing the search for information about the accident, a limitation noted by Woodcock (1995).

One set of studies can be grouped as directly related to attribution theory (Mitchell and Wood, 1980; Dejoy, 1987; Lacroix and Dejoy, 1989; Hofmann and Stetzer, 1998) (see Appendix 1 for discussion of attribution theory). These studies focus on the role of supervisory workers in the analysis of accidents and the factors that influence their attribution of cause in relation to the worker they are supervising. The studies reference Green and Mitchell’s (Green and Mitchell, 1979) attributional model and stress the distinction between causes that are internal and causes that are external to the worker. Internal causes would include the worker’s personality, ability or effort. External causes would include difficulty of task, environmental factors, available support and quality of information (Mitchell and Wood, 1980). Supervisors are shown to have a general bias for attribution to internal worker cause (Mitchell and Wood, 1980; Dejoy, 1987; Hofmann and Stetzer, 1998), with poor work history and increased severity of accident consequences increasing the rate of internal attributions (Mitchell and Wood, 1980). When attributions are directed at internal worker factors, remedies are in turn directed at the worker in the form of training or punishment (Mitchell and Wood, 1980). There are conflicting results on whether the proposal of remedial action is affected by accident consequence severity, with a study involving nurses and nursing supervisors showing increasingly punitive remedies with increased consequence of accident (Mitchell and Wood, 1980). These findings were not replicated in a study involving student participants (Lacroix and Dejoy, 1989). These studies, whilst having robust experimental design, were limited by the approach to accident stimulus, with participants given information about an accident and
then providing ratings of severity and responsibility. This approach lacked the realism of an investigation’s information search and depth of analysis.

Other research has shown the reading of accident reports to reinforce pre-existing views, with participants’ previously held beliefs affecting their interpretation of accidents (Plous et al., 1991). In a series of experiments by Plous, participants read excerpts regarding the accident at Three Mile Island in 1979 and the 1980 false missile alerts at the USA’s Strategic Air Command. Prior to reading the excerpts, the participants reported their beliefs and attitudes regarding nuclear energy and nuclear deterrence. After reading the excerpts, the participants were asked open and closed questions on their conclusions on the safety of nuclear energy and nuclear deterrence. Plous found that those that supported the technologies prior to reading the excerpts focussed on the safeguards in those technologies working, whereas those with prior opposition focused on the occurrence of the failure. Furthermore, after reading about a technological breakdown, supporters felt the chance of a catastrophic accident was lower than they previously assumed, in contrast opponents reported the opposite (chance of accident higher than previously assumed) (Plous et al., 1991). These findings show a confirmation bias style effect called biased assimilation (Lord, Ross and Lepper, 1979; Lord and Taylor, 2009). Biased assimilation is said to occur when perceptions of new evidence are interpreted in a way which assimilates the information into pre-existing assumptions and expectations (Lord and Taylor, 2009). Plous suggest this effect could be reduced through giving analysts explicit instructions to be as objective and unbiased as possible, this strategy has previously produced reductions in the biased assimilation effect (Lord, Lepper and Preston, 1984).
Table 1: Studies on bias and factors influencing accident analysts

<table>
<thead>
<tr>
<th>Study</th>
<th>Research design</th>
<th>Participants</th>
<th>Accident stimulus</th>
<th>Main findings</th>
<th>Main limitations</th>
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<tbody>
<tr>
<td>Mitchell and Wood, 1980</td>
<td>Repeated measures (counterbalanced)</td>
<td>23 nursing supervisors</td>
<td>Patient safety incident</td>
<td>General bias for attributions to nurse (nurse as cause, remedy directed at nurse)</td>
<td>Analysts provided with accident report rather than complete full investigation</td>
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<tr>
<td></td>
<td>Repeated measures (counterbalanced)</td>
<td>23 nursing supervisors</td>
<td>Patient safety incident</td>
<td>Attribution to nurse and severe consequence resulted in nurse directed remedy</td>
<td>The more serious the consequences, the more punitive the remedy</td>
</tr>
<tr>
<td>DeJoy, 1987</td>
<td>Independent measures</td>
<td>153 students enrolled on risk management course (role of worker supervisor)</td>
<td>Multiple-cause occupational accident: 6 versions/conditions</td>
<td>Supervisors focus on internal worker causes when faced with conflicting causal information</td>
<td>Analysts provided with accident report rather than complete full investigation</td>
</tr>
<tr>
<td>LaCroix and DeJoy, 1989</td>
<td>Independent measures</td>
<td>162 students enrolled on risk management course (role of worker supervisor)</td>
<td>Multiple-cause occupational accident: 8 versions/conditions</td>
<td>Internal causes produced greater ratings of worker responsibility and worker-directed corrective actions</td>
<td>Analysts provided with accident report rather than complete full investigation</td>
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<tr>
<td>Plous, 1991</td>
<td>Lab-based Observational</td>
<td>43 students: 22 supporters and 21 opponents of nuclear energy/deterrence</td>
<td>Three Mile Island nuclear accident 1980 USA false missile alerts</td>
<td>Prior beliefs affected interpretation of accidents</td>
<td>Participants not trained/experienced investigators</td>
</tr>
<tr>
<td>Study</td>
<td>Research design</td>
<td>Participants</td>
<td>Accident stimulus</td>
<td>Main findings</td>
<td>Main limitations</td>
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<tr>
<td>Lab-based observational</td>
<td>45: 24 pro-deterrence</td>
<td>1980 USA false missile alerts</td>
<td>Prior beliefs affected interpretation of accidents</td>
<td>Analysts provided with excerpt rather than complete investigation</td>
<td></td>
</tr>
<tr>
<td>Hofmann and Stetzer, 1998</td>
<td>Independent measures</td>
<td>63 students</td>
<td>Three Mile Island nuclear accident</td>
<td>Prior beliefs associated with participant interpretation of accident</td>
<td></td>
</tr>
<tr>
<td>Svensson et al., 1999</td>
<td>Lab-based observational</td>
<td>40 students (20 engineers, 20 psychologists)</td>
<td>Patient safety</td>
<td>Supervisors tended to attribute cause to worker more often than workers</td>
<td>Anonymous survey responses</td>
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<tr>
<td>Lekberg, 1997</td>
<td></td>
<td></td>
<td>Manipulated informational cues (internal or external cause)</td>
<td>Workers in teams that communicated about safety issues were more likely to attribute to internal cause</td>
<td></td>
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<tr>
<td>Woodcock et al., 2005</td>
<td>Observational Simulated</td>
<td>15 practicing safety specialists, from a wide spectrum of industries</td>
<td>Occupational accident</td>
<td>Main study aim was to evaluate simulation technique rather than investigate bias</td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Research design</td>
<td>Participants</td>
<td>Accident stimulus</td>
<td>Main findings</td>
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<tr>
<td>Quasi-experimental</td>
<td>Simulated investigation</td>
<td>106: Various job backgrounds</td>
<td>Aviation scenarios</td>
<td>Experience in investigations increased fact retrieval</td>
<td>Participants did not seem to favour a category of fact over another based-on background</td>
</tr>
<tr>
<td></td>
<td>Simulated investigation</td>
<td>15 investigators</td>
<td></td>
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<tr>
<td></td>
<td>Simulated investigation</td>
<td>16 given HFE training</td>
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</table>
Other studies have considered the influence of analyst background on investigation outcome. Svenson et al. (1999) compared legal and HFE perspectives on the analysis of three patient deaths during dialysis in hospital. A legal inquiry was contrasted with analyses by analysts with psychology (20 psychology students) and engineering (20 engineering students) backgrounds. The legal analysis attributed responsibility to an individual nurse, a result linked to both the analyst's background and the analysis aim. In contrast, the psychology and engineering analysts attributed responsibility to other agents along with the nurse, including the equipment constructor, instructors and hospital management. The study reported that the identification of acceptable solutions was related to the analyst's professional background, with the engineers identifying more solutions to avoid future incidents than the psychologists (Svenson, Lekberg and Johansson, 1999). The authors of the study advise that analysts with differing professional training should perform investigations jointly.

The study by Svenson et al. (1999) is weakened by its use of students as participants rather than experienced investigators and its lack of realism regarding the provision of an accident report to the analysts. Woodcock et al. (2005) criticise previous studies and their limitations in lacking similarity to real-world investigation tasks, with participants analysing reports rather than undertaking an investigation. They created a simulated investigation for studying the reasoning of accident investigators, with participants having experience of safety practice or investigation. An interesting finding of the first study by Woodcock et al. (2005) was that each participant retrieved different factors in the search for information about the accident. Furthermore, there was little overlap among the participants in terms of factors considered, leading Woodcock et al. to question whether safety practitioners have a common knowledge base. In contrast to earlier experiments, that found supervisors to have an attribution bias towards internal worker causes, the investigator participants emphasised management and design-centred factors more often than worker-centred factors in identification of cause (Woodcock et al., 2005). The role (e.g. analyst, attorney) of the investigators did not predict the type of conclusions reached in the investigations and overall the studies did not find
consistent bias based on analysts’ industry background (Woodcock et al., 2005). The second study of Woodcock et al. (2005) also investigated the use of analytical tools to aid investigators and found that when used more factors contributing to an accident were identified.

To summarise this set of experiments, it seems that although supervisors may be biased towards attributing causality to worker-based factors, the experience of safety professionals can lead investigations towards other managerial and design-based factors. Prior-beliefs do seem to influence the interpretation of accidents, but this has not been tested in full accident investigations or with trained investigators.

2.5.1.2 Studies interviewing accident investigators
In studies that interview accident investigators (shown in Table 2), participants tend to report influences that relate to organisational factors and pressures, rather than flawed thinking (Lundberg, Rollenhagen and Hollnagel, 2010). Lundberg et al. (2010) found themes on practical considerations during both the investigation of an accident and the design of remedial actions, and Johnson (2003) has reported on influences that can affect investigator decision-making. Both of these studies make reference to confirmation bias that arises when an analysis is conducted to simply confirm an initial hypothesis of an accident’s cause (Johnson, 2003); or remedial actions are already considered prior to the analysis, with data collection aimed at these preconceived ideas (Lundberg, Rollenhagen and Hollnagel, 2010). Ambiguity in decisions to halt a causal search also appear in the interviews, with descriptions including stopping based on an investigator’s feeling and satisfaction, and stopping when remedial actions can be formed, or not going beyond what is practical to deal with (Lundberg, Rollenhagen and Hollnagel, 2010).

Other reported influencing factors have a link to an analyst’s frame of reference, in frequency bias, recognition bias and professional bias (Johnson, 2003). Frequency bias occurs when investigators become familiar with certain causal factors that are frequently found in investigations, future accidents are then likely to be classified according to common causal categories (Johnson, 2003).
Similarly, recognition bias is described as arising when investigators have a limited vocabulary of causal factors, they then attempt to make accidents fit with those factors irrespective of the circumstances of the accident (Johnson, 2003). Professional bias occurs when an investigator’s professional colleagues or peers favour particular outcomes from causal analysis, the investigator may then be influenced to fit their analysis to the accepted outcomes (Johnson, 2003).

Table 2 Interview studies with analysts reporting on factors influencing investigation outcome

<table>
<thead>
<tr>
<th>Study</th>
<th>Method</th>
<th>Participants</th>
<th>Main findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reported in Johnson, 2003</td>
<td>Interview, survey, observational studies</td>
<td>Accident investigators</td>
<td>Author bias, confirmation bias, frequency bias, recognition bias, political bias, sponsor bias, professional bias</td>
</tr>
<tr>
<td>Lundberg et al., 2010</td>
<td>Interview study</td>
<td>22 accident investigators (different domains)</td>
<td>Factors leading investigations away from ideal mostly organisational rather than related to flawed thinking</td>
</tr>
</tbody>
</table>

  Practical considerations during investigation:
  - Expertise and competencies
  - Investigation resources
  - Availability of data
  - Political considerations
  - Stop rules

  Practical considerations during design of remedial actions:
  - Expertise and competencies
  - Potential risk created by remedies
  - Fixes may be decided upon prior to investigation
  - Decisions on implementation may not be up to investigator
  - May be outside of organizational boundaries/control
  - Ease of implementation considered
  - Cost-benefit balance
  - What is known to work

A note should be made about the limitations of these studies. In the case of Johnson (2003) the methods and results are not well reported, the description of the identified biases occur in a textbook and empirical work is referred to, but not described and no original reference relating to the data collection is provided. Lundberg et al. (2010) do a much better job of reporting a study, but
their data collection is limited to interviews, with findings subject to what investigators are able to articulate and willing to report.

2.5.1.3 Organisational influences in accident analysis

Several of the factors influencing accident investigations identified in the research (Johnson, 2003; Lundberg, Rollenhagen and Hollnagel, 2010), are related to organisational influences, with accident investigators not immune to the organisational and political pressures that surround them. Accident analysis has been summarised as a series of decision-making that is open to influence by organisation culture and the self-interests of the analysts themselves (Dien, Dechy and Guillaume, 2012). With accident investigators being normal human beings, constrained by common cognitive and organisational limits on rationality (Sagan, 1994; Dien, Dechy and Guillaume, 2012).

Investigations are susceptible to the effects of organisational culture and hierarchy protecting the organisational image and the roles of high-level executives (Sagan, 1994; Dien, Dechy and Guillaume, 2012). This is seen in two biases described by Johnson (2003): sponsor bias, which occurs when an investigation is influenced by the potential effect on the prosperity or reputation of the organisation the investigator manages or is responsible for; and political bias, arising when a high-status individual’s judgement commands influence because of their status rather than the value of the judgement itself (Johnson, 2003). Lundberg et al. (2010) also note the influence of management on investigation findings: management may be defensive when faced with criticism of themselves and may question the validity of findings; and decisions on remedial actions may also be outside of the investigator’s power and open to influence from an organisation’s hierarchy (Lundberg, Rollenhagen and Hollnagel, 2010). Sagan (1994) argues of the importance of considering the issues of power and interests in organisational safety. Organisational hierarchy plays a role with the lessons and actions favoured by the most powerful actors (the managers and executives at the top of the hierarchy) often taking precedence (Sagan, 1994). This is evidenced with the assertion of many technological accidents being blamed on human error by operators (the most
proximate cause) rather than faulty design or mismanagement by higher levels (Sagan, 1994).

Dien et al. (2012) mention the effects of a culture of efficiency, which leads investigators to focus on manageable causes where corrective measures are within organisational boundaries. This is evidenced in interviews with investigators, who suggest they may avoid suggesting remedies that are outside of organisational boundaries, are difficult to implement, aren’t known to work, or don’t fit with cost-benefit considerations (Lundberg, Rollenhagen and Hollnagel, 2010).

Accident investigators can be positioned both internally and externally to the organisation under investigation. External investigators could be more independent than internal investigators and less susceptible to organisational culture and hierarchical pressure, finding it easier to question things that an internal investigator couldn’t (Dien, Dechy and Guillaume, 2012). However, having external investigators is not considered a perfect solution, as they may be disadvantaged with a lack of understanding of power relationships and historical trends (Dien, Dechy and Guillaume, 2012). Alongside the consideration of the position of the investigation team is investigator competency, with a broad expertise needed for high quality investigations. Johnson (2003) considers a need for expertise in the domain under investigation, accident investigation itself, along with technical, engineering and human factors expertise. Dien et al. (2012) adds a need for knowledge of organisational approaches to safety to competencies in carrying out accident investigation.

The aim of an investigation is a further factor that will influence an investigator’s approach and interpretation of an accident. Rasmussen (1990) contends that an accident analysis can be done for explanation, allocation of responsibility or for system improvements. Accident explanation requires finding a cause or causes that are familiar to the analyst (Rasmussen, 1990). Allocation of responsibility will require tracing back events to identify a person who made an error and were in power of their actions (Rasmussen, 1990). Whereas system improvement is said to require a focus on the causal network and identification
of an effective cure (Rasmussen, 1990). An example of these differences found in the empirical work is seen in Svenson et al. (1999) where a legal analysis was compared with a Human Factors analysis, while the legal analysis focusses on an individual and allocation of responsibility, the Human Factors analysis considers other agents and environmental factors.

2.5.2 Section summary
This section considered the biases and organisational factors that can influence the interpretation of accidents and investigation outcomes. These biases can be both internal to the analyst, in terms of their thinking and cognitive bias, and external to the analyst, in the form of pressure to appease their organisation and managers. These factors are an important consideration in any efforts to improve healthcare incident investigation practices.

2.6 Accident analysis and analytical approach
A potential way of overcoming issues regarding flawed thinking in accident investigations is in the use of analytical tools that can guide analysts and the investigation process. Much of the focus in attempts to improve accident investigation has been on refining theories on accident causation and the development of methods for accident analysis (Woodcock, 1995; Rasmussen, 1997; Hollnagel, 2004; Leveson, 2004). Research developments regarding accident causation, the evolution of causation models and the development of corresponding analytical approaches has been reviewed previously (Hollnagel, 2004; Underwood, 2013). There is no desire for this review to duplicate work, so within this thesis this literature is covered somewhat superficially. More attention is given to STAMP and its previous application in healthcare.

2.6.1 Perspectives on accidents and models of accident causation
Reason (2008) has considered four perspectives that can be taken when viewing unsafe acts: the plague model, person model, legal perspective and system perspective. The plague model is described in terms of a reaction to epidemiological studies linking error and human error to deaths (such as to the Harvard Medical Practice Study (Brennan et al., 2004)). Human error gets put
into the terms of an epidemic and analyses conducted with this line of though would likely result in countermeasures focussing on the removal of error. Reason considers this a misleading perspective in terms of confusing error with its occasional bad consequences, pointing out that humans are fallible, with errors arising from highly adaptive mental processes (Reason, 2008).

The issue of attributing the cause of an accident to human error has been discussed at length elsewhere (e.g. Rasmussen 1990; Woods & Cook 1999; Woods et al. 2010). To summarise the issue, research in safety has given an understanding that organisations can migrate towards risk, the stage for an accident being prepared through time by the efforts of workers under competing pressures to be both efficient and thorough (Rasmussen, 1990). These normal everyday variations in a worker’s performance can release an accident, however, had that particular action or cause been avoided by some additional safety measure, the accident would very likely be released by another cause at another point in time (Rasmussen, 1990). Furthermore, there are complications in defining human error with reference to normal practice when the work is less procedural and stable, and involves complex decision-making (Rasmussen, 1990; Leveson, 2004). Therefore, explaining accidents in terms of events, acts and errors is felt to have limited application for improving the design and safety of systems (Rasmussen, 1990).

Following on from the plague model are the person and legal models, which both can continue to allow focus on human error and human as hazard thinking. The person model takes a view of unsafe acts as mostly arising from wayward mental processes such as inattention and at times, culpable negligence. With this perspective, countermeasures will often be aimed at individuals through means such as retraining and blaming (Reason, 2008). The person model is popular and appealing to organisations and particularly managerial levels due to its focus on the frontline of a work system (Reason, 2008). Reason (2008) believes the appeal is due to the ease of identifying proximal causes and the errors of people, which means an investigation need not look any further. Furthermore, the focus on errors at the frontline minimises organisational responsibility (Reason, 2008). The legal perspective takes a view that highly trained responsible professionals (e.g. doctors, pilots) should not make errors,
this view has a focus on culpability and punitive counter measures (Reason, 2008). The final perspective is in the system model, which in Reason’s view is an accident explanation that goes beyond local events and considers contributing factors in the organisation and system.

Further reflection of perspectives in accident investigation are seen in the development of accident causation models, which form the basis for investigating and analysing accidents (Leveson, 2004). The choice of accident model used in accident investigation is of fundamental importance as it can influence an investigation in terms of data collected, analysis outputs and investigation outcome (Lundberg, Rollenhagen and Hollnagel, 2009). Hollnagel (2004) in reviewing the development of accident causation models has categorised the models into three groups: sequential, epidemiological and systemic. Previous work has reviewed these model types and their strengths and weaknesses (e.g. Hollnagel 2004; Leveson 2012; Underwood 2013), so they will only be summarised here.

Sequential accident models were the first models developed in safety research and are the simplest type. They views accidents as occurring as the result of a chain of events, with an unexpected event initiating a sequence of events and consequences where the last one is the accident (Hollnagel, 2004), examples of this model type are the domino model (Heinrich, 1931) and the accident evolution and barrier model (AEB) (Svenson, 1991; Hollnagel, 2004; Reason, 2008). An investigation underpinned by this model and view of accidents would seek to identify cause-effect links, working backwards from an accident to identify underlying causes (Hollnagel, 2004). The main criticism of this model type is its oversimplification of accidents, particularly in complex cases and work systems, and the tendency to identify human error as the cause, an issue that has been well covered in previous works (Rasmussen, 1997; Hollnagel, 2004; Leveson, 2004; Salmon et al., 2011). Leveson (2004) considers these sequential models as working well for accidents caused by physical components and for relatively simple systems, but that they are ineffective for the analysis of accidents in larger systems with interactive complexity.
The second category of accident causation models given by Hollnagel (2004) are the epidemiological models, which describe an accident in analogy with the spreading of disease (Hollnagel, 2004). These models have added considerations of the contributions to accidents of performance deviations in technology and human workers, and environmental conditions (Hollnagel, 2004). The models feature consideration of barriers that could prevent accidents and the concept of latent conditions, conditions that are present within the system long before an accident occurs but that can contribute when other events trigger an accident. Latent conditions can include system design, resource provision and managerial decisions, among other things (Hollnagel, 2004) and are in-line with research on large-scale accidents that pointed to the need for accident explanation to be in terms of structural and organisational properties, rather than just a causal chain of events (Perrow, 1984; Rasmussen, 1990). Hollnagel considers the Swiss Cheese Model (SCM) (Reason, 1997) to be an example of an epidemiological model, however, Reason disagrees with this categorisation and argues that SCM has a systems view. Reason (2008) holds a belief that all accident causation models meet the criteria for the systemic perspective and considers them all to have their uses, with no single right view of accidents. He sees a model’s practical utility as most important (Reason, 2008).

The third category of accident model provided by Hollnagel (2004) is the systemic model. Models and methods within this category focus on the performance of a system as a whole, including both social and technical aspects (Hollnagel, 2004; Leveson, 2004; Salmon et al., 2011). The systemic view of accidents has been developed to fit with increases in size and complexity of human organisations. It was felt that viewing accidents as resulting from a chain of events was too simplistic and ineffective for accidents within complex systems. Rather than viewing accidents as resulting from a chain of events, systemic models view accidents as an emergent property of the overall system, arising from interactions between system components (Hollnagel, 2004; Leveson, 2004; Salmon et al., 2011). Systemic models consider the relationships between different parts of a system and how they interact with each other (Leveson, 2004). Systemic accident analysis models
and methods are highly valued in the research community (Leveson, 2004; Underwood and Waterson, 2013), however, Reason (2008) has warned that going too far with the systems perspective could be counterproductive for safety. Reason suggests that a severe systems perspective could lead to an excessive reliance on system measures and undervaluation of personal qualities. These personal qualities are important and necessary for system function, with frontline personnel unable to quickly redesign a system, but they can have the resolve to go the extra mile (Reason, 2008). People could fall prey to learned helplessness, thinking they can’t do anything as the problem is with the system (Reason 2008). Still, systemic accident analysis methods are generally more highly regarded within the research community than other methods, especially for use in analysing accidents in complex systems (Hollnagel, 2004; Leveson, 2012; Underwood and Waterson, 2014).

2.6.2 Implications for healthcare incident analysis

This discussion of the theoretical basis behind accident analysis methods has implications for healthcare, especially when considering that the RCA method adopted frequently by healthcare organisations is based on a sequential model of accident causation. Accident analyst methods guide an investigation and its analysts in the understanding of an accident scenario and the generation of effective recommendations, and potentially reduce the effect of bias.

The complexity of healthcare systems would lead us to believe that sequential models and methods are not the most appropriate to use for incidents occurring within healthcare organisations. Healthcare systems have previously been described as sociotechnical systems, or complex systems containing social and technical aspects (Carayon et al., 2006) and they can be said to display several of the characteristics of complex sociotechnical systems provided by Vicente (1999), including:

- A large problem space, with many factors to consider, such as the many different causes of ill-health.
- Social, with healthcare services composed of many different healthcare professionals, staff and patients that need to work together to make the system function effectively.
- Heterogeneous perspectives, with space for conflicting values amongst
  the various healthcare stakeholders.
- Dynamic, the effects of worker and stakeholder actions can be delayed,
  with workers having to anticipate the future state of the system.
- Hazardous, there is a high degree of potential hazard. Inappropriate
  human beliefs, decisions and actions can potentially jeopardise public
  safety.
- Coupling, healthcare systems can be composed of many interacting
  subsystems.
- Uncertainty, there tends to be uncertainty in the data available to
  workers. With workers assessing the state of the system through
  imperfect data, from clinical diagnostic techniques for example.
- Mediated interaction, with goal relevant properties unable to be directly
  observed by the human perceptual system, for example the blood
  pressure of a patient in an operating room.
- Disturbances, with workers within healthcare services having to deal
  with unanticipated events and having to improvise and adapt (Vicente,
  1999).

So, there is reason to believe that the systemic accident analysis methods
developed for use in analysing accidents in complex systems would be more
effective in healthcare than RCA.

Previous research efforts regarding patient safety and incident analysis have
developed incident analysis methods for healthcare or adopted methods from
other industries. However, most of these efforts have used methods that are
based on sequential or epidemiological accident causation models. For
example, the London Protocol (Taylor-Adams and Vincent, no date; Vincent,
Taylor-Adams and Stanhope, 1998), has been developed in the UK to guide
healthcare incident analysis. The protocol and associated research (Taylor-
Adams, Vincent and Stanhope, 1999; Vincent, Taylor-Adams and Chapman,
2000; Vincent, 2004) provide guidance for conducting interviews in incident
investigations and a framework for the identification of contributory factors
such as organisational, team and equipment factors. The thinking behind
the contributory factors framework is based on the Swiss Cheese Model and
Reason’s work on organisational accidents (Reason, 1997) and is therefore associated with an epidemiological accident causation model. The framework has been integrated into current practice RCA application and should help identify factors beyond individual person factors. But as an analytical approach, it uses a clear cause-effect link (Hollnagel, 2004) and does not model the work system or do enough to examine the interactions between system components. Similarly, the Human Error and Patient Safety (HEAPS) incident analysis tool (Wakefield, 2007; Western Australian Department of Health, 2011) developed in Australia and licensed by ErroMed (website no longer exists) has a focus on contributory factors. Other efforts have included the adoption of Failure Modes and Effects Analysis (FMEA) (Institute for Healthcare Improvement, no date; Day et al., 2006; Ashley and Armitage, 2010). FMEA is associated with a sequential event chain model and is criticised for conceptualising an accident as a linear chain of events, doing little to show other relationships between components within the work system (Leveson, 2004).

The Systems Engineering Initiative for Patient Safety (SEIPS) model (Carayon et al., 2006, 2014; Holden et al., 2013), shown in Figure 6, is another relevant approach. The SEIPS model was developed as a framework for understanding the relationships between structures, processes and outcomes in healthcare. The SEIPS model emphasises system interactions and feedback loops, with healthcare organisations able to make changes in response to the collection, analysis and use of process and outcome data (Carayon et al., 2014). The model has been used to examine patient safety, including risk assessment and can be used to make sense of incident data (Carayon et al., 2014), but SEIPS does not provide a systemic accident analysis method as such, rather a high-level framework to guide patient safety work.
Within the literature the systemic accident analysis methods of AcciMap, STAMP and FRAM are among the most commonly cited (Underwood, 2013). However, while regularly used in research, it is said the use of systemic accident analysis methods is less popular in industry accident investigation practices and work needs to be done to bridge the gap between research and practice (Underwood, 2013; Underwood and Waterson, 2013; Underwood, Waterson and Braithwaite, 2016). This thesis is focussed on the application of STAMP in healthcare, with the potential of STAMP in healthcare and some justification for the choice of STAMP introduced in Chapter 1. Further understanding of STAMP and justification for choosing the approach over AcciMap and FRAM can be found in the literature.

When it has been compared with AcciMap and SCM-based methods, STAMP has been said to more clearly embody system theory and to benefit from showing the interactions between system components (Underwood and Waterson, 2014). Moreover, STAMP benefits from modelling the safety structure of a system, rather than just focussing on the accident itself, giving a deeper understanding of the system under analysis (Salmon, Cornelissen and Trotter, 2012). Another benefit of using STAMP is the availability of comprehensive method guidance (e.g. Leveson 2012) and the many examples...

Figure 6 Systems Engineering Initiative for Patient Safety (SEIPS) model, adapted from Carayon et al. 2006 and Holden et al. 2013
of past applications found in the literature, this is in contrast to FRAM which despite being the subject of a book (Hollnagel, 2012), lacks structured method guidance. Furthermore, there are few published examples of FRAM being applied to accident analysis, which could be used to guide an application. The remainder of this review will focus on STAMP and what can be learnt from literature on its previous application.

2.7 STAMP

STAMP was developed by Nancy Leveson at MIT and there are several texts detailing STAMP (Leveson, 2004, 2015; Leveson et al., 2012). In keeping with the other systemic methods, STAMP has been developed due to dissatisfaction with sequential linear accident models and to overcome the limitations in explaining accidents in terms of events, acts and errors (Rasmussen, 1990, 1997; Hollnagel, 2012; Leveson, 2012). In STAMP’s view, accidents occur when there is an inadequate enforcement of safety constraints on system components, resulting in the loss of control of a hazardous process (Rasmussen, 1997; Leveson, 2012). What sets STAMP apart from other methods is its control theory focus, the consideration of control and feedback loops puts STAMP in line with the SEIPS framework for patient safety work. STAMP also contains techniques for both prospective risk assessment and retrospective accident analysis. Systems-Theoretic Process Analysis (STPA) is the hazard analysis technique that can be used in risk assessment, Causal Analysis based on STAMP (CAST) is the accident analysis technique (Leveson, 2012). Both STPA and CAST are based on STAMP’s view of safety and accident causation.

Following influence from systems theory, STAMP describes a system as a hierarchy of control based on adaptive feedback mechanisms (Leveson, 2012) as shown in Figure 7. This hierarchical structure is also found in AcciMap, but differentiating STAMP is the representation of interactions and communication between the different levels of a hierarchy as control-feedback loops. At each level of the hierarchy the actors that can affect the status of the system are represented as controllers e.g. decision-makers at government and regulatory levels all the way down to an organisation’s frontline operations. In the model,
the arrows connecting the controllers represent control-feedback loops present at each system level; control actions are sent down to enforce safety constraints at lower levels, with feedback on the status of the lower system levels returned up the hierarchy. The returned information (feedback) updates the mental model of a controller in terms of the status of the component they are controlling, control actions can then be updated in accordance with this information to maintain control. STAMP also considers the behaviour-shaping mechanisms on these controllers and their decision-making, including their safety responsibilities, the context of their work, environmental factors and how this has influenced any unsafe decisions. Another important feature of STAMP is its consideration of safety constraints and control in both the design and operations of the system.

Figure 7 Example of safety control structure, adapted from Leveson, 2004
Through the consideration of behaviour-shaping mechanisms and the information available to decision-makers at the time of the accident, STAMP can help to alleviate the effect of hindsight bias when making judgements on past human decisions (Leveson, 2012). The system view of STAMP also forces consideration of factors that may normally be omitted from an accident analysis (Leveson, 2004), such as organisational factors, decisions of managers and the design of the system. Which can prevent sole focus on frontline operations or following a line of inquiry based on prejudged factors and initial hypotheses. The developers of STAMP have said that the use of the approach can maximise learning from an accident and can come up with completely different views of accidents and their causes, even when using only the information presented in existing accident reports (Leveson, 2012).

Many articles on STAMP and examples of STAMP applications can be found at the MIT online resource [http://sunnyday.mit.edu/STAMP-publications-sorted.pdf](http://sunnyday.mit.edu/STAMP-publications-sorted.pdf) and this was used in the initial identification of relevant literature. This was followed up by an electronic search.

### 2.7.1 STAMP in healthcare

Few published studies that had applied STAMP in healthcare were identified, those found are summarised in Table 3. Of the four identified studies, two applied STAMP to the analysis of patient safety incidents, the other two used STAMP in a hazard analysis. As an extension to the healthcare sector there were other examples of application in the pharmaceutical and medical device industries, these studies are summarised in Table 4.

The studies reporting on the application of STAMP to the analysis of patient safety incidents (O’Neil, 2014; Samost, 2015; Leveson et al., 2016; Raman et al., 2016) have shown STAMP to have some promise in terms of its ability to generate recommendations to improve healthcare systems. However, the methods of evaluating the application of STAMP have not been comprehensive or sophisticated and the studies predominantly simply demonstrate its application. O’Neil (2014) compares a STAMP analysis and recommendations to those made in an RCA analysis and concludes that the STAMP analysis gave a broader and more comprehensive set of accident
causes and recommendations. The study is limited by using a fictionalised incident story rather than a real live full incident investigation, but the incident story is said to be realistic and used in the training of those conducting incident analysis in healthcare. The other feature of these studies that limits learning on how well STAMP could fit to healthcare is in the lack of evaluation and feedback from the healthcare stakeholders that conduct incident analysis in current practice.

Table 3 Studies applying STAMP in healthcare

<table>
<thead>
<tr>
<th>Study</th>
<th>Area</th>
<th>Analysts</th>
<th>Evaluation</th>
<th>Main findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>O'Neil, 2014 Master's Thesis</td>
<td>Fictionalised hospital pneumothorax incident analysis</td>
<td>Researcher</td>
<td>Demonstration Comparison with RCA</td>
<td>STAMP analysis resulted in a broader set of accident causes and recommendations compared to RCA</td>
</tr>
<tr>
<td>Leveson et al., 2016 Raman et al., 2016 Samost, 2015</td>
<td>Cardiovascular surgery incident analysis</td>
<td>Researchers</td>
<td>Demonstration</td>
<td>Identified the reasons behind unsafe behaviour to be related to system design</td>
</tr>
<tr>
<td>Pawlicki et al., 2016 Samost, 2015</td>
<td>Radiation oncology (hazard analysis)</td>
<td>Teams of researchers and work domain experts</td>
<td>Demonstration Comparison with FMEA</td>
<td>STAMP identified 83 unsafe control actions and 472 causal scenarios</td>
</tr>
<tr>
<td>Chatzmichailidou et al., 2017</td>
<td>Surgical instrument retention (hazard analysis)</td>
<td>Researchers</td>
<td>Demonstration Comparison with BTA</td>
<td>Concluded that STAMP and BTA can complement each other Both produced a set of solutions</td>
</tr>
</tbody>
</table>

RCA: Root Cause Analysis  
FMEA: Failure Modes and Effects Analysis  
BTA: Bow-Tie Analysis

The two studies applying STAMP in hazard analysis both report positively on the use of STAMP (Samost, 2015; Pawlicki et al., 2016; Chatzmichailidou et al., 2017). Along with demonstrating the application of STAMP, the studies make some comparison with the outputs from other hazard analysis methods in Failure Modes and Effects Analysis (FMEA) and Bow-Tie analysis (BTA). Chatzmichailidou et al. (2017) note difficulty in making direct comparisons between STAMP and BTA and instead reflect on how the methods complement each other. Pawlicki et al. (2016) noted some similarity between
the results of FMEA and STAMP, but that STAMP was uniquely different in highlighting the interaction of people, hardware and software.

Table 4 Studies applying STAMP in pharmaceutical and medical device industries

<table>
<thead>
<tr>
<th>Study</th>
<th>Area</th>
<th>Analysts</th>
<th>Evaluation</th>
<th>Main findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leveson et al., 2012</td>
<td>Pharmaceutical industry marketing of unsafe drug (hazard analysis)</td>
<td>Researchers</td>
<td>Demonstration</td>
<td>STAMP generated a new set of recommendations</td>
</tr>
<tr>
<td>Couturier, 2010</td>
<td></td>
<td></td>
<td></td>
<td>Suggest STAMP and systems dynamics can be used to re-engineer entire healthcare systems</td>
</tr>
<tr>
<td>Master's thesis</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Balgos, 2012</td>
<td>Medical diagnostic devices and medical case accident</td>
<td>Researchers</td>
<td>Demonstration Comparison with FMECA</td>
<td>STAMP identified more hazards than FMECA and generated a new set of recommendations</td>
</tr>
<tr>
<td>Master’s thesis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antoine, 2013</td>
<td>Radiotherapy devices (hazard analysis)</td>
<td>Researchers</td>
<td>Demonstration</td>
<td>Demonstrated fit of STAMP to medical device regulatory structure</td>
</tr>
<tr>
<td>PhD thesis</td>
<td></td>
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</tbody>
</table>

FMECA: Failure Mode Effects and Criticality Analysis

Studies applying STAMP in the pharmaceutical (Couturier, 2010; Leveson et al., 2012) and medical device (Balgos, 2012; Antoine, 2013) industries are similar to those in healthcare, in that they demonstrate use through application to a certain device or incident.

Overall, the studies suggest that STAMP works well in the healthcare sector, but there is a lack of evaluation against any specified criteria. Most studies use the demonstration of an application and reflections from the analysts to evaluate the method, but STAMP has been compared favourably to the use of RCA on the same fictionalised healthcare incident (O’Neil, 2014).

2.7.2 STAMP applications in other industries

There are further application examples of STAMP in other safety-critical industries, but of most interest are studies using more sophisticated methods of evaluating the application of STAMP. Three studies were identified that used more formal methods of evaluating an application of STAMP, these are summarised in Table 5.
Two studies (Salmon, Cornelissen and Trotter, 2012; Underwood and Waterson, 2014) compared STAMP with AcciMap and a method based on the Swiss Cheese Model, in the Human Factors Analysis and Classification System (HFACS) and the Australian Transport Safety Bureau model (ATSB). Salmon et al. (2012) liken STAMP to AcciMap in its focus on the entire sociotechnical system, but Underwood and Waterson (2014) suggest that STAMP more clearly embodies system theory, with its visual representation of system structure and interactions between components. Salmon et al. (2012) place a criticism of STAMP on the difficulty of fitting organisational and human failures within its taxonomy of control failures, this issue has potentially been addressed in the thesis of Stringfellow (Stringfellow, 2010) which focusses on human and organisational factors in a STAMP analysis. However, Stringfellow’s taxonomy is underused in published STAMP applications, perhaps being overlooked as a PhD thesis. Further criticism of STAMP come in potentially overlooking environmental conditions and the lack of use of the method outside of academic research (Salmon, Cornelissen and Trotter, 2012). In Underwood and Waterson’s (2014) study, the application time of STAMP was approximately double that of AcciMap and the ATSB model. Underwood and Waterson feel a further limitation of STAMP’s usage characteristics are in the method not lending itself to providing a simple graphical representation of an accident, limiting the ability to communicate the findings of an analysis when compared with AcciMap and the ATSB model. The practitioner evaluation in the third study (Underwood, Waterson and Braithwaite, 2016) also raises questions about the usability of STAMP, with the study’s accident investigator participants disagreeing that STAMP was easy to understand or use. Underwood et al. (2016) highlight a need to improve STAMP’s usability and graphical output.

These studies provide useful insights into the application of STAMP and its strengths and weaknesses. There are some limitations in the literature in only one study providing a practitioner evaluation and that with a low number of participants. None of these studies applied STAMP in healthcare, nor was there any attempt to fit the use of STAMP into a current practice investigation.
<table>
<thead>
<tr>
<th>Study</th>
<th>Area</th>
<th>Analysts</th>
<th>Evaluation</th>
<th>Main findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salmon et al., 2012</td>
<td>Outdoor activity accident</td>
<td>Researchers</td>
<td>Comparison with AcciMap and HFACS</td>
<td>Significant differences found across the 3 methods</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>STAMP had an additional analysis requirement in a need for domain data to construct SCS diagram</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Difficulty placing some of the human and organisational failures within STAMP taxonomy</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>STAMP better placed to identify technical control failures as opposed to complex human decision making and organisational failures</td>
</tr>
<tr>
<td>Underwood and Waterson, 2014</td>
<td>Train derailment</td>
<td>Researchers</td>
<td>Comparison with ATSB and AcciMap using an evaluation framework</td>
<td>STAMP more clearly embodied the concepts of systems theory</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>STAMP provides a visual description of the system structure and shows relationships between components</td>
</tr>
<tr>
<td>Underwood et al., 2016</td>
<td>Simulated investigation (partly field-based) on a rail-based accident scenario</td>
<td>6 accident investigator practitioners (not experienced in STAMP)</td>
<td>Practitioner evaluation via questionnaire and focus group</td>
<td>Use of STAMP resulted in slightly different collection of information about accident compared with ATSB</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Assessment of analyst outputs</td>
<td>Considerable variation among participants in identified system components, safety constraints and factors contributing to the accident. Participants tended to focus analysis at the frontline staff</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Some participants had difficulty in understanding the terminology of STAMP. Participants struggled to apply STAMP</td>
</tr>
</tbody>
</table>

HFACS: Human Factors Analysis and Classification System  
SCS: Safety Control Structure diagram  
ATSB: Australian Transport Safety Bureau model
2.8 Summary and gap in knowledge

This review has presented the known issues in healthcare incident investigation and how these issues relate to HFE and safety research on accident analysis. Healthcare incident investigation is limited by the same bias and influencing factors as found in other industries. These limitations are further compounded by the lack of safety expertise held by the frontline staff undertaking incident investigation, who are in turn guided by RCA, a methodological approach not suited to complex sociotechnical systems. Systemic accident analysis methods are favoured by academic researchers for the analysis of accidents in complex systems, STAMP strongly embodies the systems theory that underpins those methods and benefits from the availability of structured method guidance. However, STAMP has had limited application in healthcare and very little has been done to formally evaluate its application in this domain. Questions have been raised about the usability of STAMP in its application in other industries, but the exploratory nature of this research make the findings somewhat preliminary. There is a gap in knowledge around the application of STAMP to the analysis of healthcare patient safety incidents, including evaluation against specified criteria and in how the healthcare stakeholders that undertake incident analysis perceive the usability and utility of the approach.
Chapter 3 - Research approach

3.1 Introduction
The research problem presented in Chapter 1 and literature review in Chapter 2 has described a motivation to improve incident analysis in healthcare, it is felt that the adoption of STAMP as an analytical approach to incident analysis could improve the quality of investigation. However, the review of literature in Chapter 2 has shown few published studies applying STAMP to healthcare incident analysis and identified a gap in knowledge concerning an evaluation of the usability and utility of STAMP with healthcare stakeholders. This chapter describes the approach this thesis takes to researching the application of STAMP in healthcare and the steps taken to ensure the research is of high quality and undertaken systematically, sceptically and ethically (Robson, 2011). The sections in this chapter present information on the research approach, ethical approval process and the application and evaluation of STAMP.

3.2 Developing the research approach
In broad terms, the research approach has been described as the intersection between philosophy, research design and specific methods (Creswell, 2014). This encompasses the planning stages of research, from broad assumptions, to detailed methods, analysis and interpretation (Creswell, 2014). To develop a research approach, this research draws upon approaches, frameworks and methodology from the social sciences and design research. There is also a consideration for the approaches and methods used by previous research in accident analysis.

3.2.1 Research paradigm
Research endeavours are said to be underpinned by philosophical worldviews or paradigms (Robson, 2011; Creswell, 2014), the research paradigm forms a basis for how the research is undertaken and influences the choice of approach and methods. The research in this thesis relates to an applied research problem and in keeping with this, the approach is underpinned by the
pragmatic research paradigm, fitting the concern with applications and solutions to problems (Creswell, 2014).

Pragmatism is one of several identified research paradigms, the others including positivism and postpositivism, which are often associated with quantitative research, and constructivism and transformative, often associated with qualitative research (Robson, 2011; Creswell, 2014). Pragmatism is often discussed as a way of justifying the combination of both quantitative and qualitative methods in one piece of research (e.g. Robson 2011; Creswell 2014). The pragmatic paradigm fits this thesis due to an emphasis on the research problem rather than a system of philosophy (Creswell, 2014). Methods and procedures are chosen based on the belief that they are the most appropriate for investigating the research problem.

3.2.2 Research design
This pragmatic paradigm opens the research to a choice of qualitative, quantitative or mixed methods and the selection of types of study judged to be most appropriate to understand the research problem and answer the research questions. Robson (2011) has proposed exploration, description and explanation as three common purposes of research. But also discusses an action perspective present in many studies, which go beyond exploring, describing and explaining to facilitate action, help change or make improvements (Robson, 2011). This thesis is not just seeking to describe and explain the current situation in healthcare incident analysis, rather it is concerned with an effort to improve that situation and aims to apply a method (STAMP) in the analysis of incidents and proposal of improvements to the design of healthcare systems. The interest in improvement and the application and validation of a method for design support is congruent with design research and the research conducted in engineering design (Blessing and Chakrabarti, 2009).

Blessing and Chakrabarti (2009) describe one objective of design research as developing and validating design support, that is methods with the aim to improve design. Although they mostly refer to product design in their text, this objective can still hold true for service or system design. They stress the
importance of evaluation, which is needed to determine whether the application of design support leads to more success as determined by defined criteria (Blessing and Chakrabarti, 2009). When considering the aim of incident analysis as preventing future incidents and STAMP incident analysis as a form of design support, the generation of effective recommendations for incident prevention would be a criterion to determine its success. We would want to know whether the application of STAMP leads to the generation of remedial actions that are more effective than those proposed from current practice. But other criteria may also be important in determining the success of STAMP in healthcare. In aiming for improvement as well as understanding, design research is said to require three things:

1. A model or theory of the existing situation
2. A vision (model or theory) of the desired situation
3. A vision of the support that is likely to change the existing situation into the desired situation (Blessing and Chakrabarti, 2009)

To meet these requirements, this research develops an understanding of current practice in healthcare incident analysis, proposes the application of STAMP as a way of improving the current situation and develops a vision of how STAMP can be applied to improve current practice.

These requirements fit into a four-stage framework proposed by Blessing and Chakrabarti (2009) to assist in the planning of design research to improve the chances of obtaining valid and useful outcomes, shown in Figure 8.
These four stages and the activities within those stages are used to guide the design of the research within this thesis and can be briefly summarised as follows:

1. **Research clarification**: this stage aims to identify and refine the research problem that is the subject of the research, setting a realistic research goal through the analysis of literature. An initial description of the existing situation is developed as well as a proposal of a desired situation.

2. **Descriptive study I**: this stage further describes the current situation in the area design support is to be applied in, with the intention to determine which factors should be addressed to make improvements. This stage can use a review of literature or empirical research if the literature is not comprehensive enough.

3. **Prescriptive study**: in this stage the understanding of the current situation is used to further develop the vision of the desired situation.
and develops support aimed at advancing the current situation to the desired situation. An initial evaluation of the success of the support can be made.

4. Descriptive study II: this stage aims to evaluate the impact of the support and its ability to realise the desired situation (Blessing and Chakrabarti, 2009).

It is noted that not all stages need to be completed in every piece of research and the selection will be based on resource constraints and practical considerations, but these four-stages provide a useful framework to give structure to the research within this thesis (as shown in Figure 9). However, first there needs to be further consideration of the type of study that is used in the stages of this framework.

The research problem of this thesis is based on the application of a method in the real-world healthcare context. This leads the research to the field and the messiness of the real-world, where it is necessary to conduct the research in an open system without control over variables that would be maximised in laboratory-based experimentation. Randomised controlled trials (RCTs) are a type of research design and experimental approach, that are used in healthcare and often felt to be the gold standard for research investigation in open systems (Robson, 2011). Experiments are designed to establish causation, with the common feature of deliberately varying something to discover what happens to something else later (Shadish, Cook and Campbell, 2002). Research using RCTs randomly assign participants to groups, one group will receive the intervention being investigated, another group will receive a placebo intervention (there can be more than two groups). What has happened to those two groups is then measured, with the effect being the difference between those that received the intervention and those that didn’t (Shadish, Cook and Campbell, 2002). Experimental designs such as the RCT design are equipped to deal with research questions that ask if an intervention is effective and to measure the size of that effect. However, RCTs and other experimental designs are not equipped to answer how and why type questions directly (Robson, 2011).
The questions this research is attempting to answer are how questions and within the social sciences a different research design, the case study, has been proposed as the preferred approach when the main research questions are of a how and why nature (Yin, 2013). The case study design is also appropriate when the researcher has little control over behavioural events and the focus of the study is a contemporary phenomenon (Yin, 2013). All of which hold true for the research that forms this thesis: the research questions are of a how nature; the research interest includes the real-world healthcare context, where the researcher has little control over behavioural events; and incident analysis and issues with incident analysis are occurring in the present and ongoing, rather than an entirely historical phenomenon. The case study is a well-established research design which involves an empirical investigation of a contemporary phenomenon, within its real-life context, using multiple sources of evidence (Robson, 2011; Yin, 2013). The focus is on a particular case, the case itself could be an individual, group or organisation, and takes into account its context (Robson, 2011). This focus on a single case leads to the main criticism or limitation of the case study design, in the difficulties of making generalisations from a single case to other contexts and situations (Robson, 2011; Yin, 2013). A strategy to overcome this limitation, at least in part, is through a research design using multiple case studies. The evidence from a multiple case design is considered more robust than from a single case design, additional cases can duplicate the findings of the first case increasing the ability to convince of a general phenomenon (Yin, 2013). As in experiment-based research, replication of studies can also include variation of conditions, rather than just duplication of the initial study, one or two conditions can be altered in the additional cases to see whether the findings can still be duplicated (Yin, 2013).

This research employs a multiple case study design, STAMP is applied to patient safety incident analysis in three case studies, with the type of incident varied in each case. The case studies are situated in the design research framework provided by Blessing and Chakrabarti (2009) as shown in Figure 9.
3.3 Research clarification and descriptive stage

The research clarification stage was covered in the Chapter 2 literature review, where the research problem and gap in knowledge were defined. Also present in Chapter 2 was an initial description of the current situation in healthcare incident analysis as presented in the literature. This current situation is further explored as part of Case Study 1 and is presented in Chapter 4. This descriptive stage provides detail on the current situation in healthcare incident analysis and further exploration of how STAMP can fit into current practice. Along with the literature review, the descriptive stage uses interviews with healthcare stakeholders to describe healthcare incident analysis and current issues in this area.

3.4 Prescriptive stage

The prescriptive stage aims to investigate the application of STAMP to healthcare incident analysis, this is done in three case studies. A multiple case study design was chosen to strengthen the ability to make generalisations. Within a case study design, generalisations are made analytically, rather than
statistically, so there is no power analysis to determine the sample size, instead the choice is down to the judgement of the researcher (Yin, 2013). It is suggested that two to three replications are enough when the theory of the research is straightforward (Yin, 2013). As this research relates to the application of an accident analysis approach based on strong theoretical foundations and already applied in safety-critical industry, it is felt that three cases would provide a strong enough replication of findings to contribute to knowledge in the area.

The case studies are not simply a duplication, rather conditions are varied in each case study to provide a greater depth of understanding. The rationale for this is due to the varied nature of the healthcare context, healthcare incidents occur across hospital and community care and can be very different in nature, for example from medication prescription error incidents to patient suicide. The condition of type of patient safety incident is varied between cases: Case Study 1 analyses a large-scale hospital-based organisational incident, Case Study 2 analyses a small-scale hospital-based medication error incident, and Case Study 3 analyses a series of community-based patient suicide incidents. The progression and link between each case study is discussed further in chapters 4, 5 and 6. Five components of research design are considered especially important for case studies: a case study’s questions; its propositions; its unit(s) of analysis; the logic linking the data to the propositions; and the criteria for interpreting the findings (Yin, 2013). Details on each case study, including the selection of participants as units of analysis and methods used are provided in each case study chapter.

The case studies in this research use qualitative data and therefore take into account the fundamental characteristics of good qualitative research, in having an evolving design, the presentation of multiple realities, a consideration of the researcher as an instrument of data collection and a focus on participants’ views (Robson, 2011). The design is evolving in that each case study builds on the last, the case studies recruit multiple participants to give their views on healthcare, incident analysis and STAMP. The role of the researcher is accounted for and presented with each case study. Furthermore, the research follows two general rules for achieving validity in qualitative research, in
ensuring a fit between question, data and method and that each step in the analysis is properly accounted for (Richards and Morse, 2013).

### 3.4.1 STAMP application process

The accident analysis approach of STAMP, Causal Analysis using System Theory (CAST), is the approach used in the analysis of incidents throughout the case studies. In each case study STAMP was applied following the same protocol provided by method guidance. Professor Nancy Leveson, who developed the STAMP approach, has authored several texts which describe the process of applying STAMP. A full description of the process is given in Leveson (2012), in short, the approach is split into nine steps:

1. Identify the system and hazard involved in the loss.
2. Identify the system safety constraints and system requirements associated with that loss.
3. Document the safety control structure in place to control the hazard and enforce the safety constraints.
4. Determine the proximate events leading to the loss.
5. Analyse the loss at the physical system level.
6. Moving up the levels of the safety control structure, determine how and why each successive higher level allowed or contributed to the inadequate control at the current level.
7. Examine overall coordination and communication contributors to the loss.
8. Determine the dynamics and changes in the system and the safety control structure relating to the loss and any weakening of the safety control structure over time.
9. Generate recommendations.

Within the case studies, the author began the incident analysis using the documentary evidence from previous investigations, this is described fully in...
each case study chapter. The safety control structure model diagrams were
produced by the author using Microsoft Visio and discussed with a second
researcher until agreement was reached. In each case study the control
structure models were validated through discussion with healthcare
stakeholder subject matter experts, the models were changed in accordance
to the advice of the healthcare stakeholders where necessary. The diagrams
were used to involve healthcare stakeholders in the analysis and in the
participant evaluation of STAMP. Table 6 summarises the involvement of
healthcare stakeholders and analysts in the different stages of the STAMP
applications for each case study, further detail is provided in the case study
chapters.

Table 6 Summary of people involved in STAMP applications in each case study

<table>
<thead>
<tr>
<th>STAMP steps</th>
<th>People involved</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Case Study 1</td>
</tr>
<tr>
<td></td>
<td>Case Study 2</td>
</tr>
<tr>
<td></td>
<td>Case Study 3</td>
</tr>
<tr>
<td>1 to 3</td>
<td>Author as main analyst, outcomes agreed with another researcher</td>
</tr>
<tr>
<td>Validation of control structure model</td>
<td>9 healthcare stakeholders</td>
</tr>
<tr>
<td>4 to 9</td>
<td>2 researchers</td>
</tr>
<tr>
<td></td>
<td>2 researchers and 21 healthcare stakeholders</td>
</tr>
<tr>
<td></td>
<td>Validation of recommendations</td>
</tr>
<tr>
<td></td>
<td>n/a</td>
</tr>
<tr>
<td></td>
<td>4 healthcare stakeholders</td>
</tr>
<tr>
<td></td>
<td>3 healthcare stakeholders</td>
</tr>
</tbody>
</table>

3.5 Evaluation

A key component of this research is in determining whether STAMP can be
applied effectively in healthcare, this requires a method for evaluating its
effectiveness. In this research the application of STAMP was evaluated
through the perceptions of healthcare stakeholders on the usability and utility
of STAMP in healthcare, and through reflections on demonstrated applications
of STAMP and evaluating these applications against established criteria.

3.5.1 Healthcare stakeholder evaluation

Case studies 1 and 2 involved healthcare stakeholders in the STAMP analysis
of incidents in interviews and workshops and collected feedback on their
thoughts about STAMP. Participants were asked questions that were designed to understand their views on three areas of the application of STAMP in healthcare, in the usability, utility and potential for future application. The participants completed an evaluation questionnaire (see Appendix 4) which required them to state their level of agreement with a number of statements on a 5-point scale (strongly disagree, disagree, neither agree nor disagree, agree, strongly agree) and answer open-ended questions. The following statements and questions were used on the questionnaire:

**Usability**

Statements on usability:

- It was easy to understand the approach
- The approach was easy to apply
- The approach was presented clearly
- The templates provided were useful

Questions on usability:

- Did you have any difficulty in identifying the systems and hazards involved in the incident?
- How understandable did you find the control structure element of the approach?
- Is there something that could make the use of the approach easier?

**Utility**

Statements on utility:

- The approach has given me a different perspective on the incident
- The approach is useful in learning from the incident
- The approach is relevant to healthcare
- The approach can help to make recommendations

Questions on utility:
• How did the use of the approach impact your view and understanding of the incident?
• Are there aspects of healthcare incidents that the approach does not seem to cover?
• How well do you think the approach covers human decisions and control actions in healthcare?

Future application

Statements on future application:

• The approach would be useful in the analysis of future incidents
• Healthcare would benefit from the adoption of the approach
• We would need expert help to apply the approach

Questions on future application:

• Do you feel the approach is something you could learn to use? If so, what kind of support would you need?

General questions

• What did you like about the approach?
• What didn’t you like about the approach?

Further to the questionnaire, the interviews and workshops used to introduce participants to STAMP were audio-recorded. Participants talked through their initial thoughts on STAMP and attempts to use the approach, and were asked to expand on the questionnaire comments by providing further discussion.

3.5.2 Evaluation criteria

Criteria to use in the evaluation of the STAMP application were sought from previous literature. Criteria have been previously developed to evaluate both accident models and investigation methods (Benner, 1985; Katsakiori, Sakellaropoulos and Manatakis, 2009).

The early work of Benner (1985) developed 10 criteria for the evaluation of accident models, these are summarised in Table 7. Whereas, Katsakiori et al.
(2009) provide a set of requirements by which to evaluate accident investigation methods, summarised in Table 8. There are some common themes between the criteria for model evaluation and the requirements for investigation methods, such as: the need to represent reality (realistic criterion, validation requirement), provision of a detailed description of the accident (definitive criterion, descriptive requirement), ensuring the analysis does not lead to an oversimplification of the accident (noncausal criterion, revealing requirement) and a consideration of ease of understanding by non-specialists (visible criterion, practical requirement). The author predominantly uses the Katsakiori et al. (2009) requirements to evaluate the STAMP applications in each individual case study, with reference to Benner’s (1985) criteria made and used in the cross-case analysis presented in Chapter 7.
### Table 7 Benner’s (1985) criteria for accident model evaluation

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Realistic</td>
<td>Model must represent reality: the observed nature of the accident phenomenon, sequential and concurrent events and their interaction with time, risk-taking nature of work processes.</td>
</tr>
<tr>
<td>Definitive</td>
<td>Model must define the data required to describe the accident phenomenon. Model must drive the investigation and analysis methods. Model must use definitive descriptive building blocks.</td>
</tr>
<tr>
<td>Satisfying</td>
<td>Model must contribute to achievement of an agency's statutory mission.</td>
</tr>
<tr>
<td>Comprehensive</td>
<td>Model must encompass the development and consequences of an accident. Model must lead to complete description of the events involved, helping to avoid ambiguity or gaps in understanding.</td>
</tr>
<tr>
<td>Disciplining</td>
<td>Model must provide a technically sound framework and concepts for testing the quality, validity and relationships of data developed during an investigation.</td>
</tr>
<tr>
<td>Consistent</td>
<td>Model must provide guidance for consistent interpretation of questions arising during an investigation.</td>
</tr>
<tr>
<td>Direct</td>
<td>Model must provide for direct identification of safety problems in ways that provide options for their prompt correction.</td>
</tr>
<tr>
<td>Functional</td>
<td>Model must provide functional links to performance of worker tasks and work flows involved in an accident. Must make it possible to link accident descriptions to the work process in which the accident occurred.</td>
</tr>
<tr>
<td>Noncausal</td>
<td>Model must be free of accident cause or causal factors concepts. Addressing instead a full description of accident phenomenon, showing interactions amongst all parties and things, rather than oversimplification.</td>
</tr>
<tr>
<td>Visible</td>
<td>Model must enable investigators and others to see relevance of model to any accident under investigation easily and credibly. Interactions described should be readily visible, easy to comprehend and credible to the public and victims as well as investigators.</td>
</tr>
</tbody>
</table>

### Table 8 Katsakiori et al. (2009) requirements for accident investigation methods

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Descriptive</td>
<td>Method should provide a detailed description of the accident, guidance to identify the complete set of facts relevant to the accident and the theoretical understanding behind the search.</td>
</tr>
<tr>
<td>Revealing</td>
<td>Method should distinguish between events and underlying causes, to guide the investigator to think about underlying causes.</td>
</tr>
<tr>
<td>Consequential</td>
<td>Method should allow for the generation of specific recommendations for accident prevention.</td>
</tr>
<tr>
<td>Validation</td>
<td>The methods should be valid and reliable. A valid method should promote, as far as is reasonably possible, correspondence between findings and reality. A reliable method should facilitate agreement between results and different investigators/users.</td>
</tr>
<tr>
<td>Practical</td>
<td>The method should be practical, in that the analysis can be made by ordinary safety persons, without the need for highly trained experts.</td>
</tr>
<tr>
<td>Application field</td>
<td>The investigation method should account for the specific context of the accident.</td>
</tr>
</tbody>
</table>
3.5.3 Further evaluation

Previous research has evaluated STAMP by contrasting with other accident analysis methods (Salmon, Cornelissen and Trotter, 2012; Underwood and Waterson, 2014), including in healthcare where a STAMP application was compared with RCA (O'Neil, 2014). Case Study 2 uses a similar approach to further evaluate the application of STAMP in healthcare, by contrasting a STAMP analysis output with that of an RCA investigation.

Case Study 3 differs from 1 and 2 in that it does not use a participant evaluation of STAMP. This was partly due to practical reasons of not having enough participant time to involve them in the STAMP application. Instead the findings and recommendations from a STAMP analysis are compared to interviews with healthcare stakeholders on what they found helped them create safety.

3.6 Results analysis

The approach to analysing the results is shaped by the theoretical propositions of the research and the research questions (Yin, 2013). The research has started with the proposition that the application of STAMP could improve healthcare incident analysis. This leads the research to the application of STAMP in healthcare incident analysis and the research questions of how effective STAMP is and how healthcare stakeholders perceive the usability and utility of STAMP? This theoretical proposition guides the case study analysis, pointing to the relevant factors to be investigated and described in describing relevant contextual factors, demonstrating STAMP applications, evaluating those applications and analysing healthcare stakeholder perceptions of STAMP.

The results of each case study were analysed within each case. Participant interviews and workshops were audio-recorded and transcribed verbatim into the qualitative data analysis software, NVivo. NVivo was used to organise and manage this qualitative data, the transcriptions are coded into themes developed around the participants’ views on STAMP. Furthermore, the replication of studies in terms of STAMP application to healthcare incidents, healthcare stakeholder evaluation and evaluation against set criteria allows for a cross-case analysis. The findings from the case studies are compared and
key themes develop across all cases, this is presented in Chapter 7. Chapter 7 also considers a plausible rival explanation or hypothesis (Yin, 2013) in that the effectiveness of STAMP may be greatly reduced due to the influence of factors other than analytical approach to accidents, such as organisational culture.

3.7 Ethical approval and research governance

The process for gaining ethical approval is summarised in Figure 10. As research based in the NHS, the first stage determined whether the study would require governance and/or ethical approval from the Health Research Authority (HRA) or NHS. The requirements for this approval were then completed. In combination, ethical approval was also sought from Loughborough University Ethics Committee. Ethical approval was granted by Loughborough University Ethics Sub-committee (Human Participants) for all three case studies. All study participants gave written informed consent.

Following use of the HRA decision tool (http://www.hra-decisiontools.org.uk/research/) and discussions with NHS research governance managers, it was decided that case studies 1 and 2 did not require HRA or NHS ethical approval. Case study 3 required HRA approval and Loughborough University research sponsorship, but not NHS Research Ethics Committee approval. The process involved completion of the Integrated Research Application System (IRAS) process, development of a research protocol document following the HRA template and governance of study documentation by Loughborough University research office. Research governance was provided by Loughborough University Research Office and Leicestershire Partnership Trust Research and Development Office. The approval letter documentation is provided in Appendix 2 and Appendix 3.
Figure 10 Ethical approval process flowchart
Chapter 4 - Case Study 1

Descriptive stage – Current practice in healthcare incident analysis

4.1 Introduction
The literature review in Chapter 2 introduced the criticism of current practice in healthcare incident analysis (section 2.4). The concerns raised in the literature were based on reviews of incident investigation reports and lacked the views of healthcare stakeholders. The initial investigation in Case Study 1 sought to further explore current practice in healthcare incident analysis through interviews with healthcare stakeholders. This initial exploratory work completes the descriptive stage of the research and aims to provide an understanding of the context for the application of STAMP in the prescriptive studies, to assist in the analysis and interpretation of results.

4.2 Aims and objectives
This study aims to investigate the current state of healthcare incident investigation and related issues. The study has the following objectives:

- To gather healthcare stakeholder perspectives of healthcare incident analysis
- To identify themes in healthcare stakeholder perspectives on incident analysis

4.3 Methods
Interviews were conducted with nine healthcare stakeholders. The interviews were unstructured, with participants asked to describe previous involvement in incident investigations, the methods they've used and for their views on current practice, which led into further discussion.

The study recruited healthcare stakeholders that were involved in patient safety-related work in their organisations (e.g. staff involved in incident
investigations, heads of patient safety in providers and commissioners, patient safety researchers and educators). Participants were contacted by email via patient safety interest groups in the East Midlands regional area, such as the East Midlands Academic Health Science Network (http://emahsn.org.uk/) and the Leicestershire Improvement, Innovation and Patient Safety Unit (https://www2.le.ac.uk/partnership/liips). All participants gave written informed consent. Relevant information about the participants is summarised in Table 9.

Table 9 Summary of interview participant information

<table>
<thead>
<tr>
<th>No.</th>
<th>Role</th>
<th>Healthcare experience</th>
<th>Patient safety investigation experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Commissioner, head of patient safety</td>
<td>28 years</td>
<td>13 years in patient safety roles Knowledge of SCM and RCA</td>
</tr>
<tr>
<td>2</td>
<td>General Practitioner and Senior Lecturer</td>
<td>14 years</td>
<td>Conducted investigations in clinical role and involved in improving methods Knowledge of SCM and RCA</td>
</tr>
<tr>
<td>3</td>
<td>Provider, Trust lead for patient safety</td>
<td>35 years</td>
<td>8 years in role involving review of RCA reports 10 years investigation experience Knowledge of SCM and RCA</td>
</tr>
<tr>
<td>4</td>
<td>Commissioner, quality assurance Previously Chief Nurse</td>
<td>30 years</td>
<td>Involved in investigations and patient safety throughout career Knowledge of SCM and RCA</td>
</tr>
<tr>
<td>5</td>
<td>Nurse and Senior Lecturer</td>
<td>14 years</td>
<td>8 years in clinical and educational roles Knowledge of RCA</td>
</tr>
<tr>
<td>6</td>
<td>Commissioner, deputy director of nursing and quality</td>
<td>34 years</td>
<td>20 years Knowledge of SCM and RCA</td>
</tr>
<tr>
<td>7</td>
<td>NHS Improvement, clinical advisor</td>
<td>32 years</td>
<td>15 years Knowledge of SCM, RCA, FMEA</td>
</tr>
<tr>
<td>8</td>
<td>Hospital medic and patient safety improvement lead</td>
<td>10 years</td>
<td>4 years Knowledge of SCM, RCA, HFACS, AcciMap</td>
</tr>
<tr>
<td>9</td>
<td>Manager of simulation centre</td>
<td>20 years</td>
<td>Involved in patient safety education of clinicians Knowledge of SCM, RCA, HFACS, AcciMap, STAMP</td>
</tr>
</tbody>
</table>

SCM: Swiss Cheese Model  
RCA: Root Cause Analysis  
HFACS: Human Factors Analysis and Classification System  
FMEA: Failure Mode and Effects Analysis

The interviews were transcribed verbatim into NVivo and coded by the author into main themes.
4.4 Findings

In keeping with the literature on healthcare incident investigation, the participants suggested that current practice predominantly uses RCA as the analytical approach. Similarly, the participants’ criticisms of current incident investigation practices were in keeping with previous literature (e.g. Peerally et al. 2016). The main themes arising from the interviews were:

- Analysts may lack safety expertise
- Superficiality with a tendency to focus on individuals and blame
- Analysis outcomes influenced by ease of implementation
- Influence of organisational hierarchy
- Influence of organisational complexity
- Desire to use group discussion in future analysis

These themes are described in the following sections and illustrated with participant quotes.

4.4.1 Analysts may lack safety expertise

The participants described current practice incident investigations and stated they were generally undertaken by clinical healthcare staff. A concern regarding the quality of investigations and analysis was that these staff may be lacking in safety expertise and training in investigation techniques.

‘…it's very complicated, I think you have individuals who may be trained or not-trained in root cause analysis and investigation. I think you've got the quality of the training and that depends on how the training is delivered, who delivers it. I think you've got individuals in place that feel they don't need any training, because they've been there, seen it, done it, so you've got that sort of culture.’ – Commissioner quality assurance (Participant 4)

‘In my experience, I've found that quite often people are not skilled in RCA tools and techniques, they're not following the process as it should be followed. What people seem to find difficult with RCA is actually identifying what the care delivery problems and the service delivery problems are.’ – Regulator clinical advisor (Participant 7)
Participants felt there was a general lack of HFE and safety expertise within healthcare and the staff that undertake investigations, although this was starting to change with more education in HFE and safety.

‘I think it depends on who you speak to, so a lot of the younger consultants and practice development teams and things like that who have grown up with this idea of influences on performance. Not necessarily the jargon of Human Factors but the fact that there are other factors that influence performance. But even when I started 10 years ago, that wasn’t in the curriculum. So, I was never taught to think about how all these things work, think about how the equipment is designed what errors could come into it, we were never taught it, it is in there now, it’s beginning to be in there. So, I think it’s changing.’ – Medic and patient safety lead (Participant 8)

‘I think the technique means that’s how people go around getting the information and I think for a lot of people that we’ve trained in RCA we give them a toolkit and it’s got all of these things in it and they use them quite literally. And we’ve not to this point put in more about the Human Factors element into our training of how we train our investigators.’ – Provider patient safety lead (Participant 3)

4.4.2 Superficiality with a tendency to focus on individuals and blame

Some participants reported that investigations can seem superficial, with a tendency to focus on the actions of individuals, rather than perform a deeper system analysis. Furthermore, there were occasions when the incident reports would seek to attribute blame.

‘...and I think there’s a feeling that perhaps we’re not using incidents to get to the underlying safety issues. That we’re tending to focus mainly on the story of the events without looking at them more deeply to understand what they tell us about the underlying systems, structures, processes of care. And that even when we get that information, we’re not reliably feeding that back to the frontline. So, to some
extent there's arguably a tick box culture about the way we approach safety incidents. Incident happens, we need to do an investigation and we need to come up with action points that we then tick off and we can say right we've done that.' – General Practitioner (GP) and educator (Participant 2)

‘I think if you look at a lot of the investigations, **people will just look at the individual, they won't look at the system.** In healthcare particularly there is still, it's changing, but **there is still that belief that things go wrong because somebody did the wrong thing. And not considering why they did the wrong thing.** That's historical, it's been there for a long time, there's a whole traditional idea of individual blame vs systems blame.' – Medic and patient safety lead (Participant 8)

‘I don’t think the investigations go far enough. I think it's just like a fact-finding mission. Who did what, how did it happen, what time did it happen and what was the outcome out of it, did it affect the patient or not affect the patient. It seems to say okay let's not do that again, but it doesn't seem to go any further and I think from my opinion this is why sometimes we have the same incident happen again. We are very good at finding the facts and almost who gets the blame for it, but it doesn't always go any further than that.’ – Nurse and educator (Participant 5)

‘You've got the blame culture that still is apparent, so not our fault, it was an individual’s fault, when actually it was clearly a system issue… And we still get very defensive reports. **Blaming an individual as well, that tends to come through in some reports we see, which is interesting.**’ – Commissioner quality assurance (Participant 4)

‘…we very rarely find out what a person who was integral to an incident, what was happening for them at that specific moment in time. We don't ask them if they were okay, we don't ask them if they've not been getting any sleep or they were so busy they couldn't think straight. We ask them why they made the error. But **we don't dig into how they were on that day, was it noisy, was it down a telephone, was there any interference. There's lots and lots of things, we don't dig into that as part of RCA**’ – Provider patient safety lead (Participant 3)
4.4.3 Analysis outcomes influenced by ease of implementation

Participants reported a tendency for analysis recommendations to focus on policy and retraining, rather than system design. It was suggested this was due to the difficulties and cost in implementing large organisational change, it is simply easier to retrain an individual or alter a policy and the investigations would focus on remedial action that was easiest to implement.

‘…we looked at the themes and trends and we also looked at the action plans, and they did a piece of work whereby they reviewed the action plans and they found that most of the actions were weak actions. Relying on training staff, putting policies into place, that kind of thing, that wouldn’t fundamentally change practice.’ – Regulator clinical advisor (Participant 7)

‘…we held a learning from incidents workshop recently where we had some focus group discussion. People who are involved in patient safety investigations did say that they come up with actions so that they can demonstrate that they’ve undertaken an action. So, this is an action that we can tick off and we can say that we’ve done it, whereas I don’t think we’re being critical enough of ourselves about the actions that we recommend. And I don’t think that in a lot of cases there’s particularly any expert advice on okay well we’ve come up with this idea that we’ll design a proforma, is this actually the thing that's going to make a difference?’ – GP and educator (Participant 2)

‘So, the recommendations that come out of our reports are generally focussed on retraining or education, raising awareness that the incident has happened, reflection for the people involved, and probably writing a new policy or editing a policy. They will have an impact but they're probably not as effective (as other actions). And there's two reasons why that happens I think: because the analysis isn't in-depth enough, so we can't truly identify where the changes are that will actually make a big difference. But also, going back the old NPSA, I do remember them saying when we read the documentation that they sent out that recommendations should be focussed on things that you can actually do,'
which makes sense of course. So, there's two sides to it, there's the we don't know what the true learning is and then on the other side there are so many barriers in place to put the big effective remedies.’ – Medic and patient safety lead (Participant 8)

‘Our action planning is rubbish, so even if we do quite well on our investigation and almost stumble across the things that need doing, we write an action plan that is very weak. And we tend to fixate on the things that we think we can do. ‘We need a new IT system, has anybody got any money, no? OK’ so what we’ll do is just put a little patch in.’ – Commissioner patient safety manager (Participant 1)

4.4.4 Influence of organisational hierarchy

Some participants suggested that organisational hierarchy had an influence on the individuals undertaking investigations, with motivation for them to focus on areas that would not push responsibility to their seniors.

‘Because we write one report with one action plan. That action plan is supposed to fix it and it’s one action plan from one incident and the people writing it have only got quite a small sphere of control. So, they're not going to write it’s the chief executive’s fault, he needs to invest £2 million in this, it is career limiting. They’re not going to say that somebody in the middle made the mistake, because it’s somebody in the middle that is probably doing the investigation. So, we'll easily just fall for that easy solution which is the nurse gave the wrong drug, we’ll teach the nurse to give the right drug next time…We know it’s not the fix, but the way we do it is we go well we’ll just retrain the nurse. Because that’s the easy one to do. We could look and say, she has 45 patients to look after, she hadn’t had a break, the drug was missing from the trolley, she had to go and get it from somewhere else. And we might write all of that, but when it comes down to it we’ll retrain her, instead of saying that whole piece of that hospital needs restructuring, we need to work it differently, we need a different system for getting our drugs in.’ – Commissioner patient safety manager (Participant 1)
There was a further example of staff being overruled by seniors when raising issues regarding an investigation.

‘...when I raised that issue, I was told it shouldn't have happened anyway. But I think can we look at those issues and make sure that whatever the circumstances the team brief is done, whatever the circumstances there’s a good communication process, or the channel of communication is open. So everybody knows and is aware of what’s happening. I was overruled.’
– Nurse and educator (Participant 5)

4.4.5 Influence of organisational complexity

There was awareness of difficulties for large organisations to effectively learn from incidents and implement effective remedial actions.

‘The frustration I think for, certainly from a commissioning perspective and as a provider in the past, has been I know what I would do with that information and that learning and sometimes the frustration can be you don't actually see that enacted directly. However, I have absolute appreciation of how massive it is, how massive some of these big Acute Trusts and some of the learning, and various people and it’s everybody’s an expert and actually we need to understand exactly what will work within that organisation.’ – Commissioner quality assurance (Participant 4)

A further difficulty in healthcare incident investigation is that incidents can cross organisational boundaries, whereas an investigation may be limited to a single healthcare organisation.

‘And the work that we have been doing really is about how do we do incident investigation and learning from incidents within that kind of more collaborative framework. Because what's happened historically is if something has happened in hospital it has been investigated in the hospital. So, the hospital will look at the things that they did but it's quite likely that the error trajectory would have started somewhere else in the system. So, someone who has a bad hospital outcome, it might be that there were things that went wrong in the hospital, but it
might also be that something went wrong in Primary Care, maybe their admission was delayed or maybe their ambulance didn't arrive promptly. Or something might have happened before they reached the provider where the bad thing might have happened. So, what we’re trying to do is to look at how we do more collaborative investigation. And then how do we get that information back in a timely effective way, to the people who need to learn from it.’ – GP and educator (Participant 2)

4.4.6 Desire to use group discussion in future analysis

Some participants discussed an interest in moving on from current RCA practice, which use statements and individual interviews, to using peer panels and group discussion. The benefit of group discussion was seen in the facilitation of learning and in enabling frontline staff to design their own remedies.

‘So, one of the things that we're trying to investigate is maybe moving away from RCA as such. But using things like peer panels and stuff like that. Now I know there are pros and cons but there's also something around the dialogue and the debate with clinicians.’ – Commissioner quality assurance (Participant 6)

‘...one stage is how do you get the information out of the people who were involved in the incident. Because the information that you need from them is not just what happened but why it happened the way it did. So, for example you might get some information from a nurse on a hospital ward where they say well, we gave the wrong drug and okay that could be the end of your investigation. But you might get out of the nurse well the drug was in the wrong place. What you might get out of a bigger group of people is some discussion about the level behind that, which was well we didn't have enough time to check or we don’t follow the protocol for double signing out of drugs. Or something like that. You’re perhaps less likely to get that out of an interview with a single person, you're more likely to get that maybe out of a group of people talking about the incident together…
...So, one of the models that we're hoping to try is the idea that soon after an incident everyone involved in the incident will sit down together, perhaps with a facilitator and would talk about the incident and go through it. So rather than people being interviewed individually, which seems to be the way things happen now, people can talk about the incident.’ – GP and educator (Participant 2)

‘And what we do there is we get the team that were part of the incident together and sit and it does quite naturally flow. And we've had some good results from that, in that people immediately own what's happening, they've been very open and honest. And we've felt that we've gleaned more information about what things were like at the time, by everybody saying and reminding each other. But it helps people to open-up. And then when it comes to what would we need to change, to stop this happening again or to reduce the chances, they then come up with some of the solutions for that. Rather than a manager writing an action plan and saying here you go this is what you're going to do. And everyone going 'we can't do that' because that's what quite often happens, it feels imposed as well.’ – Provider patient safety lead (Participant 3)

4.5 Summary

The findings provide background and context for the prescriptive studies investigating the application of STAMP in healthcare. One interesting finding is in participants focussing on factors other than the analytical approach used. It may be that healthcare stakeholders have a lack of awareness of methodological issues and instead relate weaknesses in current practice to problems with the analysts chosen and organisational influences. However, some of the issues discussed and the ways the participants see incident analysis moving forward, could be assisted by using STAMP. This provides a vision for how STAMP could help current practice in incident analysis and improve the quality of investigations, by:

- Giving a system perspective and moving the analysis from a focus on individuals and blame.
- Guiding the analysis to consider the wider system, crossing organisational boundaries.
- Providing a system model (safety control structure diagram) that can be used in group discussion. This system model could facilitate an accurate comprehension of factors impacting system performance and provide a basis for a common mental model among stakeholders (Hettinger et al., 2015).

This generalisability of the study findings is limited by the small sample size and the sample of participants (who had an interest in patient safety) may not be representative of the wider healthcare community. Still, the study provides confirmation of findings from previous literature and a basis for understanding the context that STAMP will be applied in. The next part of this case study and the other two case studies apply STAMP to healthcare incidents and evaluate its effectiveness. This vision of how STAMP could improve current practice is used in the evaluation of STAMP and interpretation of findings.

**STAMP application to the 2005-2009 Mid-Staffordshire NHS Trust failings**

4.6 Introduction

The case study now moves into the prescriptive stage of the research and a focus on the application of STAMP in healthcare. Previous research investigating the use of STAMP in a healthcare context has applied the approach to hospital-based incidents of a small scale. For example, surgical adverse events involving small teams (Leveson et al., 2016; Raman et al., 2016) and in hazard analysis of a radiation oncology process (Pawlicki et al., 2016). This chapter presents a case study applying STAMP to a large-scale organisational accident in the healthcare context. A large-scale incident should provide the necessary data for a detailed system analysis to provide a demonstration of an application of STAMP in healthcare and allow for an evaluation of this application. Furthermore, previous research has lacked discourse from healthcare stakeholders regarding their perceptions of STAMP. This study conducts interviews and a workshop with healthcare stakeholders
to capture their thoughts on the usability and utility of STAMP. The failings at the Mid-Staffordshire NHS Trust between 2005 and 2009 offer the opportunity to apply STAMP to an organisational accident.

4.6.1 The Mid-Staffordshire NHS Trust failings
The failings at Mid-Staffordshire NHS Trust between 2005 and 2009 are well publicised and the subject of previous investigations (Healthcare Commission, 2009) and a public inquiry (Francis, 2013a). The initial investigation into Mid-Staffordshire NHS Trust by the Healthcare Commission in 2009 followed-up on reported high mortality rates and concerns from local people about standards of care. The final public inquiry report described the events as conditions of appalling care in the main hospital serving Stafford and its surrounding area between 2005 and 2008 (Francis, 2013a). The public inquiry report put forward 290 recommendations crossing all levels of the health service up to the Department of Health.

4.7 Aims and objectives
This study aims to examine the application of STAMP to a large-scale organisational failure in the healthcare context. To meet this aim, the study has the following objectives:

- To demonstrate the application of STAMP in a healthcare context through the analysis of the Mid-Staffordshire inquiry reports following the STAMP methodological approach
- To examine healthcare domain experts’ perspectives of STAMP’s utility and usability
- To evaluate and reflect on this STAMP application

4.8 Methods
The research design follows a case study approach (Yin, 2013), with documentary analysis and interviews used as data sources. The Mid-Staffordshire Trust case was purposefully selected for accident analysis due to its large-scale, the availability of data in the public inquiry reports and the publicity around the events increasing awareness among participants. The author first applied STAMP to the analysis of the Mid-Staffordshire case,
following this healthcare stakeholders were introduced to this demonstration of STAMP and asked to provide their thoughts on the usability and utility of STAMP in interviews and a workshop.

4.8.1 STAMP analysis

The analysis used the reports from the Healthcare Commission investigation (176 pages) (Healthcare Commission, 2009), the independent investigation under the NHS act (Francis, 2010a, 2010b) and the public inquiry (Francis, 2013b, 2013c, 2013d, 2013a) as data. The first report consisted of two volumes (455 and 367 pages), the public inquiry report consisted of an executive summary (125 pages) and three volumes (692, 668 and 434 pages).

Causal Analysis based on STAMP (CAST) was applied in accordance with Leveson’s published guidance (Leveson, 2004, 2012) and using the organisational error taxonomy provided by Stringfellow (Stringfellow, 2010). An initial analysis was conducted by the author with the analysis outcomes discussed with another HFE researcher until an agreement was reached. The safety control structure from the analysis was initially developed prior to the interviews with the healthcare stakeholders (Table 9) described in section 4.3. The interviewees were used as subject matter experts to validate the control structure model and the model was altered in accordance with the information they provided.

The initial control structure is shown in Figure 30 in Appendix 5, the final control structure is shown in Figure 11. The initial control structure included a model for both system design and system operation and was presented on an A3 sized page. The main change to produce the final control structure was a simplification of the model to make it readable and presentable on A4 sized documents, this included merging the design and operation elements.

4.8.2 Healthcare stakeholder interviews and workshop

4.8.2.1 Interview protocol

The healthcare stakeholders from the descriptive part of the case were introduced to STAMP in their interviews following the discussion of current
practice presented in section 4.3. All nine participants had prior knowledge of the Mid-Staffordshire Trust inquiry, but only one participant had previous knowledge of STAMP. Refer to Table 9 for information about the interview participants. All interviews were conducted by the author.

The interviewees were introduced to STAMP by the interviewer with the use of printed slide handouts (presented in Appendix 6). The interviewer talked through the slides and the theoretical basis of STAMP which was followed by a talk through of STAMP applications in healthcare and the Mid-Staffordshire analysis. An A3 printed copy of the safety control structure developed from the Mid-Staffordshire analysis (Appendix 5) was provided to participants and explained.

The interviews were semi-structured, with participants invited to validate the safety control structure and provide comments on STAMP during the explanation if they wished. Following this the participants were asked to complete the questionnaire on the usability and utility of STAMP (Appendix 4), with their responses followed up on by the interviewer for further discussion. The interviews were between 25 and 110 minutes in duration (mean 60 minutes). There were three shorter interviews of 25 to 30 minutes with participants that had previously attended presentations on STAMP by the author at patient safety events. All interviews were audio-recorded and transcribed verbatim.

4.8.2.2 Workshop protocol

A workshop was used to gather further healthcare stakeholder perceptions of STAMP with more efficient use of time. Workshop attendees were healthcare professionals who were involved in patient safety-related work and were undertaking postgraduate studies in HFE. Table 10 summarises the information about the nine workshop participants.
Table 10 Summary of workshop participant information

<table>
<thead>
<tr>
<th>No.</th>
<th>Role</th>
<th>Healthcare experience</th>
<th>Patient safety investigation experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Clinical lead risk and governance</td>
<td>10+ years</td>
<td>4 years Knowledge of SCM, RCA, AcciMap</td>
</tr>
<tr>
<td>11</td>
<td>Risk manager</td>
<td>7 years</td>
<td>Intermediate Knowledge of RCA, BTA, AcciMap</td>
</tr>
<tr>
<td>12</td>
<td>Educator</td>
<td>32 years</td>
<td>Minimal Knowledge of SCM, RCA, AcciMap</td>
</tr>
<tr>
<td>13</td>
<td>Information analyst infection prevention team</td>
<td>4 years</td>
<td>Knowledge of RCA, AcciMap</td>
</tr>
<tr>
<td>14</td>
<td>Emergency Department consultant</td>
<td>22 years</td>
<td>Minimal Knowledge of AcciMap</td>
</tr>
<tr>
<td>15</td>
<td>Junior ergonomist</td>
<td>13 years</td>
<td>Minimal</td>
</tr>
<tr>
<td>16</td>
<td>Patient handling trainer</td>
<td>20 years</td>
<td>3 years</td>
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<td>17</td>
<td>Moving and handling team manager</td>
<td>23 years</td>
<td>Part of current role Knowledge of ATSB, AcciMap</td>
</tr>
<tr>
<td>18</td>
<td>Back care advisor</td>
<td>17 years</td>
<td>2 years</td>
</tr>
</tbody>
</table>

SCM: Swiss Cheese Model  
RCA: Root Cause Analysis  
BTA: Bow-Tie Analysis  
ATSB: Australian Transport Safety Bureau accident investigation model

The workshop had a similar protocol to the interviews, with STAMP first introduced in a PowerPoint presentation similar to the slides used in the interview hand-outs (shown in Appendix 7). Following the introduction, participants were provided with a copy of the previously developed safety control structure and a printout of a newspaper report on the Mid-Staffordshire failings (see Appendix 7). Participants were asked to participate in the analysis and to complete the evaluation questionnaire (Appendix 4). Following completion of the questionnaire the participants were invited to give comments, which lead to some discussion of the approach, this discussion was audio-recorded and transcribed verbatim. The workshop was 60 minutes in duration and all participants provided written informed consent.

4.9 Results

4.9.1 STAMP analysis

Information from the inquiry reports was used to identify the systems, hazards and safety requirements related to the failures. A model of the safety control structure at Mid-Staffordshire NHS Trust at the time of the failings was then
built, this model was slightly altered after discussion in the interviews and the final version is provided in Figure 11. While a STAMP analysis considers both design and operations, these are presented within one diagram. The roles and responsibilities of controllers at each system level were then analysed, starting at the lower system level and the physical processes involved in the incidents (see Appendix 8).

The previous investigation reports used as data for the analysis had predominantly focussed on the areas of the hospital with suspected high mortality rates and/or had been the subject of a high number of complaints. This included Stafford hospital's accident and emergency (A&E) department, emergency assessment unit and Wards 7, 8, 10, 11 and 12.

4.9.1.1 System, hazards and safety requirements
The goal of a healthcare system is to promote and protect the health and wellbeing of its users. The inquiries into the Mid-Staffordshire incidents describe issues of poor care received by patients, with episodes of patient harm and an overall high mortality rate. Therefore, this analysis focuses on the control structure related to the standards of care and the reduction of avoidable harm to the patient. The associated hazards are patient exposure to poor standards of care, with relevant loss events defined as death, injury or illness to a patient. The system safety requirements can be identified as follows:

1. Reduce avoidable harm from rates of healthcare associated infections (ensure a clean environment and patients’ hygiene needs met).
2. Patient to receive required medical treatment efficiently.
3. Fulfil patients’ nutrition and hydration needs.
4. Avoid patient harm from falls (preventative measures and reporting/recording of falls).
5. Prevent harm from confused patients to themselves or others (risk assessments and observations where necessary).
6. Avoid drug errors.
4.9.1.2 Safety control structure

The safety control structure developed in the analysis is shown in Figure 11, due to the size of the control structure the full depth and detail of the analysis could not be provided within the main diagram. The main diagram provides an overview of the system, the full analysis is heavily detailed, so only examples of the analysis at different levels are provided in this chapter in Figure 12 and Figure 13, the full analysis is provided in Appendix 8. The positions of Figures 12 and 13 within the main diagram are highlighted.
Figure 11 Mid-Staffordshire safety control structure
### Safety-related responsibilities:
- Ensure high standards of care, hygiene and cleanliness are maintained
- Organise and supervise wards and junior staff
- Ensure reporting and investigation of incidents

### Context:
- Trust lacked senior nurses e.g. only 3 matrons across whole trust up to 2008 when number was increased to 12
- A&E chronically understaffed in terms of consultants and nurses
- Reported low staff morale following strain of trust financial difficulties, cuts and difficulties in delivering acceptable standards of care
- High sickness rates among staff
- Some community support services not satisfactory for discharge
- Pressure to discharge patients to accommodate patient intake from A&E
- Large variation in standards of care between wards

### Unsafe decisions and control actions:
- Inadequate enforcement of constraints: Cases of poor standards of care
- Inadequate feedback: Pressurised junior staff to alter records on discharge times to meet targets
- Inadequate communication channels/learning processes: Forceful management styles, particularly in A&E, stopped junior staff from raising concerns
- Inadequate execution of control action with ineffective management of discharge processes: Premature discharge, protracted discharge processes, failure to communicate arrangements to patients, failure to ensure adequate support
- Inadequate safety management processes: Cases of alleged staff misconduct not being addressed with governance proceedings
- Inadequate safety management and learning processes: Staff appraisal and professional development afforded low priority
- Inadequate feedback: Incident report forms sometimes found to be inaccurate and misleading

### Mental model and feedback flaws:
- Focussed on meeting targets, which was seen as a priority across trust
- Disengagement between management and clinicians
- Reporting of incidents did not seem to result in action
- Trust staff isolated from other trusts and developments in care for continuous learning and understanding of status of trust

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### Senior nurse/ward management

**Supervision**

### Nursing staff and healthcare assistant team

**Communication**

**Incident reporting**

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### Safety-related responsibilities:
- Ensure high standards of care are maintained
- Report incidents and concerns

### Unsafe decisions and control actions:
- Inadequate execution of control actions, with cases of inadequate care provision:
  - Inadequate patient hygiene practices
  - Inadequate prevention of patient falls, issues with observation, recording and risk assessment
  - Inadequate patient handling practices
  - Inadequate pressure area care
  - Failure to monitor and maintain drip bags
  - Failure to ensure nutritional requirements met
  - Minimal patient observation and examination
  - Communication and coordination issues: Inadequate record keeping and lack of clear registration of patient transfer between wards. Lack of appropriate nutrition and hydration charts
  - Communication issues: Reports of issues with attitudes of staff towards patients and families impacting on patients raising concerns

### Context:
- Working in busy, chaotic and understaffed wards
- Receiving inadequate training and development
- A lack of senior staff in some areas
- Equipment lacking in some areas of the hospital
- Working with patients with a high dependency level
- Staff were reluctant to speak out against the poor standards of care in fear of wrath of some senior nurses
- Staff expected to falsify records in order to avoid breaching waiting time target

### Mental model and feedback flaws:
- Reporting of incidents did not seem to result in action, which deterred future reporting
- Layout of hospital made it difficult to observe patients in some areas
- Trust staff isolated from other trusts and developments in care for continuous learning

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**Figure 12 Analysis of nursing care**
## Clinical governance, audit and infection control teams

### Safety-related responsibilities:
- Improve patient care and outcomes through systematic review, evaluation and implementation of change
- Ensure high standards of care, hygiene and cleanliness are maintained

### Unsafe decisions and control actions:
- Inadequate safety management and learning processes:
  - Clinical audit weak and disjointed. Lacked planning and not linked to other governance
  - A lack of follow-up after audits to ensure changes and improvements were made
  - Inadequate robustness in review of patient deaths
  - Did not participate in the audits of specialist medical and surgical societies
  - Coordination and communication issues: Disconnect between divisions, departments within divisions and the central audit team
  - Inadequate enforcement of safety constraints: Hygiene and cleanliness standards not maintained
  - Inadequate interactions with external bodies: Did not report 2005-2006 increase of C. difficile to HPA, SHA and trust board

### Context:
- Continual change in clinical leadership at board level – clinical governance predominantly overseen by director of nursing
- Clinical governance lead did not feel adequately trained or experienced for role
- No lead for clinical audit for a year prior to April 2007
- Clinical audit lead had other research and development commitments and a substantial workload
- Director of infection control role regularly changed between personnel
- Improvements in infection control in 2008 noted by DH and HCC

### Mental model and feedback flaws:
- Filtering of information on complaints and incidents did not give adequate information for board to judge standards
- Reassured that high mortality rates were due to poor coding
- Inadequate use of data to drive and generate audit

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### Division level leadership and senior clinical staff

### Safety-related responsibilities:
- Ensure quality and safety of patient care
- Ensure learning and improvement following investigation of incidents and complaints
- Manage systems for the management of risk to patient safety and wellbeing. Ensure reporting of serious incidents to SHA and NPSA

### Unsafe decisions and control actions:
- Inadequate enforcement of constraints: Failed to maintain high standards of care
- Inadequate safety management and learning processes: Complaints and incident investigations undertaken by frontline staff. Staff lacked training and time for investigation resulting in varied quality
- Inadequate enforcement of constraints: Surgical division described as dysfunctional in RCS review
- Inadequate enforcement of constraints: Problems in medical and surgical divisions often listed on risk register but not resolved
- Inadequate allocation of resources: A&E had issues with low staffing levels, lack of leadership, lack of equipment and lack of high quality training

### Context:
- Responsibility for most of risk management and governance system devolved to divisions in 2007
- Trust cost improvement plan in action with board setting savings plan and divisions responsible for implementation
- Cost improvement plans were identified as a risk to patient safety and wellbeing
- High staff turnover and sickness, difficulty recruiting
- Changes in staff skill mix resulted in a lack of senior nurses and increase in support staff
- Disconnect between clinical staff and management with clinicians feeling their concerns were ignored

### Mental model and feedback flaws:
- Clinicians felt concerns were not listened to by trust leadership and the trust focused on financial strategy
- A closed culture among clinicians with reluctance to adopt national guidance such as from NICE

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Figure 13 Analysis of Trust clinical governance
4.9.2 Participant responses on usability of STAMP

Responses for STAMP’s usability are presented in Figure 14, participants were more negative about the usability of STAMP than they were its utility, with 45% of participants disagreeing that it was easy to understand (72% neutral or negative) and 34% disagreeing that it was easy to apply (78% neutral or negative). Responses on usability are dependent on the way STAMP was presented and the time available to explain and demonstrate STAMP. Several participants made comments about needing more time and practice with the method, however, they were largely positive about the presentation of STAMP (56% positive responses) and the provision of templates in the control structure output (61% positive).

Figure 14 Healthcare stakeholder perception of STAMP usability (n=18)
The comments provided by participants and responses to open questions give further insight into their perception of STAMP. The study asked a lot of the participants in getting an understanding of STAMP from a one-off presentation with little time to digest. The participants described their struggle to grasp STAMP’s concepts, but this initial exposure garnered some interesting insights.

‘I don’t think it is easy to understand, I can’t get my head around it and that’s why I say perhaps it would have been better if I could have read about it and digested it, that might have been easier perhaps… It’s almost mapping isn’t it, it’s almost a process mapping type thing. That’s what you’re doing isn’t it. And you’re looking for weaknesses in the process? And what could be strengthened to prevent an incident from occurring.’ – Regulator clinical advisor (Participant 7)

‘…it’s not a way of thinking that people are that familiar with, or historically it’s not a way that people have been familiar with. There’s probably a generation of doctors coming through now who have a little bit more understanding of the patient safety agenda. But in terms of looking at different models for understanding an incident, I doubt many healthcare people will be able to, unless they have a very specific patient safety brief, will be able to say well actually I prefer a control-feedback model, or I prefer a root cause analysis technique because of this. I don’t think people are that sophisticated, but in a way that’s about how you translate the method/model into something that’s accessible to the people at the frontline.’ – GP and educator (Participant 2)

‘…but it was for me a convoluted system. And the reason I talk about the applicability in practice, I think and I’m not too good at the tool, but I feel that this could take a long time, to get through all these loops. You know if somebody can do it, it’s great. I think in healthcare, and I’ve been working like 16 years in the hospitals, if something seems to be a little, just a tiny bit difficult or time consuming it won’t go any further. I think probably because everybody is so busy, and they are thinking okay if it’s taking 15 or 20 minutes just to explain that to me, how long is it going to take me to use it or to do it.’ – Nurse and educator (Participant 5)
‘It’s just about more time to understand it, so that’s not a criticism of this. I think if we were going to apply this we would need training.’ – Commissioner quality assurance (Participant 4)

‘It’s a lot to take in if you haven’t got any Human Factors or systems background and you need to learn the language. I think it’s one of the more complex tools of the ones I’ve come across in terms of immediately being able to get into it.’ – Educator (Participant 9)

4.9.2.1 Case specific issues of usability
Mid-Staffs itself is a large complex case which impacts on the usability of STAMP and there are potential case-specific issues of usability which are mentioned by the participants.

‘I suppose it just looks a bit complex maybe, well that looks complex but that’s the Mid-Staffs, and that was complex anyway wasn’t it. Looking at these sorts of models, it looks easier to understand in a simple sort of form presented there (examples of smaller scale incident in aviation and healthcare). And those examples are easier to understand I think. When I first saw that I thought it was too much, but I guess that’s what happened didn’t it in terms of Mid-Staffs, it was complex. But the actual concept itself looks straightforward.’ – Regulator clinical advisor (Participant 7)

‘I would say I disagree that it is easy to use for such a complex case. I think I could do it on a smaller case more easily. And, we might be able to do quite an interesting one on the syringes. Because I think that’s quite fascinating around how that happened. And how the change happened without a control. So, I think that would be quite an interesting one. The hazard here (Mid-Staffs) is huge and complex.’ – Commissioner safety manager (Participant 1)

4.9.2.2 Difficulties and time taken to do a full system analysis
Also linked to the size of the Mid-Staffs case, but with a potential generalisation to other case studies, is the time and human resource needed to do a full system analysis. Mid-Staffs is somewhat different to normal incident
investigation practice as it was the subject of a national public inquiry and the inquiry had resources far beyond a healthcare provider investigation. The participants made a point of needing to see STAMP being used in normal practice incident investigations.

‘One of the problems I think, is if you start looking at a whole sociotechnical system using this approach, what you’ll end up with is you can get into so much detail so quickly, that you end up making it massively overcomplicated. So what level of controls will you be putting in and suddenly you start going well if I need to put a control for this, do I need to put a control for this. So, you need to be very tightly controlled on what you are trying to get from your analysis. You could almost do a STAMP analysis for every single aspect of this STAMP analysis. Because within treatment/care/hygiene/discharge process, you could do a STAMP analysis, just on those things there, or just on treatment. Did the treatment work, did they know what treatment they were going to have? And suddenly it’s like wow and if you actually did it for the whole multi-factor it would actually blow everyone’s minds.’ – Emergency Department Consultant (Workshop participant 14)

‘I think that Staffs is an example where you had somebody make a report for national learning, so using this structure where every part of it is so relevant to failures at every single level. But that took somebody and a team fulltime to investigate the system. There’s two reports with recommendations which are still being acknowledged and therefore I’m not sure how applicable this would be within the time limits available in a hospital.’ – Workshop participant

4.9.2.3 User-friendly definitions and control-feedback in healthcare

There were some concerns about the language used in STAMP and defining what is a control or feedback in the healthcare context. Furthermore, with clinical staff often undertaking incident investigation there will need to be some translation of terms into language they are familiar with, as they are neither system engineers nor human factors specialists.
'It doesn’t describe things how we describe things, I think it's the language, it isn't congruent with healthcare staff and that is going to switch them off.’ – Commissioner safety manager (Participant 1)

‘And when you say a control or control measure, how are you kind of defining those? Budget is a control measure I guess yeah. Would workforce review be a control mechanism or a feedback, it depends what you mean by it probably. I was going to make the same point about clinical audit, that in a way audit is both a feedback mechanism and a control mechanism. I think probably workforce planning is the same isn't it.’ – GP and educator (Participant 2)

‘I think in terms of being very clear about which things are control mechanisms and which are feedback mechanisms that's probably quite important to crystallise…And I think with clear definitions over feedback, control mechanisms and the human controller and the control process, if you can come up with definitions of that and it might even be worth thinking about is if you were thinking about using these in real life investigations is to do that and try and sense check that with people who are front facing clinicians. And with some patient safety people and say does this make sense to you and getting some feedback on your definitions.’ – GP and educator (Participant 2)

‘I think systems theory I get because I've read about it a lot and done work with it and I think my concern always with these sorts of things is that the people in healthcare that generally do the investigations are the frontline staff, people that have worked on the frontline. So, their language is very different to the management strategic language as such. And so often trying to explain to people what we mean by company/management/regulatory agencies is difficult and actually defining who these different groups are I think is important. So, I think that has to be described more to be able to support people to use it.’ – Medic and patient safety lead (Participant 8)
4.9.2.4 Model too prescriptive

There were comments about the method or model being too prescriptive. This is perhaps a reflection on the provision of a control structure that was near completion, rather than the participants being able to build the model from scratch.

‘…and then there’s also a question about whether, it’s a little bit about any qualitative research, do you do a kind of grounded theory approach, where you start with the facts of the case and try and build the model. Or do you start with this as a framework and then say this is an example of and try and fit the data to the model or do you fit the model to the data. The difficulty with grounded theory type approaches where the data rules is that it’s very resource intensive because you have to remake a model every single time, the problem with a framework approach is that you miss the unexpected because you’re not looking for it. So, if it’s a thing about getting understanding I think there’s got to be enough flexibility in the model that you can kind of also identify x factors, the unexpected, the stuff that doesn't fit into the model and not lose that or make people who are involved in the investigation feel like that sort of x factor stuff isn't of interest because it doesn't fit to the model.’ – GP and educator (Participant 2)

‘Far too complicated and rather than the method guiding you through the process, I'm finding that we're looking at evidence to try and fit it in, it's like a reverse effect.’ – Workshop participant

4.9.2.5 Control structure does not highlight flaws

The participants also voiced concerns about the control structure appearing robust in the templates provided. That it showed the present structure without highlighting weaknesses, giving the impression the system was functioning well.

‘I think a limitation is it does need a bit of explaining to go with it, for example when we’re aware what the failures were, you have to think what the failure could be and then attach it to the diagram. It doesn't immediately tell you what’s happened, but I get that it’s a tool for looking at something. But
I think you could very easily look at that (control structure) and think that everything is fine, because all this stuff is there (control structure).’ – Workshop participant

‘It’s not telling me anything about the humans in here. Would you need another one that parallels the human part of it? Could you add some of the human bits that were happening. This is really just an organisational structure. But you could have an overlay that says, 'telling what they want to hear', 'asking only what they want to know', that's what was happening here, these people told them only what they thought they wanted to hear and when fed back down they only asked what they wanted to hear. But on this structure, you don’t see that weakness, because you see it goes up and goes around and you think that looks good, that's what we need to do.’ – Commissioner safety manager (Participant 1)

4.9.3 Participant responses on utility of STAMP

The scale-based responses on the utility of STAMP in healthcare are presented in Figure 15. Most of the responses were positive, particularly in terms of STAMP’s relevance to healthcare and the method giving a different perspective, with 78% of participants giving a positive rating (agree or strongly agree). Participants were more negative about how useful the application of STAMP was in learning from the incident and in helping to make recommendations (17% disagreeing to both statements), the reasoning behind this is explored further in the answers to open-ended questions.
4.9.3.1 Participant discussion of Mid-Staffordshire incident based on control structure diagram

As an aside to the main aims and results of the study, in exploring the safety control structure diagram the participants discussed the issues involved in the Mid-Staffs incidents. One main topic of discussion was on the filtering of information from the frontline, to hospital management, Trust board and beyond. Or in other words a lack of vertical alignment through inadequate feedback. This resulted in incomplete mental models and understanding of the hospital’s status among leaders and regulators.

“Well it all started down here didn’t it really, because people were trying to tell them there was something wrong. But then it wasn’t actually getting filtered up was it. And then these guys at the top and the Trust Board, they were only given a certain amount of information. Which was filtered here somewhere because they thought well, we better not let them know because we’ll end up losing our jobs. So, there was a certain amount of filter applied here as well. For me there's something here about filters at play, as well, in terms of how the problem is reported and
‘One of the things was that staff performance was felt to be an HR job, so the board didn’t look at the serious incident reports, because they said that’s HR or that’s operational and we’re strategic. So, the board had it in their head that they were strategic and these serious incidents where patients were coming to harm, which were probably poorly written, weren’t even viewed, they were not even sighted on them. Now, the nurses stopped writing incident reports because they were ignored, so they stopped making them.’ – Commissioner safety manager (Participant 1)

‘I think that’s common across the NHS, things stop here or sometimes here, but rarely get to there (pointing to levels on diagram). I think, without making excuses for NHS organisations, I think some of that is down to the fact that… if you think of a triangle and the bottom of the triangle is very wide and it’s all of the clinical things that are going on across an organisation with 6500 staff and thousands of patients, all of that is going on. And then once a month there are a few hours that they get to hear about things, so it’s got to channel up, so things get honed, pressed and then the idea is that the Trust board get to know the highlights, the high-level things, but what’s squeezed out along the way is dependent on who is doing the filtering as it were. If you think of it like a sieve almost.’ – Provider patient safety lead (Participant 3)

4.9.3.2 System versus person perspective
While there were positive comments around STAMP’s systems view and its avoidance of blame, there is a feeling that further consideration of individual attitude, behaviour and personality is important in healthcare.

‘This is more a systems non-blame isn’t it, there definitely needs to be more of this in healthcare. And this is how we try to work, very much around the system approach so why did the individual do that. So, for me it’s the understanding of the individual within the system and what I mean by that is what was the individual doing, what was their role, what was the
expectations, what pressure was there?’ – Commissioner quality assurance (Participant 4)

‘I think a big part of healthcare and I don't care what anybody says, but a big part of healthcare depends upon the consultants and their attitude. So, there's a lot of work that staff do within hospitals that panders to consultants' personalities, that plays a massive part. The behaviour and the personality of the individual is huge, a massive part. And I've worked with many different consultants in my time, both medical and surgical, so I think you've got that whole ego that you pander to.' – Commissioner quality assurance (Participant 4)

‘So, what did I like about the approach, no blame. No system is truly no blame but what this almost says is that if you were approaching this from the point of view of a clinician you can almost say we've been here before and we understand that this incident in front of you relates to the whole system. And if I'm the person who is involved in the incident, I can say that there was a problem here, here, here and here. And the people who are facilitating this discussion are expecting that because they've put it in the model.' – GP and educator (Participant 2)

‘Well I like the systems approach. It's quite interesting though because I think you could use it just to map out what a system already looks like rather than looking at it for incidents. Just to highlight to people the complexity of the system they're working in, then if they're thinking of introducing a new policy or procedure, actually understanding how it was going to fit into that and how that would work in practice. Because then you will probably realise there are 20 different interfaces and changes and processes and controls that you'd have to change to get that result changed. So, it's quite useful I think in that way, to describe how complex the system is rather than just looking at incidents.' – Educator (Participant 9)

Furthermore, there were felt to be intricacies of healthcare work that STAMP’s high-level system view may miss the detail of.
‘I think you can remove the human too much, in healthcare a lot of the potential errors come from human interfaces, I think you miss out the nuances, the small little things which might be missed looking at the system. Which may be squishy bits, we might not capture that. So, if you could combine this with the Swiss Cheese Model maybe, that sort of model.’
– Workshop participant

‘I think that with most of these systems methods that they need to be contextualised to healthcare more, I think that’s always the issue with a system method coming from outside of healthcare…And the other thing with healthcare is that because there are so many people involved with it and fairly little technology, there’s always the question that actually looking at the wider system, the environment therefore does take the focus off the teams and the individuals. So, by being system focussed we’re actually being detrimental to our incident investigations because we’re not looking where we need to look as much. There’s arguments for both sides.’ – Medic and patient safety lead (Participant 8)

‘The working norms have a much bigger impact and I think the environmental influences are much less controlled for in healthcare. There's no way that you would let a plane take-off in the state that some A&E departments run to or even the state that our emergency clinic gets to on some days, just in terms of numbers of patients crowding in. So, the environment is less controlled. And I think it's important that that is kind of reflected, I think the bit that's missing potentially from this model is that there are some environmental inputs at each level. And even that some of the things that happen further up will shape the environment. From things that happen at this level will impact on decisions about hospital buildings and whatever that affects the model. There’s just so many things, the environment is much less controlled and there’s a lot of less structured stuff that goes on in healthcare.’ – GP and educator (Participant 2)

Some participants did comment positively on STAMP’s consideration of mental models, in terms of an individual’s decision-making and shared mental models in decision-makers throughout the system.
‘What I liked about it was the mental model, the process, because I think that's important, that shared mental model. Which I don't think people often have. Or one level up believes that the person below them is adhering to policies and procedures or they understand what they're doing, and their mental model is different and hence that loop breaks down when there are errors and mistakes. Because they're working on a completely different mental model or a slightly different mental model. So, I think that for me was very interesting because healthcare is very much about mental models, although there are policies and procedures and clinical guidelines and stuff. It's very much the people on the ground make a decision based on their experience and what they understand the system to be.’ – Educator (Participant 9)

4.9.3.3 Oversimplification and underplaying of relationships, culture and environmental factors

There were comments to suggest STAMP’s control-feedback focus may not capture or document the softer side of healthcare systems, including culture and relationships between organisations. Some participants felt the control structure provided a simplified view that didn't account for the complexity of relationships and relationship building between personnel and organisations, and how these relationships affect safety management. Culture was also a talking point in terms of relationships between groups and the behaviour of individuals.

‘I think there's something for me about… this model’s fine…but a lot of this is dependent on the relationship with other people. I think it’s dependent on trust building. I think the control structure diagram is very straightforward from a model perspective. But, when one is managing patient safety there are also the intricacies of relationship building when it comes to the commissioners versus the providers. NHS England versus commissioners, Care Quality Commission (CQC) again is seen as another authority. Everyone is on the same page, if a patient was to ask, yes, we’re all here for patient safety, but it is about how that is then
mobilised. And then we manage another provider and it's a very different relationship.’ – Commissioner quality assurance (Participant 4)

‘Culturally there’s a layer of things that happen in terms of relationships between these different groups that’s going to have an impact on how the model works as well. So, I’m just thinking about this as a discussion, if I was picking up on this model and using it for a discussion, I might be saying well I’d like to also bring in what were the environmental factors, or the cultural factors, and trying to make people more aware of those.’ – GP and educator (Participant 2)

Further comments referenced a perceived underplaying of culture within the STAMP control structure and method.

‘Is it missing anything? Healthcare environment, workplace climate as well, because that’s a big thing for us. So, we’ve got our organisational culture but if you go to our maternity unit compared to our acute medical unit the atmosphere there would be so different.’ – Medic and patient safety lead (Participant 8)

‘You might want to think about that. About how this methodology can be applied to culture. Because I think when we talk about culture, what are we talking about, we’re talking about individuals at play in a system aren’t we. We’re talking about behaviours, we’re talking about personalities as well, which is what I've just described. And I think it's also about how those personalities are managed. And I don't mean sort of performance managed, I mean how does the system manage an individual personality, whatever it might be. So, within healthcare we have egos, we have people/consultants that have perhaps been in the post for years and years and think they know it all, so we have that culture. We have individuals that are perhaps not trained well enough or have a lack of confidence or have had a bad experience and therefore their confidence has been knocked. So, you've got all of that at play. You've got the pressure of targets, you've got the hours that staff have been on duty. You've got a team that might not function together well enough, because the team dynamics haven't been thought through.’ – Commissioner quality assurance (Participant 4)
‘It's often about the culture of the organisation and leadership as well. I think very much so. Certainly, I see that in my current role. And it's having a strong executive team who are well known to staff and think that's really important. And the sort of culture that's initiated in the organisation, if it's an open culture and the staff feel able to report and escalate concerns and things like that. I think you can't underestimate that really.’ – Regulator clinical advisor (Participant 7)

4.9.3.4 Safety constraint concept and potential negative impact on innovation

One participant pointed to a potential negative consequence of a rigid control structure that could apply too much constraint, particularly in terms of innovation and change. It was felt that healthcare was already too bureaucratic and not optimal for innovation.

‘Now healthcare is criticised for being very bureaucratic. And one of the things when you talk to the military, the reason that things have advanced so quickly in the military is because the surgeon general, when they were doing all their amputations, they used to sew the flap round the end in a particular way. And at the end of each week, he would have a teleconference with his surgeons and everything and they'd say you know what we've had a few of those wounds breaking down this week it's not holding. So, they go right, next week we're going to do it like this. We're going to try crossing it over a different way, using a different stitch and let's see if that's better. So next week, that's what they did. In healthcare, not a chance, you might have to write a paper on it, you'd have to get your evidence, you're going to have to look at NICE guidance. We couldn't do that at that speed. That's the structure and that's what they're able to do.’ – Commissioner safety manager (Participant 1)

4.9.3.5 The layout of the control structure diagram

Positive comments about the diagram reflected its mapping of the whole system. Some participants viewed the diagram as a process map or simple organisational hierarchy.
‘So, all of this (pointing to model) I know, and all of what went wrong I know, it (diagram) looks like the usual linear hierarchical approach I would look at.’ – Commissioner safety manager (Participant 1)

Some participants questioned the layout of the control structure diagram, particularly the vertical hierarchy which left patients at the bottom. The concern was that they were being viewed as less important than those higher on the diagram.

‘Do you know the over thing as well, an optical thing, I don’t think this (diagram) should be this way round, I think it should be something like that. Or even inverted. Because I just think it implies that they’re right at the top and the patients are right at the bottom. I think there’s something about the patients and how do they translate across this thing. I think they should be all the way along, it’s their pathway. So that’s the patient pathway or the experience maybe.’ – Commissioner quality assurance (Participant 6)

Furthermore, several participants mentioned communication and coordination across organisations that may be on the same level when looking at a vertical hierarchy. This coordination amongst organisations on the same level of hierarchy is perhaps not best represented in a vertical hierarchy control structure.

‘…so that’s my observation, if we’re looking up and down this (control structure diagram) for the solution, is it right? And do we need to look more across here at this level for the solution.’ – Commissioner safety manager (Participant 1)

The diagram was felt to be too simplified, of course there is a trade-off here between having a usable and readable diagram of appropriate size, and the inclusion of relevant and necessary detail.

‘The other thing that you haven’t got in this, is the complex thing around commissioners, the fact that we’re all the same but all slightly different. They’ve all got their own identity. So, for one acute provider, they’ve got 26 commissioners to report to. Specialised commissioning,
because they’re a commissioner and so are public health and screening.’
– Commissioner quality assurance (Participant 6)

‘There’s a whole set of cross-organisational things. Because the
implication of the model is that this group is responsible for everything that
affects this group. And I recognise that there’s some control and feedback
mechanisms that will sort of skip that group, and some that will go around
in circles across those layers. And the difficulty coming back to what
we’ve been looking at doing across organisations is that there’s much
less communication across providers. And there’s filtering at each
stage.’ – GP and educator (Participant 2)

‘And I can see there being some difficulty in accounting for the sort
of complexity, because these people will not necessarily be working
all to the same systems. The nurses will be using different methods of
documentation, different checklists, different guidelines from the ones that
the doctors will be using. So, these people are often not working to the
same remit and working to the same specific documents.’ – GP and
educator (Participant 2)

4.9.3.6 Learning from the incident and making recommendations
When describing the issues with making recommendations, the issues were
not method specific, rather a current and ongoing problem in terms of
recommendations being actionable and then being implemented.

‘I think it does help with understanding the incident. I think the difficulty
is…there’s an argument that the learning is only done when the
changes are made. And I don’t think this rectifies it, I think it’s a kind of
diagnostic aid and potentially an aid to the kind of things that you might
want to put in place. So, I think it probably gives you a diagnosis and
potentially a prescription.’ – GP and educator (Participant 2)

‘Once we’ve done it (the STAMP analysis) how do we then decide what
we’re going to do? Because we’re getting used to picking out which bits
didn’t work, but then how are we going to decide what we’re going to do
with those. Because actually when we look at this (control structure), lots
of these things look like a good idea and probably someone put them in, in relation to something previously. So how do we know what will work? With this, so we don’t want Mid-Staffs to happen again and we map this out. How do we know where to start? That’s roughly where we get to at the end of an investigation, whatever method we’ve used, if we’ve found a lot of things, how do we know which one to start with and then how do we know the best way of fixing that.’ – Workshop participant

‘What tends to happen is it (recommendations) focusses down the chain, so you tend to focus on the lowest actors and do weak solutions like training and things like that. So, it’s about how could a tool like this support the fact that you need to bring it to the higher level, and then how is that communicated across and that’s a really interesting challenge. Because it sounds like the responsibility when these things are passed back flows down to the lowest denominator.’ – Workshop participant

Method specific problems referred to, include the need for expertise in using the method.

‘I don’t know how useful it is to learn from an incident if you’re really not well versed in the technique. And I think you need to have an expert there who understands the process to actually get the learning out from it.’ – Educator (Participant 9)

Furthermore, the systems view was felt to perhaps lead to recommendations that weren’t affordable to healthcare or were out of the control of the organisation investigating.

‘Because it will take us down to a system that we can’t afford. It’s going to do it too well! Or it’s going to make recommendations out of our control. So then would there need to be a hierarchy (of recommendations), but then we’ll always go for the cheap option.’ – Commissioner safety manager (Participant 1)
4.9.4 Participant responses on future application of STAMP

Participants were asked further questions on STAMP’s potential for future application in healthcare, with their responses summarised in Figure 16. Most participants felt positive that STAMP would be useful in the analysis of future incidents (67% agree or strongly agree), but that healthcare would need expert help to apply (67% agree or strongly agree). Participants were less positive that healthcare would benefit from the adoption of STAMP (39% agree or strongly agree). This seems contradictory to the positivity around STAMP’s use in future incident analysis but may be a product of the complexity around incident analysis and political factors influencing implementation of remedial actions.

![Figure 16 Healthcare stakeholder perception of STAMP's potential future application (n=18)](image)

Figure 16 Healthcare stakeholder perception of STAMP's potential future application (n=18)

Participants noted the potential use of the control structure diagram in group discussion.

‘...I think presenting people with a model as the basis of a discussion could be quite useful, whether you present it to them as an individual or whether you present it to them as a group, on theoretical grounds I think
there's an argument for doing both. Because in a group you'll often pick up on the things like the shared experience, so you'll pick up on the working norms. You'll pick up on the times when the policy is not followed. Or you have a conflict between what's on paper and what we do. And there's quite a lot of those. People develop these informal workarounds and sometimes don't think about the potential consequences of them. Talking to people as individuals you're more likely to get the more personal thing of I feel I did this wrong, but someone might not say something in a group if they're likely to be judged negatively by their peers. But equally that relies on a good facilitator. But I think giving people a model that they can conceptualise the incident with would be a very useful way of leading to discussion.’
– GP and educator (Participant 2)

Expert help was felt to be particularly necessary in moving from analysis to effective remedial action.

‘Where expert help might be needed is around facilitation of helping people to decide on and implement effective new feedback and control mechanisms. Because there's a whole set of skills involved in effective control and feedback intervention and a lot of the recommendations that come out of the investigations, as written at the moment, suffer from a little bit of politicians’ logic. This idea that something must be done, or we need to demonstrate that we're doing something. Whereas what should be happening is we should be saying okay let's look at the facts of the case, integrate that with relevant theory, and I think that involves safety systems people, and make an intervention that's likely to work and then audit to see if it is working. And I think we tend to make huge numbers of recommendations as a result of patient safety incidents, but they're often things that are easily achievable and perhaps don't relate to the kind of deeper systems issues.’ – GP and educator (Participant 2)

4.9.4.1 The most negative critiques and comments
Within the workshop, three participants gave a more negative critique of STAMP in comparison to other workshop and interview participants. These comments are of interest in showing the potential extremities of reactions to
STAMP. However, this negativity may be a product of the workshop structure and the limited time participants had to learn about and use STAMP, as evidenced in the comments.

‘Implies control systems work, too many assumptions…To do it properly, it is too complicated’ – Emergency Department Consultant (Workshop participant 14)

‘Doesn’t show where things went wrong. It’s a picture, no analysis…It’s too complicated’ – Clinical lead risk and governance (Workshop participant 10)

‘So complicated, I think things can be easily missed, rather than STAMP guiding you through the investigation process you are fitting the evidence into STAMP. Far too complicated for an hour session’ – Moving and handling team manager (Workshop participant 17)

4.9.5 Overall evaluation of STAMP application

4.9.5.1 Descriptive requirement

The descriptive component relates to the requirement for the method to guide an investigator to identify the complete set of events and circumstances relevant to the accident (Katsakiori, Sakellaropoulos and Manatakis, 2009). In this case, as a re-analysis of a previously completed investigation, this is difficult to evaluate. What can be said is that STAMP showed a capacity to organise a large amount of information into a hierarchical structure and control-feedback format. This format demonstrated how limitations in information flow effected the decision-making of workers and managers at all levels and their ability to fulfil safety responsibilities.

4.9.5.2 Revealing requirement

This component requires the method to distinguish between events and underlying causes (Katsakiori, Sakellaropoulos and Manatakis, 2009). STAMP fulfils this requirement; the method goes beyond a consideration of events alone and considers system structure in terms of control-feedback loops.
Furthermore, STAMP has a consideration for the interactions and connections between the system’s technical aspects, people and the organisation.

4.9.5.3 Consequential requirement
This requirement means the method should allow for specific recommendations to be formulated to prevent future accidents. STAMP should allow for this and this has been shown previously (e.g. Leveson et al. 2016). However, in this case due to the number of recommendations made in the original reports, it is difficult to formulate recommendations that are different to the original investigation in order to evaluate STAMP based on this requirement.

4.9.5.4 Validation requirement
This component requires the method to be valid and reliable. Facilitating agreement between different investigators/analysts and the results they produce, and correspondence between analysis findings and reality (Katsakiori, Sakellaropoulos and Manatakis, 2009). This is not possible to evaluate in this case due to the analysis being completed by one researcher.

4.9.5.5 Practical requirement
This requirement considers the need for training to use the method, with domain personnel able to use the method rather than just highly trained experts. There is reason to believe that STAMP requires substantial training in order to use effectively (e.g. Underwood et al. 2016), this is further evaluated in the questions to healthcare stakeholders who are mostly in agreement that they need training and/or external help.

4.10 Discussion
The application of STAMP to the Mid-Staffordshire case organised the public inquiry data into a format of control-feedback structure and process models for human decision-making. STAMP was a good fit for the issues of vertical alignment within the hospital and connections to external organisations. And STAMP was both descriptive and revealing in providing a way of organising and communicating the underlying system issues. One benefit of the use of STAMP was the visual output in the safety control structure diagram and
process models, which allowed for discussion of the case with participants. Healthcare stakeholders were generally positive about STAMP’s utility, but less positive about its usability.

A main theme arising from the healthcare stakeholder comments regarded a system versus person perspective in viewing incidents and incident cause. In keeping with Reason’s (2008) warning for issues at the extremities of both a system and person perspective (see literature review 2.6.1). Some participant comments displayed a wariness of the systems view of STAMP and the potential detraction from individual responsibility and professionalism that is highly valued in healthcare. Along with issues of underplaying the role of personalities and attitudes in safety management, there was a concern that a high-level system view may not consider the detail and nuances of healthcare work. Taking a system view the impact of personalities and attitudes could be considered as a failure of the system to effectively identify and control for these issues (Dekker, 2011) but it may still be that a STAMP-based investigation overlooks these types of problems. In terms of the details of work and in particular, worker adaptation and deviation from policy and procedure may be better accounted for in a Safety II type view and a FRAM analysis. Some participants also felt STAMP may underplay cultural aspects.

Definitions of terms are a key point in both the utility and usability of STAMP. Defining precisely what a control action is in healthcare proved difficult for the author and the participants. Furthermore, there is a thought that actions beyond those enforcing safety constraints may be important to capture in a healthcare STAMP analysis. This will be revisited throughout the thesis, along with other issues of usability, with evidence from further case studies.

4.10.1 Limitations
The purposive sampling meant selected participants already had an interest in patient safety and through it, HFE methods. This sample may not be representative of the wider healthcare stakeholder population.

A further limitation comes in this being a reanalysis rather than investigation from scratch. A reanalysis could not show how STAMP could influence data
collection and the analysis was reliant on a previously undertaken investigation. Furthermore, participants were only partially involved in analysis, as it was not practical to train them in STAMP and this limitation will be reflected in their perception of STAMP.

4.10.2 Reflective Summary
One point made by the participants was an interest in how STAMP would fit within the confines of a current practice hospital-based investigation, rather than to a national public inquiry. This is an interesting line of inquiry followed up in a further case study. Furthermore, it was noted that healthcare deals with a range of incidents that stretches to suicide and homicide in mental health care, which may be vastly different to the type of incident analysed in this case study. It would be interesting to see how STAMP deals with this type of incident and this is followed up in a further case study.

A major theme was around the system versus person perspective and STAMP potentially underplaying individual factors and the nuances of healthcare work. This study did not interview healthcare staff directly involved in the incidents or that worked for Mid-Staffordshire Trust. Another interesting line of inquiry would be to investigate the differences between a STAMP analysis of past events and in-depth interviews with relevant healthcare stakeholders to explore their experiences of work.
5.1 Introduction

The previous chapter demonstrated the application of STAMP to a large-scale organisational disaster, which was the subject of a highly-resourced national inquiry. The first study and comments from study participants highlighted the need to demonstrate STAMP’s application in regular patient safety incident investigation practices. Application in regular practice will enable the consideration of constraints on practice in terms of time available, human resource and availability of incident data. Incident investigations are undertaken on all identified serious incidents, which are often on a small scale, such as medication error incidents.

Within healthcare there is growing awareness of issues with current practice in incident investigation, with questionable quality of investigations and analysis resulting in ineffective recommendations and action plans (Wu, Lipshutz and Pronovost, 2008; Kellogg et al., 2016; Peerally et al., 2016). Limitations identified include an over reliance on the promotion of a flawed reductionist approach in RCA and a lack of utilisation of external safety expertise (Wu, Lipshutz and Pronovost, 2008; Kellogg et al., 2016; Peerally et al., 2016). The application of an HFE researcher-led STAMP analysis could potentially improve the quality of incident investigation, this study aims to integrate a STAMP analysis into current practice.

5.1.1 Case study setting

The study is centred on a medication error incident (an insulin overdose case from a prescription error) involving two healthcare providers in the UK serving a population of around one million; an Acute Trust employing over 14,000 staff with a 900-bed hospital and a Trust providing community health services which employs over 5,000 staff. The incident involved a patient being administered an overdose of insulin on three occasions following a drug prescription error.
Drug prescription errors have previously been identified as the most common type of medication error (Bates et al., 1995; Leape et al., 1995) and in the UK, it is believed that up to 1.5% of hospital prescriptions may contain a medication error (Dean et al., 2002).

The events leading up to the incident can be summarised as: A patient was admitted to a hospital emergency department following a fall at home and subsequently transferred between wards. After being found to have a high blood glucose level a review by a diabetes specialist nurse (DSN), it was suggested that the patient should start insulin glargine U100 10 units once per day. The recommended dosage was misread by the prescribing doctor and 100 units were prescribed instead of 10 units. The high dosage was administered twice at one provider ward and then following discharge to another provider ward, a further time before the error was identified by an advanced nurse practitioner. The patient was subsequently readmitted to hospital.

The incident was the subject of a formal investigation, undertaken through RCA by a team of healthcare professionals. The investigation followed the NPSA level one investigation profile (NPSA, 2008): Level one is a most commonly used concise investigation for incidents that resulted in no, low or moderate harm to the patient. This investigation team included an investigation chair, two team leads and seven team members. Information gathered by this team included interviews with key staff involved in the incident, statements from nursing and medical staff involved in the incident, a review of an incident report form, review of medical and nursing records, and review of procedures and protocols. The report from this investigation was subsequently used as the initial basis for the STAMP analysis.

5.2 Aims and objectives
The study aims to investigate the application of an HFE-led STAMP analysis within a current practice healthcare incident investigation. To meet this aim, the study has the following objectives:
• To facilitate the application of STAMP in an ongoing medication incident investigation
• To compare the original RCA-based recommendations with the recommendations formed after the STAMP analysis
• To examine healthcare domain experts’ perspectives of STAMP’s utility and usability
• To evaluate and reflect on the STAMP application

5.3 Methods

5.3.1 STAMP analysis
Based on the RCA-based investigation report, STAMP was applied through two healthcare stakeholder workshops facilitated by two HFE researchers with the following profiles:

1. Junior HFE researcher (the author), a graduate member of the Chartered Institute of Ergonomics and Human Factors (CIEHF) whom had previously graduated from an MSc in HFE, currently PhD researcher on healthcare systems ergonomics. This researcher acted as the main facilitator and analyst.

2. Senior HFE researcher, an associate member of the CIEHF and lecturer in systems HFE with 14-year research experience in healthcare ergonomics. This researcher oversaw and supervised the analysis.

The two HFE researchers conducted an initial STAMP-based incident analysis using the data from the RCA report.

The process of applying STAMP to accident analysis is presented in section 3.4.1 and described fully elsewhere (Leveson, 2012), the steps were slightly modified in this case study and are used in further descriptions of the method process. So, the process is summarised here again, into the following eight steps:

1. Identify the system and hazard involved in the incident
2. Identify the safety-related constraints and responsibilities, associated with that incident

3. Document the safety control structure in place to enforce the safety constraints and control the hazard

4. Determine the proximate events leading to the incident and analyse the frontline operations present at the lower level of the control structure

5. Analyse the higher levels of the control structure determining how and why these managerial levels contributed to the inadequate control of the hazard

6. Examine overall coordination and communication issues between controllers that could have contributed to the incident

7. Determine any changes and weakening in the control structure that occurred over time and contributed to the incident

8. Generate recommendations for remedial action and strengthening of the safety control structure (Leveson, 2012)

The application of STAMP in this study contained several stages and these are summarised in Table 11 with detail on the people involved and the time taken to complete. Two HFE researchers carried out step 1-3 prior to step 4-8, which were carried out with healthcare staff.

For step 1-3, two HFE researchers carried out the reanalysis of the RCA report using STAMP. The two researchers created a draft safety control structure model to be utilised in the subsequent healthcare stakeholder workshops, this is presented in Figure 52 in Appendix 9.
<table>
<thead>
<tr>
<th>Steps</th>
<th>People involved</th>
<th>Time</th>
<th>Outputs</th>
</tr>
</thead>
<tbody>
<tr>
<td>STAMP step 1-3 (Reanalysis of the RCA report)</td>
<td>Senior and junior HFE researchers</td>
<td>5 hours</td>
<td>Safety control structure</td>
</tr>
<tr>
<td>Preparation of material for workshops</td>
<td>Senior and junior HFE researchers</td>
<td>8 hours</td>
<td>Safety control structure templates</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Step-by-step method guide</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Presentation slides</td>
</tr>
<tr>
<td>STAMP step 4-8 (Workshop 1 and 2)</td>
<td>Senior HFE researcher</td>
<td>3 hours</td>
<td>Validated safety control structure</td>
</tr>
<tr>
<td></td>
<td>Junior HFE researcher</td>
<td></td>
<td>Ideas for recommendations</td>
</tr>
<tr>
<td></td>
<td>Additional researcher</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>18 healthcare stakeholders</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Senior HFE researcher</td>
<td>2 hours</td>
<td>Validated safety control structure</td>
</tr>
<tr>
<td></td>
<td>Junior HFE researcher</td>
<td></td>
<td>Information on incident and healthcare work domain</td>
</tr>
<tr>
<td></td>
<td>3 healthcare stakeholders involved</td>
<td></td>
<td>Ideas for remedial action</td>
</tr>
<tr>
<td></td>
<td>in RCA of the incident</td>
<td></td>
<td>Healthcare stakeholder feedback on approach</td>
</tr>
<tr>
<td></td>
<td>Healthcare stakeholder present at workshop 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Synthesis of workshop outputs and documentation of recommendations</td>
<td>Junior HFE researcher</td>
<td>8 hours</td>
<td>Recommendations for remedial action</td>
</tr>
</tbody>
</table>

### 5.3.2 Healthcare stakeholder workshops

The study involved healthcare stakeholders in the STAMP analysis with facilitation by external HFE researchers. The involvement of healthcare stakeholders as domain experts is imperative in the validation of STAMP’s system models (Hettinger et al., 2015) and the development of more relevant and effective recommendations for change. Stakeholder involvement was done through two workshops. The workshops introduced accident analysis concepts and the STAMP approach presented by an HFE researcher. Following the introduction, the safety control structure system model was provided to the participants and they were invited to take part in the analysis using a step-by-step method guide. The first workshop aimed to develop recommendations for remedial action, in addition to this the second workshop aimed to evaluate the utility and usability of STAMP with feedback from the original RCA investigation team.
5.3.2.1 *Workshop 1*

The first workshop was three hours in duration with 18 attendees from healthcare including members of local commissioning groups, patient safety managers, front line staff and patient representatives, facilitated by three HFE researchers. All participants were from the same regional healthcare where the incident occurred, but none of them were involved in the original RCA investigation. The workshop was arranged through a patient safety group with participants invited by the group administration, no further information was collected on the participants. Following the introduction to STAMP the participants were asked to participate in the incident analysis, working in three separate groups each with a safety control structure system model, method guide and facilitation by an HFE researcher. The presentation slides from the workshops are shown in Appendix 10.

5.3.2.2 *Workshop 2*

The second workshop was two hours in duration and facilitated by two HFE researchers. The workshop was attended by four healthcare professionals (with an average of 31 years healthcare experience), including three involved in the original RCA investigation, participant information is summarised in Table 12. During this workshop, following the presentation of the concepts of STAMP, the safety control structure system model was validated, and the participants were invited to contribute to the analysis, using the model and STAMP concepts as discussion points. At the end of the workshop the participants were asked to give feedback on the utility and usability of the STAMP approach. This workshop was audio-recorded.
Table 12 Summary of workshop participant information

<table>
<thead>
<tr>
<th>Participant</th>
<th>Role</th>
<th>Healthcare experience</th>
<th>Patient safety investigation experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Advanced nurse practitioner – diabetes</td>
<td>34 years</td>
<td>Very little</td>
</tr>
<tr>
<td>2</td>
<td>Consultant nurse advanced practitioner</td>
<td>33 years</td>
<td>Intermediate Knowledge of SCM, RCA</td>
</tr>
<tr>
<td>3</td>
<td>Medication safety pharmacist</td>
<td>30 years</td>
<td>Several years Knowledge of SCM, RCA, FMEA</td>
</tr>
<tr>
<td>4</td>
<td>Clinical director</td>
<td>27 years</td>
<td>19 years Knowledge of SCM, RCA, FMEA</td>
</tr>
</tbody>
</table>

SCM: Swiss Cheese Model
RCA: Root Cause Analysis
FMEA: Failure Mode Effects Analysis

5.4 Results

5.4.1 STAMP analysis

5.4.1.1 Comparison between STAMP and RCA processes

Key information from the RCA and STAMP processes is presented in Table 13. Along with the different analysis methods used, there were differences in the people involved, their areas of expertise and the approach to group work. The timescales set for completion of the investigation in the policy is 60 working days, but the actual time taken for the RCA process was not recorded. The HFE-led analysis added 26 working hours.
Table 13 RCA and STAMP processes

<table>
<thead>
<tr>
<th>People involved</th>
<th>RCA</th>
<th>STAMP</th>
</tr>
</thead>
<tbody>
<tr>
<td>People involved</td>
<td>Assistant Chief Nurse</td>
<td>HFE researchers</td>
</tr>
<tr>
<td></td>
<td>Patient Safety Coordinators</td>
<td>Healthcare stakeholders</td>
</tr>
<tr>
<td></td>
<td>Diabetes Consultant</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consultant Nurse</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lead Specialist Nurse</td>
<td>Original investigation team members:</td>
</tr>
<tr>
<td></td>
<td>Education and Practice</td>
<td>Senior Diabetes Specialist Nurse</td>
</tr>
<tr>
<td></td>
<td>Development Lead</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Senior Diabetes Specialist Nurse</td>
<td>Medication Safety Lead</td>
</tr>
<tr>
<td></td>
<td>Medication Safety Lead</td>
<td>Pharmacist</td>
</tr>
<tr>
<td></td>
<td>Consultant Nurse</td>
<td>Consultant Nurse</td>
</tr>
<tr>
<td>Expertise</td>
<td>Work domain</td>
<td>HFE with work domain input</td>
</tr>
<tr>
<td>Time taken</td>
<td>Unrecorded</td>
<td>26 hours</td>
</tr>
<tr>
<td>Data used</td>
<td>Interviews and written statements from staff involved in incident</td>
<td>RCA report</td>
</tr>
<tr>
<td></td>
<td>Incident report form</td>
<td>Healthcare staff involvement in workshops</td>
</tr>
<tr>
<td></td>
<td>Medical, nursing and electronic records</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Procedures and protocols</td>
<td></td>
</tr>
<tr>
<td>Collaborative work</td>
<td>Meeting</td>
<td>Workshops</td>
</tr>
<tr>
<td></td>
<td>Review group</td>
<td></td>
</tr>
<tr>
<td>Analytical approach</td>
<td>Linear cause-effect model with contributory factors</td>
<td>Systemic model with control-feedback focus</td>
</tr>
<tr>
<td>Representations used</td>
<td>Fishbone diagram</td>
<td>Safety control structure</td>
</tr>
</tbody>
</table>

The RCA investigation was led by two Patient Safety Coordinators with a team of seven clinical staff and chaired by an Assistant Chief Nurse. The RCA used data from interviews and documentation which was analysed using timeline, fishbone diagram and incident decision tree tools. This process can be described as predominantly work domain expertise led, using a linear cause effect analysis model. In contrast, the STAMP process was led by HFE expertise, with the facilitated participation of work domain experts through workshops, using a systemic accident analysis model.

5.4.1.2 Comparison between STAMP and RCA outputs

The RCA identified a root cause in the prescription error by the doctor following misinterpretation of the specialist nurse recommendation, stated as human error. Incorrect dose administration by the nurses was also identified as a service/care problem. These two issues were then the subject of further analysis using the incident decision tree and fishbone diagram.
The RCA approach uses a contributory factors classification framework (NPSA, 2009) and maps identified factors to an Ishikawa fishbone diagram (Ishikawa 1982; NPSA, 2016) as seen in Figure 17. The classification framework encourages identification of contributory factors from an individual to organisational level and presents these in list form.

Figure 17 RCA Fishbone diagram

The RCA can be contrasted with the STAMP approach where a qualitative model of the system is formed which includes modelling relationships and interactions between system components through control-feedback loops, as shown in Figure 18.
The control structure could be modelled up to government level as shown in Case Study 1, however, a system boundary was placed around the care provided in the hospital and community care centre and stops at management level. This boundary was placed to fit the information provided within the RCA report and to keep the analysis within the locus of control of the healthcare providers.

STAMP’s safety control structure model is used to identify weaknesses in the control structure and control-feedback flaws. STAMP considers four types of hazardous control actions (Leveson, 2012):

i. Control actions necessary to enforce safety constraint are not given (control action not given)

ii. The necessary control actions were provided too early or too late (incorrect timing)
iii. Unsafe control actions were provided (unsafe control action given)

iv. Control action stops too soon or is applied too long (incorrect duration)

STAMP also analyses the behavioural shaping mechanisms for decision-making of the actors within that system in terms of a process or mental model. This being the actor’s understanding of current system status which needs to be regularly updated. The mental model of a decision maker can be incorrect due to poor feedback and incorrect information about system status as illustrated in Figure 19. The identified control flaws are compared with the contributory factors identified by the RCA in Table 14.

Figure 19 STAMP analysis of individual controller
Table 14 RCA contributory factors and STAMP control flaws

<table>
<thead>
<tr>
<th>System level</th>
<th>RCA identified contributory factors</th>
<th>STAMP identified control flaws</th>
</tr>
</thead>
</table>
| **Diabetes specialist nurse** | Ambiguity in the recommendations in terms of written clarity | **Control flaw**: Issue in communication and coordination with prescribing doctor  
**Mental model**: Recommendation correctly interpreted and correct prescription made  
**Feedback flaw**: No feedback post recommendation |
| **Doctor (hospital)** | **Patient**: Altered neurology, poor history of diabetes compliance. IV steroids falsely elevated blood glucose  
**Task**: New prescription should trigger check of dose  
**Communication**: Misread prescription  
**Team**: Advice written on form was unclear  
**Training**: Insulin e-learning not mandatory  
**Working condition**: Not doctor’s base ward  
**Equipment**: Glargine available in different strengths | **Control actions not given**: Doctor did not question high recommended dosage or review suggestion thoroughly  
**Mental model**: Incorrect understanding of patient status and required prescription  
**Feedback flaw**: Coordination and communication issue in handwritten notes and lack of face-to-face handover at time of writing prescription  
No feedback after prescription made |
| **Failure to further query the recommended dose** | **Individual**: Both nurses in post for 12 months or less with no previous competency issues  
**Task**: Glargine medication stock was on ward  
**Communication**: Dose not cross checked between form completed by specialist nurse and doctor’s prescription  
**Team**: Both nurses part of an established team  
**Training**: Insulin e-learning not mandatory for staff  
**Working condition**: Prescription completed on form, not electronic prescribing | **Control action not given**: Nurse did not query the dosage except for with peers and did not cross-check with specialist nurse documentation or patient notes  
**Mental model**: Accepted doctor’s prescription as correct. Nurses recognised prescription as a large dose but they had seen large doses of insulin prescribed before  
**Feedback flaw**: The charts readily available to ward nurses had high dosage on them. The nurse questioned between themselves but not to specialist nurse or senior staff |
| **Nurse (hospital)** | **Pharmacy (hospital)** | **Control action not given**: Pharmacy did not cross-check prescription against patient records (medication stock was on ward). Prescription was checked prior to patient being transferred but issue not identified  
**Mental model**: Prescription is appropriate |
| **Failure to query dose of the insulin prescribed** | **Control action not given**: Nurse did not query the dosage |
| **Pharmacy (hospital)** | **Organisational (hospital)** | **Control action provided too late**: Assessment form documentation not in format currently advised. Not updated until triggered by incident |
| **Organisational (hospital)** | **Nurse (Community)** | **Control action not given**: Nurse did not query the dosage  
**Mental model**: Accepted prescription as correct  
**Feedback flaw**: Medication dosage had been administered twice previously and on discharge documentation |
| **Nurse (Community)** | **Previous administration of dose and discharge documentation provided rationale for nurse to administer dosage** |
The RCA focussed on the hospital doctor and nurses and the factors contributing to their involvement in the incorrect prescription and administration. The use of an incident decision tree tool, that seeks to determine the actor’s intention and blameworthiness of human error (Reason, 1997; Meadows, Baker and Butler, 2005), absolves those actors of blame, but this focus means less attention is paid to other areas of the system, as shown in Table 14.

A major difference between RCA and STAMP is in STAMP’s modelling of the system. RCA does not model the relationships between system components and it does not build a model of the system. Contributory factors are attached to the identified service problem and presented in list form, whereas the control-feedback relationships presented in STAMP’s safety control structure provide analysis of interactions within the system.

Another major difference is in STAMP’s explicit consideration of both the system operation and the system development or design. The consideration of system design led the analysis to questioning the processes involved in the introduction and redesign of the diabetes assessment form and the change management processes involved in the specification, creation, review and approval of the form. There was also questioning about the design of information systems, with information given to the prescribing doctor split between electronic and paper format.

5.4.2 Recommendations

Both analyses produced recommendations to prevent future incidents, with a summary of these presented in Table 15. In comparing the analyses recommendations, STAMP generated additional recommendations for system-level improvement, especially with consideration that two system-level improvements from RCA referred to the initiatives which were already being conducted prior to the incident: i) the review and implementation of the new diabetes assessment form; ii) the implementation of the insulin strategy. The RCA-based recommendations focussed on staff training and personal reflection, whereas the STAMP analysis broadened the discussion and recommendations to systemic issues (service development and change management), rather than just the operation management issues.
Table 15 Comparison of recommendations for remedial action from RCA and STAMP analyses

<table>
<thead>
<tr>
<th>Category of countermeasure</th>
<th>RCA-based recommendations</th>
<th>STAMP-based recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individual behaviour</td>
<td>Personal reflection to be undertaken</td>
<td>Ensure doctors, nurses and pharmacists are given clear safety responsibilities (check and query) and understand these responsibilities</td>
</tr>
<tr>
<td></td>
<td>Roll out and ensure compliance to insulin safety e-learning for all medical and nursing staff</td>
<td></td>
</tr>
<tr>
<td>Tools, technology and physical environment</td>
<td>Review and implement new diabetes assessment form</td>
<td>Review and implement new diabetes assessment form</td>
</tr>
<tr>
<td></td>
<td>Review electronic information system for potential inclusion of DSN treatment recommendation</td>
<td>Review electronic information system for potential inclusion of DSN treatment recommendation</td>
</tr>
<tr>
<td></td>
<td>Feedback to pharmaceutical company about name of medication</td>
<td>Feedback to pharmaceutical company about name of medication</td>
</tr>
<tr>
<td>Tasks and organisation</td>
<td>Implement insulin safety strategy (on-going)</td>
<td>Ward management to regularly reinforce to nurses the expectation to query prescriptions where there is a concern regarding dose or administration instructions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ensure channels of enquiry to ward leadership or original treatment team are available</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ensure prescribers, dispensers and administrators of medication have comprehensive and clear information of patient status and treatment plan</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Train DSN’s as prescribers to enable them to prescribe insulin at time of patient assessment</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Design process to include DSN check with patient after administration of medication</td>
</tr>
<tr>
<td>Change management</td>
<td>None</td>
<td>Revise the design process (specification and testing) for form templates and other electronic and paper-based information systems.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Revise the documentation review process. The review process needs to be able to efficiently manage change, with timely review and implementation of new documentation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ensure future design of software includes specification and assessment of user needs</td>
</tr>
</tbody>
</table>
5.4.3 Participant responses on usability of STAMP
The participants were generally positive about the usability of STAMP as shown in Figure 20. Although their comments suggested that it was difficult to understand at first and they felt they needed more practice and examples to get to grips with the method. None of the participants disagreed with any of the statements on usability, with 75% agreeing STAMP was easy to apply and easy to understand.

[Graph showing participant responses on usability]

Figure 20 Healthcare stakeholder perception of STAMP usability (n=4)
As well as desiring more time and further opportunities for application, the participants pointed out some of the difficulties in evaluating their use of STAMP, having used it on an incident they had previously been involved in investigating.

'We need another session with longer time to go through an example. It would also be useful to look at an incident which had not been investigated before to see how the solutions were different from other analysis. With the example used we had been involved in looking at it and therefore not
coming at it fresh. Use this method first and then compare with conducting an RCA.’ – Medication safety pharmacist (Participant 3)

‘It was initially hard thinking in this way as it was a different approach. Confidence and competence will increase with repeated use.’ – Clinical director (Participant 4)

5.4.4 Participant responses on utility of STAMP

The healthcare stakeholders played a vital role in providing work domain knowledge and contributed to the analysis and generation of recommendations. Feedback on the utility of the STAMP approach was generally positive, with all four participants agreeing that STAMP was useful in learning from the incident and it can help make recommendations, as shown in Figure 21.

![Figure 21 Healthcare stakeholder perception of STAMP utility (n=4)](image_url)
The participants found the approach helped them think about the incident in a systemic way as shown in the following quotes.

‘The approach enables us to think more broadly about system controls and failure points’ – Clinical director (Participant 4)

‘Previously I felt my team were really to blame, but after this I now know it was multifactorial and all the people involved had a part to play’ – Advanced nurse practitioner (Participant 2)

‘It made me think of the interactions between people. All the groups/individuals involved and where the problem could occur or how it could be picked up. It helped look at the staff groups and their interactions with each other.’ – Medication safety pharmacist (Participant 3)

‘It was useful to see and discuss the various different interactions where the problem could have occurred, and communication perhaps didn’t happen or could go wrong. It gives a good view of the mechanisms in place for feedback and how people are making the decisions.’ – Medication safety pharmacist (Participant 3)

5.4.5 Participant responses on future application of STAMP

The participants were positive about the future application of STAMP in healthcare, as shown in Figure 22. On future application, in the comments given, all participants indicated that further experience with the method and HFE experts’ help would be required.
5.4.6 Overall evaluation of STAMP application

5.4.6.1 Descriptive requirement
As noted by the participants, the descriptive requirement, in terms of the guidance provided by the method to identify the complete set of facts relevant to the incident, is difficult to evaluate in this case. This is due to the investigation and fact-finding being undertaken prior to the STAMP intervention. STAMP does order the information about the incident into visual outputs.

5.4.6.2 Revealing requirement
As in the first case study, STAMP has guided the analysis to think about underlying causes rather than just events. The participants noted this as a positive in their feedback on STAMP, that it helped them think systemically and particularly about the interactions between people and teams. Furthermore, STAMP’s consideration of system development/design pushed the analysts to ask questions beyond the immediate incident, particularly in terms of change processes and equipment design.
5.4.6.3 Consequential requirement
In this case STAMP was used in the development of recommendations for incident prevention. These moved beyond those identified by the RCA analysis and included recommendations at different levels of the hospital system. In terms of implementing these recommendations, practical issues still apply as they would with any analysis tool.

5.4.6.4 Validation requirement
For STAMP’s models and analysis, validation came through the input from work domain experts. Inter-rater reliability, in terms of agreement between different investigators using the method was not tested as such, rather agreement was reached through discussion between the different researchers and participants.

5.4.6.5 Practical requirement
The participants felt they would have difficulty conducting a STAMP analysis without further support and training. However, the intervention with HFE researchers facilitating STAMP was not particularly resource intensive.

5.5 Discussion
This study applied an HFE-led STAMP analysis in a current practice healthcare incident investigation. In doing this, the study built on the findings from Case Study 1 (Chapter 4) by considering the constraints of normal practice in healthcare incident investigation and applying STAMP to a common hospital-based small-scale incident. The use of STAMP and collaboration between HFE and healthcare stakeholders was found to facilitate systems thinking, impacting the thinking of some of the original investigators of the incident and guided the development of underlying system-based recommendations. Healthcare stakeholders were generally positive about STAMP’s utility, usability and potential future use. Participants didn’t have as much trouble analysing this case as they did with the complexity of the Mid-Staffs case and were more involved in the analysis and development of recommendations. Again, the participants felt they needed more practice and
more time to learn STAMP. Furthermore, many felt external help was required to apply the method properly.

Findings from Case Study 1 showed the development of more effective remedial actions to be a key feature in participants’ thoughts and they were not all convinced this could be improved by STAMP. Here, participants were positive about their ability to make additional recommendations based on the STAMP analysis. However, this does not remove the issues with implementation of remedial actions.

5.5.1 Limitations
In this case study, an obstacle was found in healthcare stakeholder availability and getting stakeholders together in the same place, at the same time, to conduct a STAMP workshop of worthwhile duration. The first workshop was opportunistic in its use of a patient safety interest group platform to use a prearranged group session to perform the analysis. For the second workshop there were difficulties in getting the group together at the same place and same time, it was heavily reliant on a facilitation from one of the participants and after expecting around 10 stakeholders to attend only four turned up for the second workshop. The session was not long enough to achieve a full analysis and explore all issues in depth, but extra time was not available. These factors mean the analysis is heavily reliant on the work done by the HFE analysts and this is limited by their knowledge of the incident and healthcare system, particularly in this case where only limited data was available from the single incident report.

5.5.2 Reflective summary
STAMP can be effectively used to conduct analyses on batches of similar incidents. Leveson, et al (2016) used 30 adverse cardiovascular surgery events using one safety control structure with various control flaws from all incidents overlaid. This both increases the quality of the analysis through the additional data and cuts the time taken for each individual analysis. Although slowing the response to each individual incident these would be actioned through initial RCA analysis, with the HFE analysis providing a review process. In this way, HFE expertise can be effectively utilised in collaboration with
healthcare professionals. Future studies may benefit from this aggregated incident analysis.
Chapter 6 - Case study 3: STAMP aggregated analysis of patient suicide incidents

6.1 Introduction

The two previous case studies have drawn interest towards the use of multiple incidents in an aggregated analysis to improve the data available to use in STAMP. Furthermore, Case Study 1 developed a theme around STAMP’s application in healthcare being limited by a system view potentially overlooking the details and intricacies of healthcare work. The case study presented in this chapter seeks to explore these areas further, applying STAMP in an aggregated analysis and comparing findings to those found in an interview study with frontline workers on what they find creates safety in their everyday practice.

Reason (2008) has raised concern with taking too extreme a view with either a system or person perspective regarding the understanding of safety incidents. Reason sees a weakness in the system view in an excessive reliance on system measures and a disregard for the personal qualities of individuals and the impact on safety (Reason, 2008). The importance of understanding work as performed at the frontline and how practice creates safety has been noted elsewhere (Woods and Cook, 2002). The ideas collected and packaged as Safety-II also highlight the benefit of understanding everyday function in the workplace and the full range from normal routine performance, exceptionally good performance, near-misses and incidents or accidents (Hollnagel, 2014; Shorrock, 2014).

The potential weakness in making safety recommendations from analysing incidents alone (Hollnagel, 2014) and in taking a strong system view (Reason, 2008), makes for an interesting study in comparing findings from a STAMP incident analysis with findings from in-depth interviews with workers on safety practices. It also provides a further form of evaluating the utility of STAMP in healthcare. In this case study, STAMP is applied to the investigation of patient suicide in community-based mental health care. Patient suicide was discussed
by a participant in Case Study 1 as an example of the very different types of incidents that healthcare needs to investigate, there was interest in how STAMP would perform in this type of investigation.

6.1.1 Patient suicide in community-based mental health care

Suicide is a major public health concern with close to 800,000 deaths by suicide each year worldwide (World Health Organization, 2017). In England, around 4,500 people end their own lives each year and an estimated 27% of those had contact with mental health services within the 12 months preceding their death (Appleby et al., 2017). Over the past 25 years mental health care has transitioned from an institution-based care model to a predominantly community-based care model (Gilburt et al., 2014). This means that patients with an ‘acceptable’ level of suicidal risk are managed within the community setting, where risk of suicide is potentially higher than within inpatient care. Although the multiple factors involved make comparisons between the settings difficult, suicide rates among patients of community-based crisis resolution home treatment teams were higher per episode (14.6 per 10,000 episodes) than in patients per inpatient hospital admission (8.8 per 10,000 hospital admissions) in England between 2003 and 2011 (Hunt et al., 2014).

This case study focussed on the community-based mental health care services of a Mental Health Trust in England, this included community mental health teams (ongoing support for complex and serious mental health problems), crisis teams (urgent support for a mental health crisis) and psychological service teams (support through psychological therapy). The Mental Health Trust serves a population of one million and employs over 5500 members of staff. Suicides of people known to the Trust are subject to investigation and incident analysis. This study reviewed 41 of the Trust’s suicide incident reports (average length 26 pages) where patients had been involved with community-based care.

6.1.2 Aims and objectives

This study aims to examine the application of STAMP to the aggregated analysis of patient suicide incidents. To meet this aim, the study has the following objectives:
• To demonstrate the application of STAMP to the analysis of a cluster of patient suicide incidents
• To evaluate the validity of the analysis findings through comparison with interviews with frontline workers on what helps them create safety in practice
• To evaluate and reflect on the STAMP application

6.2 Methods
The research follows a case study design (Yin, 2013) with suicide incident reports and interviews with staff used as data sources. The case study focussed on the community-based mental health care services of a Mental Health Trust in England, this included community mental health teams (ongoing support for complex and serious mental health problems), crisis teams (urgent support for a mental health crisis) and psychological service teams (support through psychological therapy).

6.2.1 STAMP analysis

6.2.1.1 Data collection
First, this study reviewed 43 incident reports (mean length 26 pages) and 41 incident reports where patients had been involved with community-based care were selected for STAMP analysis. Figure 23 and Figure 24 summarise the incidents by patient age, gender and suicide method. The suicide methods are consistent with national data where hanging/strangulation and self-poisoning by overdose are the most common methods for patient suicide in England (Appleby et al., 2017). Two incident reports did not provide patient age and gender. The investigations in the reports had been conducted by experienced mental health professionals using RCA as the analytical approach.
6.2.1.2 Incident analysis protocol

STAMP was applied to the analysis of 41 suicide incident reports. The application of STAMP followed the process described by Leveson (2012) and used in Case studies 1 and 2. The analysis considered four main types of hazardous control actions (Leveson, 2012): i) control actions necessary to enforce safety constraint are not given; ii) the necessary control actions were provided too early or too late; iii) unsafe control actions were provided; iv) a control action stops too soon or is applied too long.

The STAMP analysis was initially conducted by the author, the RCA reports were coded in qualitative data analysis software (NVivo) to identify controllers, control-feedback loops, control failures, feedback flaws, communication and coordination issues, and underlying patterns. Following the development of an
initial control structure and findings, the analysis was discussed with another HFE researcher and alterations made until an agreement was reached. The safety control structure was validated in an initial group session with three managers from the Trust (including two Consultant Psychiatrists), a further group session was conducted to discuss the findings and recommendations (control structure shown in Appendix 11 was used in this discussion). Information on the manager participants is provided in Table 16.

6.2.2 Interview protocol
Semi-structured interviews were conducted with 20 community-based mental health professionals: a group interview with the three managers to validate the system model and to get an overview of operations; two group interviews with six and five participants from crisis teams (eight Registered Mental Health Nurses, two Support Workers, one Social Worker); four individual interviews with Community Mental Health Team staff (two Consultant Psychiatrists and two Community Psychiatric Nurses); two individual interviews with psychological services staff (two Psychotherapists). A summary of participant information for the managers, community teams and psychological services is provided in Table 16, the crisis teams participant information is summarised in Table 17.

Participants were identified by a manager at the Trust who was collaborating in the research, they were then invited to interview through email. The sampling of participants aimed to include stakeholders from the three main areas of crisis teams, community teams and psychological services. But as the nature of crisis teams increases their suicide prevention work it was felt necessary to include more participants from this area.
Table 16 Participant information for managers, community team and psychological service

<table>
<thead>
<tr>
<th>Participant</th>
<th>Role</th>
<th>Experience in service area</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Medical director/consultant psychiatrist</td>
<td>20+ years</td>
</tr>
<tr>
<td>2</td>
<td>Service manager/consultant psychiatrist</td>
<td>20+ years</td>
</tr>
<tr>
<td>3</td>
<td>Service manager</td>
<td>20+ years</td>
</tr>
<tr>
<td>4</td>
<td>Consultant psychiatrist</td>
<td>20+ years</td>
</tr>
<tr>
<td>5</td>
<td>Consultant psychiatrist</td>
<td>10+ years</td>
</tr>
<tr>
<td>6</td>
<td>Community psychiatric nurse</td>
<td>10+ years (with time in crisis team)</td>
</tr>
<tr>
<td>7</td>
<td>Community psychiatric nurse</td>
<td>10+ years</td>
</tr>
<tr>
<td>8</td>
<td>Psychotherapist and clinical lead</td>
<td>10+ years</td>
</tr>
<tr>
<td>9</td>
<td>Consultant psychotherapist</td>
<td>5+ years as consultant</td>
</tr>
</tbody>
</table>

Table 17 Participant information for crisis teams

<table>
<thead>
<tr>
<th>Participant</th>
<th>Role</th>
<th>Experience in crisis service</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Registered mental health nurse</td>
<td>13 years</td>
</tr>
<tr>
<td>11</td>
<td>Social worker</td>
<td>8 years</td>
</tr>
<tr>
<td>12</td>
<td>Registered mental health nurse</td>
<td>1 year</td>
</tr>
<tr>
<td>13</td>
<td>Registered mental health nurse</td>
<td>1 year</td>
</tr>
<tr>
<td>14</td>
<td>Support worker</td>
<td>1 year</td>
</tr>
<tr>
<td>15</td>
<td>Registered mental health nurse</td>
<td>Under 6 months</td>
</tr>
<tr>
<td>16</td>
<td>Registered mental health nurse</td>
<td>8 years</td>
</tr>
<tr>
<td>17</td>
<td>Registered mental health nurse</td>
<td>3 years</td>
</tr>
<tr>
<td>18</td>
<td>Registered mental health nurse</td>
<td>2 years</td>
</tr>
<tr>
<td>19</td>
<td>Registered mental health nurse</td>
<td>2 years</td>
</tr>
<tr>
<td>20</td>
<td>Support worker</td>
<td>2 years</td>
</tr>
</tbody>
</table>

The interviews probed the decision-making process of clinicians, the constraints they operated within and methods they found useful to be successful regarding suicide prevention. This was in line with studies and theories on Naturalistic Decision Making (NDM), which provides approaches to studying critical decision making in the real world (Klein, 1999) and the ideas behind Safety-II (Hollnagel, 2014).

The interviews covered the following topics/questions: How suicidal risk and signals of risk are detected; the process of deciding on response to patient status and thresholds for responses; and the methods staff find useful in dealing with the complexity of the work activities. All interviews were conducted by the author at the participant’s place of work and were between 30 to 60 minutes in duration. The interviews were semi-structured with the use of a topic guide, with deviation allowed to adapt to participant responses. All interviews were audio-recorded, with the recordings transcribed into NVivo and coded into themes. Participants gave written informed consent.
The data analysis and coding relied on the theoretical propositions (Yin, 2013) of Safety-II (Hollnagel, 2014), in that workers would make adaptations in their practice to ensure the system can function. This guided the initial interview topics which were then used to organise and code the interview data, themes then developed within these topics. The interview data was coded by one researcher (the author) but the findings from the study were presented back to another HFE researcher, the managers involved in the group interview and other mental health professionals from the Mental Health Trust at the end of the data analysis. Discussion and comments were invited providing a form of member checking for qualitative validation (Creswell, 2014).

6.2.3 Evaluation of STAMP

Participant evaluation of the usability and utility of STAMP was not conducted in this case study, as explained in section 3.4 of Chapter 3. The application of STAMP is evaluated through the comparison of the STAMP analysis findings with findings from the interviews and against evaluation criteria (Katsakiori, Sakellaropoulos and Manatakis, 2009). The individual interviewees did provide comments on aspects of STAMP having been introduced to the safety control structure diagram, due to time constraints this was not possible in the group interviews.

6.3 Results

6.3.1 STAMP analysis

The processes involved in suicide prevention were modelled as a safety control structure (Figure 25) and its weaknesses identified from the incident report analysis were represented. The model identifies the controllers that influence the system and the control-feedback loops that enable them to change and receive information on the system and patient status. Weak feedback can result in a controller having an incorrect understanding of the system state, which can impact on their ability to make decisions, an example of an individual controller process model is provided in Figure 26. Controls can be weak and ineffective in changing the system to the desired state.
The suicide prevention control structure could have been modelled up to government level as in Case Study 1, but a system boundary was drawn around the regional healthcare the Mental Health Trust was part of, to keep the analysis within the locus of control of the healthcare provider. The police could also be included as a separate controller, however a team from the crisis services works with the police and they attend incidents in a triage vehicle together. The suicide incident reports refer to this crisis response unit, so it has been modelled as such. Similarly, urgent care includes professionals from crisis response within their units and this is represented by the crisis response controller.

![Suicide prevention safety control structure](image)

Figure 25 Suicide prevention safety control structure
The five main weaknesses in the control structure were identified as:

1. Inherent weakness controlling a dynamic risk in community environment

There is an inherent weakness in the control structure in patients having freedom in the community, this limits feedback with patients not under constant observation and places responsibility on the patient to adhere to treatment plans. There were 17 cases where patients have committed suicide without any change in their risk / psychiatric status being detected.

2. Patient non-attendance/non-compliance issues

One major theme in the incident reports that weakens both feedback on patient status to the clinician and the effectiveness of treatment controls is poor patient engagement. Eleven of the reports noted significant patient engagement issues. This includes non-attendance at appointments, declined medical advice and non-adherence to treatment.
3. Patient declines support/service options offered

In four of the reports it is noted that the patient recently presented in a period of crisis but did not receive crisis support or inpatient treatment. In these cases, the patients discussed voluntary admission or further crisis support with the clinicians but were not suitable for forced admission under the Mental Health Act (legislation covering rights of people with a mental health disorder). The patients have then declined crisis and inpatient treatment, in one case this was due to the service the patient was referred to being away from the region they lived in.

4. Patient new to service, recent handover or awaiting appointment

There were patients yet to be assessed by the service they were to enter before the suicide incident or having had few appointments; with seven cases where the service had two or less appointments with the patient prior to the incident.

5. Communication, coordination and process issues

With care provided by multidisciplinary teams and changes in patient status resulting in changes to service provision, coordination between controllers is critical. There were seven cases with examples of coordination and communication issues, with staff sick leave, differences in electronic record keeping between services, administration issues in referrals and lack of required service expertise resulting in disrupted care.

6.3.1.1 Recommendations from STAMP analysis

The recommendations formed from the STAMP analysis centre around the inherent limitation in predicting and controlling human behaviour. The control structure needs to be strengthened with this weakness in mind, to that end recommendations for remedial action are as follows:

- To work towards improvement in patient engagement through service design. This is not a quick fix and would require further research involving patients, to understand the issues they have in engaging with the service.
- To stop out-of-area referrals.
- To ensure prompt follow-up of new referrals.
- The electronic record keeping issues had been or were being improved prior to this study. But a recommendation can be made for better change management when new IT systems are introduced in an organisation to ensure access to patient records are available to other care providers.

The above recommendations are limited by their resource-intensive nature, with them requiring further research or more capacity within the services (local inpatient space, extra appointments).

6.3.2 Interviews

6.3.2.1 Participant comments on STAMP

The individual interviewees were introduced to an early draft of the STAMP analysis safety control structure. After a brief explanation of STAMP concepts in terms of control-feedback loops they were asked to comment on how the model fits to suicide prevention. Interesting comments were made around the assumption the system can control or apply safety constraints to control human behaviour.

‘So, this is a kind of structure of services and availability isn't it? [referring to safety control structure]. I think there's a premise in there which I would already think is false was that it is an indication of things going wrong. So, it's all about risk, and risk is never obliterated when it comes to suicide. And it's about balance of risks and you can never completely get rid of risk. And it's also about in the end it comes down to the decision of the individual, whatever the system is doing. So, if someone decides to jump off a car park, they have in the end made that decision and there is a notion that services can take responsibility for that. But we can't. In the end it comes down to that individual. So that's one premise that actually there's a person involved here that's making the decision themselves. And the second premise is it's about balancing risks and that's both on a population level, not necessarily
the population as a whole but the population of our patients. And it's about for an individual’ – Consultant Psychiatrist

‘And then there are all the things outside our control, so we have this sort of job of as part of our job of preventing people killing themselves or helping people not kill themselves. And yet so much of that is out of our control because if you want to, you would view yourself as an autonomous being and what's going on in your life is altering how you feel and to think that a professional you see every few weeks has some control over that, you wouldn't think that and yet that's the position that we're placed in. So, I can't do anything about cuts in benefits, I can do my best to write letters etc. but I can't do anything about the actual government policy, I can't do anything about the increase in relationship breakdowns in our society. Which hugely increases human misery, even though it also decreases it in another way. I can't do anything about my patient having been abused sexually when they were a child, I'm here doing my best to help people deal with what goes on in their lives as well as them having a mental illness. I can't do anything about lots of that stuff.’ – Consultant Psychiatrist

The premise of control-feedback loops was also questioned in terms of a structure that can become restrictive. A system that attempts to monitor or feedback on patient behaviour can restrict the relationships between clinician and patient.

‘Have you included things that come up from the bottom, because there are things that come up. What I mean is, all the policies are a response to the patients’ pathology. So, something happens, an adverse event, because I think risks are there in life, you can't prevent everything, but something happens and then there is a policy to make sure it doesn't happen again. So, I mean it feeds from human nature basically and then all the policies, you can see that in everything, terrorism, whatever, trying to control, monitor. It's the same, you need to monitor everything as if there's an illusion that you can monitor. I think you can to an extent
monitor, but there is an illusion that you can know everything if you have the right systems in place.’

Question from AC – ‘Meaning it becomes too restrictive?’

‘Yes, that’s what I mean. I don’t know the answer, because obviously you have to react if something happens, I think there is a lot of pressure to react. But I think you’re right, I think trying to tick all the boxes make sure you’ve done everything right is extremely restrictive. And just to add, I think it’s a disservice to the patient because right now patients cannot tell us anything. They know everything needs to get reported so we lost that relationship. So, it’s the intrusion of the policy in the consulting room, and I don’t say that everything should be kept between patient and clinician, I’m not saying everything should be, but there is some common sense that is not there anymore.’ - Psychotherapist

6.3.2.2 Deeper probing into working practice and decision-making

The interviews with staff revealed a complex decision-making process with participants describing the input and detection of changes in patient status, and decision making and response to patient status. The decision-making elements display three main considerations and trade-offs clinicians are making in their judgements: i) being patient-centred in terms of clinical need, patient desires and patient circumstances; ii) a resource consideration in terms of their individual emotional, time, experience and skill resource and the resources available within services; iii) a legal and procedural responsibility with constraints from laws and regulations. Responses are then made accordingly, but the entire process unfolds with a level of uncertainty and ambiguity due to the imperfect nature of information on patient status and ability to predict future behaviour. The overall decision-making process described by the participants can be summarised into the control-feedback mechanisms of the STAMP safety control structure (Figure 27).
158

Figure 27 Decision making process for suicide prevention

6.3.2.2.1 Understanding patient status – feedback and detection of risk

With the inherent weaknesses and uncertainty in gaining an insight into patient status, a holistic approach is taken to risk management. Inputs that went into decision-making included three interlinked elements: i) knowledge built up about the patient over the course of their care; ii) the information disclosed by the patient within the working relationship; iii) understanding of patient status gained through clinical assessment processes.

Within the formal assessments and ongoing monitoring of patient status there are judgements made on the level of suicidal thoughts and intent. Current patient presentation is considered alongside patient diagnosis and risk factors. Non-verbal communication plays a key role in these assessments.

‘We’re using our knowledge, our skills, our gut instinct as well sometimes. To determine someone’s risk at that moment, knowing it can change’ – Crisis Team Support Worker

‘The mental state obviously is important, but the mental state is contributed by many other personal and social circumstances as well. So, some
patients if they're having issues with relationships or issues with finance or jobs. So, when you're making your plan you need to look into those aspects otherwise, we may not be able to manage the risk adequately and also in terms of gauging to what extent the patient risk can change’ – Consultant Psychiatrist

‘Gauging all the non-verbal sorts of responses, are they engaging, what are their responses like.’ – Crisis Team Mental Health Nurse

Building depth to understanding a patient occurs over the course of their care. With a long-term clinician to patient relationship enabling an understanding beyond what can be gained from only assessments and patient records and enhancing the ability to spot patterns in patient presentation.

‘For every new patient you do a full assessment, you get as much information as possible. But listening to the patient, looking from the notes is very different from you being involved in the patient's care all through. Because there are many subtle things which happen between a patient and the clinician which is not documented, which cannot be expressed in words.’ – Consultant Psychiatrist

This is of concern to crisis services which generally have much shorter-term working relationships with patients and are reliant on information from other professionals.

‘A lot of the time we're using secondary information. We try and gather as much information as we can because we don't have the luxury of building a relationship. Very often you're allocated your work and it'll be the first time you've laid eyes on the person.’ – Crisis Team Support Worker

The strength of the relationship and rapport with the patient is perceived as key in assessing patient status. Within community care there is often a reliance on the patient coming forward and confiding with the clinician with regards to any periods of crisis, this requires a trusting relationship with the patient. The crisis services are heavily reliant on clinicians’ ability to build an almost instant rapport with the patient.
‘It’s about reading people. There’s a lot of science and psychiatry behind it but it’s all about engagement. If you can’t engage with your client and if you can’t get into where they’re at and their mental state, you don’t know what’s going on. And they will shut down and they will not tell you what you need to know.’ – Crisis Team Mental Health Nurse

‘…and the patient coming forward is partly the patient taking some responsibility for their own safety. It will partly be about me building up a relationship with them which means that they think that they want to die, but instead of killing themselves they will contact the doctor. Because they trust the doctor, the doctor has told them that they can contact the doctor, there is that little bit of ambivalence in them. Which is helped by knowing that doctor is there and will help.’ – Consultant Psychiatrist

6.3.2.2.2 Decision-making and trade-offs
Along with the clinically indicated need of the patient, clinicians need to consider the patient’s circumstances and desires, the services and resources available to treat the patient, and procedural and legal obligations. All this is considered within a level of uncertainty and ambiguity with the difficulties in detecting risk, predicting human behaviour and the dynamic nature of the risk. The understanding of uncertainty is shown in descriptions of decision-making.

‘…and my judgement, along with my community nursing colleague who knows her well too, is that she is less likely to give into those feelings of wanting to be dead with the support of her family round her. Both because that is supportive to her in building up her ambivalence against suicide and because it reminds her of how her family will feel if she dies. So, we have made a judgement that rather than lock her up in hospital. She’s less likely to do it (commit suicide) if she’s in the community. But I cannot say she won’t do it.’ – Consultant Psychiatrist

i) Dilemma around being patient-centred

Mental health professionals need to consider both the clinical need identified for the patient and the patient’s own desires and circumstances. This creates a collaborative decision-making process, planning with the patient rather than
just for the patient. A balance is needed to maintain patients’ sense of responsibility for their own lives, both for the sake of the service resource and for the patient’s quality of life.

‘We don't want then the patient to become more dependent on the services and we need to help the patient to develop more autonomy and build more strengths within the community in managing those situations rather than relying on the services.’ – Consultant Psychiatrist

‘Sometimes intervening is not helpful to them. It might feel counter-intuitive, but sometimes…. basically, what will happen, if every time, he knows now that if he takes an overdose I will be motherly or looking after him, then he would keep taking the overdose. So, there will be a reinforcement.’ - Psychotherapist

There is also a feeling that the fit to patient desires can go too far towards customer service, rather than clinical need.

‘I think it's the customer service mentality, so this is what I need, I'm telling you what I need, you need to do what I need.’ - Psychotherapist

ii) Dilemma around being resource-constrained

Decisions on responses to changes in patient status are also affected by the quantity and the quality of the service and treatment options available.

‘One is resource issue, because if people would have for example more psychotherapy, talking treatments, you wouldn't put them on too many antidepressants.’ - Psychotherapist

‘But for one individual, you're still doing the best for that individual that you can with the resources you've got. And that then becomes wrong (e.g. suicide) but the decision for the individual given the resources you've got may not have been wrong.’ – Consultant Psychiatrist
iii) Dilemma around being procedurally and legally-obliged

Consideration of legal and procedural obligation is also a factor that impacts decision-making. There is a threat of litigation if something untoward were to happen, with documentation and procedures in place to protect clinicians.

‘It's more about making sure we're not open to litigation. So, clinicians, I think one of the things that impacts on decision making is fear.’ - Psychotherapist

‘You have to consider how everything you do, every action you take, everything you document would look if the worst happened and somebody lost their life.’ – Community Psychiatric Nurse

6.3.2.3 Recommendations from interviews - what helps things go right?

The interviewees were also asked about what helped them to be successful and the results revealed a strong theme on the importance of peer-support, with other suggestions of the importance of using multiple sources to gather patient information and matching patients with clinician’s skillset. Further discussion centred around the more technical or clinical aspects of instilling hope and working with the patient to help them understand that suicide is not the solution to their problems. Due to the more clinical nature of these points they are beyond the scope of this study and will not be discussed further here.

Both informal peer-support through conversations with colleagues and formal peer-support in the form of supervision and multi-disciplinary group meetings were perceived to be valuable.

‘More important to all this is the corridor discussions I have with my colleagues, that is very powerful and that’s very important. If I'm not sure what I need to do with this patient, how I need to manage the risk and when I see my colleague, when we are having coffee or if it is something which is very urgent, I can pick up the phone and then say look I need some help and advice. That kind of, I can call, I know that I have some of my colleagues whom I can call anytime of the day and not have to think at all
that I'm disturbing them. And I similarly respond in the same way.’ – Consultant Psychiatrist

‘...everyone has supervision. So, I go and talk to them about what happened, and they help me think about aspects of the presentation and the risk. That I might, I might struggle with. Because we all have blind spots. So yeah that's important, to have supervision, to have a space outside of the relationship you have, the assessment, where you can reflect.’ – Psychotherapist

‘...it is that experience, but you can learn from it without actually having the experience yourself, definitely.’ – Crisis Team Mental Health Nurse ‘...and that's the importance of supervision and group supervision and those daily discussions that we have.’ – Crisis Team Mental Health Nurse

‘I think one of the things about this team is that we all come from vary varied backgrounds both from our experience working within our own disciplines but then we also are made up of different disciplines as well. So, there's nurses, there's mental health nurses, there's learning disability nurses, there's social workers, there's occupational therapists, there's people from psychology backgrounds, there's doctors and psychiatrists. But I think one thing that's being looked at, at the moment is how we share our knowledge, because there's a huge wealth of it, how we share that amongst ourselves. And I think that's something that's going to be implemented shortly in the form of staff delivering teaching packages. Because sometimes I think we take our own knowledge for granted but then we don't know the value of that until someone says oh that's a good idea, until you realise that you're coming at things from a different point of view.’ – Crisis Team Mental Health Nurse

Interviewees discussed how they use multiple sources to build up information about the patient, including information from family, friends and other agencies to form a complete picture.
‘Sometimes what you hear from the patient, what you see in the patient, may not be the complete picture. So, in those instances we must go beyond the patient, which will be family, friends or other agencies who are involved in the patient care and probably his previous involvement with other services.’ – Consultant Psychiatrist

Participants discussed one method of coping and adapting to the wide range of patient needs through carefully matching patients with a clinician’s skillset.

‘You need to match the member of staff. Knowing your patient and knowing your members of staff and being able to match the two as best as you can.’ – Crisis Team Mental Health Nurse. ‘Yes, that's an art as well.’ – Crisis Team Mental Health Nurse

‘I think also because as a team we see patients in the morning, if you've identified a particular member of staff and think they might be able to see this in more detail, then within reason you can kind of facilitate that to happen. I've been to see a patient and I wasn't sure if what I was seeing was a learning disability or autism and that's not my strength. But I know that my colleague has that strength and we're in the same team, so we were able to facilitate that she went to see them the next time. So, it's little things like that's sharing our knowledge, because we are our own resource.’ – Crisis Team Support Worker. ‘Staff are the most important resource, take everything else away and we'd still make a difference.’ – Crisis Team Mental Health Nurse

6.3.3 Overall evaluation of STAMP

6.3.3.1 Descriptive requirement

One difference between original investigation reports and STAMP analysis was that the original analysis has a big focus on patient history, going back through their clinical records to judge whether the treatment had been appropriate. This clinical aspect would not necessarily come up in an analysis focussed on control-feedback as STAMP does and would require clinical expertise to analyse. There is a suggestion that in this case STAMP may not guide the analysis to consider clinically relevant facts.
6.3.3.2 Revealing requirement
As in the other cases, STAMP considers interactions among system components and distinguishes between events and system issues. There may be underlying causes of a clinical nature that relate to treatment options and clinical judgement that would require clinical expertise to analyse.

6.3.3.3 Consequential requirement
A consideration of STAMP’s recommendations is in keeping with the consequential requirement of accident investigation (to formulate specific recommendations for prevention). The recommendations made from the STAMP analysis tend to be system measures that require extra resource and are out of the control of and not directed towards individual clinicians. In contrast, the suggestions made by interviewees are things that they can do individually and within their teams, the role of the organisation would be to facilitate these activities as best it can. Table 18 contrasts the recommendations between STAMP incident analysis and interviews with healthcare staff.

Table 18 Comparison of recommendations from incident analysis and interviews

<table>
<thead>
<tr>
<th>Focus</th>
<th>STAMP analysis of incidents</th>
<th>Participant consideration of what helps them</th>
</tr>
</thead>
<tbody>
<tr>
<td>Focus</td>
<td>Uncertainty in predicting and controlling human behaviour</td>
<td>Trade-offs and dilemmas in decision-making</td>
</tr>
<tr>
<td>Recommendations</td>
<td>Service design for patient engagement</td>
<td>Facilitate formal and informal peer support</td>
</tr>
<tr>
<td></td>
<td>Prompt follow-up for new patients</td>
<td>Matching clinician’s skillset to patient</td>
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<tr>
<td></td>
<td>Stopping out-of-area referrals</td>
<td>Gather information on patient status from multiple sources</td>
</tr>
<tr>
<td></td>
<td>System design to allow communication between provider IT systems</td>
<td></td>
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</tbody>
</table>

6.3.3.4 Validation requirement
STAMP has a focus on controls enforcing safety constraints, in this case this concept may put too much emphasis on a control the healthcare stakeholders do not have. Although at a system level the focus on enforcing constraints may
be more fitting, in terms of governance structures and regulation, at the level of the individual clinician and patient the management of risk is not simply about enforcing constraints. And the most restrictive or constrained practice such as admission to inpatient care may not be right for every patient.

The results suggest that more consideration is required for how clinicians manage to overcome the uncertainties and difficulties in preventing suicide. Furthermore, STAMP’s process model format for a decision-maker’s mental model is perhaps too simplified and would benefit from consideration of the trade-offs decision-makers deal with. These weaknesses in STAMP are relevant to the validation requirement and it may be oversimplifying reality to the point of overlooking key considerations. This is further shown in considering the differences in recommendations between the STAMP analysis and what staff themselves put forward as helping them manage suicidal risk, a comparison is shown in Table 18.

6.3.3.5 Practical requirement

In this case study, the analysis was undertaken by the author with healthcare stakeholders used for further information and validation of outputs. As in the other cases it is felt that STAMP requires more expertise than is held in those currently undertaking investigations in healthcare.

6.4 Discussion

The study explored the application of STAMP in the analysis of community-based patient suicide incidents. This application was evaluated by comparing the findings with the findings of interviews with frontline staff. As expected, STAMP gave a system-level understanding and produced recommendations based around system measures. The exploration of working practice in the interviews highlighted some limitations of the STAMP analysis, which are summarised as:

- An oversimplification of decision-making and a need for further consideration of the trade-offs and dilemmas that occur in the complex tasks of clinical judgement.
• STAMP’s focus on the enforcement of safety constraints meaning a lack of consideration of the positive action workers take and the way they adapt and overcome to the difficulties in their work.

Previous work in suicide prevention has been criticised for being overly focussed on risk assessment and the identification of general risk factors (example risk factors include use of alcohol, being 55 years of age plus and being separated/widowed/divorced) (Mulder, 2011). The risk assessment approach assumes that suicide could be reduced if risk of suicide is assessed more frequently and more rigorously, however, risk assessment doesn’t remove the uncertainty around the potential for suicide (Mulder, 2011; Franklin et al., 2017). Recent suicide prevention literature has proposed a more holistic approach (Mokkenstorm et al., 2017) and has taken influence from James Reason’s work on organisational accidents (Reason, 2000). This literature argues for the use of a multilevel system view, encompassing: a direct approach to suicidal behaviours; continual improvement of the quality and safety of care processes; and an organisational commitment to the goal of zero suicides (Mokkenstorm et al., 2017). This type of framework could be extended to include the use of control-theory based system safety approaches, such as STAMP, in the analysis of system hazards and suicide incidents.

6.4.1 Limitations

As with the other two case studies this study is limited by using investigation reports as the basis for the incident analysis, rather than a full investigation from scratch. This is discussed further in the overall discussion in the next chapter, along with potential future research.

Having only one analyst to code the suicide incident reports and interview data provides a further limitation. Some measures were used to increase qualitative validity such as the validation of the STAMP model by subject matter experts, having a second HFE researcher give opinion on the STAMP analysis and further member checking of the study findings. However, there was no checking for reliability in terms of having other analysts code the data and checking agreement between findings.
Chapter 7 - Discussion

7.1 Introduction

This thesis sought to answer two main questions: 1) How effective is STAMP in healthcare incident analysis? and 2) How do healthcare stakeholders perceive the usability and utility of STAMP in healthcare incident analysis? To answer these questions, empirical research has been conducted in the form of three case studies, which have been presented in the previous three chapters. This chapter provides a cross-case analysis of the three studies and presents the main themes and findings.

7.2 Cross-case analysis

The three case studies were linked by their application of STAMP to healthcare, but conditions were varied in the type of incident STAMP was used to analyse. The three case studies can be summarised as follows:

- Case Study 1 applied STAMP to a large-scale organisational failure through the analysis of the Mid-Staffordshire public inquiry, healthcare stakeholders provided feedback on their thoughts on the usability and utility of STAMP.
- Case Study 2 applied STAMP to a small-scale medication prescription error incident and the re-analysis of an RCA investigation, healthcare stakeholders involved in the original RCA gave feedback on their perceptions of the usability and utility of STAMP.
- Case Study 3 applied STAMP to the analysis of aggregated patient suicide incidents in community care. This case study did not collect healthcare stakeholder feedback on STAMP usability and utility. Instead the study compared the findings of the STAMP analysis with the findings of interviews with mental health professionals on what they found helped them to perform effectively in the prevention of suicide.

The following sub-sections present a cross-analysis of the findings from these case studies.
7.2.1 Participant perceptions of the usability of STAMP - Cases 1 and 2

Overall, the participants in Case Study 2 were more positive about the usability of STAMP than in Case Study 1. Participant responses on Case Study 1 (Mid-Staffordshire case) were particularly negative about the ease of understanding with 45% giving a negative response (72% negative or neutral rating) and ease of application with 34% giving a negative response (78% negative or neutral rating). Participants in Case Study 2, where STAMP was applied to a smaller-scale incident within the participants’ workplace, were more positive about ease of understanding and ease of application, with 75% providing positive responses and none providing negative responses. The Mid-Staffordshire case is a large and complex organisational failure and the subject of several long reports. The complexity of the case and the short duration of time that participants had to explore the case and STAMP would impact their assessment of STAMP. Participants felt they needed additional time, further training and external help. Participants in both cases suggested they would need help and external expertise to apply STAMP in the future.

In the current practice of healthcare incident analysis, senior frontline personnel undertake incident investigations alongside their clinical working activities. This practice creates difficulties in finding time to provide sufficient training in STAMP. Furthermore, comments from healthcare stakeholders suggested they were put off by the initial complex appearance of STAMP. It is perhaps not feasible for the method to fit into current practice, rather STAMP needs external expertise to apply effectively in healthcare. Case Study 3 demonstrated an external application, whereby initial incident analysis reports were aggregated and used to analyse suicide prevention in community care. The input of healthcare stakeholders is still needed, to validate models and results, but their time is used more effectively if the analysis is done by external safety researchers or professionals.
7.2.2 Participant perceptions of the utility of STAMP – Cases 1 and 2

Overall, participants were positive in their ratings of the utility of STAMP. In Case 1 participants were particularly positive about STAMP providing a different perspective and its relevance to healthcare (78% gave a positive response). Participants in Case I were more mixed about the application of STAMP being useful in learning from the incident and it helping to make recommendations. The Mid-Staffordshire case did not lend itself to making recommendations, in part due to the sheer number of recommendations made in the original public inquiry investigation. Within Case 2, the author and participants were able to make additional recommendations than the initial investigation and in accordance with this, participants were more positive in their ratings on usefulness in learning and helping to make recommendations.

The discussion around the utility of STAMP in learning from incidents and making recommendations, regarded factors involved in making and implementing remedial actions, that were outside of the accident model or method used. This is discussed further in section 7.4.

7.2.3 Overall evaluation of STAMP application - Cases 1, 2 and 3

Within each case study STAMP was evaluated against a set of requirements provided by Katsakiori et al. (2009), this section attempts a cross-case evaluation with further consideration of the criteria for accident model evaluation given by Benner (1985).

7.2.3.1 Descriptive requirement

The descriptive requirement relates to an analysis method providing guidance in order to identify the set of facts relevant to an accident (Katsakiori, Sakellaropoulos and Manatakis, 2009) and is in accordance with Benner’s definitive criterion. This requirement is difficult to evaluate against in this research due to the use of incident reports as data, rather than performing full investigations with initial data collection. Something can be said for STAMP’s organisation of the data however, particularly in consideration of Case Study
1, where a large amount of information about the incident was incorporated into STAMP’s structure. STAMP’s concept of accidents was a good fit for the data provided in Case Study 2 and 3 also, although it cannot be said from this research that STAMP would have provoked the same information search and data collection as the initial investigations.

7.2.3.2 Revealing requirement
The revealing requirement states that an accident investigation method should distinguish between events and underlying causes. This distinction should guide an investigator to considering underlying causes (Katsakiori, Sakellaropoulos and Manatakis, 2009). A related criterion is Benner’s (1985) noncausal criteria, whereby an accident model should address full descriptions of accident phenomenon, showing interactions among all parties and things. Generally, systemic accident analysis methods are praised for their consideration of underlying causes and interactions between system components, and it is this that sets them apart from earlier linear methods (Hollnagel, 2004; Salmon et al., 2011). Within this research, participants praised STAMP for its consideration of interactions between individuals, teams and the organisation, particularly within Case Study 2. Throughout the case studies STAMP has been shown to go beyond a search for superficial cause. STAMP considers the enforcement of safety constraints at each level of the system and models the interactions between system components (controllers) in control-feedback loops. In both Case Study 2 and 3 STAMP revealed system weaknesses that had not been articulated in the original investigation reports. For Case Study 2, the consideration of system design moved the investigation towards the proposal of system measure remedial actions. For Case Study 3, the conceptualisation of control-feedback loops articulated weaknesses in the system control structure due to uncertainty regarding suicidal behaviour. This uncertainty may be well known to frontline clinical staff, but not necessarily understood by the non-clinical managers involved in designing the system and coroners involved in investigating suicides. It is felt that STAMP meets this revealing requirement.
7.2.3.3 Consequential requirement

To meet this requirement, an accident investigation method needs to allow for specific recommendations to be generated for prevention of future accidents (Katsakiori, Sakellaropoulos and Manatakis, 2009). The application of STAMP in Case Study 2 and 3 allowed for recommendations to be made for prevention of medication incidents and patient suicide.

A criticism of current practice in healthcare incident analysis is in the low quality of the proposed remedial actions, which are felt to be weak and ineffective measures focussing on training and policy (Wu, Lipshutz and Pronovost, 2008; Kellogg et al., 2016; Peerally et al., 2016). Case Study 2 showed an increase in the generation of system measure solutions following the use of STAMP compared with the initial RCA investigation. The proportion of influence on the generation of recommendations that was due to the presence of HFE researchers compared with use of STAMP is not known, but participants did agree that STAMP helped them to make additional recommendations. There is some limitation in evaluating based on the quality of generated recommendations, when their effectiveness is only truly known after they are implemented, and their impact measured. However there has been some attempt to rank the strength of proposed solutions by the NPSA as shown in Figure 28 (Trbovich and Shojania, 2017), with policy change and retraining towards the bottom for effectiveness.

Hierarchy of effectiveness

![Figure 28 Hierarchy of effectiveness adapted from Trbovich and Shojania, 2017](image-url)
Something that can be noted is that the stronger effectiveness actions are considered to take more effort and in Case Study 3 the recommendations from the incident analysis would be resource-intensive. Case Study 3 perhaps displayed a general weakness of making recommendations from incident analysis alone, with recommendations generated from the incident analysis being resource intensive but also beyond the control of those implementing change. When compared with what frontline workers found helped them to perform to their best, which showed actions that can be taken within their teams and organisations, and not reliant on extra money or changes beyond their locus of control. This reveals a need to take more considerations of working practice and the positive actions taken by frontline workers to prevent incidents, alongside the safety constraints and system measures focussed on by STAMP incident prevention. Despite this limitation of incident analysis operating in isolation, as an analysis tool it is felt that STAMP meets this consequential requirement.

7.2.3.4 Validation requirement

The validation requirement constitutes validity in the correspondence between the analysis findings and reality, and reliability in facilitating agreement in analysis results between different users (Katsakiori, Sakellaropoulos and Manatakis, 2009). Benner (1985) also proposes a criterion for accident models to be realistic, in that the models must represent reality and the observed nature of the accident phenomenon. In the case studies in this research, agreement was reached between analysts through discussion over the safety control structure models produced and these models were also validated with healthcare stakeholders along with analysis findings. So, while issues with reliability and validity were reduced through the process taken for the analysis, reliability and validity were not formally tested. Katsakiori et al. (2009) found few validation or reliability studies within the literature and postulated that this is due to the difficulties evaluating these criteria.

Inter-rater reliability could be tested by having different analysts apply STAMP to an accident and their findings compared to check for agreement, but this would require several analysts trained in STAMP. Trained STAMP analysts
were not available for this research project, but formal testing of reliability in STAMP analyses in healthcare and other industries should be a priority for future research. Previous research has assessed the reliability of STAMP in application to the South Korea Sewol Ferry accident (Filho, Jun and Waterson, 2017). Four applications of systemic accident analysis were compared, two using AcciMap and two using STAMP. In comparing the identification of contributory factors, the study found the reliability between the two STAMP applications (61% of identified factors were common between applications) to be higher than the two AcciMap applications (31% of identified factors were common between applications) (Filho, Jun and Waterson, 2017). When considering the recommendations made from each application, the authors of the study reported that the recommendations reflected the focus and knowledge of the analyst. In this thesis, the literature review in Chapter 2 introduced the influence of analysis aim and analyst background on the outcomes of accident analysis. It may be a suboptimal approach to compare applications by different analysts which may have started with different aims. Reliability could be tested in controlled conditions where analysts set out with the same analysis aim, furthermore, using multiple analysts with varied backgrounds could also provide interesting findings pertaining to the effect of analyst background.

In this research project, the validity of the STAMP safety control structure was in some way tested through feedback from healthcare stakeholders and their thoughts on how it fits to healthcare systems. Areas of contention here were in a need to clarify the definition for control actions in healthcare and whether the system model oversimplifies healthcare systems and misses some of the important nuances of healthcare work. These issues are discussed in more detail in section 7.3. The lack of formal testing of the validity of STAMP applications is a key limitation of this research. To test for validity in accident analysis there needs to be an agreement on what the reality of the accident situation was, this is difficult due to the nature of analysing a past event upon which there is incomplete knowledge. However, there is potential in setting up a panel of subject matter experts that can provide broad expertise on the accident situation, between them the panel can agree on a reality of the
accident situation. Multiple analysts could then undertake a STAMP analysis of the accident, the outcomes of these analyses can then be evaluated against the predetermined reality to give an understanding of the validity of STAMP analysis. This research project focussed on the usability, utility and feasibility of using STAMP in healthcare. Formal testing of the validity of STAMP applications is a large undertaking and an area deserving of its own focus in future research.

7.2.3.5 Practical requirement
The practical requirement relates to the need for education and training to use STAMP. From participant comments and ratings of STAMP usability it can be said that training is needed to use the method effectively. Participants, although having had limited exposure to STAMP, felt they needed external help and/or further training to apply the method in the future. Previous research has also highlighted that accident investigators find STAMP to be a complicated method to use (Underwood, Waterson and Braithwaite, 2016).

7.2.3.6 Application field
The application field requirement specifies that an analysis method should account for the specific context of the accident. This requirement is at the crux of this thesis, in the effectiveness of STAMP when applied to the specific context of healthcare incidents. STAMP was considered relevant to healthcare by the participants and the three case studies have demonstrated its use in healthcare. But the method is not tailored to healthcare and does not account for the language used by healthcare personnel. This application field requirement is discussed more in sections 7.3.4 and 7.4, and in making recommendations for the application of STAMP in healthcare.

7.2.4 Summary of main themes
More interesting than the Likert scale ratings of the usability and utility of STAMP were the comments made by participants’ during their exploration of the method. The combination of participant comments and author reflections on the use of STAMP are synthesised into themes on the application of STAMP in healthcare. Four overarching themes are discussed in the following
sections, these are: system versus person perspective; human controller decision-making; modelling the soft elements of healthcare systems in STAMP; STAMP language – defining terms for healthcare.

### 7.3 Emerging themes on STAMP application in healthcare

#### 7.3.1 System versus person perspective

A theme developed from comments of healthcare stakeholder participants in Case Study 1 regarded a deliberation between a system and person perspective. Participants in Case Study 1 and 2 liked STAMP's system overview, the consideration of interactions between people, teams and the organisation, and the system focus shifting concentration from individual blame. But in the first case study there were some concerns that too far a move to a systems view may mean underplaying the role of the individual. This concern echoes the warnings of James Reason (2008) and his proposal of the weaknesses of taking too extreme a view from either a system or person perspective.

The weakness of an extreme system view is said to be in an excessive reliance on system measures and a disregard for personal qualities (Reason, 2008). Too strong a system view could lead to learned helplessness (Reason, 2008), with individuals believing they are powerless to affect change in a flawed system. Case Study 3 tested features of the system versus person perspective by comparing a STAMP incident analysis with frontline worker interviews focussing on what helped them to perform effectively in working practice (regarding prevention of patient suicide). The STAMP incident analysis did not facilitate the identification or understanding of the importance of activities such as peer-support, matching clinician skillset to patients and the holistic approach to understanding patient status. These positive aspects of work were overlooked by a focus on the failure of the system to enforce safety constraints. However, this is not something that would be picked up in a traditional person perspective of incidents, where workers are seen as a potential hazard (Reason, 2008).
In an overview of safety work in safety critical industries, Vincent and Amalberti (2016) have classified three main approaches to safety for healthcare: ultra-adaptive, high reliability and ultra-safe. The findings from Case Study 3 were comparable to the ultra-adaptive model, in which risk is embraced and risk management is heavily reliant on the judgement, adaptability and resilience of individuals. The ultra-adaptive model prioritises adaptation and recovery strategies, power is given to experts, with safety improvements coming through peer-to-peer learning, shadowing, acquiring professional experience and personnel having awareness regarding their own limitations (Vincent and Amalberti, 2016). Much focus is given to the positive actions of individuals rather than excessive reliance on system measures. The STAMP incident analysis in the case studies did not capture much in the way of positive actions, rather the focus is on enforcing safety constraints, however this is perhaps a more general limitation of incident analysis rather than just the STAMP method. Woods and Cook (2002) have previously recommended a more holistic approach to reactions to failure that include consideration of how working practice creates safety. The comments from participants in Case Study 1 tended to focus on the negative aspects of individual performance. However, they did articulate that STAMP may overlook the important details and nuances of working practice in healthcare. This includes variations in procedures and protocols that different clinical specialisms work to and the deviations workers make from written protocol, in essence the difference between work as done versus work as imagined (Hollnagel, 2015). Consideration of positive actions and adaptations by workers is the thought-line of research in resilience engineering (Hollnagel, Woods and Leveson, 2006) and Safety-II (Hollnagel, 2014).

It is the author’s recommendation that when using STAMP in healthcare, consideration is given to the positive actions and adaptations of healthcare workers, rather than sole focus on the controlling actions they take to enforce safety constraints. In-depth consideration of working practices will also help to ensure a consideration of Work-as-Done and avoid a STAMP analysis that leans too far towards Work-as-Imagined (Hollnagel, 2015; Braithwaite, Wears and Hollnagel, 2017). Making sure to get an understanding of how work is
actually carried out, rather than just how it is planned beforehand or evaluated after it has taken place (Hollnagel, 2015). This can be achieved by extending STAMP to include ideas and techniques that have been categorised into Safety-II, such as gaining an understanding of worker adaptations through interviews and observations of working practice. The difficulty comes in incorporating this into the STAMP safety control structure model. FRAM attempts to analyse adaptations and had a diagrammatic output to present the findings, but it lacks the structured model that STAMP has and it would not be easy to represent the nuances and complexities of work in a simple and readable model. Rather than disrupting the structure of the control structure model and the overview it provides, it may be better to use STAMP alongside another method that can provide an in-depth analysis of current practice, such as the approach taken to Case Study 3.

7.3.2 Human controller decision-making

Although it takes a system view, STAMP does analyse the behaviour of individuals in modelling the decision-making of human controllers. A particular finding of Case Study 3 was the potential for STAMP to oversimplify human decision-making and lack representation of the trade-offs made in decisions by healthcare workers.

In considering human decision-making, STAMP takes into account the safety-related responsibilities of controllers, the context their decisions are taken in and the controller’s mental model. Decision-making is presented as a process model (Figure 29), inadequate decisions are usually depicted as the result of flaws in the controller’s mental model (e.g. in Case Study 2 the nurses administering the medication had feedback informing them it was the correct dose). But with the more complex decisions involving clinical judgement, such as in Case Study 3, there is scope for further consideration of trade-offs.
Case Study 3’s focus on clinician decision-making in suicide prevention revealed potential trade-offs in accounting for resource constraints, patient clinical need and circumstances, and procedural obligations. Due to the level of uncertainty regarding suicidal behaviour in the community setting, a clinician’s mental model is always likely to be flawed. Decisions are made using clinical judgement with various factors weighed-up and trade-offs made, as illustrated in the following quotes:

‘...and my judgement, along with my community nursing colleague who knows her well too, is that she is less likely to give into those feelings of wanting to be dead with the support of her family round her. Both because that is supportive to her in building up her ambivalence against suicide and because it reminds her of how her family will feel if she dies. So, we have made a judgement that rather than lock her up in hospital. She’s less likely to do it (commit suicide) if she’s in the community. But I cannot say she won’t do it.’ – Consultant Psychiatrist

‘...for one individual, you’re still doing the best for that individual that you can with the resources you’ve got. And that then becomes wrong (e.g. suicide) but the decision for the individual given the resources you've got may not have been wrong.’ – Consultant Psychiatrist
Within Case Study 3 it was felt important to make explicit consideration of the complex decisions mental health care staff make and the contention with multiple trade-offs between being patient-centred, resource-constrained and legally-obliged. Decisions around risk management and patient care are too complex to be evaluated only in terms of completeness of mental model. There is room within a STAMP analysis to allow for further consideration of decision-making in terms of responsibilities and context, but the role of trade-offs is not made explicit.

Trade-offs in decision-making have been addressed in resilience engineering literature (Righi, Saurin and Wachs, 2015), where there is a focus on how to help people cope with complexity under pressure to achieve success (Woods & Hollnagel, 2006). Previous research into the work of aircraft maintenance technicians identified decision shaping factors of schedule pressure and operator effort optimisation, airworthiness, cost saving, and operator accountability in aircraft maintenance technicians (Nathanael, Tsagkas and Marmaras, 2016). These factors were suggested as potentially common to decision-making in other safety critical industries (Nathanael, Tsagkas and Marmaras, 2016) and are broadly comparable to mental health care staff considerations of clinician capacity and service resources, patient and clinical need, and regulatory and legal considerations.

Clinician trade-offs related to compromise of risk, such as discharging a patient early to accommodate another patient needing care, have been the subject of research taking a naturalistic decision making approach (Reader, Reddy and Brett, 2018). A variance in decision preferences among intensive care unit clinicians was found, with clinicians making decisions to fit resource and operational constraints in a dynamic environment (Reader, Reddy and Brett, 2018). Further to this, Patterson and Wears (2015) discuss system-level trade-offs between adaptive capacity and efficient production in a pharmacy. Their case study described a situation where demands on the system had greatly increased, while resource allocation had remained static, a situation not unlike that in community mental health care. The extraordinary resilient behaviours and adaptive capacity of individuals had masked the system’s reduced ability to sustain performance under stress (Patterson and Wears, 2015). Patterson
and Wears (2015) warn that the system leaders may be prevented from recognising the individual efforts required for success and the increasing risk from further demands on the system. This again highlights that incident analysis alone might not give the full picture of safety performance in healthcare systems, STAMP incident analysis would benefit from explicit consideration of trade-offs and the positive actions of workers.

The author highlights a need for STAMP to consider the trade-offs healthcare workers make in their decision-making, alongside inaccurate or incomplete mental models. Safety science literature has presented the need for in-depth consideration of working practices in the systems under investigation, during accident analysis or safety improvement projects (e.g. Woods and Cook, 2002; Hollnagel, 2014). The area of Naturalistic Decision Making (NDM) (Klein, 1999, 2008) has built up knowledge of human decision-making in work and critical situations, and provides techniques for studying this decision-making. In safety science and NDM, observations of working practice and in-depth interviews with workers are often used to probe decision-making in the real world. Alongside a STAMP analysis, the author recommends that a more in-depth probing into decision-making is used, one that goes beyond incomplete mental models and gets a richer picture of working practices. This is particularly important in healthcare contexts where clinical judgement plays a key role, such as in mental health care and can be achieved using interviews and observations based on the techniques of NDM.

7.3.3 Modelling the soft elements of healthcare systems in STAMP

Culture was consistently referred to by participants as an element lacking from the STAMP safety control structure model, particularly in Case Study 1. Culture is defined in the Oxford English dictionary as ‘the distinctive ideas, customs, social behaviour, products, or way of life of a particular nation, society, people, or period.’ Definitions provided for safety culture are generally in keeping with this definition of culture, the Health and Safety Commission have provided a definition (see below) that is regularly cited in safety culture literature (Health and Safety Executive, 2005):
‘The safety culture of an organisation is the product of individual and group values, attitudes, perceptions, competencies, and patterns of behaviour that determine the commitment to; and the style and proficiency of, an organisation’s health and safety management’ (Health and Safety Commission, 1993).

The breadth of this definition and the scope of a STAMP analysis (as demonstrated in Case Study 1) open a challenging debate as to whether STAMP has inadequacies regarding consideration of culture. STAMP is modelling the structure an organisation has in place to enforce safety constraints on behaviour, this could include monitoring and control of individual and group values, attitudes etc. STAMP is also considering an organisational hierarchy and within that the organisation’s health and safety management. So, there is overlap in the definition of safety culture and the analytical approach of STAMP.

Leveson makes several references to safety culture in literature on STAMP (Leveson, 2012) and in introducing the need for an approach such as STAMP states that: ‘the struggle for a good safety culture will never end because it must continually fight against the functional pressures of the work environment. Improvement of the safety culture will therefore require an analytical approach directed toward the behaviour-shaping factors in the environment.’ (Leveson 2012, p. 52). STAMP is later described in this text as the analytical approach to achieving this, including in the design of operating conditions and the safety management control structure. Stringfellow (2010) suggests a set of general factors to consider in a STAMP analysis which includes safety culture. Leveson (2012) suggests that the important contextual and behaviour-shaping factors become clear during the process of explaining why people acted the way they did in a STAMP analysis. So, there is consideration of safety culture in a STAMP analysis, but we must remember that the participants of this research were being introduced to STAMP for the first time and perhaps need more guidance towards aspects such as culture. Stringfellow (2010) has provided some guidance in suggesting an analysis should consider if organisational culture allows for honest reporting by lower level individuals, for example.
Participants made comments on STAMP while exploring a safety control structure, rather than a textbook and it can be said that issues with culture do not jump out from a control structure diagram. Indeed, one criticism of STAMP arising in participant feedback was that the control structure model didn’t tell them what went wrong, rather it showed what was in place at the time. Some participants discussed the model further and suggested that it didn’t capture the complexity in the relationships between people, teams and organisations. Another suggested it didn’t show the humanness (these aspects are also guided towards by Stringfellow (2010)). Taken together it seems the criticism of STAMP was directed more towards the safety control structure model and an inability to represent the softer elements of healthcare systems.

Hollnagel (2006) believes fixed diagrammatic structures such as tree, graph or network are inadequate as a representation of the potential for complex accidents and this inadequacy is a consequence of the systemic view of accidents (Hollnagel, 2006). Graphical representations focusing on descriptions of links between parts are said to be unable to account for how a stable system may suddenly become unstable and struggle to represent dynamic bindings or couplings (Hollnagel, 2006). The safety control structure model shows fixed links representing control-feedback loops, but as the participants commented it does not show the strength of, or changes in, the relationships between teams and organisations. Participants from commissioning bodies were particularly descriptive of the relationships they had to build and maintain with provider organisations, the differences between the relationships with different providers and the effect this had on safety management. In Case Study 3, the strength of the dynamic relationships between a patient and the service, or patient and clinician, were also an important factor regarding their safety. When analysing an accident these factors would likely be unearthed (as Leveson (2012) points out) but it is not apparent to people looking at the control structure model and is not easy to represent in a fixed diagram structure.

The model is beneficial in reducing the need to search through hundreds of pages of an accident report document to gain an understanding of an accident. But comments from healthcare stakeholders highlight a need for the model to
show the control structure weaknesses more explicitly and for the model to reference organisational factors such as relationships and culture.

7.3.4 STAMP language – defining terms for healthcare

The language of STAMP was also questioned in terms of its representation of healthcare systems. It was not always clear to the author what needed to be captured as a control in the analysis of healthcare incidents and participants also requested clarity in the definition of control. Furthermore, in Case Study 3, some participants felt the term control was not representative of their relationships with patients, which didn’t allow for them to control patient behaviour as such.

The use of the control and feedback terms comes from systems and control theory and Leveson has described the idea of control actions as follows:

‘An example of a control action is the imposition of constraints upon the activity at one level of a hierarchy, which define the ‘laws of behaviour’ at that level. Those laws of behaviour yield activity meaningful at a higher level. Hierarchies are characterised by control processes operating at the interfaces between levels.’ – Leveson (2012, p. 64)

In Case Study 3 the meaningful activity is in preventing loss of human life (patient suicide), towards the bottom of the hierarchy, clinicians may use control actions such as instilling hope in a patient, facilitating a change in a patient’s belief that suicide is the solution to their problems, or prescribing medication. So, while they may not have complete control, they are performing actions to constrain a patient’s suicidal behaviour. You can however sympathise that at the frontline of mental healthcare, the proposition that they could potentially be seen to fail to control suicidal behaviour, a dynamic process containing a high level of uncertainty, could cause friction. So, while not necessarily conceptually wrong, there is reason to consider the use of the term control for the benefit of acceptance and usability in healthcare.

We can also see in these examples of control actions in mental healthcare that there could be a huge breadth of potential actions to consider in healthcare. This brings us to the comments on clarity of definition and the question, what
are controls in healthcare? There is a balance to be struck between being too prescriptive and in providing clarity and guidance to new users of STAMP. It is the author’s reflection that, to some degree, it becomes apparent when going through the accident analysis as to what the control actions were and what was important to capture within the model. But then this needs to be explained and articulated to healthcare stakeholders, whether they are involved in the analysis or in validating the model and findings.

A previous section of this discussion deliberated on the need for a healthcare STAMP analysis to ensure consideration of the positive actions and adaptations of healthcare workers that may not be directly related to enforcing constraints. These actions may not necessarily occur vertically down a hierarchy and could be support within teams. Here cautionary advice is given on how the term control may be interpreted and the need to clarify what is meant by control within the STAMP analysis. Particularly when the healthcare stakeholders are not fully involved in the analysis and may not see the link between hazard, safety constraints and control actions. It needs to be made clear that the analysis is interested in the actions taken by healthcare workers to prevent an unwanted loss, rather than there being an assumption that they should have complete control of a process.

7.4 Would STAMP make a difference to current practice?

The literature review in Chapter 2 and exploratory descriptive study at the start of Case Study 1 described issues with current practice in healthcare incident analysis. One of the limitations of current practice was in the analytical approach used, RCA, but this was not felt to be the only factor reducing the effectiveness of incident investigation. It would be naïve to think that a change from RCA to STAMP alone could make drastic and sustained improvements to investigation quality. The healthcare literature and participant comments on current practice were largely in agreement with safety literature on factors influencing investigation outcome.

Accident investigation can be influenced by several factors including the background and knowledge of the analyst (Rasmussen, 1990; Lundberg, Rollenhagen and Hollnagel, 2010), the accident model used (Lundberg,
Rollenhagen and Hollnagel, 2009), the time and resources available for the investigation and proposed remedial actions being constrained by practical considerations (Lundberg, Rollenhagen and Hollnagel, 2010). We also have to consider that an accident investigator is human and not immune to cognitive bias (see Appendix 1) or political and organisational pressures (Johnson, 2003; Dien, Dechy and Guillaume, 2012). Within the case studies of this thesis, STAMP was applied by the author, who has a background in HFE and is external to the NHS organisations subjected to analysis. So, when compared with current practice, not only was the method changed but also the influences on the individual analyst. A proposal of the author is that for STAMP to be effective in healthcare it needs to be performed by analysts with experience and training in the STAMP method, there is a further requirement of safety/HFE expertise and the input of healthcare stakeholders. In addition, there needs to be awareness of the factors influencing investigation outcome.

The need for training to provide competence in using STAMP may seem like a barrier to adoption of the method, but there are ways to accommodate this. Currently local healthcare provider incident investigations are undertaken by busy frontline clinical workers and they may benefit from using methods with better usability characteristics such as AcciMap. However, healthcare also contains patient safety specialists and managers at provider, regional and national level. These managers and specialists may have the required motivation and safety expertise to undertake training in STAMP and to use the approach in the analysis of clusters of patient safety incidents. Furthermore, it is expected that the recruitment of HFE and safety specialists in healthcare should increase in the future, these specialists also have potential as STAMP users. This would provide healthcare with the capability of undertaking effective systemic accident analysis and benefit from a control-theory perspective of patient safety incidents.

Within the case studies and analyses of this research, input was sought from healthcare stakeholders with specialist knowledge on the work domain and this was combined with the knowledge of HFE researchers. Work domain knowledge is a vital part of the analysis and when combined with HFE knowledge can produce good quality analysis outcomes. Collaboration is
necessary as neither group of analysts hold the requisite knowledge from both domains. But this collaboration has its challenges, such as the limited time healthcare stakeholders can give and communication between the two professional groups with their different technical terms and jargon.

The use of STAMP as a systemic accident analysis method should also benefit investigation outcome in comparison to sole use of the RCA cause-effect model as occurs in current practice (Hollnagel, 2006; Lundberg, Rollenhagen and Hollnagel, 2009). STAMP contains a combination of systemic thinking with qualitative systems modelling and detailed analysis of human decision making. While RCA, although including identification of contributory factors to incidents, lacks a description or explanation of the relationships and interactions between humans and components across the system. This limits the understanding of how these factors shape behaviour and impact human decision-making. Within this thesis the use of STAMP is shown to be of benefit to the development of remedial actions.

Although beneficial, this combination of method and expertise does not remove the organisational and political factors that can influence investigation outcome and implementation of remedies. These issues are beyond the scope of this thesis and of individual incident investigations, but it is a known problem that has led to calls for independent investigation bodies in healthcare (Macrae and Vincent, 2014) and the development of the Healthcare Safety Investigation Branch (HSIB) in the UK.

7.5 Methodological considerations and limitations
The limitations of the research have been considered throughout the research, with some discussion of limitations with each individual case study. As qualitative case study research, the research design suffers from limitations common to this type of study, the strategies taken to lessen limitation effects are discussed in the following sections.

7.5.1 Qualitative validity
Consideration of validity in qualitative research has been described as a test or check on the accuracy of the findings, if they are accurate according to the
researcher, participant and the readers of the research (Creswell, 2014). Terms used in discussion of validity of qualitative research include trustworthiness, authenticity and credibility (Creswell, 2014). Steps have been taken throughout the research to ensure validity, but of course there are trade-offs in the decisions taken in research design that mean limitations still occur.

Robson (2011) describes threats to validity that can occur in qualitative research in description, interpretation and theory. A valid description requires accurate and complete data, within this research this has been ensured through audio-recording and full transcription of participant interviews and comments on STAMP. While workshop 1 in Case Study 2 wasn’t audio-recorded, the workshop wasn’t used in evaluating the application of STAMP in healthcare, rather it was used to provide more information for the incident analysis itself. Efforts have been made to convey the findings of the research with a rich, thick description (Creswell, 2014), including in the descriptions of case study context and setting, and the quotes from participants.

Interpretation normally refers to the interpretation of results from people, such as the comments from the interviews and workshops with healthcare stakeholders. A threat to interpretation comes in imposing a framework on what is happening rather than this emerging from the data (Robson, 2011). No framework was applied to the interpretation of participant perspectives in the interviews and workshops. The evaluation questionnaire was fixed in terms of the scale-based questions, but it also included open questions and participants were asked for further comments and discussion. The scales are limited in forcing participants to agree or disagree with a statement provided by the researcher rather than articulate their own view, but these questions were used to lead into the further discussion and were never presented alone. In interpreting the findings, evidence is provided for each theme and within the case studies this is in the form of rich descriptive quotes from different participants, providing multiple perspectives (Creswell, 2014).

The main threat regarding theory is in not considering alternative understandings of the phenomena studied (Robson, 2011; Yin, 2013). The literature review and case studies have considered the role of factors beyond
analytical approach that impact the quality and outcomes of incident investigation. This has enabled the viewing of the application of STAMP in healthcare within the context of normal practice where other factors could diminish the impact of the approach. Furthermore, a point has been made to include negative (Creswell, 2014) participant feedback on STAMP, even when they ran counter to the themes such as the more extreme views in Case Study 1.

The research could have considered alternative system accident analysis methods such as in previous research comparing STAMP with AcciMap (Salmon, Cornelissen and Trotter, 2012; Underwood and Waterson, 2014). This could further have benefitted the research in allowing participants to relate their views on STAMP to another approach, for example AcciMap is more usable than STAMP. However, there was felt to be difficulties in one analyst applying different methods, with the author being the main analyst. The first application by whichever method first used would likely set how the analyst thought about the incident, the second method then just a rejig of this analysis and not exploring the depth of the approach or how this method would view the incident independently. Order effects could potentially be avoided through counterbalancing and changing the order of method first used, but then the number of case studies would need to be increased and the research approach changed to include fixed design studies (Robson, 2011). This research has instead sought to investigate the application of one method, in depth.

7.5.1.1 Bias and rigour
All research involving people presents issues of bias and rigour (Robson, 2011). There is a need to clarify the bias the researcher brought to this research (Creswell, 2014) and the relationship between researcher and setting, and between researcher and participants (Robson, 2011).

Both Robson (2011) and Creswell (2014) discuss the potential benefit of spending a long time in the field, that it gives the researcher an in-depth understanding of the phenomenon under study, helping to increase the accuracy and validity of findings (Creswell, 2014). The researchers can become more accepted by participants which can help reduce initial reactivity
and the trusting relationship reducing the likelihood of respondents giving biased information (Robson, 2011). This research was not ethnographic in nature and the researcher dipped in and out of the case study setting, without spending prolonged periods of time with participants. This could potentially reduce the relationship between researcher and participants, most of which were only met on one occasion for interview or workshop. But the research was not designed to be ethnographic, nor to only describe the phenomenon, rather it was about application of a method, still there is a potential limitation here. Efforts were made to triangulate different data sources and use different approaches to examine the application of STAMP, using multiple perspectives and in demonstrating the application in detail and discussing its effectiveness with reference to established criteria. Furthermore, established relationships can have a negative effect, with prolonged involvement potentially increasing researcher bias with their role as researcher and interpretation of findings affected by their relationships and feelings towards the setting (Robson, 2011).

Other approaches to increasing rigour come in triangulation through using more than one observer/researcher (Robson, 2011; Creswell, 2014). Further observers can check the accuracy of data collection and analysis. This research is limited by predominantly having only one researcher conduct interviews and workshops, and code the findings. However, this avoids deviation in interview and workshop procedures and drifts in the definition of codes from coordination and communication issues between coders. And from a practical standpoint this was individual research, not team research, other researchers were not available to undertake data collection and results analysis. Parts of the research did involve member checking (Robson, 2011; Creswell, 2014), with publications and outputs of the research involving healthcare stakeholders from the case study setting, giving them the opportunity to check the researcher’s accounts and findings for accuracy. This occurred in Case Study 2 and 3, but not Case Study 1. Case Study 3 was even presented back to healthcare professionals from the healthcare provider involved at an educational event. Furthermore, the research had auditors (Creswell, 2014) in the author’s supervisor and internal examiner throughout the research process. The research was also regularly presented to peers
(Robson, 2011) in research group meetings, a doctoral consortium, Loughborough Design School presentations and conferences, with feedback taken onboard.

A further strategy for increased rigour came in the keeping of a record of activities (Robson, 2011; Yin, 2013) involved in the research, including audio-recordings, transcriptions, details of the data analysis and a journal documenting notes taken during interviews. This audit trail is both electronic with NVivo records and paper-based with notebooks and journals.

7.5.2 Qualitative reliability
Qualitative reliability regards whether a researcher’s approach is consistent across different researchers and different projects (Creswell, 2014). Ideas of standardisation can be problematic for qualitative research, where methods are generally non-standardised and precludes formal reliability testing, Robson (2011) instead advises to avoid common pitfalls in data collection and analysis (e.g. equipment failure and transcription errors) and being able to show that the research has been conducted thoroughly, carefully and honestly. This brings us back to the documentation of research activities and audit trail, explained in the previous section, with the procedures of the case studies in this research documented with as many steps of procedures as possible (Yin, 2013).

There was a slip in terms of documentation of steps within workshop 1 of Case Study 2, where participant information was not collected. This was in part due to a convenience sampling of using a pre-arranged education event. However, participants did introduce themselves along with their role in healthcare, but this was not documented by the researcher as it was in the other workshops. When considering the role of this workshop and the overall aim of the research this lack of documentation of participant information is not an issue. The workshop was used to gather more perspectives and information about the patient safety incident itself, along with preparing the researcher for the use of STAMP in the next workshop where its application was evaluated through participant feedback. The participants of workshop 1 were not used in the healthcare stakeholder evaluation of STAMP.
7.5.3 Generalisability

Both Robson (2011) and Creswell (2014) consider qualitative research to be most concerned with internal generalisability, in the generalisability of the conclusions within the setting studied, rather than external generalisation beyond that setting (Robson, 2011). As Creswell puts it, the intent of qualitative inquiry is not to generalise findings to individuals, sites or places outside of those under study (Creswell, 2014).

However, Robson (2011) stresses that the lack of statistical generalisations in qualitative research does not preclude generalisability beyond the specific setting studied. This research is concerned with the application of STAMP in healthcare incident analysis and has investigated the effectiveness of this potential application with case studies applying STAMP to specific incidents in certain settings. So, there is a concern with external generalisability and analytical generalisations have been made concerning the application of STAMP in healthcare settings other than those studied.

The generalisations in this research are not made to populations but rather theoretical propositions (Yin, 2013), in that STAMP can be applied to other areas of healthcare, with similar factors influencing the usability, utility and effectiveness of STAMP. Analytical generalisation made from the case studies are based on replication logic in the demonstrations of STAMP applications and the evaluation against criteria in the cross-case analysis. This replication provides insight into the use of STAMP in varied healthcare contexts and themes were developed across the case studies, it is reasonable to believe the themes would hold true across further healthcare contexts, but this is not known for certain. As with other research endeavours an element of doubt is held. There may be more issue in making generalisations solely from the participant evaluation of STAMP. The participants of this research were volunteers and most held an interest in patient safety and/or HFE that may not be true of a wider sample. Those without an interest in patient safety may have different perspectives of STAMP than those included within this research and this should be considered when interpreting the findings.
7.5.4 Incident analysis approach

Another consideration regarding limitations is the incident analysis procedure. The incident analysis was done from previous reports on the incidents and not part of a full investigation, this is a limitation previously noted by Woodcock when reviewing accident analysis literature (Woodcock, 1995; Woodcock et al., 2005). Not conducting a full investigation means the research does not see how STAMP would have driven and influenced data collection, there may be missing data that could be included, or STAMP may not have helped identify certain data.

There was also a lack of testing of the reliability of STAMP, with the analysis undertaken by the author and agreement reached with another researcher, rather than having different analysts conduct an analysis and testing for reliability through seeing if there was agreement between analysis findings from the different analysts.

7.6 Summary

To summarise this discussion, the key findings of the research are presented in Table 19.
Table 19 Summary of key findings and recommendations for applications of STAMP in healthcare

<table>
<thead>
<tr>
<th><strong>Key findings</strong></th>
<th><strong>Recommendations for STAMP</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>STAMP difficult to use for those newly introduced to the approach.</td>
<td>There is a requirement for training and/or external facilitation for effective application.</td>
</tr>
<tr>
<td>STAMP has utility in application to varied incidents and facilitates the generation of system measure recommendations.</td>
<td>STAMP has potential to be used in the investigation and analysis of patient safety incidents.</td>
</tr>
<tr>
<td>Healthcare stakeholders positive about the utility and future application of STAMP.</td>
<td>STAMP may be most effective when used by safety specialists such as patient safety managers and HFE specialists.</td>
</tr>
<tr>
<td>STAMP incident analysis may overlook the positive safety-related actions of healthcare workers and the nuances of work.</td>
<td>STAMP incident analysis should be combined with a deep understanding of working practice and worker adaptations through observations and interviews.</td>
</tr>
<tr>
<td>STAMP’s consideration of human controller decision-making is too simplistic when applied to certain healthcare contexts.</td>
<td>STAMP analyses need to consider the dilemmas faced by clinical staff and trade-offs made when making complex clinical judgements and decisions.</td>
</tr>
<tr>
<td>Control structure diagrams may be seen to make everything look okay and overlook cultural, relationship and environmental factors.</td>
<td>Control structure diagrams should make explicit reference to system weaknesses/vulnerabilities and cultural, relationship and environmental factors.</td>
</tr>
<tr>
<td>There can be difficulties defining control actions in healthcare and the term ‘control’ can be perceived as inappropriate by healthcare stakeholders.</td>
<td>Care should be taken when using the term ‘control’, ensure healthcare stakeholders understand these are the actions taken to prevent unwanted loss and guide with context specific examples.</td>
</tr>
<tr>
<td>The analytical approach taken to incident analysis does not work in isolation.</td>
<td>A need to consider choice of analyst and the factors that influence incident investigation outcome.</td>
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</table>
Chapter 8 - Conclusions

8.1 Summary of main findings
This research set out to examine the application of STAMP in healthcare and develops a better understanding of how STAMP could be used in healthcare incident analysis. The research collected healthcare stakeholder views on the usability and utility of STAMP and demonstrated the application of STAMP in three case studies in different healthcare contexts.

Healthcare stakeholders felt they would need external expert help and/or lengthy training and practice to apply STAMP effectively. Several stakeholders found STAMP to be a complicated method and an issue was found with the language and terminology used in STAMP for those without system safety and HFE experience. It is expected that future applications of STAMP would be conducted by analysts with the requisite expertise, rather than frontline healthcare workers with minimal training in incident investigation. However, healthcare stakeholders can contribute to a STAMP analysis and are needed for their clinical expertise and work domain knowledge.

STAMP was effective in providing an analysis of a system, considering interactions between system components and generating recommendations for prevention of future incidents, particularly regarding system measures. Furthermore, healthcare stakeholders were mostly positive about its utility and potential future application.

Although STAMP considers individual human controllers and decision-making, there is potential to overlook some of the personal qualities and positive actions of individuals valued highly in healthcare. This may be an issue for incident analysis generally and it is previously suggested that safety management should not rely on incident analysis alone, with a need to consider normal practice, near misses and full range of performance variation. There is a need to consider what helps healthcare professionals create safety and the adaptations they make to function successfully within the system. But at the same time healthcare should not rely too much on individual resilience, which may conceal system issues while healthcare systems migrate to failure.
and healthcare needs methods such as STAMP to identify system issues and help propose system remedies.

Based on the findings from the case studies the author can make recommendations to increase the effectiveness of STAMP applications in healthcare:

- Ensure consideration of the positive action healthcare workers take to create safety, along with the actions they take to enforce safety constraints.
- Make explicit consideration of trade-offs in decision-making when analysing human controllers.
- The safety control structure diagram should represent the weaknesses in the structure and make explicit reference to cultural, organisational relationship and environmental factors.
- Care should be taken when using the term ‘control’ with healthcare stakeholders, ensure they understand these are the actions taken to prevent unwanted loss and guide with context specific examples.

STAMP can be applied effectively to healthcare incident analysis, but it needs to be undertaken by the right analysts, with the necessary data and time resources, and with consideration for the biases and organisational influences that can affect incident investigation outcomes.

8.2 Summary of contributions
This research has made several contributions to knowledge, although the research used a method developed by others and previously applied in healthcare, the original contributions include:

- Demonstrated the use of STAMP in new healthcare contexts in the application to a large-scale hospital-based organisational incident (Mid-Staffordshire case) and to the analysis of community-based patient suicide incidents.
- Involved healthcare stakeholders in the argument for using STAMP in healthcare by gathering their perspectives on the usability and utility of STAMP. This was further enhanced with consideration of the
application of STAMP with reference to current practice in healthcare incident investigation.

- Evaluated the application of STAMP to healthcare incident analysis within a research design that had greater generalisability than previous studies in the area, with a multiple case strategy and evaluation against specified criteria.
- Made suggestions to improve STAMP, in the recommendation that consideration of trade-offs in decision-making is added to the human controller process model.

Overall, this research filled a gap in understanding concerning the application of STAMP in healthcare incident analysis and how it can be integrated into current incident investigation practice.

8.3 Future work

There is the opportunity to confirm the findings through further studies applying STAMP in different healthcare context and the involvement of a wider group of healthcare stakeholders. But rather than just replication, this research can also build into further work.

8.3.1 STAMP-led full investigation

A limitation of this work was in the use of incident reports as the basis for the STAMP analysis. Future work could complete full STAMP-led investigations, allowing STAMP to guide the identification of information about the incident. STAMP could then be evaluated against the full range of requirements and criteria for accident analysis models and methods.

8.3.2 Compare STAMP with applications of other systemic accident analysis methods

Early in this research STAMP was identified as the method of choice to overcome some of the limitations of current healthcare incident analysis practice. But other systemic accident analysis techniques may offer similar or further benefits. FRAM wasn’t used due to the lack of method guidance and example applications at the time of the research, but a skilled analyst could apply the method and contrast with a STAMP application to the same incident.
Similarly, AcciMap could be contrasted with STAMP in application to healthcare incidents with feedback from healthcare stakeholders on usability and utility. There is also potential for methods to be combined to see the benefit of taking a multi-method approach to incident analysis.

8.3.3 Formal testing of the validity and reliability of STAMP applications
The reliability of STAMP in terms of agreement between results of an analysis between different investigators was not examined, nor was the validity of STAMP applications in comparing analysis outputs with a predetermined accident reality. With the availability of STAMP trained analysts, different investigators could apply the method to the same incident(s) and the outputs and findings compared. With more investigators, further factors can be considered in terms of analyst background, experience and knowledge, and how this effects analysis outcome when the same analytical approach is used. Testing of validity could be performed by putting together a panel of experts to discuss and agree upon the reality of an accident situation, STAMP analysts could then perform an investigation, with their outputs compared with the panel’s accident reality.

8.3.4 Train healthcare stakeholders in STAMP
If healthcare stakeholders can be made available for thorough training in STAMP, they could be trained and allowed to conduct investigations and analysis themselves. Outputs from their analysis could then be evaluated and they could give more comprehensive evaluation of the usability and utility of STAMP. Research of this type could be used in the development of healthcare specific training in STAMP.

8.3.5 Incorporate trade-offs in controller decision-making in further applications of STAMP
The consideration of trade-offs could be included in future applications of STAMP in healthcare and other industries. This consideration of trade-odds was only developed in the final case study of this research. Further research
could investigate whether certain trade-offs are present in other industries and other areas of healthcare.

8.3.6 Test the use of the control structures developed in the case studies as part of an STPA hazard analysis

This research project has focussed on accident analysis, but STAMP has a hazard analysis method in STPA. It would be interesting to perform hazard analyses using the control structures developed in this research to identify leading indicators to future incidents (Leveson, 2015). This would demonstrate a proactive, rather than reactive, application of STAMP in healthcare.

8.3.7 Further case studies

Further case studies examining the application of STAMP in healthcare could vary certain conditions, such as using in the context of systems with more technical aspects such as medical devices and software. Or taking consideration of other aspects of the wider system that are outside the scope of healthcare such as the media and legal components. The media and legal components were not comprehensively analysed in the case studies of this research, but their influence was mentioned by participants, such as in how patient suicide was reported in the local newspapers and the influence of coroner investigations. These areas could be included in the wider safety control structure or in the consideration of the benefit of using other methods.
References


Filho, A., Jun, G. and Waterson, P. (2017) ‘Four studies, two methods, one


Stringfellow, M. V (2010) *Accident Analysis And Hazard Analysis For Human And Organizational Factors*. Massachusetts Institute of Technology.


Appendices

Appendix 1: Psychology literature pertinent to analyst bias

There is a large body of work on psychological bias and this section does not attempt to cover the whole area. The aim is to provide a summary of background experimental research that gave rise to the thinking and terms used in discussing bias in accident analysis. To give an overview, the literature describes the role of perception when determining causality and the attributional errors that can occur when people make judgements on past events. Errors in attribution have been linked to both cognitive and motivational forces and are an important consideration in efforts to maximise learning from accidents.

An early consideration of perception and causal attribution comes from Heider (1944). Heider (1958) is credited with the development of attribution theory which deals with how a perceiver uses information to arrive at causal explanations for events, including the information gathered and how it is combined to form a causal judgment (Fiske and Taylor, 1991). The theoretical beginning of attribution theory has motivated numerous experimental works on perception and bias in causal analysis and attributions of responsibility. Heider (1944) uses themes from previous experimental work to describe how a perceiver of an event will attribute cause by connecting a change (effect) with an origin (cause). The perceiver then integrates the identified cause and effect into one unit (causal unit), where the change gains meaning from the origin it is connected to (Heider, 1944). There is a tendency for a person to be identified as a causal origin, the interpretation of an effect then becomes dependent on the value judgements the perceiver places on that person: If the perceiver disparages the person, they will attribute failures to that person’s characteristics and successes to luck or unfair practice (Heider, 1944). Similarity and proximity also said to play a part in causal unit formation, if two events are similar to each other, or near each other, one is likely to be perceived as being the cause of the other (Heider, 1944). Studies on attribution theory have tended to focus on the perceived causes of other people’s
behaviour and has been the subject of a previous review (Kelley and Michela, 1980).

Attribution of responsibility and the defensive-attribution hypothesis

Hollnagel (2004), using a quote from Nietzsche (1844-1900) (Nietzsche, 1990) describes desire for control and relief of anxiety as motivational forces behind the search for explanations for accidents. There is some empirical work examining these motivations, in the testing of the defensive-attribution hypothesis; a theoretical position on the role of self-protective motives in the attribution of responsibility for an accident. Heider (1944) has noted a tendency for people to be identified as causal origins of events. Building on this, Walster hypothesised that the greater the consequences of an accident are, the greater the tendency to attempt to assign responsibility to someone (Walster, 1966).

This tendency to attribute responsibility occurs despite people having no real control over many of the events that happen to them (techniques to prevent accidents may be unknown or practically unrealistic to implement) (Walster, 1966). Walster suggests that this is due to people finding the attribution of responsibility to be reassuring. Perceivers of an accident can relieve themselves with the thought that it couldn’t happen to them by chance. By attributing responsibility or blame to the victim, or another person, fear is alleviated from the perceiver because it was a predictable, controllable event, with someone responsible (Walster, 1966). The perceiver can then protect themselves by believing that the behaviour of the person responsible is controllable in some way, perhaps by punishing or isolating those responsible (Walster, 1966). In this sense the attribution of causality by the perceiver of an accident is motivated by self-defence and the feeling of protection.

It is suggested that the motivation to assign responsibility increases with increases in the magnitude of event consequence. As the greater the consequence, the more unpleasant it is to a person to consider that event as able to happen to themselves (Walster, 1966). It is this hypothesis, of the perceiver of an accident increasing attribution of responsibility to a potential perpetrator with increasing magnitude of consequence, that is tested in the
literature. These ideas later became known as the defensive-attribution hypothesis (Burger, 1981). Walster tested this hypothesis in experimental studies, these are summarised in Table 20. Walster’s experiments have a similar basic protocol; an accident or major decision is described to a group of participants, but the participants are randomly assigned into conditions for magnitude of accident consequence. The conditions for consequence will include low to high severity but may also have variation in the person the accident causes damage to (e.g. have only the potential perpetrator suffering damage and/or a separate person that could not reasonably be considered the perpetrator). The participants are then asked to rate the responsibility of the potential perpetrator. The experiments gave mixed results.

Walster’s first study (Walster, 1966) supported the hypothesis that the tendency to assign responsibility to a person (who could reasonably be deemed responsible) was increased with increasing severity of consequence. But further studies (Walster, 1967) failed to replicate these results, with one experiment (Experiment I in Walster, 1967) even producing the opposite result, with increasing magnitude of consequence lowering the assignment of responsibility. Walster did find evidence that the greater the consequences of a major decision, the greater the tendency for a perceiver to exaggerate the foreseeability of the outcome of an event (Walster, 1967). This finding was again explained with the motivating factor of self-protection. The greater the consequence, the more secure an individual will feel by believing it was orderly and predictable. Furthermore, it’s suggested that when an outcome was more serious, people are likely to spend more time analysing the cause-effect relationships, this increased time spent on thinking about the event makes it seem more predictable (Walster, 1967).
Table 20 Walster’s experiments testing the defensive-attribution hypothesis

<table>
<thead>
<tr>
<th>Study</th>
<th>Experimental design</th>
<th>Participants</th>
<th>Event stimulus</th>
<th>Effect of increased consequence magnitude</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walster, 1966</td>
<td>Independent measures</td>
<td>88 students</td>
<td>Car accident</td>
<td>Increased responsibility attribution</td>
</tr>
<tr>
<td>Walster, 1967</td>
<td>Independent measures</td>
<td>153 students</td>
<td>Decision to buy a house: Future value dependent on event</td>
<td>Decreased responsibility attribution</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Increased rating of ability to anticipate outcome</td>
</tr>
<tr>
<td>Walster, 1967</td>
<td>Independent measures</td>
<td>213 students</td>
<td>Decision to buy a house: Future value dependent on event</td>
<td>No relationship with responsibility attribution</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Increased rating of ability to anticipate outcome</td>
</tr>
</tbody>
</table>

Shaver (1970) speculated that the variations in Walster’s findings could be explained by a relevance factor. In other words, whether perceivers believe an accident could realistically happen to themselves and thus deem it a threat. Moreover, Shaver speculated that the relevance (similarity) of the potential perpetrator to the perceiver could also influence attribution of responsibility. Shaver undertook a series of experiments (Shaver, 1970a, 1970b) based on Walster’s earlier work but taking into account the similarity of a potential perpetrator to the participants, these experiments are summarised in Table 21.

Shaver’s experiments (Shaver, 1970a, 1970b) failed to replicate Walster’s earlier finding of increased assignment of responsibility with increased magnitude of consequence. His findings did show an effect of similarity; when the perceiver was personally similar to the perpetrator, they were found to be more lenient regarding attributions of responsibility and judgements towards the perpetrator. Shaver felt these results to be a fit with the defence-attribution hypothesis. The perceiver could assign responsibility when personal similarity was low due to feeling safe in the knowledge that they are not like this person and so protected from the accident. However, he considers an alternate explanation for the findings, with the instruction for considering personal similarity could be interpreted as meaning to have increased empathy towards them. The participants could also attribute considerations of themselves, such as being a careful person, to the potential perpetrator.
Motivated by the mixed results regarding evidence for the defensive-attribution hypothesis, Burger (1981) examined the effect size through a meta-analysis. The combined results of 22 studies showed a statistically significant but weak tendency for more responsibility to be attributed to an accident perpetrator in severe rather than mild consequences. When the variables of participant and perpetrator personal and situational similarity were accounted for, much stronger support is found for the defensive-attribution hypothesis (Burger, 1981).
Table 21 Shaver's experiments testing the influence of relevance on the defensive-attribution hypothesis

<table>
<thead>
<tr>
<th>Study</th>
<th>Experimental design</th>
<th>Participants</th>
<th>Event stimulus</th>
<th>Effect of increased consequence magnitude</th>
<th>Effect of relevance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shaver, 1970a</td>
<td>Independent measures</td>
<td>68 students</td>
<td>Car accident</td>
<td>No relationship with responsibility attribution</td>
<td>Responsibility attribution increased with age of perpetrator</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Varied consequence magnitude</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Varied perpetrator age</td>
<td></td>
<td>Same age perpetrator judged to be more careful</td>
</tr>
<tr>
<td>Shaver, 1970a</td>
<td>Independent measures</td>
<td>30 students</td>
<td>Car accident: severe consequence only</td>
<td>Not tested</td>
<td>Personal similarity lessened attribution of responsibility and increased judgmental lenience</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Varied perpetrator characteristic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shaver, 1970a</td>
<td>2 by 2 factorial</td>
<td>40 students</td>
<td>Accident at work</td>
<td>Trend towards lower responsibility attribution</td>
<td>Tendency to judge the relevant perpetrator as more similar in mild consequence condition, reverse true in severe conditions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(19 male, 21 female)</td>
<td>Varied consequence magnitude</td>
<td>Increased rating of ability to anticipate consequences</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Male perpetrator</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shaver, 1970b</td>
<td>Independent measures</td>
<td>54 students</td>
<td>Car accident</td>
<td>No relationship with responsibility attribution</td>
<td>Perpetrator judged to be more similar in characteristics to participant when they had insurance</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Varied consequence magnitude and insurance compensation</td>
<td>Regardless of severity, less responsibility attributed when perpetrator had insurance</td>
<td></td>
</tr>
<tr>
<td>Shaver, 1970b</td>
<td>Independent measures</td>
<td>46 university psychology students</td>
<td>Car accident: severe consequence compensated by: Perpetrator, Other, None</td>
<td>Assigned responsibility lower when perpetrator insurance pays compensation</td>
<td>Not tested</td>
</tr>
</tbody>
</table>
Hindsight bias
The experiments of Walster (1967) and Shaver (1970b) found evidence for a link between accident outcome severity and perceiver ratings of foreseeability; with study participants giving higher ratings for the foreseeability of an event outcome with increased severity of consequence. Fischhoff continued these early empirical tests of the effect of hindsight on perceptions of predictability of event outcomes (Fischhoff 1975). This effect became known as the hindsight bias; the tendency for people with outcome knowledge to falsely believe they would have predicted the reported outcome of an event and to deny the outcome information has influenced their judgement (Hawkins and Hastie, 1990). This effect is a potential issue for accident investigation and analysis, with the outcome knowledge investigators have. Analysts may overestimate the foreseeability of the accident outcome to the people involved at the time of the event (without outcome knowledge) and there is potential to be overly judgemental of their actions (Woods and Cook, 1999).

Fischhoff’s initial experiments on hindsight bias are summarised in Table 22, the experiments present participants with descriptions of historical events and a series of possible outcomes. Participants are randomised into groups, with some given knowledge of the outcome of the event and others not (conditions with different outcomes labelled as true and another condition without an outcome labelled as true). Participants are then asked to rate the likelihood of each event outcome, or in some experiments asked to guess the judgments of outcome ignorant participants regarding outcome likelihood. Participants consistently rated the likelihood of possible outcomes as higher when they had knowledge of the outcome, even when asked to ignore this knowledge. Fischhoff also found that participants’ ratings of the importance of each evidence item, given in the descriptions of events, were influenced by outcome knowledge. Furthermore, when guessing how outcome ignorant people would rate the likelihood, participants with outcome knowledge attributed higher probabilities in their estimates.
<table>
<thead>
<tr>
<th>Study</th>
<th>Experimental design</th>
<th>Participants</th>
<th>Event stimulus</th>
<th>Outcome measure</th>
<th>Effect of hindsight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fischhoff, 1975</td>
<td>Independent measures</td>
<td>367 students</td>
<td>Historical and clinical events</td>
<td>Rating of likelihood of possible outcomes</td>
<td>Reporting an outcome consistently increased its perceived likelihood</td>
</tr>
<tr>
<td>Fischhoff, 1975</td>
<td>Independent measures</td>
<td>80 students</td>
<td>Historical and clinical events</td>
<td>Rating of likelihood of possible outcomes (participants asked to ignore outcome knowledge)</td>
<td>Reporting an outcome consistently increased its perceived likelihood</td>
</tr>
<tr>
<td>Fischhoff, 1975</td>
<td>Independent measures</td>
<td>94 students</td>
<td>Historical and clinical events</td>
<td>Guess the judgements of other outcome ignorant students on likelihood of outcomes</td>
<td>Participants with outcome knowledge attributed higher probabilities to outcome likelihood given by outcome ignorant others</td>
</tr>
</tbody>
</table>

Since Walster and Fischhoff’s experiments, there have been numerous works investigating hindsight bias. This empirical research on hindsight bias has been the subject of a previous review (Hawkins and Hastie, 1990). Hawkins and Hastie’s review (1990) splits studies on hindsight bias into two groups: studies using event outcome judgement tasks (as in Fischhoff 1975) and studies using almanac question judgement tasks.

The almanac question judgement tasks look for a knew-it-all-along effect using general knowledge questions. The basic protocol sees one group of participants answer a set of questions, they are then told the correct answer and attempt to remember their own responses. Another group of participants answer the questions and then attempt to remember their responses without being given the correct answers. A further group of participants sees the questions with the answers and are then asked to respond as they would have had they not been told the answers (Fischhoff, 1977). People tend to
overestimate both how much they knew and would have known (Fischhoff, 1977).

Hawkins and Hastie (1990) accept there is a hindsight effect and through reviewing previous research, produce a taxonomy of five explanatory mechanisms for hindsight bias:

i. Creeping determinism (a term introduced by Fischhoff 1975), a process in which outcome information is integrated into a person’s knowledge about the events preceding the outcome (creeps into their mental representation of events)

ii. Outcome knowledge affects the selection of evidence to make a judgment

iii. Outcome knowledge affects the evaluation of evidence

iv. Outcome knowledge affects the manner in which evidence is integrated

v. Outcome knowledge affects the response generation process

They conclude that creeping determinism is the most common mechanism underlying observed hindsight effects. But that the other mechanisms are plausible and it is likely that, in certain situations, a combination of the mechanisms produce the hindsight effect (Hawkins and Hastie, 1990).

Since the review, two meta-analyses have been conducted (Christensen-Szalanski and Willham, 1991; Guilbault et al., 2004) that provide support for an effect of hindsight bias. A 1991 meta-analysis including 122 studies on hindsight bias found only a small effect size of hindsight bias in probability assessment, the authors found the effect to be moderated by participants’ familiarity with the task (Christensen-Szalanski and Willham, 1991). A more recent meta-analysis including 95 studies also found that hindsight bias does exist, with the effect size considered to be in the small to medium range (Guilbault et al., 2004). There were larger hindsight effect sizes in studies using general knowledge questions than in studies using real-world events (Guilbault et al., 2004).
Outcome bias

As with hindsight bias, outcome bias concerns the effect of outcome knowledge on judgements of past events. Outcome bias is markedly different however, in that it is the phenomenon of knowledge of a negative outcome affecting a perceiver's judgement of a decision maker's actions at the time of an event.

Baron and Hershey (1988) conducted one of the initial studies on outcome bias. The basic protocol of outcome bias studies can be described as: Participants are given descriptions of decisions made by others under conditions of uncertainty. The descriptions are given with an outcome of a decision, some positive outcomes, some negative. Participants are asked to evaluate the decision, including the quality of thinking and competence of the decision maker. Studies on outcome bias are summarised in Table 23, the experiments consistently show an outcome bias, with participants favourably evaluating past decisions when told of a good outcome, in comparison to evaluations with a worse outcome.

For accident investigation the implication is that the decisions and actions leading up to a negative outcome will be judged more harshly than those with a successful outcome. However, sometimes good processes can lead to unsuccessful outcomes, it is then premature to make changes to an organisation based purely on an unsuccessful outcome (Henriksen and Kaplan, 2003).
<table>
<thead>
<tr>
<th>Study</th>
<th>Experimental design</th>
<th>Participants</th>
<th>Event stimulus</th>
<th>Main findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baron and Hershey, 1988</td>
<td>Repeated measures (counterbalanced)</td>
<td>20 students</td>
<td>Medical decisions</td>
<td>Outcome bias found: Good outcome meant higher rating of decisions</td>
</tr>
<tr>
<td>Baron and Hershey, 1988</td>
<td>Repeated measures (counterbalanced)</td>
<td>41 students</td>
<td>Medical decisions</td>
<td>Outcome bias found: Good outcome meant higher rating of decisions</td>
</tr>
<tr>
<td>Baron and Hershey, 1988</td>
<td>Repeated measures (counterbalanced)</td>
<td>17</td>
<td>Monetary gambles</td>
<td>Outcome bias for amount of money won: Better outcome meant higher rating of decision Decisions given higher ratings if decision not taken had lesser outcome</td>
</tr>
<tr>
<td>Baron and Hershey, 1988</td>
<td>Repeated measures (counterbalanced)</td>
<td>29</td>
<td>Medical decisions</td>
<td>Outcome bias found: Good outcome meant higher ratings of decisions and future competence of decision maker</td>
</tr>
<tr>
<td>Baron and Hershey, 1988</td>
<td>Independent measures</td>
<td>111 psychology students</td>
<td>Monetary gambles</td>
<td>Outcome bias found: Good outcome meant higher rating of decisions Participants did not appear to think they were using outcome as basis for decision</td>
</tr>
<tr>
<td>Lipshitz, 1989</td>
<td>2 by 2 factorial</td>
<td>178 male military officer students</td>
<td>Military decisions</td>
<td>Outcome bias found: Successful outcome meant decisions more justified, follow superior process and decision maker seen more favourably</td>
</tr>
<tr>
<td>Caplan et al., 1991</td>
<td>Independent measures</td>
<td>112 anaesthesiologists</td>
<td>Medical decisions</td>
<td>Outcome bias found: A worse outcome decreased ratings of appropriate care</td>
</tr>
</tbody>
</table>

Table 23 Experiments on outcome bias
Confirmation bias

Within safety literature, Johnson (2003) describes confirmation bias as an attempt by investigators to ensure that any causal analysis fits their initial ideas about an accident (Johnson, 2003). This description seems to refer to a conscious and deliberate act of case building, but confirmation bias could also occur without the awareness of the investigator (Nickerson, 1998). In general, the term confirmation bias is used to refer to a less explicit and less conscious, one-sided case-building process (Nickerson, 1998). Confirmation bias includes selectivity in the acquisition and use of evidence, and restriction of attention to a favoured hypothesis (Nickerson, 1998).

A review of experimental studies on confirmation bias finds support for the phenomenon, stating that evidence is extensive and strong (Nickerson, 1998). Nickerson’s review has grouped studies and experimental works on the different phenomena concerning cognitive bias, although with the review being narrative in nature, it does not provide much detail on the experiments themselves. An effort is made here to describe the phenomena of concern to accident analysis and provide a summary of the experimental works evidencing them.

One concern to accident investigation is the potential for an analyst to make efforts to confirm an initial hypothesis regarding an accident explanation and not to consider any alternative hypothesis. Laboratory-based studies have investigated the focus on confirmatory strategies, these are summarised in Table 24. The general protocol for studies in this area asks participants to form an initial hypothesis regarding a basic research question, then gives options to the participant to seek evidence to confirm or disconfirm their hypothesis or test alternative hypotheses. The studies have shown participants tend to use a confirmatory strategy, rarely testing alternative hypotheses (Mynatt, Doherty and Tweney, 1977, 1978; Doherty et al., 1979) and often keep or return to their initial hypothesis even when it has been disproven (Mynatt, Doherty and Tweney, 1978).
### Table 24 Studies investigating tendency to focus on initial hypothesis and seek confirmatory evidence

<table>
<thead>
<tr>
<th>Study</th>
<th>Experimental design</th>
<th>Participants</th>
<th>Event stimulus</th>
<th>Main findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mynatt et al., 1977</td>
<td>Independent measures</td>
<td>45 students</td>
<td>Formulated hypotheses about motion of particles in a simulation</td>
<td>Participants tended to choose confirmatory testing of their initial hypothesis</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3 groups instructed to either confirm, disconfirm or test</td>
<td>Rarely tested alternative hypotheses</td>
</tr>
<tr>
<td>Mynatt et al., 1978</td>
<td>Independent measures</td>
<td>16 students</td>
<td>Discover laws of particle motion in an artificial universe (simulated environment)</td>
<td>Participants tended to use confirmatory strategies</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>One group of participants instructed in strong inference (SI)</td>
<td>Permanently abandoned falsified hypotheses only 30% of the time</td>
</tr>
<tr>
<td>Doherty et al., 1979</td>
<td>Independent measures</td>
<td>121</td>
<td>Archaeology research: Participants formed hypothesis on origin of a pot</td>
<td>Participants tended to seek evidence to confirm their initial hypothesis</td>
</tr>
</tbody>
</table>

People may also give preferential treatment to evidence supporting existing beliefs. Relevant to this is Festinger’s theory of cognitive dissonance (Festinger, 1957, 1964), which describes the state of discomfort people feel when a mental conflict occurs from a situation involving conflicting attitudes, beliefs or behaviours. This is a potential motivator for people that have committed to an attitude, belief or decision, to then gather supportive information and neglect unsupported information to avoid this unpleasant state of conflict (Hart et al., 2009).

Hart et al. (2009) performed a meta-analysis to assess whether exposure to information is guided by motivations to defend their pre-existing beliefs or by an accuracy motivation, whereby information is processed in an objective, open-minded way. They included 91 studies that measured information selection based on pre-existing beliefs, attitudes or behaviour. The included study protocols are like those in Table 24, usually laboratory-based, participants make a decision or report an attitude, they are then given the
opportunity to receive information. Participants choose whether to receive information that agrees with their prior belief or disagrees with their prior belief. The meta-analysis provides evidence of confirmation bias, finding biases in the selection of information, with people nearly two times as likely to select information that is congenial rather than uncongenial to their pre-existing beliefs (Hart et al., 2009). Their findings showed confirmation bias to be positively correlated with factors of information quality, commitment and close-mindedness. Whereas the bias was negatively correlated with participants’ confidence in their pre-existing belief (Hart et al., 2009).

Summary
In summary, there is evidence of several biases that could affect the objectivity of an accident investigation. Accident investigators need to be wary of the following potential effects:

- Severe accident consequences increasing attribution of responsibility to those involved
- Personal similarity affecting the judgement of those involved
- A tendency to overestimate foreseeability of an outcome to those involved
- The issues with judging decisions and actions on outcome alone
- A tendency to seek information to confirm prior beliefs without considering alternative hypotheses
Appendix 2: Loughborough University sponsor approval letter

9 February 2017

Dear Dr Jun

Project Title: Prevention of Suicide-Taking a Human Factors Approach

Chief Investigator – Dr Gyuchan Thomas Jun, Loughborough Design School

Other Investigators – Nye Canham, Loughborough Design School
Dr Fabida Noshad, Leicestershire Partnership NHS Trust
Dr Satheesh Kumar, Leicestershire Partnership NHS Trust
Dr Vinod Kumar, Leicestershire Partnership NHS Trust

I can confirm that we are now in receipt of the permission letter from Leicestershire Partnership NHS Trust for the above project which is sponsored by Loughborough University. The above study now has approval to commence. Clearance to proceed is issued on 9 February 2017.

Yours sincerely

[Signature]

Jacqueline Green
Research Governance Officer
Appendix 3: Health Research Authority approval letter

Dr Gyuchan Thomas Jun
Lecturer
Loughborough University
LDS 1.44 Loughborough Design School
Loughborough University
LE11 3TU

07 February 2017

Dear Dr Jun

**Letter of HRA Approval**

**Study title:** Prevention of suicide - taking a Human Factors Approach

**IRAS project ID:** 219594

**REC reference:** 17/HRA/0209

**Sponsor** Loughborough University

I am pleased to confirm that [HRA Approval](#) has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

**Participation of NHS Organisations in England**

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. Please read Appendix B carefully, in particular the following sections:

- **Participating NHS organisations in England** – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities.
- **Confirmation of capacity and capability** - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- **Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)** - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details
and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices
The HRA Approval letter contains the following appendices:
- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval
The attached document “After HRA Approval – guidance for sponsors and investigators” gives detailed guidance on reporting expectations for studies with HRA Approval, including:
- Working with organisations hosting the research
- Registration of Research
- Notifying amendments
- Notifying the end of the study

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

Scope
HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback
The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please email the HRA at hra.approval@nhs.net. Additionally, one of our staff would be happy to call and discuss your experience of HRA Approval.

HRA Training
We are pleased to welcome researchers and research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

Your IRAS project ID is 219594. Please quote this on all correspondence.
Yours sincerely

Joanna Ho
Assessor

Email: hra.approval@nhs.net

Copy to: Mr Peter Townsend, Sponsor Representative, Loughborough University
Dr Dave Clarke, Lead R&D Contact, Leicestershire Partnership Trust
Mr Aneurin Canham, Co-Investigator, Loughborough University
Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Confirmation of Insurance Cover]</td>
<td>1.0</td>
<td>20 July 2016</td>
</tr>
<tr>
<td>IRAS Application Form [IRAS_Form_10012017]</td>
<td></td>
<td>10 January 2017</td>
</tr>
<tr>
<td>IRAS Application Form XML file [IRAS_Form_10012017]</td>
<td></td>
<td>10 January 2017</td>
</tr>
<tr>
<td>IRAS Checklist XML [Checklist_10012017]</td>
<td></td>
<td>10 January 2017</td>
</tr>
<tr>
<td>Letter from funder [Letter from Carlton Hayes]</td>
<td>1.0</td>
<td>18 November 2016</td>
</tr>
<tr>
<td>Letter from sponsor [Letter from Sponsor]</td>
<td>1.0</td>
<td>03 January 2017</td>
</tr>
<tr>
<td>Participant consent form [Informed Consent Form: Prevention of Suicide - taking a Human Factors Approach]</td>
<td>1.0</td>
<td>20 December 2016</td>
</tr>
<tr>
<td>Participant Information Sheet (PIS) [Participant Information Sheet: Prevention of Suicide - taking a Human Factors Approach]</td>
<td>1.0</td>
<td>20 December 2016</td>
</tr>
<tr>
<td>Research protocol or project proposal [Research Protocol: Prevention of Suicide - taking a Human Factors Approach]</td>
<td>1.0</td>
<td>07 December 2016</td>
</tr>
<tr>
<td>Summary CV for Chief Investigator (CI) [Dr Gyuhan Thomas Jun CV]</td>
<td>1.0</td>
<td>12 December 2016</td>
</tr>
</tbody>
</table>
Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the, participating NHS organisations, capacity and capability and Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria) sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Name: Mr Peter Townsend
Tel: 01509222450
Email: P.A.Townsend@lboro.ac.uk

<table>
<thead>
<tr>
<th>Section</th>
<th>HRA Assessment Criteria</th>
<th>Compliant with Standards</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>IRAS application completed correctly</td>
<td>Yes</td>
<td>No comments</td>
</tr>
<tr>
<td>2.1</td>
<td>Participant information/consent documents and consent process</td>
<td>Yes</td>
<td>It was noted that the IRAS reference was not included on the Participant Information Sheet and Consent Form; this has been waived on this occasion however, sponsor should consider this on any subsequent amendment to the study.</td>
</tr>
<tr>
<td>3.1</td>
<td>Protocol assessment</td>
<td>Yes</td>
<td>No comments</td>
</tr>
<tr>
<td>4.1</td>
<td>Allocation of responsibilities and rights are agreed and documented</td>
<td>Yes</td>
<td>The Sponsor has worked with the Participating NHS Organisation on the study design. Agreements are already in place, therefore no Statement of Activities/Schedule of Events or any other site agreement will be expected.</td>
</tr>
<tr>
<td>4.2</td>
<td>Insurance/indemnity</td>
<td>Yes</td>
<td>Sponsor indemnity in place for the</td>
</tr>
<tr>
<td>Section</td>
<td>HRA Assessment Criteria</td>
<td>Compliant with Standards</td>
<td>Comments</td>
</tr>
<tr>
<td>---------</td>
<td>-------------------------</td>
<td>--------------------------</td>
<td>----------</td>
</tr>
<tr>
<td></td>
<td>arrangements assessed</td>
<td></td>
<td>design and management of the study; NHS indemnity applies to the conduct of the study. Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the activities expected of them for this research study</td>
</tr>
<tr>
<td>4.3</td>
<td>Financial arrangements assessed</td>
<td>Yes</td>
<td>Funding has been secured from Carlton Hayes Mental Health Charity for this study. No funding will be provided to the Participating NHS Organisation</td>
</tr>
<tr>
<td>5.1</td>
<td>Compliance with the Data Protection Act and data security issues assessed</td>
<td>Yes</td>
<td>No comments</td>
</tr>
<tr>
<td>5.2</td>
<td>CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed</td>
<td>Not Applicable</td>
<td>No comments</td>
</tr>
<tr>
<td>5.3</td>
<td>Compliance with any applicable laws or regulations</td>
<td>Yes</td>
<td>No comments</td>
</tr>
<tr>
<td>6.1</td>
<td>NHS Research Ethics Committee favourable opinion received for applicable studies</td>
<td>Not Applicable</td>
<td>No comments</td>
</tr>
<tr>
<td>6.2</td>
<td>CTIMPS – Clinical Trials Authorisation (CTA) letter received</td>
<td>Not Applicable</td>
<td>No comments</td>
</tr>
<tr>
<td>6.3</td>
<td>Devices – MHRA notice of no objection received</td>
<td>Not Applicable</td>
<td>No comments</td>
</tr>
<tr>
<td>6.4</td>
<td>Other regulatory approvals and authorisations received</td>
<td>Not Applicable</td>
<td>No comments</td>
</tr>
</tbody>
</table>
Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.

This is a non-commercial single-centre study, where all research activities as described in the research application will be undertaken by the participating NHS organisation. Therefore, there is only one site-type.

If this study is subsequently extended to other NHS organisation(s) in England, an amendment should be submitted to the HRA, with a Statement of Activities and Schedule of Events for the newly participating NHS organisation(s) in England.

The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website.

If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.

The Participating NHS organisation in England will be expected to formally confirm their capacity and capability to host this research according to local requirements.

- Following issue of this letter, participating NHS organisations in England may now confirm to the sponsor their capacity and capability to host this research, when ready to do so. How capacity and capacity will be confirmed is detailed in the Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria) section of this appendix.
- The Assessing, Arranging, and Confirming document on the HRA website provides further information for the sponsor and NHS organisations on assessing, arranging and confirming capacity and capability.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).

A Local Collaborator has been identified at the Participating NHS Organisation.
GCP training is **not** a generic training expectation, in line with the [HRA statement on training expectations](#).

**HR Good Practice Resource Pack Expectations**

<table>
<thead>
<tr>
<th><strong>This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>It is unlikely that letters of access or honorary research contracts will be applicable, except where local network staff employed by another Trust or University are involved (and then it is likely that arrangements are already in place). Where arrangements are not already in place, network staff (or similar) undertaking any of the research activities listed in A18 or A19 of the IRAS form (except for administration of questionnaires or surveys), would be expected to obtain an honorary research contract from one NHS organisation (if university employed), followed by Letters of Access for subsequent organisations. This would be on the basis of a Research Passport (if university employed) or an NHS to NHS confirmation of pre-engagement checks letter (if NHS employed). These should confirm enhanced DBS checks, including appropriate barred list checks, and occupational health clearance. For research team members only administering questionnaires or surveys, a Letter of Access based on standard DBS checks and occupational health clearance would be appropriate.</td>
</tr>
</tbody>
</table>

**Other Information to Aid Study Set-up**

<table>
<thead>
<tr>
<th><strong>This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>The applicant has indicated that they <strong>do not intend</strong> to apply for inclusion on the NIHR CRN Portfolio.</td>
</tr>
</tbody>
</table>
Appendix 4: Questionnaire for participant STAMP evaluation

Method Evaluation Questionnaire

If you don’t mind could we have a contact details and email address in case of any follow-up?

What is your job role?

How many years’ experience do you have working in healthcare?

How much experience do you have of patient safety investigations?

Which accident analysis methods have you previously used?

For the following Likert scale questions please put a cross in the circle of the response that best characterises how you feel about the statement.

**Approach utility**

<table>
<thead>
<tr>
<th></th>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Neither agree nor disagree</th>
<th>Agree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>The approach has given me a different perspective on the incident/system</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>The approach is useful in learning from the incident</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>The approach is relevant to healthcare</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>The approach can help in identifying weaknesses in the safety control structure</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>
The approach can help to make recommendations to strengthen the safety control structure

<table>
<thead>
<tr>
<th></th>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Neither agree nor disagree</th>
<th>Agree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>The approach can help</td>
<td></td>
<td></td>
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<tr>
<td>make recommendations</td>
<td></td>
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<tr>
<td>to strengthen the</td>
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<tr>
<td>safety control</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>structure</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

How did the use of the approach impact your view and understanding of the incident?

Are there aspects of healthcare accidents that this approach does not seem to cover?

How well do you feel the approach covers human decisions and control actions in healthcare?

**Approach usability**

<table>
<thead>
<tr>
<th></th>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Neither agree nor disagree</th>
<th>Agree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>It was easy to understand the approach</td>
<td></td>
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<tr>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>The approach was easy to apply</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The approach was presented clearly</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The templates provided were useful</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Did you have any difficulty in identifying the system and hazards involved in the accident?
How useful and understandable did you find the control structure element of the approach?

Is there something that could make your use of the approach easier?

**Future application**

<table>
<thead>
<tr>
<th></th>
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<th>Disagree</th>
<th>Neither agree nor disagree</th>
<th>Agree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>The approach would be useful in the analysis of future incidents</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Healthcare would benefit from the use of this approach</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>We would need expert help to apply the approach</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Do you feel the approach is something you could learn to use? If so, what kind of support would you need?

**General**

What did you like about the approach?

What didn’t you like about the approach?

Do you have any additional comments?
Appendix 5: Case Study 1 initial control structure for Mid-Stiffs incidents

Figure 30 Initial model of Mid-Staffs control structure
Appendix 6 Case Study 1 presentation slide handouts

Accident Models

Systems Theoretic Accident Model and Processes (STAMP)

Inadequate
Causal Analysis based on STAMP

Systems Theoretic Accident Model and Processes (STAMP)

Leveson, 2011
How is STAMP different?

- Accidents are more than a chain of events
- Treat accidents as a control problem
- Prevent accidents by enforcing constraints on component behaviour and interactions

Control Structure

- Recruitment
- Selection
- Training
- Medical screening
- Working hours regulation
- Day-to-day manpower planning

- Signalling
- Rail tracks
- Train scheduling
- Procedures
- Regulations

Train Driving
Draw the control structure

- High-level

(Mental Model)

Undesirable Environmental Inputs

Inadequate

Control Actions

Missing or incorrect Feedback

Controlled Process

Human Controller

Safety-related responsibilities

Inconsistent Mental Model

(Leveson, 2011)
Control Actions

Four Types of Inadequate Control Actions
1. Not Given
2. Unsafe ones are given
3. Too early, too late (Timing)
4. Stop too soon or applied too long (Duration)

Classification of Control Flaws

1. Inadequate enforcement of constraints (control actions)

2. Inadequate execution of control action

3. Inadequate or missing feedback
CAST – Accident analysis

There are 9 steps to the approach:

- Identify the system and hazard involved in the incident
- Identify the system safety constraints and system requirements associated with that incident
- Document the safety control structure in place to control the hazard and enforce the safety constraints
- Determine the proximate events leading to the incident
- Analyse the incident at the physical system level
- Analyse the higher system levels determining how and why each successive higher level allowed or contributed to inadequate control
- Examine overall coordination and communication contributors to the incident
- Determine the dynamics and changes in the system and the safety control structure relating to the loss and any weakening of the safety control structure over time
- Generate recommendations
Appendix 7: Case Study 1 slides from workshop presentation

Systems Theoretic – Key Concepts

Systems thinking:
- emergence, hierarchy, communication, control *(Checkland, 1993)*
  - Emergent properties – ‘the whole is greater than the sum of its parts’ *(Aristotle)*
  - Hierarchical control structures – upper level imposing safety constraints on lower level *(Rasmussen + Checkland + Leveson)*
  - Communication of information for purposes of regulation or control *(Checkland, 1993)*: control – feedback loops
  - View of accident as resulting from the loss of control of a hazardous process *(Rasmussen, 1997; Leveson, 2004)*

Accidents are more than a chain of events, they involve complex dynamic processes

STAMP treats accidents as a control problem, not a failure problem

Prevent accidents by enforcing constraints on component behaviour and interactions *(John Thomas, 2013)*
STAMP – Accident Model - Hierarchical Safety Control Structure

System Design:
Checklists
IT
Pharma
Training
Medical
device

System Operation:
Care
Treatment

Down arrows are control actions/constraints
Up arrows feedback/measurement channel

(Adapted from Levinson, 2004)

Accident - an undesired or unplanned event that results in a loss

Hazard – A system state that, together with a set of worst-case environmental conditions, will lead to an accident

Analysis - Find the inadequate control that caused the accident
STAMP steps

1. Identify the system and hazard involved in incident
2. Document the safety control structure
3. Determine the proximate events
4. Analyse the incident – how and why each level allowed inadequate control
5. Examine overall coordination and communication contributors
6. Determine weakening in safety control structure over time
7. Generate recommendations

Small-scale incident

Drug prescription medication error
- Diabetic patient admitted to ED following fall at home
- Found to have high blood glucose levels by nurse
- Recommended to start insulin U100 10 units once per day
- Handwriting misread by Dr and 100 units prescribed (10 times recommendation)
- Administered twice at hospital and once at community centre

- Step 3 (proximal events)
Step 1

<table>
<thead>
<tr>
<th>System</th>
<th>Medication prescription and administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accident</td>
<td>Patient harmed through administration of incorrect medication</td>
</tr>
<tr>
<td>Hazard</td>
<td>Patient prescribed/recommended incorrect medication</td>
</tr>
</tbody>
</table>

Step 2 –
Document safety control structure
Controllers

Four conditions required to control a process:
1. **Goal condition** - Controller must have a goal or goals
2. **Action condition** – Controller must be able to affect the state of the system
3. **Model condition** – Controller must contain a model of the system
4. **Observability condition** – Controller must be able to ascertain the state of the system
Process model

Controllers use a process model to determine control actions

Understanding of system state

Control-feedback loop

Step 4. Analyse the incident – Hazardous control actions

1. Inadequate enforcement of constraints (control actions)
2. Inadequate execution of control action
3. Inadequate or missing feedback
Prescribing doctor level

Analyse at every level

Step 5. Overall coordination and communication issues

Step 6. Changes over time
### Step 7. Generate recommendations

<table>
<thead>
<tr>
<th>Control flaw</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Inadequate control with communication flaw in handover</td>
<td>1. Design and implement new form template</td>
</tr>
<tr>
<td>2. Missing control on design process of information tools and systems</td>
<td>2. Include user needs in design of information systems</td>
</tr>
<tr>
<td>3. Inadequate or missing feedback to doctor on system state</td>
<td>3. Specialist nurse to be trained as prescriber</td>
</tr>
<tr>
<td>4. Inadequate execution of control with communication flaw</td>
<td>4. Discussion with pharmaceutical company over name of medication</td>
</tr>
</tbody>
</table>

### Exercise – Large scale

**Mid-Staffordshire Trust failings as a loss of control**

- Poor care provided at Stafford Hospital between 2005 and 2009.
- Estimated 400 to 1200 patients died as a result.

**Step 1. Identify the system and hazard involved**

**Hazard** – poor quality of care?

**System** – quality of care control structure
Organisational error taxonomy – Stringfellow Dissertation pg 108-110

1. Inadequate assignment of goals, control authority and responsibilities to controllers
2. Inadequate allocation of resources to controllers throughout the organization
3. Inadequate assignment of controller hierarchy
4. Inadequate communication channels provided for in the organization
5. Inadequate communication of system-level goals and constraints
6. Inadequate safety management and learning processes
7. Inadequate interactions with external bodies
**STAMP steps**

1. Identify the system and hazard involved in incident
2. Document the safety control structure
3. Determine the proximate events
4. Analyse the incident — how and why each level allowed inadequate control
5. Examine overall coordination and communication contributors
6. Determine weakening in safety control structure over time
7. Generate recommendations

**Discussion – critique from you**

**STAMP concepts**
- Good fit with healthcare?
- Control theory and healthcare incidents

**STAMP application in healthcare**
- Usability
- Utility
- Barriers to adoption
Mid Staffs hospital scandal: the essential guide

With a new inquiry into the causes of poor care at the hospital being released, the findings may have ramifications for the rest of the NHS. Study the issue in depth and learn all you need to know about what happens next with our essential guide

Denis Campbell
Wed 6 Feb 2013 08.49 GMT

1. What is the Mid Staffs scandal?
2. Why is it in the news again now?
3. How did the poor care come to light?
4. The public inquiry
5. The first Francis inquiry: what was care like?
6. What did the Healthcare Commission find?
7. Why was care so bad?
8. So who failed to spot problems at Stafford and/or do enough to stop them?
9. How will the Mid Staffs scandal affect the NHS?

1. What is the Mid Staffs scandal?
A disputed estimate [see footnote] suggested that between 400 and 1,200 patients died as a result of poor care over the 50 months between January 2005 and March 2009 at Stafford hospital, a small district general hospital in Staffordshire. The report being published on 6 February 2013 of the public inquiry chaired by Robert Francis QC will be the fifth official report into the scandal since 2009, and Francis’s second into the hospital’s failings.

The often horrifying evidence that has emerged means "Mid Staffs" has become a byword for NHS care at its most negligent. It is often described as the worst hospital care scandal of recent times. In 2009 Sir Ian Kennedy, the chairman of the Healthcare Commission, the regulator of NHS care standards at the time, said it was the most shocking scandal he had investigated.

It is commonly known as the Mid Staffs scandal because Stafford hospital was and is run by the Mid Staffordshire NHS hospital trust, which in 2008 acquired foundation trust status, making it semi-independent of Department of Health (DH) control. Decision-making and especially cost-cutting as part of its pursuit of that status was later cited as a key reason why poor care took hold and was allowed to persist for so long.

. Back to the top

2. Why is it in the news again now?
On Wednesday 6 February Francis will publish the report of his 31-month-long public inquiry into the scandal. His first report, published in February 2010, was an independent report under the NHS Act rather than a full-blown public inquiry. It examined the quality of care at Stafford hospital in 2005-09 and the many reasons why it was so bad, such as inadequate staffing, and produced devastating conclusions.
The public inquiry began in July 2010. Its remit was to investigate what a wide range of commissioning, supervisory and regulatory bodies and systems in the NHS had done to detect poor care at Stafford and to intervene. As such it probed the role of the bodies and individuals all the way from the hospital itself - including the trust's board and its patient liaison group - up to the most senior figures at the Department of Health in Whitehall, including ministers, senior civil servants and key figures in the NHS.

Its brief included its duty "to examine why problems at the trust were not identified sooner; and appropriate action taken. This includes, but is not limited to, examining the actions of the Department of Health, the local Strategic Health Authority, the local primary care trust(s), the Independent Regulator of NHS Foundation trusts (Monitor), the Care Quality Commission, the Health and Safety Executive, local scrutiny and public engagement bodies and the local coroner."

3. How did the poor care come to light?

Although care was poor from at least the start of 2006, concerns about that only began emerging in mid-2007. At that time the Healthcare Commission (HCC), the then NHS care regulator, became anxious that Stafford seemed to have unusually high death rates, drawing on information from Professor Brian Jarman, an expert in patient safety and hospital death rates at Imperial College London.

By January 2008 the watchdog had identified seven different patient safety alerts at Stafford: warning signs that there were problems. Dissatisfied with the hospital's explanation for the apparently high mortality rate - that it was down to "coding errors" - the HCC told a team of its investigators under Heather Wood, renowned as its "hard cases woman", to get to the bottom of what was happening at the hospital. That was the first of the five inquiries.

Julie Bailey, whose 86-year-old mother Bella died in the hospital as a result of poor care in late 2007, also played a key role in exposing the Mid Staffs scandal. She quickly came across other families who had lost a loved one, realised there was a problem and, with other bereaved relatives, formed the campaign group Cure The NHS to demand a public inquiry and hold those responsible to account.

4. The public inquiry

Andrew Lansley, the then health secretary, commissioned the full public inquiry in June 2010, soon after the coalition took power. It was held under the Public Inquiries Act 2005. Labour in 2009 and 2010 had refused to accede to persistent requests from relatives of victims of the Mid Staffs scandal to hold such an inquiry. Instead ministers commissioned the first Francis report as well as two other, separate inquiries into specific aspects of how the hospital and local healthcare system operated. They were led by Professor George Alberti, the DH's national clinical director for emergency care, and Dr David Colin-Thome, his counterpart at the DH for primary care. They reported in April 2009.

Francis began gathering evidence in July 2010. He initially hoped to deliver a report to ministers by early 2011. Instead it became a particularly in-depth and long-running inquiry. The inquiry took oral evidence from 164 witnesses over the 139 days it sat between November 2010 and December 2011, and also received 87 witness statements and 39 provisional statements, and over a million pages of evidence in total.

https://www.theguardian.com/society/2013/feb/05/mid-staffs-hospital-scandal-guide
Tom Kark QC, counsel to the inquiry, and Francis himself questioned witnesses.

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5. The first Francis inquiry: what was care like?
Francis’s report into care at Stafford hospital in February 2010, based on evidence from over 900 patients and families, was scathing. "I heard so many stories of shocking care," he said. "They were people who entered Stafford hospital and rightly expected to be well cared for and treated. Instead, many suffered horrific experiences that will haunt them and their loved ones for the rest of their lives."

Francis cited a litany of failings in the care of patients. "For many patients the most basic elements of care were neglected," he said. Some patients needing pain relief either got it late or not at all. Others were left unwashed for up to a month. "Food and drinks were left out of the reach of patients and many were forced to rely on family members for help with feeding." Too many patients were sent home before they were ready to go, and ended up back in hospital soon afterwards. "The standards of hygiene were at times awful, with families forced to remove used bandages and dressings from public areas and clean toilets themselves for fear of catching infections." Patients’ calls for help to use the toilet were ignored, with the result that they were left in soiled sheeting or sitting on commodes for hours “often feeling ashamed and afraid”. Misdiagnosis was common.

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6. What did the Healthcare Commission find?
Care at Stafford was “appalling”, the watchdog’s report said. The Guardian reported at the time that it found “inadequately trained staff who were too few in number, junior doctors left alone at night and patients left without food, drink or medication as their operations were repeatedly cancelled. Receptionists with no medical training were expected to assess patients coming in to A&E, some of whom needed urgent care.”

The then health secretary Alan Johnson said there had been “a complete failure of management to address serious problems and monitor performance, [which] led to a totally unacceptable failure to treat emergency patients safely and with dignity”. Bruce Keogh, the NHS’s medical director, condemned the trust’s “complete failure of leadership”. HCC chairman Sir Ian Kennedy said its report was “a shocking story … of appalling standards and chaotic systems for looking after patients. These are words I have not previously used in any report.”

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7. Why was care so bad?
“A chronic shortage of staff, particularly nursing staff, was largely responsible for the substandard care,” Francis found in his first report.

In addition, morale was low and “while many staff did their best in difficult circumstances, others showed a disturbing lack of compassion towards their patients”, he added. “Staff who spoke out felt ignored and there is strong evidence that many were deterred from doing so through fear and bullying.”

He laid much of the blame on the trust’s ruling board. The action they took to investigate and resolve concerns “was inadequate and lacked an appropriate sense of urgency”. Its members also “chose to rely on apparently favourable performance reports by outside bodies, such as the Healthcare Commission, rather than effective internal assessment and feedback from staff
and patients". He was particularly critical of the trust's failure to take patients' complaints seriously enough.

Crucially, Francis also highlighted the key impact of the trust board's decision to try to save £10m in 2006-07, as part of its desire to gain foundation trust status. "The board decided this saving could only be achieved through cutting staffing levels, which were already insufficient." It also ignored staff's concerns, he added.

He also mentioned that "many people expressed alarm at the apparent failure of external organisations to detect any problems with the trust's performance" and recommended a separate inquiry look into that.

That led directly to the latest Francis inquiry, which reports on Wednesday 6 February.

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8. So who failed to spot problems at Stafford and/or do enough to stop them?

The report of the public inquiry is likely to find that almost every link in what should have been the NHS's chain of monitoring and scrutinising hospital care, and intervening if necessary, did not do its job properly. He has investigated the actions of scores of bodies and individuals, both locally and nationally. The record, performance and reputation of many of them are likely to face detailed criticism, including the management and board of the hospital itself, the various regulators involved (Healthcare Commission, its successor the Care Quality Commission and Monitor) and senior figures at the Department of Health.

As Francis's first report said, that inquiry heard evidence "that none of them [external organisations charged with overseeing the trust], from the PCT to the Healthcare Commission, or the local oversight and scrutiny committee, detected anything wrong with the trust's performance until the HCC investigation." The landmark report will, over many hundreds of pages, detail what he then also called "the actions and inactions of the various organisations to search for an explanation of why the appalling standards of care were not picked up."

His task is to explain why so many people failed so badly, and to make sure it does not happen again.

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9. How will the Mid Staffs scandal affect the NHS?

Francis's new report will prompt much soul-searching about why some NHS organisations end up providing inadequate, inhumane and dangerously substandard care to some or many patients. Many people will say in effect "Mid Staffs must never happen again", and Francis will set out how to ensure this is the case. It comes amid rising concern about care, and the behaviour of some of the NHS's huge workforce, which was encapsulated by health secretary Jeremy Hunt that "the crisis in standards of care" - not coping with rising demand at a time of tight budgets or making £20bn of efficiency savings by 2015 or reconfiguring hospital services so more patients can be treated in or near their homes - was the service's biggest challenge.

David Cameron and Jeremy Hunt will doubtless point to initiatives they have taken - such as bringing in a "friends and family" test of hospital care and exploring tough "Ofsted-style" ratings for hospitals - as having at least started to tackle the problems Francis has spent so long pursuing.

But his recommendations are likely to go further than this. Ministers, NHS regulators and the new NHS Commissioning Board are already debating the merits of changes that have been
proposed from various quarters such as regulation of healthcare assistants, legal minimum staffing levels on NHS wards, a legally-binding "duty of candour" on all NHS staff to admit to mistakes, a blacklist of failed NHS managers and many others. However, if Francis decides that in effect NHS regulation at the time failed - he can hardly conclude otherwise - then ministers may come under pressure to introduce much more robust regulation. That, though, is opposed by bodies such as the NHS Confederation, which represents hospitals, and National Voices, an alliance of 130 charities.

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Appendix 8: STAMP analysis of Mid-Staffordshire NHS Trust failings

STAMP analysis: Hospital physical processes

Physical hospital safety controls

Safety requirements and constraints violated:
- Provide facilities and equipment to treat patients
- Enable monitoring of patient condition

Failures and inadequate controls:
- Inadequate defibrillators for each resuscitation trolley in A&E
- Inadequate layout of assessment unit, limiting patient observation
- Inadequate number of beds in specialist and critical care units
- Lack of facility for non-invasive ventilation on respiratory ward
- Inadequate function of cardiac monitors (missing or not working)
- Inadequate equipment for traction or specialist hoists

STAMP analysis: Hospital clinician and support staff system level

Auxiliary staff – porter, receptionist, cleaner

<table>
<thead>
<tr>
<th>Safety-related responsibilities:</th>
<th>Context:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ensure high standards of hygiene and cleanliness are maintained</td>
<td>Porters having to act as security rather than specialist security staff</td>
</tr>
<tr>
<td>Undertake duties to support care</td>
<td>Not enough porters with number decreased as part of staff cuts</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Unsafe decisions and control actions:</th>
<th>Mental model and feedback flaws:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inadequate control actions: Cleaners not maintaining high standards of cleanliness</td>
<td>Coordination and communication issues among staff</td>
</tr>
<tr>
<td>Inadequate control actions: Hand gels not refilled in some areas</td>
<td>A&amp;E waiting area view obscured</td>
</tr>
<tr>
<td>Inadequate enforcement of constraints: Cases of patients abscording</td>
<td></td>
</tr>
<tr>
<td>Inadequate assignment of control authority: Receptionists in A&amp;E relied upon to assess patients and raise concerns to nursing staff, despite lacking clinical training</td>
<td></td>
</tr>
</tbody>
</table>
### Senior Nurse/Ward Management

**Safety-related responsibilities:**
- Ensure high standards of care, hygiene and cleanliness are maintained
- Organise and supervise wards and junior staff
- Ensure reporting and investigation of incidents

**Unsafe decisions and control actions:**
- Inadequate enforcement of constraints: Cases of poor standards of care
- Inadequate feedback: Pressurised junior staff to alter records on discharge times to meet targets
- Inadequate communication channels/learning processes: Forceful management styles, particularly in A&E, stopped junior staff from raising concerns
- Inadequate execution of control action with ineffective management of discharge processes: Premature discharge, protracted discharge processes, failure to communicate arrangements to patients, failure to ensure adequate support
- Inadequate safety management processes: Cases of alleged staff misconduct not being addressed with governance proceedings
- Inadequate safety management and learning processes: Staff appraisal and professional development afforded low priority
- Inadequate feedback: Incident report forms sometimes found to be inaccurate and misleading

**Context:**
- Trust lacked senior nurses e.g. only 3 matrons across whole trust up to 2008 when number was increased to 12
- A&E chronically understaffed in terms of consultants and nurses
- Reported low staff morale following strain of trust financial difficulties, cuts and difficulties in delivering acceptable standards of care
- High sickness rates among staff
- Some community support services not satisfactory for discharge
- Pressure to discharge patients to accommodate patient intake from A&E
- Large variation in standards of care between wards

### Nursing Staff and Healthcare Assistant Team

**Safety-related responsibilities:**
- Ensure high standards of care are maintained
- Report incidents and concerns

**Unsafe decisions and control actions:**
- Inadequate execution of control actions, with cases of inadequate care provision:
- Inadequate patient hygiene practices
- Inadequate prevention of patient falls, issues with observation, recording and risk assessment
- Inadequate patient handling practices
- Inadequate pressure area care
- Failure to monitor and maintain drip bags
- Failure to ensure nutritional requirements met
- Minimal patient observation and examination
- Communication and coordination issues: Inadequate record keeping and lack of clear registration of patient transfer between wards. Lack of appropriate nutrition and hydration charts
- Communication issues: Reports of issues with attitudes of staff towards patients and families impacting on patients raising concerns

**Context:**
- Working in busy, chaotic and understaffed wards
- Receiving inadequate training and development
- A lack of senior staff in some areas
- Equipment lacking in some areas of the hospital
- Working with patients with a high dependency level
- Staff were reluctant to speak out against the poor standards of care in fear of wrath of some senior nurses
- Staff expected to falsify records in order to avoid breaching waiting time target

**Mental model and feedback flaws:**
- Focussed on meeting targets, which was seen as a priority across trust
- Disengagement between management and clinicians
- Reporting of incidents did not seem to result in action
- Trust staff isolated from other trusts and developments in care for continuous learning and understanding of status of trust

---

*Figure 33 Analysis of nursing care*
### Pharmacist

**Safety-related responsibilities:**
- Check prescription sheets and deal with non-compliance to guidelines

**Unsafe decisions and control actions:**
- Inadequate feedback: Did not always provide feedback on prescribing to doctors

**Context:**
- Hospital did not have a pharmacist dedicated to each ward
- Pharmacists did not have enough time to be involved in wards

---

### Consultant

**Safety-related responsibilities:**
- Ensure best standards of care are achieved
- Provide efficient high quality service
- Supervise junior doctors
- Report concerns about patient safety

**Unsafe decisions and control actions:**
- Inadequate enforcement of constraints: Sometimes deviated from guidelines on which antibiotics to use (the guidelines are there to prevent risk of C difficile)
- Inadequate enforcement of constraints: Junior doctors received insufficient support and advice
- Inadequate execution of control action: Examples of delayed diagnosis, misdiagnosis and inappropriate discharge
- Coordination issues: Some diagnostic questions not followed up due to constant changes in staff

**Mental model and feedback flaws:**
- Reporting concerns about an individual clinician seen as an exceptional event
- Issues with what and where to report when whole areas of the hospital not functioning properly
- Lots of policies e.g. on antibiotics, which were not easily accessible

**Context:**
- There was a lack of emergency medicine consultants and middle grade staff in A&E, making it difficult to treat critically ill patients, supervise junior doctors and provide efficient high quality service
- Issues with low numbers of nurses and reduction in experience were reported to heads and director. But needs for more staffing gave in to financial pressures

---

### Junior doctor

**Safety-related responsibilities:**
- Ensure best standards of care are achieved
- Report concerns about patient safety

**Unsafe decisions and control actions:**
- Inadequate execution of control action: Examples of issues with diagnosis and inappropriate discharge

**Context:**
- Under pressure from senior nurses to discharge patients to meet targets in A&E
- A lack of supervision and insufficient support and advice given to junior doctors in A&E
- A lack of consultants in some areas meant junior doctors having to cover on quiet nights

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Figure 34 Analysis of hospital pharmacists

Figure 35 Analysis of consultants and junior doctors
STAMP analysis: Trust leadership and clinical governance

<table>
<thead>
<tr>
<th>Clinical governance, audit and infection control teams</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Safety-related responsibilities:</strong></td>
</tr>
<tr>
<td>• Improve patient care and outcomes through systematic review, evaluation and implementation of change</td>
</tr>
<tr>
<td>• Ensure high standards of care, hygiene and cleanliness are maintained</td>
</tr>
<tr>
<td><strong>Context:</strong></td>
</tr>
<tr>
<td>• Continual change in clinical leadership at board level – clinical governance predominantly overseen by director of nursing</td>
</tr>
<tr>
<td>• Clinical governance lead did not feel adequately trained or experienced for role</td>
</tr>
<tr>
<td>• No lead for clinical audit for a year prior to April 2007</td>
</tr>
<tr>
<td>• Clinical audit lead had other research and development commitments and a substantial workload</td>
</tr>
<tr>
<td>• Director of infection control role regularly changed between personnel</td>
</tr>
<tr>
<td>• Improvements in infection control in 2008 noted by DH and HCC</td>
</tr>
<tr>
<td><strong>Unsafe decisions and control actions:</strong></td>
</tr>
<tr>
<td>• Inadequate safety management and learning processes:</td>
</tr>
<tr>
<td>• Clinical audit weak and disjointed. Lacked planning and not linked to other governance</td>
</tr>
<tr>
<td>• A lack of follow-up after audits to ensure changes and improvements were made</td>
</tr>
<tr>
<td>• Inadequate robustness in review of patient deaths</td>
</tr>
<tr>
<td>• Did not participate in the audits of specialist medical and surgical societies</td>
</tr>
<tr>
<td>• Coordination and communication issues: Disconnect between divisions, departments within divisions and the central audit team</td>
</tr>
<tr>
<td>• Inadequate enforcement of safety constraints: Hygiene and cleanliness standards not maintained</td>
</tr>
<tr>
<td>• Inadequate interactions with external bodies: Did not report 2005-2006 increase of C.difficile to HPA, SHA and trust board</td>
</tr>
<tr>
<td><strong>Mental model and feedback flaws:</strong></td>
</tr>
<tr>
<td>• Filtering of information on complaints and incidents did not give adequate information for board to judge standards</td>
</tr>
<tr>
<td>• Reassured that high mortality rates were due to poor coding</td>
</tr>
<tr>
<td>• Inadequate use of data to drive and generate audit</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Division level leadership and senior clinical staff</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Safety-related responsibilities:</strong></td>
</tr>
<tr>
<td>• Ensure quality and safety of patient care</td>
</tr>
<tr>
<td>• Ensure learning and improvement following investigation of incidents and complaints</td>
</tr>
<tr>
<td>• Manage systems for the management of risk to patient safety and wellbeing. Ensure reporting of serious incidents to SHA and NPSA</td>
</tr>
<tr>
<td><strong>Context:</strong></td>
</tr>
<tr>
<td>• Responsibility for most of risk management and governance system devolved to divisions in 2007</td>
</tr>
<tr>
<td>• Trust cost improvement plan in action with board setting savings plan and divisions responsible for implementation</td>
</tr>
<tr>
<td>• Cost improvement plans were identified as a risk to patient safety and wellbeing</td>
</tr>
<tr>
<td>• High staff turnover and sickness, difficulty recruiting</td>
</tr>
<tr>
<td>• Changes in staff skill mix resulted in a lack of senior nurses and increase in support staff</td>
</tr>
<tr>
<td>• Disconnect between clinical staff and management with clinicians feeling their concerns were ignored</td>
</tr>
<tr>
<td><strong>Unsafe decisions and control actions:</strong></td>
</tr>
<tr>
<td>• Inadequate enforcement of constraints: Failed to maintain high standards of care</td>
</tr>
<tr>
<td>• Inadequate safety management and learning processes: Complaints and incident investigations undertaken by frontline staff. Staff lacked training and time for investigation resulting in varied quality</td>
</tr>
<tr>
<td>• Inadequate enforcement of constraints: Surgical division described as dysfunctional in RCS review</td>
</tr>
<tr>
<td>• Inadequate enforcement of constraints: Problems in medical and surgical divisions often listed on risk register but not resolved</td>
</tr>
<tr>
<td>• Inadequate allocation of resources: A&amp;E had issues with low staffing levels, lack of leadership, lack of equipment and lack of high quality training</td>
</tr>
<tr>
<td><strong>Mental model and feedback flaws:</strong></td>
</tr>
<tr>
<td>• Clinicians felt concerns were not listened to by trust leadership and the trust focused on financial strategy</td>
</tr>
<tr>
<td>• A closed culture among clinicians with reluctance to adopt national guidance such as from NICE</td>
</tr>
</tbody>
</table>

Figure 36 Analysis of Trust clinical governance
### Trust Board – non executive and executive directors (non-clinical)

#### Safety-related responsibilities:
- Ensure quality and safety of patient care
- Ensure learning and improvement following investigation of complaints
- Ensure trust has systems for the management of risk to patient safety and wellbeing
- Ensure reporting of serious incidents to SHA and NPSA

#### Unsafe decisions and resulting control actions:
- Did not act on issues at trust prior to external investigation
- Inadequate allocation of resources: Low numbers of senior nurses and consultants
- Unidentified hazards: Lacked consideration of risks of staffing levels
- Focussed on financial and corporate governance over standards of care
- Inadequate risk assessment for clinical floor reconfiguration and staffing mix
- Target driven and focussed on delivery of A&E waiting time target

#### Mental model flaws:
- Non-executives reliant on information given by executives aware of some issues but unaware of concerns with standards of care until HCC investigation in 2008
- Non-executives thought issues were being rectified by executives and disconnected from operational activity
- Did not have full understanding of organisational status which had poor usability

#### Context:
- Applying for foundation trust status with focus on financial and corporate governance
- Non-executives lacked NHS experience
- Considerable change in board membership since 2005
- Pressure to meet targets, with significant savings needed
- High staff turnover and sickness, with difficulty recruiting

#### Inadequate interactions with external bodies:
- Meetings on governance held privately and closed to public scrutiny
- Disputed negative reports
- Did not share all serious untoward incident reports with SHA and NPSA
- Did not report 2005-2006 increases in c.difficile to HPA and SHA
- Did not share RCS report on dysfunctions in surgical division with Monitor during review

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### Trust Board – chief nurse, director of nursing, medical director

#### Safety-related responsibilities:
- 2003 to 2006: medical director gave medical advice to trust board and connection between board and consultants, no other specific roles
- Director of nursing responsible for strategic response to clinical risk management
- Create culture for effective hygiene and infection control
- Clinical governance, effectiveness and audit

#### Unsafe decisions and control actions:
- Failed to comply with recognised standards of clinical audit
- Chief nurse introduced an online reporting system which had poor usability
- Inadequate risk assessment for proposed changes, such as clinical floor layout and staffing mix
- Failed to ensure adequate nursing staff on wards

#### Mental model flaws:
- Medical director did not feel they had a leadership role, did not often perform walkarounds of wards
- Medical director aware of some problems but not concerned requiring urgent action
- Chief nurse focussed on strategic concerns
- Director of nursing believed the review committee followed up on action plans from complaints

#### Coordination issues between director of nursing/chief nurse and chief operational officer:
- Responsibility for risk assessment of nursing staffing
- Operating officer felt managerial responsibility for nursing staff but not clinical standards

And with director of nursing and complaints review committee (including non-executives):
- Not aware who followed up on action plans from complaint investigation

---

### Inadequate assignment of responsibilities to controllers:
- Medical director at times lacked specific responsibility
- Director of nursing and chief operating officer had overlaps between roles

#### Inadequate assignment of controller hierarchy:
- Devolved responsibilities to divisional management including trust wide issues such as staffing

#### Inadequate allocation of resources:
- Reduction in beds and staff
- Nursing shortages on wards
- Issue with skill mix and lack of senior nurses

#### Inadequate communication channels provided for the organisation:
- Filtered information on complaints and incidents did not give adequate information for board to judge standards
- Ignored clinician concerns, including on risks of clinical floor reconfiguration and low nurse staffing
- Generally poor clinical engagement

#### Inadequate safety management and learning processes regarding incidents and complaints:
- Action plans for complaints not followed up
- Legal team inquest reports not shared with other trust governance to be considered as part of risk management
- Staff incident reporting system difficult to use
- No regular auditing of antibiotic practice until 2007
- Ineffective clinical audit and lack of follow-up to ensure improvements made

#### Control action not given or not followed:
- Wards did not meet hygiene or environmental cleanliness standards

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**Figure 37 Analysis of Trust Board**

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STAMP analysis: Regional healthcare governance

<table>
<thead>
<tr>
<th>Safety-related responsibilities:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Commission high quality services and hold providers to account for provision of safe and high quality services</td>
</tr>
<tr>
<td>• Monitor provider performance and improve quality of commissioned services</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Unsafe decisions and control actions:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Inadequate feedback from monitoring of trust’s quality and safety performance: The PCT lacked locally agreed performance measures and relied on trust’s self-declaration of issues and monitoring by other organisations</td>
</tr>
<tr>
<td>• Inadequate enforcement of constraints through unidentified hazards: Failed to identify hazards relating to trust’s 2005 staff reduction proposals</td>
</tr>
<tr>
<td>• Inadequate allocation of resources: The trust was short staffed in terms of nurses and consultants</td>
</tr>
<tr>
<td>• Ineffective control actions to enforce safety constraints and remedy trust performance issues: The design of available control actions, such as financial penalties, did not enforce constraints on trust’s safety and quality related performance</td>
</tr>
<tr>
<td>• Inadequate execution of control actions (late control action): Actions to enforce safety constraints were late and applied after PCT was made aware of issues by HCC review, and concerns raised in meetings with campaigners (cure the NHS group) and local GPs</td>
</tr>
<tr>
<td>• Inadequate coordination with controllers and decision makers: PCT not made fully aware of issues following external peer reviews of trust’s care for critically ill and injured children. If aware PCT could ensure remedial action and follow-up</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Context:</th>
</tr>
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<tbody>
<tr>
<td>• Available action against provider non-compliance with obligations was limited</td>
</tr>
<tr>
<td>• One action in response to non-compliance was financial penalties. However, the hospital trust had financial difficulties and PCT did not want to take actions that would further destabilise the hospital trust</td>
</tr>
<tr>
<td>• No real option to commission alternative provider with local need for a service</td>
</tr>
<tr>
<td>• The PCT was subject to reorganisation during this time period. So had to devote time to restructuring and lost corporate memory and experience</td>
</tr>
<tr>
<td>• There was a lack of guidance available to the PCT on how to set-up and monitor provider performance</td>
</tr>
<tr>
<td>• The PCT lacked relevant clinical expertise in comparison to providers who could use their knowledge to rebut concerns about performance</td>
</tr>
<tr>
<td>• Improvements in 2008/09 with use of local quality data, Department of Health operating framework, requirements for providers to comply with NICE guidance and monitoring through annual patient questionnaire</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Mental model and feedback flaws:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Lacked an understanding of the issues at the trust due to limited data gathering and reliance on trust’s self-declaration</td>
</tr>
<tr>
<td>• Became more aware of status of trust and performance issues after HCC investigation and meeting with campaigners</td>
</tr>
<tr>
<td>• Focus on financial performance over quality and safety. Fault in system design with lack of clarity on safety responsibility</td>
</tr>
<tr>
<td>• Limited patient and public involvement</td>
</tr>
</tbody>
</table>

Figure 38 Analysis of Primary Care Trust (PCT) regulator
<table>
<thead>
<tr>
<th><strong>Safety-related responsibilities:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Ensure the delivery of safe, quality services through effective clinical governance arrangements in PCTs and NHS Trusts</td>
</tr>
<tr>
<td>• Keep in place arrangements for monitoring and improving the quality of care provided</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Unsafe decisions and control actions:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Inadequate organisational change process: SHA did not have capacity to continue to performance manage trust. PCTs not equipped to take over trust performance management as expected by SHA</td>
</tr>
<tr>
<td>• Inadequate organisational change process: ineffective handover on reorganisation and lack of systematic approach to retaining organisational memory</td>
</tr>
<tr>
<td>• Inadequate identification of hazards: PCT and trust pressured to achieve financial and waiting time targets without due regard for impact on patient care</td>
</tr>
<tr>
<td>• Inadequate feedback and monitoring of safety performance: SHA feedback from PCT and trust focussed on meeting targets rather than safety. SHA safety monitoring relied upon trust self-assessment or serious concerns being brought to their attention</td>
</tr>
<tr>
<td>• Inadequate feedback on safety performance (2006 to 2007): SHA identified need for safety metrics including on medication errors and avoidable deaths. After discussion with PCTs and trust, metrics instead focussed on access to treatment and indirect measures of safety</td>
</tr>
<tr>
<td>• Inadequate safety management and learning processes: SHA did not ensure incident reports received from the trust were scrutinised, or that investigations were completed with the development of action plans and key lessons recorded</td>
</tr>
<tr>
<td>• Inadequate enforcement of constraints, SHA did not take action or ensure action taken: PCT reports to SHA (2008), external review reports and SHA risk assessment (2007) raised concerns about safety of care in the trust. Issues raised included hospital related infection, hygiene standards, high mortality rates, low staffing and standards of care. This information did not raise due concern regarding issues at trust. SHA took action on hospital related infection and challenged trusts in area on mortality rates, reassured by PCT and trust actions on other issues</td>
</tr>
<tr>
<td>• Time lag in execution of control action: Issues with trust nurse staffing levels raised to SHA by trust director of nursing in 2007. Supported director of nursing but propositions not presented to the trust board until a year later</td>
</tr>
<tr>
<td>• Inadequate organisational change process: On trust gaining foundation status, SHA did not alert Monitor to issues with mortality rates</td>
</tr>
<tr>
<td>• Inadequate interactions with external bodies: SHA were defensive toward HCC investigation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Context:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• SHA a small organisations with 1.5 members of staff for each organisation for which it was responsible</td>
</tr>
<tr>
<td>• Confusion over extent to which SHAs were expected to address safety concerns. SHA not given capacity to performance manage providers</td>
</tr>
<tr>
<td>• SHA going through a period of extensive reorganisation, reduction in size and management of financial issues in a difficult financial climate</td>
</tr>
<tr>
<td>• The SHA relinquished responsibility for the trust when it gained foundation status in February 2008, Monitor assumed ongoing responsibility. SHA still had a role performance managing PCT commissioning the trust</td>
</tr>
<tr>
<td>• Priorities for the newly organised SHA handed down from Department of Health focussed on finance and restructuring of the NHS as a whole. It was assumed that provider organisations were capable of delivering safety and quality without detailed performance management</td>
</tr>
<tr>
<td>• Following the reorganisation the intention was for the SHAs to delegate function as provider performance managers to PCTs</td>
</tr>
<tr>
<td>• There was no nationally determined safety metrics or quality measures in 2006</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Mental model and feedback flaws:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• There was no comprehensive handover following reorganisation and some organisational memory was lost</td>
</tr>
<tr>
<td>• The information the SHA received did not give them concerns about the quality of care the trust provided or make it stand out from other trusts. Although external reviews of the trust had raised concerns</td>
</tr>
<tr>
<td>• Did not receive reports of all serious untoward incidents relating to the trust</td>
</tr>
<tr>
<td>• Monitoring of provider performance was limited to compliance with national targets. This did not distinguish trust adversely from other trusts in the region</td>
</tr>
<tr>
<td>• Believed that provider trust boards would be monitoring quality and safety of care</td>
</tr>
<tr>
<td>• On reorganisation, information from handover had focussed the SHA on issues at organisations other than the trust</td>
</tr>
<tr>
<td>• Reassured by the monitoring of trust and actions undertaken by PCT. The PCT reports to SHA tended to balance negative aspects with good potentially presenting a more favourable view of trust status</td>
</tr>
<tr>
<td>• SHA aware of reported high mortality rates at trust since 2007. Coding used in analysis made significance of rates questionable and this was SHA focus</td>
</tr>
<tr>
<td>• SHA lacked collation of information or dashboard to give full picture of issues</td>
</tr>
</tbody>
</table>

Figure 39 Analysis of Strategic Health Authority (SHA) as regulator
<table>
<thead>
<tr>
<th>Health Protection Agency (HPA)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Safety-related responsibilities:</strong></td>
</tr>
<tr>
<td>• Reduce episodes of healthcare associated infections by providing advice and support to NHS organisations</td>
</tr>
<tr>
<td>• Provide national surveillance of hospital associated infections</td>
</tr>
<tr>
<td><strong>Unsafe decisions and control actions:</strong></td>
</tr>
<tr>
<td>• Design does not enforce constraints: The organisation was designed to provide feedback to providers and regulators and did not have available control actions to enforce constraints</td>
</tr>
<tr>
<td>• Inadequate coordination among controllers and decision makers: Concerns were shared with the trust and PCT but not escalated to SHA prior to 2009. Concerns were not shared with Monitor or HCC</td>
</tr>
<tr>
<td><strong>Context:</strong></td>
</tr>
<tr>
<td>• Had concerns about trust’s management of hospital acquired infections in 2006, 2008 and 2009</td>
</tr>
<tr>
<td>• The trust had an outbreak of C. difficile in 2008 and a repetition in 2009</td>
</tr>
<tr>
<td>• A support organisation rather than a regulator, it could only provide information and advice</td>
</tr>
<tr>
<td>• Gave advice to trust and raised concerns following outbreaks, but some advice not taken and did not have the power to enforce constraints</td>
</tr>
<tr>
<td><strong>Mental model and feedback flaws:</strong></td>
</tr>
<tr>
<td>• Some unclear guidance and lack of understanding on when to share information with different regulators</td>
</tr>
</tbody>
</table>

Figure 40 Analysis of Health Protection Agency (HPA)

<table>
<thead>
<tr>
<th>Local General Practitioners (GPs)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Safety-related responsibilities:</strong></td>
</tr>
<tr>
<td>• Report concerns about patient safety</td>
</tr>
<tr>
<td><strong>Unsafe decisions and control actions:</strong></td>
</tr>
<tr>
<td>• Inadequate enforcement of constraints/feedback: Did not express concerns about the trust until the HCC investigation had begun</td>
</tr>
<tr>
<td>• Coordination and communication issues: A large proportion of local GPs were not actively involved in the consortia that could collect local views and deliver concerns to the PCT</td>
</tr>
<tr>
<td>• Coordination and communication issues: The local consortia and PCT discussions did not regularly discuss issues of healthcare quality</td>
</tr>
<tr>
<td>• Coordination and communication issues: GPs may have been unclear as to the communication channels through to the PCT</td>
</tr>
<tr>
<td><strong>Context:</strong></td>
</tr>
<tr>
<td>• When formally asked for their views in April 2008, a majority of GPs expressed concern about the quality of care received by their patients</td>
</tr>
<tr>
<td>• Complaints included poor nursing care, low levels of nurse staffing and inadequate out of hours cover in A&amp;E</td>
</tr>
<tr>
<td><strong>Mental model and feedback flaws:</strong></td>
</tr>
<tr>
<td>• Dealt with issues concerning individual patients directly with trust consultants</td>
</tr>
<tr>
<td>• Dealt with concerns relating to individual patients on a case-by-case basis</td>
</tr>
<tr>
<td>• Did not connect their role in the commissioning process with information from their patients</td>
</tr>
</tbody>
</table>

Figure 41 Analysis of local GPs' role in reporting safety concerns
### Patient and Public Involvement groups (PPI)

<table>
<thead>
<tr>
<th>Safety-related responsibilities:</th>
<th>Context:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Report patient and public concerns</td>
<td>• PPIf and LINk relied on untrained volunteers and received little support or guidance</td>
</tr>
<tr>
<td>• Patient and Public Involvement Forum (PPIF) had the power to inspect the trust</td>
<td>• PPIf was a small group of 8 to 10 people meeting monthly.</td>
</tr>
<tr>
<td>• Local Involvement Networks (LINks) intended to obtain and analyse information from a wide range of sources</td>
<td>• Two members of PPIf resigned over dissatisfaction with PPIf leadership. Both gave stories to local press</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Unsafe decisions and control actions:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Inadequate feedback: Routes through which patients and the public can communicate issues about health services and hold them to account were largely ineffective</td>
<td>• PPIFS were replaced with Local Involvement Networks (LINks) in 2008</td>
</tr>
<tr>
<td>• Inadequate feedback: PPIf did inspect the hospital on several occasions. Despite issues being raised by a member regarding cleanliness and hygiene practices, final reports to the trust emphasised the positives. PPIf felt trust was showing improvements</td>
<td>• LINk struggled to recruit members due to a lack of interest</td>
</tr>
<tr>
<td>• Inadequate feedback: PPIf comments on HCC annual health check did not express the strong criticisms from some members and balanced comments with positive remarks</td>
<td>• From the set-up of local LINk in 2008 it was preoccupied with its own governance issues</td>
</tr>
<tr>
<td>• Coordination and communication issues: The trust blocked the flow of information to the PPIf. PPIf leadership lacked the training and experience to challenge the trust effectively</td>
<td>• LINk members reluctant to conduct inspections without indemnity insurance</td>
</tr>
<tr>
<td>• Inadequate feedback provided in system design: PPIf had limited engagement with patients and the public. PPIf not equipped to fulfil this role</td>
<td>• LINk did not address issues at trust before the publication of HCC inspection report</td>
</tr>
<tr>
<td>• Inadequate feedback: LINk did not undertake any visits to inspect the hospital</td>
<td>• DH had inadequate organisational change process for shift from PPIf to LINks</td>
</tr>
</tbody>
</table>

### Mental model and feedback flaws:

- PPIf not kept fully informed about trust status. Information given to them was controlled by trust
- PPIf acted as representatives of the public but had little engagement with patients and the public
- LINk did not take information and evidence from the CURE the NHS group

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**Figure 42 Analysis of patient and public involvement groups**
### Local authority overview and scrutiny committee (OSC)

#### Safety-related responsibilities:
- The local council authority OSC had the power to review and scrutinise the planning and operation of local health services
- Make reports and recommendations for improvement to local NHS bodies

#### Context:
- A small committee with limited resources that did not have a role in performance management of NHS bodies
- Committee concentrated on ensuring health services address the needs of local communities
- Received information about the hospital predominantly from the Trust itself, but also PPIF, PCT, media and the public
- Focus on scrutiny of the Trust increased when CURE the NHS and the start of HCC investigation increased concern

#### Unsafe decisions and control actions:
- Inadequate enforcement of constraints: Prior to concerns being raised by CURE the NHS and the HCC investigation, the committee lacked critical scrutiny of the hospital.
- Inadequate feedback: Relied on information from the Trust. Lacked critical scrutiny of Trust plans in relation to staffing changes and issues with cleanliness raised by patients’ forum.

#### Mental model and feedback flaws:
- Dependant on information from the Trust

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Figure 43 Analysis of local authority overview committee
STAMP analysis: National governance

Safety-related responsibilities:
- Drive improvement in quality of care
- Publish data relating to the provision of healthcare by each NHS body
- Conduct visits and inspections of NHS bodies
- Annually review each NHS organisation under jurisdiction. Assess provision of healthcare, if significant failings found, report and make recommendations
- Review NHS complaints that had not been resolved locally
- Ensure robust intervention in tackling poor performance

Unsafe decisions and control actions:
- Design of control action does not enforce constraints: HCC had no direct enforcement powers. Limited to making recommendations to Secretary of State and Monitor
- Inadequate feedback provided in system design: The standards set out by the DH which were used in HCC reviews were not felt to be effective as an assessment of quality (too specific in some areas, too broad in others e.g. does the organisation have systems in place rather than criteria to see if those systems are effective)
- Inadequate feedback: Overreliance on trust self-declaration, although this was cross-checked against other information. HCC had developed techniques to reduce the need for routine visits
- Inadequate feedback: core standards assessment did not mean a physical inspection of premises, patients, staff or service, it could be confined to an inspection of paperwork.
- Inadequate feedback, inadequate sensor operation: HCC risk-based core standards assessment of trust in July 2007 failed to detect any non-compliance (documentation assessed, not physical inspection)
- Late control actions: Complaint handling workload was so high it delayed completion of investigations and limited ability of HCC to use regulatory functions in response to complaints and limited follow-up to confirm action plans had been implemented
- Late control actions: Did not launch formal investigation until 2008 (based on concerns about mortality statistics, reports from campaigners and visits to trust). Lengthy investigation then oversaw gradual improvements
- Inadequate interactions with external bodies: Monitor and Deanery not notified of intention to investigate trust and concerns relevant to them. Deanery unaware of serious training issues until 2009
- Inadequate control actions: HCC did not follow-up on issues raised about trust from complaints and external reviews in 2006

Context:
- HCC started as an organisation in 2004
- Board of directors hired and fired by secretary of state
- Monitor developed as a second regulator to regulate Foundation Trusts
- HCC and Monitor developed on the back of recommendations from the Bristol Inquiry (Professor Kennedy). The inquiry had recommended for one organisational regulator, not two, to ensure clarity of roles and responsibilities
- Department of Health set standards with input from HCC during its development
- Aimed to bring together data about NHS and analyse systematically to produce a richer picture
- The act of regulating the PCT commissioning function was not well understood
- HCC assessment was against national targets and core standards and produced a score in two parts: quality of service and use of resources
- Function of complaints handling was a heavier workload than expected and took up a large proportion of HCC time
- Other organisations pressuring HCC to stop investigation

Mental model and feedback flaws:
- Unaware of West Midlands peer review of trust's children's services
- Reassured by trust's actions having received negative reports in 2006 and 2007
- The checks of paperwork and self-declaration did not give full picture of trust status on several issues, including hygiene standards
- HCC patient and staff survey findings produced in 2007 put trust in bottom 20% of trusts in the country. HCC put more value in assessment of documents and policies
- Until 2008 HCC did not have a means of systematically feeding local information from local assessors throughout organisation
- Higher levels of HCC not aware of trust's application for foundation status. Although regional inspectors were aware. Monitor did not communicate with HCC about application and so were unaware of HCC forthcoming inspection when granting trust foundation status
- Mortality rate alerts received from 2007 and HCC began to monitor proactively and review alerts. In the beginning HCC satisfied by trust's responses. Alerts received from various trusts often with innocent explanation for outliers

Figure 44 Analysis of Healthcare Commission (HCC)
### Safety-related responsibilities:
- Authorise, monitor and regulate NHS foundation trusts
- Powers to intervene in a foundation trust when there was significant non-compliance with statutory requirements
- Monitor not given specified role in regulation of quality of care

### Context:
- Established in 2004 as an independent regulator of foundation trusts, Monitor had limited clinical managerial experience and expertise
- Authorised trust foundation status and took on responsibility for trust with that status authorised in 2008
- Policy and DH encouraged Monitor not to be a performance manager and not to micromanage and undermine responsibility of foundation trust boards
- Served formal intervention notice to trust in March 2009
- At time of HCC trust report publication, Monitor was engaged in intervention at another trust, with limited capacity to deal with multiple interventions
- Following HCC investigation and changes at trust, Monitor commissioned an external review into its own performance by KPMG

### Unsafe decisions and control actions:
- Inadequate enforcement of constraints with unidentified hazards: Lacked effective consideration of potential effects of cost saving and staff cuts on patient safety
- Inadequate enforcement of constraints with ineffective and delayed controls: Failed to act on concerns at trust to which it was aware and responded with undue delay (waited for HCC to finish investigation)
- Inadequate enforcement of constraints with control action not provided in system design: Following inquiry Monitor was given power to notify Secretary of State that foundation trust is failing to justify deauthorisation of foundation status. And power to start process of deauthorisation after giving notice to foundation trust of failure to meet specified requirements (repealed in 2012). Did not have these actions at time of Mid-Staffs failings
- Inadequate coordination among controllers, due in part to system design: HCC inspected and reported quality at trust but had to have Monitor intervene for foundation trust. Monitor ended up waiting for HCC investigation to finish before taking action and a change in trust leadership

### Mental model and feedback flaws:
- Did not know about concerns raised during build-up to HCC investigation prior to authorising trust foundation status
- Took the view that it would be inappropriate to take action on trust before the HCC investigation was finished
- Frustrated about HCC investigation duration and felt there was enough to act on without further analysis but did not feel it could act prior to investigation conclusions. Wanted HCC to make a recommendation to Monitor

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Figure 45 Analysis of Monitor
### Safety-related responsibilities:
- Ensure proper standards in the practice of clinicians and clinically qualified leaders
- Provide guidance to clinicians and training establishments on maintaining and improving performance with reference to patient safety
- Investigate concerns on information related to fitness to practice of clinicians. Deal firmly and fairly with clinicians whose fitness to practice comes into doubt – sanctions include: warnings, conditions on registration, suspension, removal from register
- Publish standards of conduct, performance and ethics for nurses (NMC), doctors (GMC) and other registered clinical professions (HCPC)

### Context:
- Act on complaints or information received that raises concern about professional conduct and required the information to include named individuals
- Professional regulators seen as place to report after concerns had been raised to local organisations
- Professional regulators seen as places to report individual clinicians rather than whole system failure
- GMC received information or complaints about 32 doctors working at the trust during period under review by inquiry
- Royal College of Surgeons undertook a review of trust surgical services in 2007 and 2009, expressed several concerns and gave recommendations to the trust
- Regulator for individual practitioners and not the system as a whole

### Unsafe decisions and control actions:
- Inadequate feedback: At the time of failings the GMC, NMC and HCPC lacked proactive monitoring of issues and were reliant on information being provided to them
- Inadequate feedback: GMC did not consolidate information from one trust and systematically identify trends
- Inadequate coordination and communication among controllers: GMC did not receive any information about HCC investigation from the trust or postgraduate deanery (GMC was given some information by HCC in 2008, but perhaps not all relevant information)
- Inadequate coordination and communication among controllers: NMC not fully informed about HCC investigation until 2 weeks before publication of report

### Mental model and feedback flaws:
- There was a lack of referrals to professional regulators by professionals when they had concerns
- The trust did not have a proper policy to refer clinicians to professional regulators
- Lack of feedback on issues at trust limited professional regulators’ awareness
- Royal College of Surgeons critical review of trust not shared with GMC
- NMC only made aware of 3 cases concerning quality of care of nursing at trust during period reviewed by inquiry
- HCPC had not received any information regarding issues at the trust

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Figure 46 Analysis of regulators of clinical profession
<table>
<thead>
<tr>
<th>National Patient Safety Agency (NPSA)</th>
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<tbody>
<tr>
<td><strong>Safety-related responsibilities:</strong></td>
</tr>
<tr>
<td>• Implement and operate the national system for learning from error and adverse events</td>
</tr>
<tr>
<td>• Share information with NHS regulatory and oversight bodies</td>
</tr>
<tr>
<td>• National Reporting and Learning System (NRLS) to identify risks at a national level</td>
</tr>
<tr>
<td>• Send patient safety alerts, solutions to address repeatedly encountered medical problems, as national guidance</td>
</tr>
<tr>
<td><strong>Context:</strong></td>
</tr>
<tr>
<td>• Not a regulatory body. Had no regulatory powers and not responsible for monitoring performance of individual organisations</td>
</tr>
<tr>
<td>• NRLS fully implemented in 2005</td>
</tr>
<tr>
<td>• Healthcare staff could report incidents through their local organisation, directly to NPSA website or through a specialist group</td>
</tr>
<tr>
<td>• Patients and public could report safety incidents through a local organisation or through NPSA website</td>
</tr>
<tr>
<td>• NRLS reporting was voluntary</td>
</tr>
<tr>
<td>• NPSA sent 6 cause for concern letters to trust between November 2008 and June 2010 (not exceptional compared to other trusts)</td>
</tr>
<tr>
<td>• NPSA not designed to review its data as a regulatory organisation would.</td>
</tr>
<tr>
<td>• NPSA felt that concerns about individual trusts, local learning and local change was remit of SHA, PCT and HCC</td>
</tr>
<tr>
<td>• NPSA began sharing increasing amounts of information with SHA from 2007</td>
</tr>
<tr>
<td>• NPSA set-up and operating during a period of healthcare reorganisations, therefore relatively low priority given to reporting system</td>
</tr>
<tr>
<td><strong>Unsafe decisions and control actions:</strong></td>
</tr>
<tr>
<td>• Inadequate feedback: Poor standards of nursing care probably under-reported in voluntary incident reporting system</td>
</tr>
<tr>
<td>• Inadequate feedback: Patient incidents possibly under-reported</td>
</tr>
<tr>
<td>• Inadequate assignment of goals, control authority and responsibilities in system design: NPSA the only organisation external to the trust that routinely received reports of issues, such as staffing shortages, from trust’s own reporting system. However, NPSA not equipped or designed to analyse individual reports, nor share them with other bodies which monitored and regulated the trust’s performance (they only received reports on serious untoward incidents)</td>
</tr>
<tr>
<td>• Inadequate coordination and communication among controllers: NPSA did not inform HCC, SHA or PCT about letters of concern sent to trust. NPSA did not routinely communicate with regulators and only did so once after HCC investigation due to heightened alert</td>
</tr>
<tr>
<td>• Ineffective control action, action does not enforce safety constraints: Trust’s compliance with NPSA patient safety alerts by deadline given was 67% 2004 to 2008, and 76% 2008 to 2009 (only slightly below average for peers)</td>
</tr>
<tr>
<td>• Inadequate coordination and communication amongst multiple controllers: NPSA did not follow-up on failure of trusts to implement safety alerts, believing it was the role of SHAs and PCTs. SHA did not receive safety alerts and did not monitor trust compliance</td>
</tr>
<tr>
<td><strong>Mental model and feedback flaws:</strong></td>
</tr>
<tr>
<td>• Trust A&amp;E had a low rate of incident reporting in 2006-2008 (indicative of lack of learning culture)</td>
</tr>
<tr>
<td>• NPSA did not receive information on mortality rates</td>
</tr>
<tr>
<td>• Trust responded to letters of concern to a reasonable standard</td>
</tr>
<tr>
<td>• NPSA inquiry line only received one email (from a senior staff nurse) of potential interest to inquiry. This was not acted upon by NPSA as out of their normal practice</td>
</tr>
</tbody>
</table>

Figure 47 Analysis of National Patient Safety Agency
| NHS Litigation Authority (NHSLA) and National Clinical Assessment Service (NCAS) |
|---|---|
| **Safety-related responsibilities:** | **Context:** |
| • NHSLA Collects information about nature and number of claims made against trust. Sets risk management standards for all NHS organisations and assess organisations against those standards | • NHSLA is not a regulator and is concerned with management of claims made against NHS |
| • NCAS advised trust on appropriate actions when concerned about practice of a doctor, dentist or pharmacist | • Mid-Staffs Trust used its NHSLA rating in support of its self declarations to HCC |
| **Unsafe decisions and control actions:** | • Trust reported a cluster of cases to NCAS in 2007 and 2009 following Royal College of Surgeons peer review |
| • Coordination and communication flaws: NHSLA assessment of trust in 2007 found no cause for concern. The ratings given by NHSLA were used by the trust in support of its self declarations to regulators. Ratings wrongly thought by some to verify the presence of good quality care | **Mental model and feedback flaws:** |
| | • NHSLA rejected claims that standards assessment could be used to indicate satisfactory standards of care. Potential for others to incorrectly interpret meaning of rating |
| | • Trust did not share Royal College of Surgeons report with NCAS |

Figure 48 Analysis of NHS litigation authority
### Safety-related responsibilities:
- GMC had duties relating to the oversight of approved practice setting establishments for undergraduate training and foundation year 1
- PMETB had responsibilities for foundation year 2 and onwards
- Foundation school Deans oversaw quality and performance in the training provided

### Context:
- GMC/PMETB inhibited by lack of choice of realistic intervention options

### Unsafe decisions and control actions:
- Unidentified hazards: Lacked consideration of risk of placing trainees in a trust incompliant with minimum safety and quality standards
- Inadequate enforcement of constraints: Trust had declared non-compliance with development and training standards (2005 and 2007). Trust still passed GMC assessment
- Coordination issue: GMC assessment relied on HCC assessments and trust self-declaration. GMC had no powers of audit or inspection
- Ineffective feedback: Monitoring of training lacked gathering of information on trust compliance with safety standards

### Mental model and feedback flaws:
- Training regulators may have had too narrow a view of their role regarding oversight of medical training and had inadequate thought regarding wider patient safety implications
- GMC did not look at or was not aware of information on trust’s high mortality rates and the increasing concerns of HCC
- HCC, SHA and trust failed to ensure that PMETB and GMC were aware of serious concerns with trust A&E in 2008

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**Figure 49 Analysis of medical training boards**
### Safety-related responsibilities:
- Enact a general duty on every employer to ensure, so far as is reasonably practicable, the health, safety and welfare of all its employers.
- This duty is also owed to people who are put at risk by the activities of persons at work.

### Unsafe decisions and control actions:
- Communication and coordination issues with other regulators: Some lack of sharing of information between HSE and other regulators such as HCC. System design lacked a repository for sharing knowledge.
- Inadequate coordination among controllers: A lack of clarity on which organisational body regulates what. With some overlap in responsibilities between HSE and healthcare regulators. A lack of awareness of each other’s limitations regarding control actions (HSE only regulator with powers of prosecution).

### Context:
- Does not investigate matters of clinical judgement or quality of care.
- HSE deals with the major non-clinical risks to patients such as trips and falls.
- Investigations relating to non-employees were restricted by national guidance.
- Hospitals only a very small proportion of HSE’s work.
- Conducted both proactive and reactive inspections.
- Trust inspected in 2007 as a result of a national directive and further inspections occurred following reporting of injuries, diseases and dangerous occurrences regulations (RIDDOR).

### Mental model and feedback flaws:
- Limited information sharing from HCC.
- HCC did not inform HSE formally of investigation until January 2009.
- No complaints made to HSE by any patient group.

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**Figure 50 Analysis of Health and Safety Executive**

**STAMP analysis: Government-level**
### Safety-related responsibilities:
- Allocate overall healthcare system resources and lead the direction of the NHS
- Responsibility for stewardship of the healthcare regulatory system
- 2005 objective to enhance the quality and safety of services for patients

### Context:
- Tendency for system to reflect the political ambitions of the government of the time
- Frequent reorganisation of NHS structure
- Distinction between DH and NHS is blurred and NHS often not treated as separate from government
- Increasing pressures on resources
- NHS run at an operational level by SHAs, PCTs and provider trusts. DH does not manage individual hospitals, with a push for decentralisation and local management
- Objectives for both higher quality services and value for money
- The report ‘An Organisation with a Memory’, Sir Liam Donaldson published in 2000 had drawn attention to need for clinical governance and system safety principles. But there had been a challenge in ensuring the acceptance and implementation of these principles by front-line professionals
- System focused on finance over quality of care
- The regulatory model was developmental
- Constant reorganisation of NHS had undesirable consequences

### Unsafe decisions and control actions:
- Inadequate enforcement of constraints, design of regulatory system does not enforce constraints:
  - Inadequate coordination between regulatory agencies
  - Inadequate feedback with lack of inclusion of patient and family voices in regulatory system
  - Inadequate feedback with flaws in quality assessment and interpretation in regulatory system
  - Inadequate organisational change process for reassignment of roles in reorganisation of SHA and PCT. PCT not capable of monitoring quality as required by DH
- Unidentified hazards: DH required NHS to reduce costs without impacting on services. DH did not have means to identify the potential impact on patient safety
- Unidentified hazards: Reorganisations of NHS took place without comprehensive impact or risk assessment
- Inadequate allocation of resources: Deficits caused redundancies and ward closures throughout country, potential impact on patient safety unaccounted for
- Inadequate enforcement of constraints, unsafe control actions given: Government policy gave the impression that priorities such as hitting targets for waiting lists and achieving financial balance, were more important than patient safety
- Inadequate feedback: System relating to complaints sent to DH was inadequate. Complaints were not processed by DH

### Mental model and feedback flaws:
- Trust performance indicators did not show a problem at the trust
- Assumed that providers would maintain standards while reducing costs
- DH received 119 letters of complaint about the trust in period reviewed, but conducted no analysis of them. DH passed the letters on to the trust
- Patient safety not always at forefront of DH thinking and in turn NHS manager thinking. Operated with incomplete models of work as imagined, rather than work as done

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Figure 51 Analysis of Department of Health
Appendix 9 Case Study 2 initial control structure

Figure 52 Initial Case Study 2 control structure used in discussion with healthcare stakeholders
Appendix 10: Case Study 2 workshop presentation slides
Along with the slides shown in Appendix 6, the following slides were used in Case Study 2.

CAST (Causal Analysis based on STAMP)

1. Identify system hazard violated and the system safety design constraints

2. Construct the safety control structure as it was designed to work
   - Component responsibilities (requirements)
   - Control actions and feedback loops

3. For each component, determine if it fulfilled its responsibilities or provided inadequate control.
   - Context
   - Process Model Flaws

CAST (2)

4. Examine coordination and communication

5. Consider dynamics and migration to higher risk

6. Determine the changes that could eliminate the inadequate control (lack of enforcement of system safety constraints) in the future

7. Generate recommendations
Context – Cardiac Surgery

- The patient had been admitted to the cardiac care unit (CCU) where he was being supported with a left ventricular assist device to bridge to transplant. When a heart became available, the patient was taken to the operating room, and an uncomplicated cardiac transplantation was completed. Shortly after surgery, the patient showed worsening left ventricular function. The patient was placed on extracorporeal membrane oxygenation and treated for presumed transplant rejection. Careful analysis of the patient's chart revealed that immunosuppression had been ordered but never given preoperatively.

(Leveson, 2016)

1. Identify system hazard violated and the system safety design constraints

<table>
<thead>
<tr>
<th>Hazard</th>
<th>Safety Constraint</th>
<th>Safety Constraint Violated</th>
</tr>
</thead>
<tbody>
<tr>
<td>?</td>
<td>?</td>
<td>?</td>
</tr>
</tbody>
</table>

Hazard: Conditions or events that can lead to an accident

(Leveson, 2016)
1. Identify system hazard violated and the system safety design constraints

<table>
<thead>
<tr>
<th>Hazard</th>
<th>Safety Constraint</th>
<th>Safety Constraint Violated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient unprepared for operation</td>
<td>Surgical checklist (Timeout)</td>
<td>Preoperative medication was not administered</td>
</tr>
</tbody>
</table>

Hazard: Conditions or events that can lead to an accident

(Leveson, 2016)

2. Safety control structure

(Leveson, 2016)
3. For each component, determine if it fulfilled its responsibilities or provided inadequate control.

<table>
<thead>
<tr>
<th>Loop</th>
<th>Safety responsibilities</th>
<th>Inadequate control action</th>
<th>Context in which decisions made</th>
<th>Process or mental model flaws</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (CCU RN)</td>
<td>Administer preoperative medications</td>
<td>Did not administer preoperative immunosuppression</td>
<td>New leadership in cardiac surgery, pushing cardiac transplant further</td>
<td>Not aware that they needed to give the immunosuppression</td>
</tr>
<tr>
<td></td>
<td>Report concerns about patient to the surgical team</td>
<td>Did not tell surgical team</td>
<td>The order in the EHR does not specify who is responsible for carrying out the order</td>
<td>Not aware that they needed to give the immunosuppression</td>
</tr>
</tbody>
</table>

(Leveson, 2016)
4. Examine coordination and communication

- CCU RN assumed preoperative medication was administered
  - No feedback was provided
  - Feedback was inadequate (incorrect, ambiguous or missing)

(Leveson, 2016)

2. Safety control structure

(Leveson, 2016)
5. Consider dynamics and migration to higher risk

Loop 6
- OR team order all preoperative medications and testing the night before

Loop 5
- EHR has a poor layout in terms of giving clear orders from the physician to the nursing staff and providing feedback regarding the carrying out those orders

(Leveson, 2016)

6. Determine the changes that could eliminate the inadequate control in the future

- Clear feedback on who is in charge of which task (medication administration)
- Formal structure for handoff communication between CCU nurse and surgical team
- Time-out should include a question specific to immunosuppression (only antibiotic check in the existing Time-out)

(Leveson, 2016)
7. Generate recommendations

- **Tailor the checklist** to make it more specific to cardiac surgery rather than using one that is designed to be useful in every operation
- **Redesign of EHR interface** to provide clear feedback regarding the status of the medication ordered and carried out and who is responsible for what task
- **Better change management procedure** – Risk assessment in place before any change

(Leveson, 2016)

### Insulin Overdose Case

1. On 15th of November Patient CS, a 70 year old female who resides in care home with mild dementia, was admitted to an acute medical ward with an intracranial bleed due to a fall. She presented with altered neurology and impaired cognitive function. The intracranial bleed was treated conservatively with a 5 day course of IV steroids.

2. On the 19th of November the patient was identified as having raised blood sugars and was reviewed by a Diabetes Specialist Nurse (DSN) who recommended starting Insulin Glargine (a long acting insulin) 10 units daily. This was verbally handed over to the On call and the ward nurse. The DSN documented her recommendations on the Diabetes team pink diabetics form and this was inserted into the main body of the notes. The notes entry stated

3. "Commence Glargine U100 10 units OD".

4. The Dr prescribed 100 units Glargine once a day. This dose was administered to the patient on the 19th and 20th of November. Patient CS was transferred to a rehabilitation ward ready for discharge. The TTO (To Take Out) was written as "Glargine 100 units OD".

5. On the 21st of November the patient was transferred to the Evington Centre (general rehab ward) and 100 units of glargine was administered on arrival. 100 units was administered on the 22nd and 23rd of November. The patients' blood sugars were noted to be low and the patient was readmitted to Emergency Department on the 24th of November with hypoglycaemia.

6. The patient was treated with IV Fluids until the 25th of January when the blood sugars stabilised.
Part One

1. Identify the system(s) and hazard(s) involved in the loss.

2. Identify the system safety constraints and system requirements associated with that hazard.

3. Document the safety control structure in place to control the hazard and enforce the safety constraints.

4. Begin to identify the roles and responsibilities of each component in the structure (controls and feedback)
Appendix 11: Suicide prevention control structure used in discussion

Figure 53 Initial suicide prevention control structure