A study of how to effectively leverage incident investigations to better inform system safety

Cora McCaughan

Thesis submitted for the Degree of Doctor of Philosophy (Ph.D.),

School of Psychology,

Trinity College,

University of Dublin,

2020
DECLARATION

I declare that this thesis has not been submitted as an exercise for a degree at this or any other university and it is entirely my own work.

I agree to deposit this thesis in the University’s open access institutional repository or allow the Library to do so on my behalf, subject to Irish Copyright Legislation and Trinity College Library conditions of use and acknowledgement.

Signature:

June, 2019
Acknowledgement

I sincerely thank my supervisors - Professor Nick McDonald and Professor Sam Cromie - for their invaluable guidance, enthusiasm and patience. Nick helped me to stay focussed on the importance of this thesis for learning from incidents in the most global sense, while Sam helped me to discern what was most important to achieve, and how to do this meticulously.

I also thank the following who supported me in doing this work:

- My former National Incident Management and Learning Team (NIMLT) colleagues: Annette Macken, Margaret McGarry, Dr Samantha Hughes, Marie Boles, and Deirdre Coyne - who helped with the reliability testing work. I also thank them for the intensive and enlightening discourse that helped to develop the ideas that prompted this research. Other NIMLT colleagues that also helped in many ways were: JP Keogh, Vanessa Dunne, Mary King, Fiona Culkin, Aisling Boland, and Geraldine Donaghhy.
- My managers who provided encouragement and practical support: Mary Culliton, Dr Joe Devlin, John Kenny, and Patrick Lynch.
- The Divisional Leads for Quality and Patient Safety in the HSE who engaged in this work: Deirdre O’Keeffe, Margaret Brennan, Annemarie Oglesby, Angela Alder, Gerry Clerkin, and Dr. JP Nolan.
- My amazingly professional work colleagues Debbie Kavanagh, and Gerard Gibbons – who patiently and expertly kept the show on the road when I needed to take leave to do this work.

Sincere thanks go also to my Dad, Tom O’Reilly, and my inspiring sister, Jane McGuirk, who believed in me and rallied hard when I had a mountain to climb. I thank my great friends Debbie Keyes, Denise Keoghan, Andrea Mullery and Paula Mullery, for always being there for me. Doing this research took up a lot of my family time over the last seven years or so, and I am deeply grateful to my wonderful husband Rory, and my amazing boys – Conan and Callum - for their perseverance and support, and especially for seeming interested when I really needed it!
Summary

This thesis describes a study of how to effectively leverage incident investigations to better inform system safety.

Chapter 1 describes the current state of the art. It explores theories of accident causation and their respective strengths and weaknesses. It considers the role of investigations in managing system risk, and the challenges of learning from incidents in healthcare. It highlights gaps in the research including gaps related to (i) evaluating the quality of individual investigation reports; (ii) identifying factors that affect investigation quality; and (iii) identifying patterns of causal factors from groups of individual investigation reports that can better inform system wide safety improvement.

Chapter 2 presents the history of the Health Service Executive (HSE) which is the organisational context within which this research was conducted. It shows that the HSE has been continuously restructuring and that this poses challenges for developing, maintaining and evaluating consistent high-quality investigation processes. Examples are presented that show that learning from incidents is (i) not straightforward or automatic, (ii) requires a level of professionalism and consistency, and (iii) requires a paradigm shift from asking “why did this happen again?” to “why did this happen in the first place?” Interventions to improve investigation professionalism and consistency are described. To a large extent, this thesis focuses on evaluating whether these interventions did or can result in better quality investigations and consequently more effective organisation wide learning from incidents.

Chapter 3 describes study 1, the first of four studies reflected in this thesis. This study involves the development of a tool to reliably evaluate the quality of incident investigation reports, including the quality of the analytic trace for investigation findings. It outlines an iterative action research approach to develop a rigorous and reliable Investigation Quality Evaluation Tool (IQET).

Chapter 4 describes study 2 which applies the IQET to determine the extent to which HSE investigations meet stated quality standards. It assigns Investigation Quality Scores (IQSs) and considers what is done well, and what needs to improve. It demonstrates that the quality of HSE
investigations compares favourably with investigations conducted in NHS England showing that interventions to improve investigation quality yield dividends. Nevertheless, areas for improvement are identified. By application to the HSE the chapter demonstrates that the IQET can be applied to evaluate the quality of investigations in healthcare.

Chapter 5, which chronicles study 3, shows that data about attendance at training, and data from the evaluation of investigation quality can be used to empirically test hypotheses about the determinants of investigation quality. The results challenge existing notions about what is important in investigations. It shows that focusing more on causal factors improves investigation quality. The findings provide strong evidence for informing investigation PPPGs\(^1\) and training. All of this is important for developing the theoretical basis of investigation science.

The analysis in study 4 to identify patterns in causal factors from the group of investigation reports outlined in chapter 6 results in a clearer picture of the complex pattern of factors that cause harm across the HSE than we have had before. It highlights the importance of analysing causal data from across the system and across time. It shows a way though the problem of the mismatch of single investigations that can only focus on ‘a linear pathway to failure’ to a predictive model of complex system functioning that is sufficiently robust to support credible preventive interventions.

Chapter 7 describes the practical requirements of training and resourcing individuals to use the IQET, and to conduct on-going analysis to identify patterns in causal factors from groups of investigation reports. It demonstrates that the cost of on-going application is minuscule compared with the costs of incidents. It highlights the benefit of improving staff and public confidence in investigation processes. Finally, it considers the applications for the HSE, for policy, and for other jurisdictions and domains.

Chapter 8 examines how far the findings of this research go towards achieving its aim, how they fit with the existing literature, their applied and theoretical implications, and directions for future research. It describes a model for continuously improving how to enhance learning from incident investigations for more effective organisation wide safety improvement.

\(^1\) PPPGs: Policies, Procedures, Protocols, and Guidelines
Abstract

Purpose: The purpose of this thesis was to explore how to effectively leverage incident investigations to better inform system safety.

Method: Four studies were conducted to achieve the purpose of this research. **Study 1** used an iterative action research approach to develop and test an Investigation Quality Evaluation Tool (IQET) to rigorously and reliably evaluate the quality of serious incident investigation reports, including evaluating what Dekker (2006) referred to as the analytic trace for investigation findings. **Study 2** applied the IQET to evaluate the quality of serious incident investigation reports assigning Investigation Quality Scores (IQS) and identifying what was done well and what needed to improve. **Study 3** used data from (i) the evaluation of investigation quality, and (ii) attendance at investigation training - to empirically test hypothesis about the determinants of investigation quality. **Study 4** conducted a thematic analysis of further details of contributory factors identified in investigation reports to identify patterns in causal factors.

Results: **Study 1** showed reasonable IQET inter-rater reliability whereby this was excellent in 55.5% (n=5) of cases (kappa value ranging from .756 – .859), and fair to good in the remaining 44.44% of cases (n=4) (kappa value ranging from .418 - .587). **Study 2** found that IQSs ranged from 13.79% - 78.13% with a mean of 45.17%. Elements satisfactorily done most frequently included placing events in chronological order in the chronology, and evidence of review of records. Elements not satisfactorily done related to generalizing from investigations, and not using the hierarchy of controls to develop recommendations. **Study 3** revealed that there was a positive statistically significant correlation between IQS and (i) attendance at NIMLT\(^2\) training; (ii) having investigation expertise on the investigation team; (iii) having a team of not less than 2 and not more than 3 investigators; (iv) conducting individual interviews; and (v) adherence to the definition of Key Causal Factor (KCF) in investigation guidelines. **Study 4** identified nine main

\(^2\) NIMLT: National Incident Management and Learning Team
themes in causal factors including (i) Care pathways, PPGs and other tools that support care delivery (ii) education, training and supervision; and (iii) Governance and risk management.

**Conclusions:** This thesis shows that it is possible to develop a reliable tool to comprehensively evaluate the quality of investigation reports and that data from this can be used to empirically test hypotheses about the determinants of investigation quality. It reflects analysis at a deeper level of causal factors to identify patterns in causal factors in a larger batch of investigations from a wider span of the health system than done in previous research. It reveals that the outcome of this analysis identifies emergent system features which (i) add to information about existing risks, (ii) identify newly emerging risks, and (iii) are important for informing safety improvement across the organisation. It achieves a resolution of the contradiction between the complexity of the system and the need to identify sufficient cause to implement prevention. Above all, the findings of this thesis supports a change in the concept of how to generalize from investigations for system wide learning, and presents a model of how to continuously improve how to do this.
## Table of contents

<table>
<thead>
<tr>
<th>Chapter 1 – Introduction</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>The state of the art related to learning from incidents in healthcare</td>
<td>17</td>
</tr>
<tr>
<td>1.1. The level and cost of harm in healthcare</td>
<td>18</td>
</tr>
<tr>
<td>1.2. Theories of accident causation, system safety, and system learning</td>
<td>20</td>
</tr>
<tr>
<td>1.3. The role of incident investigation in managing system safety</td>
<td>27</td>
</tr>
<tr>
<td>1.4. The challenge of learning from incidents in healthcare</td>
<td>28</td>
</tr>
<tr>
<td>1.4.1. Studies that did not consider all available information necessary to identify causes</td>
<td>29</td>
</tr>
<tr>
<td>1.4.2. Studies that focused on “surmised” causes rather than actual causes</td>
<td>31</td>
</tr>
<tr>
<td>1.4.3. Studies that focused on superficial causes as opposed to systemic causes</td>
<td>33</td>
</tr>
<tr>
<td>1.4.4. Studies that focused on parts of the health system and subsets of incident types</td>
<td>54</td>
</tr>
<tr>
<td>1.4.5. Studies that match types of incidents to a limited number of incident causes</td>
<td>36</td>
</tr>
<tr>
<td>1.4.6. Absence of Human Factors and system safety expertise in investigations</td>
<td>37</td>
</tr>
<tr>
<td>1.4.7. Limited research about the quality of investigations and how to evaluate this</td>
<td>38</td>
</tr>
<tr>
<td>1.4.8. Limited research about the factors that affect investigation quality</td>
<td>39</td>
</tr>
<tr>
<td>1.4.9. Limited analysis of groups of investigation reports to identify patterns in causal factors</td>
<td>40</td>
</tr>
<tr>
<td>1.5. Discussion</td>
<td>43</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chapter 2 – The organisational context</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Learning from incidents in the HSE</td>
<td>47</td>
</tr>
<tr>
<td>2.1. Introduction</td>
<td>47</td>
</tr>
<tr>
<td>2.2. History and scope of the HSE</td>
<td>48</td>
</tr>
<tr>
<td>2.2.1. On-going restructuring of the HSE</td>
<td>49</td>
</tr>
<tr>
<td>2.3. History of investigation structures in the HSE</td>
<td>55</td>
</tr>
<tr>
<td>2.3.1. Investigation structure prior to the establishment of the HSE</td>
<td>55</td>
</tr>
<tr>
<td>2.3.2. Investigation structure following establishment of the</td>
<td></td>
</tr>
</tbody>
</table>
2.3.3. Cases that highlighted the need to improve investigation quality

2.3.4. Cases that highlighted some progress in investigation quality

2.4. **Initiatives taken to improve investigation professionalism and quality**

2.4.1. Updating investigation guidelines

   Move from the epidemiologic model to the systemic model
   Evolution of the term “Key Causal Factor”
   Evolution of a tool to audit compliance with guidelines

2.4.2. Delivery of training to support guideline implementation

   The evidence base for investigation training
   Evidence based investigation training design and delivery
   Findings of the analysis of participants’ feedback

2.5. **Discussion**

<table>
<thead>
<tr>
<th>Chapter 3 – Study 1</th>
<th>Developing and reliable tool to evaluate investigation report quality</th>
</tr>
</thead>
</table>

3.1. **Introduction: Review of the literature to identify quality markers and evaluation tools**

   3.1.1. VA NCPS\(^3\) Investigation Quality Evaluation Tool
   3.1.2. NPSA\(^4\) RCA\(^5\) Investigation Quality Evaluation Tool
   3.1.3. The rationale for developing and exhaustive IQET\(^6\)

3.2. **Method: Iterative action learning approach for developing IQET**

   **STEP 1: Checking the evidence base for developing IQET 1**
   **STEP 2: Qualitative Inter-rater reliability testing IQET 1**

   *Reviewers*
   *Methods*
   *Results*

   **STEP 3: Testing and enhancing IQET 1 through evaluation of 2013 reports to develop IQET 2**

---

\(^3\) VA NCPS: Veteran Affairs National Centre for Patient Safety (i.e. in the USA)
\(^4\) NPSA: National Patient Safety Agency (i.e. in the UK)
\(^5\) RCA: Root Cause Analysis
\(^6\) IQET: Investigation Quality Evaluation Tool
3.3. Discussion 123

Chapter 4 – Study 2
Applying the IQET to evaluate investigation report quality 129

4.1. Introduction 129

4.2. Review of criteria for high quality investigations 130

4.3. Method 132

4.3.1. Sample 132

4.3.2. Application of IQET to evaluate 2013 & 2014 reports 133

4.3.3. Method for Investigation Quality Scoring (IQS) 134

4.3.4. Method for determining whether KCFs\(^7\) were adequately supported by the evidence 134

4.3.5. Analysis of the quality of investigation reports 135

4.4. Results 135

4.4.1. Summary of quantitative results 135

4.4.2. Result from IQS process 138

4.4.3. Detailed results 142

4.5. Discussion 167

Chapter 5 – Study 3
Analysis of factors predicting the quality of investigations 177

5.1. Introduction 177

5.1.1. Review of the literature on factors affecting investigation quality 178

---

\(^7\) KCFs: Key Causal Factors
5.1.2. Review of assumptions about what makes a better investigation team and process

5.2. Method

5.3. Results

5.3.1. Attendance and NIMLT\(^8\) Investigator Training

5.3.2. Timeliness of investigations

5.3.3. Size and makeup of investigation teams

   Number of investigators

   Use of investigation experts

5.3.4. The scope in time of the chronology

5.3.5. The number of interviews

5.3.6. Individual interviews

5.3.7. Adherence to the definition of Key Causal Factors

5.3.8. Investigation method used

5.4. Discussion

Chapter 6 – Study 4
Analysis to identify patterns in causal factors

6.1. Introduction

6.2. Method

6.2.1. Determining patterns of (i) Broad Contributory Factor types, and (ii) Contributory Factors

6.2.2. Timeliness of investigations

6.3. Results

6.3.1. Patterns of Broad Contributory Factor types

6.3.2. Patterns of Contributory Factors

6.3.3. Patterns identified from “further details of Contributory Factors”

   Theme 1: Rapid deterioration

   Theme 2: Planning and monitoring

   Theme 3: Communications

   Theme 4: Access

   Theme 5: Equipment, facilities, and environment

   Theme 6: Care pathways, PPPGs, and other tools to

\(^8\) NIMLT: National Incident Management and Learning Team
6.4. Discussion

<table>
<thead>
<tr>
<th>Chapter 7 – Application</th>
<th>241</th>
</tr>
</thead>
<tbody>
<tr>
<td>To effectively leverage investigations to better inform system safety</td>
<td></td>
</tr>
</tbody>
</table>

7.1. Introduction

7.2. What can the approach taken in this research offer healthcare systems?

7.3. Implementation requirements

7.3.1. Training of individuals to use the IQET

7.3.2. Resourcing people to use the IQET

7.3.3. The need to have a single person identifying patterns in causal factors

7.3.4. Effective communication & training to promote evaluation of investigation quality & analysis to identify causal factors

7.4. Cost benefit of the approach taken for healthcare systems

7.4.1. Smaller investigation teams

7.4.2. Good quality investigations don’t necessarily require more resources

7.4.3. The benefits of evaluating quality

7.4.4. The benefits of analysing patterns in causal factors

7.4.5. Cost benefit analysis

7.5. What happened to the approach in the interim

7.5.1. Handover of learning from identification of patterns in causal factors

7.5.2. Investigation quality evaluation & analysis of causal patterns continued

7.5.3. Audit priorities are informed by patterns in causal factors

7.5.4. Additional training for investigators

7.6. Application for HSE policy and other jurisdictions

7.7. Discussion
8.1. Introduction 262

8.2. How has this thesis advanced the state of the art? 263

8.2.1. Learning for the HSE, other health systems, and other domains 263

Need for investigation stability, consistency, professionalism and focus on causes 263

Investigations from the whole system can be evaluate to improve investigation quality 263

Data about investigation quality can be used to identify determinants of investigation quality 264

Identifying patterns in causal factors from groups of investigations can inform better system wide safety improvement 265

8.2.2. Implications for theory 266

Changing the concept of how we generalize from investigation for system wide learning 266

The fallacy of preventing similar incidents recurring based on learning from one incident 270

Continuously improving how we generalize from investigations for system wide learning 271

8.2.3. Implications for policy and implementation 279

Investigator training 279

Investigation team size and make up 280

Investigation quality evaluation feedback to investigators 280

Identification of factors that affect investigation quality 281

Analysis of groups of investigations to identify patterns in causal factors 281

8.3. Reflection about the role of the author in the thesis 282

8.4. Strengths and limitations of the thesis 284

8.5. Next steps (Unfinished business) 287

References 290

Appendices 290

Appendix 1: Details of course content for 3 day systems analysis investigator training

Appendix 2: Samples of the respondents’ comments as outlined on completed Evaluation Forms (Modules 1, 2 and 3)

Appendix 3: Investigation Quality Evaluation Tool 1 (IQET 1)
Appendix 4: Investigation Quality Evaluation Tool 2 (IQET 2)
Appendix 5: Investigation Quality Evaluation Tool 3 (IQET 3)
Appendix 6: Results of quantitative reliability testing of the IQET 4
Appendix 7: Investigation Quality Evaluation Tool 4 (IQET 4)
Appendix 8: Comparing the IET with the other five Evaluation Tools showing where the other Evaluation Tools do and do not have questions that are equivalent to the IET
Appendix 9: Details of investigation reports that fell within this study
Appendix 10: Details of reasons for delays in investigation timelines
Appendix 11: Further details of investigation reports that did not include a summary of investigation methodology used
Appendix 12: Details from the comments section of the IQET related to the summary of the methodology section of 2015 reports
Appendix 13: Details of quality of data collected
Appendix 14: Details from comments section of the IQET related to whether chronologies were sufficiently detailed
Appendix 15: Expanded details from comments on IQET related to whether contributory factors were adequately supported by evidence within the investigation report
Appendix 16: Details from the comments section of IQET related to whether recommendations were linked clearly to Contributory Factors
Appendix 17: Details from the comments section of the IQET related to whether investigations were written impartially
Appendix 18: Details of investigation guidelines followed correlated to date investigation commenced
Appendix 19: Details of the preliminary reviews and other kinds of reviews by (i) Division; (ii) Brief description of incident; (iii) Number and type of investigators; (iv) Whether any of the investigators had attended any HSE NIMLT Systems Analysis Investigation Training; (v) Whether KCFs were identified or not; (vi) Whether there was satisfactory evidence to support identified KCFs; Timeliness of the investigations; and (vii) Investigation Quality Scores
Appendix 20a): Themes identified from thematic analysis of further details of contributory factors showing data items under each theme
Appendix 20b): Data items included as further details of contributory factors, but discarded from the thematic analysis as they did not appear to be further details of contributory factors

List of tables

Table 1.1: Showing the three models of accident causation referred to by Dekker (2006) and their respective weaknesses and strengths
Table 2.1: Showing changes over time in the HSE vision, mission, values, objectives, and structures, including incident management and investigation structures
Table 3.1: Time taken to review and input data from review of investigation quality onto Excel spread sheet.
Table 3.2: Tool for tallying individual investigation report quality IQSs.
Table 3.3: Criteria used to underpin decisions about which sections of the evaluation tool were quality scored for investigation quality scoring (IQS) purposes and which were not.
<table>
<thead>
<tr>
<th>Table 3.4:</th>
<th>Showing details of how the criteria referred to above were applied to each question within IQET to decide which questions would be scored for IQS purposes.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Table 3.5:</td>
<td>Reliability of IQSs between reviewers for each case</td>
</tr>
<tr>
<td>Table 4.1:</td>
<td>Results of analysis of investigation reports related to yes/no answers on the IQET.</td>
</tr>
<tr>
<td>Table 4.2:</td>
<td>Table comparing the timeframes for completion investigation reports in 2013 and 2014.</td>
</tr>
<tr>
<td>Table 4.3:</td>
<td>Cross tabulation showing whether reports identify Key Causal Factors or state that no Key Causal Factors are identifiable cross tabulated with whether reports identified Key Causal Factors or not for 2014 reports.</td>
</tr>
<tr>
<td>Table 4.4:</td>
<td>Cross tabulation for whether key causal factors were identified or not with whether this was adequately supported by evidence in the report (for 2013 report, 2014 reports, and both 2013 and 2014 reports).</td>
</tr>
<tr>
<td>Table 4.5:</td>
<td>Showing cross tabulation for whether key causal factors were identified by the original investigators vs whether they were deducible from the evidence within reports (for 2013 reports, 2014 reports, and both 2013 and 2014 reports).</td>
</tr>
<tr>
<td>Table 4.6:</td>
<td>Showing cross tabulation of 2014 reports that identified KCFs with reports that identified CFs.</td>
</tr>
<tr>
<td>Table 4.7:</td>
<td>Showing the results of the assessment as to whether CFs and/or recommendations appeared to be applicable outside of the site where the incident occurred, compared with whether reports stated this.</td>
</tr>
<tr>
<td>Table 4.8:</td>
<td>Showing the results of evaluation of investigation reports related to the apology given/referred to.</td>
</tr>
<tr>
<td>Table 4.9:</td>
<td>Showing whether investigation reports reflected the investigation guidelines used correlated with the year the investigation commenced.</td>
</tr>
<tr>
<td>Table 4.10:</td>
<td>Showing what investigation guidelines were followed as reflected in 2013 &amp; 2014 reports respectively.</td>
</tr>
<tr>
<td>Table 4.11:</td>
<td>Comparison of the findings of the evaluation of the quality of serious incident investigation reports between the NHS and the HSE.</td>
</tr>
<tr>
<td>Table 5.1:</td>
<td>Showing cross tabulation of IQS with information about whether investigators had attended any HSE Systems Analysis Investigator Training.</td>
</tr>
<tr>
<td>Table 5.2:</td>
<td>Showing whether investigations were conducted by investigation experts, subject experts or a combination of these compared with whether KCFs (or a finding that no KCFs were identifiable) were adequately supported by evidence within 2013 and 2014 reports.</td>
</tr>
<tr>
<td>Table 5.3:</td>
<td>Showing the proportion of reports that were systems analysis investigations, preliminary reviews or other per year and in total.</td>
</tr>
<tr>
<td>Table 5.4:</td>
<td>Comparison between preliminary review, “Other” types of investigations, and Systems Analyses in relation to use of definition of KCF in line with Guidelines; whether reports reflected satisfactory evidence to support KFCs (Or a finding that none were identifiable); and average quality scores.</td>
</tr>
<tr>
<td>Table 5.5:</td>
<td>Comparison between the range of scores and mean scores for (i) all 45 x investigations completed in 2014, (ii) 35 x systems analysis investigations, (iii) 6 x preliminary reviews, and (iv) 4 investigations that used some other method.</td>
</tr>
</tbody>
</table>
Table 6.1: Framework of Contributory Factors from the Guidelines for Systems Analysis Investigation of Incidents and Complaints (HSE, 2012) which in turn is from the London Protocol (Taylor-Adams et al., 2004)

Table 6.2: Showing the frequency of contributory factors (2013 and 2014 reports combined)

Table 6.3: Showing key themes identified from the thematic analysis of the further information about contributory factors data.

Table 6.4: Cases of failure to detect and respond to rapid deterioration per service, and outcome.

Table 7.1: Showing what a cost benefit analysis of the on-going (i) application of the IQET to evaluate investigation quality, and (ii) analysis of groups of investigation reports to identify patterns in causal factors - to enhance incident investigations and how we learn from them – would look like.

List of figures

Figure 3.1: Design of this study to develop the Investigation Quality Evaluation Tool.

Figure 3.2: Tool for calculating final IQS for individual investigation reports.

Figure 4.1: Showing the application of the IQET as per steps 3 and 6.

Figure 4.2: Graph showing the proportion of investigations that demonstrated satisfactory evidence in relation to each of the 41 elements of quality scored (IQS)

Figure 5.1: Showing whether investigators had attended 1, 2, or 3 days of HSE NIMLT 3 day Systems Analysis Investigator Training

Figure 5.2: Scatter plot diagram of the cross tabulation of time to complete investigations with IQS

Figure 5.3: Box plot showing average and range of IQSs for different sizes of investigation teams.

Figure 5.4. The relationship showing whether investigators had attended 1, 2, or 3 days of HSE NIMLT 3 day Systems Analysis Investigator Training

Figure 5.5. The relationship showing the number of interviewees reflected in 2014 investigation reports

Figure 5.6: Box plot showing the average and range of scores for systems analysis investigations, preliminary reviews, and “Other” investigations completed in 2014.

Figure 6.1: Showing the frequency of Broad Contributory Factors Types (2013 & 2014 reports)

Figure 6.2: Showing the frequency of Broad Contributory Factors Types (Results from 2013 & 2014 combined)

Figure 6.3: Showing the frequency of sub-contributory factors (2013 and 2014 shown separately)

Figure 6.4: Thematic map showing the nine main themes and their sub-themes

Figure 6.5: Thematic map showing the links between the nine main themes

Figure 8.1: Model of how to continuously improve how to generalise from investigations for system wide learning.
Chapter 1 - Introduction

The state of the art related to learning from incidents in healthcare

Overview of chapter 1

1.1. The level and cost of harm in healthcare
1.2. Theories of accident causation, systems safety and system learning
1.3. The role of incident investigation in managing safety in the system
1.4. The challenge of learning from incidents in healthcare

- Studies that do not consider all available information necessary to identify causes
- Studies that focus on ‘surmised’ causes as opposed to actual causes
- Studies that focus on superficial causes as opposed to systemic causes
- Studies that focus on part of the health system and subsets of incident types
- Studies that match types of incidents to a limited number of causes
- Absence of Human Factors and system safety expertise in investigations
- Limited research about the quality of investigations and how to evaluate this
- Limited research about the factors that affect investigation quality
- Limited analysis of groups of investigation reports to identify patterns in causal factors

1.5. Discussion

The overall aim of this research is to explore how to effectively leverage incident investigations to better inform system safety.

This chapter scrutinizes the literature related to this, focusing first on the level and cost of incidents. It shows that not attempting to improve safety based on learning from incidents is not justifiable and not an option. It goes on to appraise theories of accident causation, system safety and organisational learning and the apparent irreconcilable differences between some of these theories. Next, it considers the role of incident investigation in managing risk in the system, and the challenge of learning from incidents. This is followed by a critique of the tendency for studies (i) not to consider all information necessary to identify incident causes; (ii) to focus on surmised cause as opposed to actual causes; (iii) to focus of superficial causes as opposed to deeper systemic causes, (iv) to focus on only part of the health system and
subsets of incident types; (v) to focus on matching types of incidents to a limited number of potential incident causes; and (vi) to reflect an absence of Human Factors and System Safety expertise in investigations.

Next, this chapter identifies gaps in literature about (i) investigation quality and how this can be evaluated; (ii) the factors that affect investigation quality; and (iii) how to identify patterns in causal factors from groups of investigation reports for organisational learning.

Finally, this chapter discusses the evidence available that we can build upon, and the empirical and conceptual gaps in the literature that need to be bridged – in order to understand better how to effectively leverage incident investigations to inform better system safety.

1.1. The level and cost of harm in healthcare

A World Health Organisation (WHO) report in 2008 identified that tens of millions of patients worldwide suffer disabling injuries or death due to unsafe medical care every year (World Health Organisation, 2008). The following year, a subsequent WHO report stated that nearly one in ten patients is harmed while receiving health care in well-funded and technologically advanced hospital settings and that much less is known about the burden of unsafe care in non-hospital settings, where the majority of health care is delivered globally (World Health Organisation, 2009). A more recent WHO report (World Health Organisation, 2018) addressed the non-hospital setting stating that half the global burden of patient harm originates in primary and ambulatory care, with as many as four out of 10 patients facing safety lapses. This report goes on to state that this may account for over 6% of hospital bed days and more than 7 million admissions in OECD countries. It estimated that up to 80% of harm in primary care settings can be avoided.

de Vries et al., (2008) conducted a systematic review of the literature on in-hospital adverse events identified by retrospective chart reviews and found eight studies including a total of 74 485 patient records. They found that the median overall incidence of in-hospital adverse events was 9.2%, with a median percentage of preventability of 43.5%. More
than half (56.3%) of the patients that experienced an adverse event experienced no or minor disability, whereas 7.4% of events resulted in death.

Retrospective chart reviews conducted to identify adverse events in adult acute non-psychiatric services - in Australia, Brazil, Canada, France, Ireland, the Netherlands, New Zealand, Portugal, Spain, Sweden, Thailand, the UK, and the USA - found that approximately 3%–17% of hospital admissions were associated with an adverse event; that approximately 50% - 70% of the adverse events were preventable; and that approximately 1.5% -21% resulted in death (Aranaz-Andrés et al., 2008; Baker et al., 2004; Brennan et al., 1991; Davis et al., 2002; Matlow et al., 2012; Mendes et al., 2009; Schiøler et al., 2001; Soop et al., 2009; Sousa et al., 2014; Thomas et al., 2000; Vincent et al., 2001; Williams et al., 2008; Wilson et al., 1995; Zegers et al., 2009).

The Irish National Adverse Event Study (INAES) (Rafter et al., 2016) found that the prevalence of adverse events in admissions was 12.2%, with an incidence of 10.3 events per 100 admissions. Over 70% of events were considered preventable. Two-thirds were rated as having a mild-to-moderate impact on the patient, 9.9% causing permanent impairment and 6.7% contributing to death.

So we know from this that preventable incidents occur on a daily basis in healthcare settings around the world and in Ireland. Tragically, this includes adverse events that result in death and serious harm.

The financial impact of incidents is also considerable. Approximately 15% of total hospital activity and expenditure is a direct result of adverse events, and the costs of prevention are dwarfed by the cost of failure (Klazinga (2017)).

The WHO (2002) identified that adverse events exact a high toll in financial loss. This WHO report stated that, in the United Kingdom of Great Britain and Northern Ireland consequent additional hospital stays alone cost about £2000 million a year. Paid litigation claims cost the National Health Service (NHS) around £400 million annually, in addition
to an estimated potential liability of £2400 million for existing and expected claims. The total national cost of preventable adverse medical events in the United States of America, including lost income, disability and medical expenses, was estimated in this WHO report at between US$ 17 000 million and US$ 29 000 million annually. This report concluded that the erosion of trust, confidence and satisfaction among the public and health care providers is an additional cost of adverse events.

The report by the Office of the Inspector General in the US (Levinson, 2010) estimated hospital care associated with adverse and temporary harm events cost Medicare an estimated €324 million in one month alone in 2008 (i.e. October 2008). These estimated costs did not include additional costs required for follow up care.

A paper on the detection of adverse events in a Scottish Hospital (Williams et al., (2008)) estimated that additional costs of adverse events in terms of bed days Scotland-wide could cost £297 million per annum.

The Irish National Adverse Events Study (INAES) (Rafter et al., 2016) found that a mean of 6.1 added bed days was attributed to adverse events, representing an expenditure of €5550 per event. This study estimated the cost to the Irish Exchequer of adverse events in adult inpatients in acute hospital services at over €194 million.

Based on the strong evidence in the literature about the (i) very high rates of avoidable death and serious harm; (ii) excessive financial costs; and (iii) loss in public trust and confidence in health services – failure to enhance how we learn from serious incident investigations for more effective organisation wide safety improvement is not justifiable and not an option.

1.2. Theories of accident causation, system safety and system learning

Clearly adverse events are very costly in terms of loss of human life, injury to health, financial costs, and loss of trust amongst the public in health services. So, it is critical to have a sophisticated understanding of
how such events arise out of a complex system such as health care, and how we can understand and address their causes.

In conceptual work related to theories of accident causation, system safety and organisation learning - Dekker (2006) described the challenge of identifying causes of incidents. He detailed three types of accident models that underpin understanding of how accidents occur, some of which he believed were better for some purposes than others as follows:

(i) **The sequence-of-events (domino) model**: The Root cause analysis (RCA) method of investigation is an exemplar of the sequence-of-events accident model. RCA comes from a technical engineering perspective where linear patterns of causality follow clearly understood scientific/engineering principles. Dekker (2006) stated that the sequence-of-events model saw accidents as a chain of events that led up to a failure. One event caused another, and so on, until the entire series produced an accident. Based on this model, accidents are considered to be prevented by taking one link from the chain, by removing one domino, or by inserting a barrier between any two dominoes.

The London Protocol for the systems analysis investigation of clinical incidents (Taylor-Adams et al., (2004), Page 5) had stated that:

> “The term ‘root cause analysis’ originates from industry, where a group of tools are used to identify root causes from the investigation and analysis of incidents. To us the term root cause analysis, while widespread, is misleading in a number of respects. To begin with it implies that there is a single root cause, or at least a small number. Typically however, the picture that emerges is much more fluid and the notion of a root cause seems a gross oversimplification. Usually there is a chain of events and a wide variety of contributory factors leading up to the eventual incident. The investigation team needs to identify which of these contributory factors have the greatest impact on
the incident and, more importantly still, which factors have the greatest potential for causing future incidents”.

On a related note, Dekker (2006) advised that:

“Mishaps have dense patterns of cause, with contributions from all parts and corners of the system, and typically depend on many subtle interactions. Putting one countermeasure in place somewhere along (what you thought was like) a linear pathway to failure may not be enough. In general, it is extremely unlikely that the precise sequence of events, or confluence of factors, will repeat itself, whether you put a barrier there or not. Complex systems have many parts that interact and are tightly coupled to one another. They can generate unfamiliar, unexpected interactions that are not immediately visible or comprehensible. Just slicing through one sequence of interactions you have now understood by looking at it in hindsight, leaves the door wide open for others to develop.” (Dekker, (2006), Pages 85-86).

So, establishing causal pathways, as in RCA, is difficult where there are several or many causes.

Percarpio et al., (2008) reviewed the effectiveness of RCA on improving patient safety and found that there had been no controlled trials that tested the RCA framework. They identified twenty-three articles that described the RCA process, 38 articles that presented RCA case studies, and 12 articles that analysed weaknesses of the RCA framework. Eleven of the case studies measured RCA effectiveness, three using clinical outcome measures and eight using process measures. All 11 articles reported improvement of safety following RCA. RCA participants reported difficulty in forming causal statements and in developing/implementing corrective actions. Criticisms of RCA included the uncontrolled study design and participant biases.

Percarpio et al., (2008), concluded that, overall, the limited literature on RCA effectiveness provided anecdotal evidence that RCA improved safety. At the same time, it highlighted the numerous
theoretical problems with the analytical framework. They stated that (i) formal studies at the system level and cost-benefit analysis were needed to determine the effectiveness of RCA, (ii) structured publication of case studies would support shared knowledge and would provide benchmarks for improvement, and (iii) enrichment of the RCA literature body would enable reproducibility of improvement work, optimization of analysis, and validation of the framework itself.

(ii) **The epidemiological model:** is in line with Reasons (1995) model of accident causation. Reason (1995) described that the accident sequence began with the negative consequences of organizational processes (i.e. decisions concerned with planning, scheduling, forecasting, designing, specifying, communicating, regulating, maintaining, etc.). These decisions were themselves the products of influences and constraints created by the financial, economic and political context in which the organization functioned. These were what Reason (1995) referred to as **latent failures** which were transmitted along various organizational and departmental pathways to the workplace where they created the local conditions that promoted errors and violations (e.g. high workload, deficient tools and equipment, time pressure, fatigue, low morale, conflicts between organizational and workgroup norms, and the like). These unsafe acts were referred to by Reason (1995) as **active failures**, and were distinguished from latent failures both by the relatively short time it took to show their adverse effects, and by their location. Whereas latent failures occurred within the upper echelons of the system and were created by people who were often remote in both time and space from the hazards, active failures were committed by those at the immediate human-system interface (the 'sharp end').

Dekker (2006) stated that this model saw accidents as related to latent failures that hid everything from management decisions to procedures to equipment design. That is to say – these “pathogens” did not normally become visible, or wreak havoc unless they were
activated by other factors. Based on this model, accidents were considered to be prevented by identifying and knocking out pathogens, or by making sure they did not get activated.

Though Dekker (2006) considered that this model oversimplified accident causation, he acknowledged that it had been helpful in portraying the imperfect organisational structures that let accidents happen. But he believed that it did not specify much about the processes that created the holes in the layers of defences, nor how active and latent failures interacted.

Reason’s model was based on major accident enquiries in rail, North Sea oil, and shipping etc. These had massive resources and time to explore many different causal pathways. This work changed the way we think about system safety. While it is not clear how or why individual incident investigations in healthcare should emulate this approach, the approach represents an important standard for disaster enquiries in domains outside of healthcare. Exploration of the transferability of learning about this to the domain of healthcare is important, justified, and required.

(iii) The systemic model: is in line with Hollnagel’s “new perspective” on safety called safety II (Hollnagel, (2014)). Dekker (2006) stated that this model saw accidents as emerging from interactions between system components and processes, rather than failures within them. As such, accidents came from the normal workings of the system; they were a systematic by-product of people and organisations trying to pursue success with imperfect knowledge and under the pressure of other resource constraints (scarcity, competition, time limits). Based on this model, accidents were considered by Hollnagel (2014) and Dekker (2006) to be prevented by understanding better how people and organisations normally functioned; and how they did or did not adapt effectively to cope with complexity. This model focused on the challenge of explaining why people gradually came to see deviant behaviour or system performance as normal or acceptable – not to judge behaviour as deviant from the outside and with hindsight. Dekker concluded that
an added advantage of the systemic model was that it could deal with non-linear interactions.

The difficulty with achieving a systemic approach to investigations was highlighted by Behr et al., (2015) who examined how framing affects the analysis of critical incidents in the hospital sector and the types of frames that were used by inquiry teams. They emphasised that many commentators recommended that inquiries should focus on systems failures, and that despite this the literature suggested that critical incidents tended to highlight the roles that individual actions and decisions played in adverse events and therefore allocated blame (Kohn et al., 2000). Such inquiries were found to have adverse effects, such as reducing the willingness of staff to report critical incidents (Dunbar et al., 2007).

Behr et al., (2015) considered three serious incidents which occurred in Dutch hospitals between 2000 and 2010 each of which had both internal investigations commissioned by the hospital and external investigations conducted by independent advisory bodies or the Inspectorate. These researchers found three types of frame in the different inquiries which were linked to the expertise of the investigation team members - namely (i) a professional frame, (ii) a managerial frame and (iii) a governance frame. They suggested that each frame highlighted a different aspect of risk that, in practice, it was possible for different investigation frames to coexist as they could encompass each other; for example, the professional frame with its emphasis on professional error could be part of the managerial frame with its focus on the failure of management to identify professional errors which in turn could be encompassed within the governance frame in which the overall governance systems fail to identify professional and managerial failure.

The systemic approach described here by Behr et al., (2015) is somewhat at odds with the systemic approach described by Hollnagel (2014) and Dekker (2006). For example, some of the frames described by Behr et al., (2015) prevent the identification of some system causes. These frames also focus on errors and failures by professionals,
managers, and governance structures which is not in line with the notion conveyed by Hollnagel (2014) and Dekker (2006) that accidents emerge from interactions between system components and processes, rather than failures within them.

Nevertheless, two points made by Behr et al., (2015) are important in the discussion about theories of accident causation, system safety, and organisational learning namely (i) the problem with limiting investigation perspectives or “frames”, and (ii) the impact investigators backgrounds and expertise have on investigation perspectives or “frames”.

Table 1.1 below summarises each of the three accident models described by Dekker (2006) that underpin understanding of how accidents occur showing their respective weaknesses and strengths.
contribution each has to make to (i) the theory of accident causation, (ii) understanding system safety, and (iii) organisational learning from incident investigations in healthcare. We need to find a way to combine the strengths of these three approaches but overcome their weaknesses. It is not obvious how to do this, particularly as they are most often presented as mutually incompatible alternatives, and even as irreconcilably ideologically opposed. However, the weakness of the arguments for incompatibility is that they are based on statements of principle that have not been empirically tested in a pragmatic way. A more profound analysis of the problem of learning from incidents in healthcare is called for, particularly as this relates to difficulties with achieving satisfactory causal analyses in the healthcare domain.

1.3. The role of incident investigation in managing safety in the system

Diverse sources of information can be used to inform the understanding and management of safety and risk in the healthcare system. These include (i) risk assessments; (ii) audits; (iii) near miss and incident reporting systems; and (iv) service user feedback via surveys, comments, or complaints.

So, serious incident investigations are only one source of information used to inform the understanding and management of safety and risk.

There are strengths and weaknesses related to information derived from incident investigations compared to other information used to manage risks. Weaknesses include that (i) the particular set of events that gave rise to an incident are exceedingly unlikely to occur again so great care is needed when deriving transferable lessons from an individual incident, (ii) incidents are considered retrospectively and so are subject to hindsight bias, and (iii) by the time an incident is investigated, some data will no longer be available, or may be subject to recall limitations.

On the other hand, investigations are very important as they (i) are occasions when most or all the safety barriers have failed and they present crucial opportunities to learn how to improve safety, (ii) they
are necessary to provide answers to the person(s) harmed or their family; and (iii) they are a requirement of safety, health and welfare at work legislation, and insurers.

Since serious incidents need to be conducted for the reasons set out in the previous paragraph - and since there is no way of knowing in advance which incidents will give the best information for safety improvement purposes – the seriousness of the incident is the best criterion to use to inform decisions to conduct thorough investigations (McCaughan et al., (2013)) meaning that all serious incidents should be thoroughly investigated. These investigations should provide (i) answers for the person(s) harmed or their family that are as complete and factual as they can possibly be, (ii) learning for better understanding of risk, and (iii) learning to better inform system safety.

1.4. The challenge of learning from incidents in healthcare

As stated, incident investigation should provide us with valid and reliable information about the system, why it fails, and what needs to be done to improve safety. So it is important to take seriously the incident investigation process and to consider how investigation data is best gathered, represented, and communicated.

Much of the literature highlights the challenge of learning from incidents in healthcare (Leape & Berwick (2005); Brennan et al., (2005); Landrigan et al., (2012); Longo et al., (2005); Shekelle et al., (2013); Shojania et al., (2013); Austin et al., (2014); Baines et al., (2015); Kellog et al., (2017)).

This is not surprising considering that Leap et al., (1998) said that:

“Modern healthcare presents the most complex safety challenge of any activity on earth”.

As highlighted in section 1.2 above, according to Dekker (2006) incidents have dense patterns of causes, with contributions from all corners and parts of the system, and typically depend on many subtle interactions. It follows that identifying these dense patterns of causes and subtle interactions has to be extremely challenging given that Morrison (2013)
describes that socio-technical systems involve people operating complex technologies within highly defined and regulated parameters, across different domains. Healthcare is a highly complex socio-technical system with a diverse range of environments including, but not limited to hospitals, social care settings, community care settings, and primary care with patients moving within and across these settings. Care is delivered by multidisciplinary, distributed healthcare teams who rely on effective team work and communications to ensure effective and safe patient care (Weller et al., 2014). Team work is often characterised by a highly dynamic team membership, involvement in multiple teams and fast team formation (Cahill et al., 2018). The sophisticated technologies used in healthcare - and the range and complexity of patient conditions treated - require a highly skilled and diverse workforce of healthcare professionals. Elaborate structures and processes are required to enable the complex socio-technical system that is healthcare to deliver on its purpose which is to improve the health of the population it serves (Health Service Executive, 2018). The challenge is compounded by the fact that the health needs of the population are constantly changing.

Following a search for literature that focused on leveraging incident investigations to better inform system safety, a high volume of literature was identified related to investigations in healthcare with less literature focused on how investigations could inform system safety. This literature is summarised below highlighting the gaps that need to be addressed by research if we are to fully understand and overcome the challenge of learning from incidents to improve system safety in healthcare.

1.4.1. Studies that did not consider all available information necessary to identify causes

Dekker (2006) highlighted that it was important that investigations avoid leaps of faith and that they left an analytic trace for investigation findings. But some studies seemed not to consider all relevant available information to help identify incident causes. Rather, these studies seemed to require leaps of faith to identify causes. Some such studies
focused on healthcare staff and/or service users ideas about the causes of incidents (Cooper et al, (1984), ElBardissi et al, (2007), Bowie et al, (2008); Coombes et al, (2008)) without interviewing other relevant individuals and/or triangulating interview information with other relevant information such as healthcare records.

For example, a study by Coombes et al, (2008) related to intern prescribing errors involved interviews with interns involved in the prescribing errors. This paper identified that on 10 occasions, interns assumed that another senior doctor would have checked the drug order before administration of the drug to the patient. It would seem important to know why the interns thought this and interviewing the relevant senior doctors would appear to be very important in gaining an accurate understanding of this. Also, one interviewee stated that: “I was told what to prescribe, but I didn’t know about not using it [enoxaparin] in renal impairment”. Again, it would seem important to have interviewed the individual that told this intern to prescribe this drug to learn why they thought this was correct at the time.

In their study of the frequency and causes of dispensing errors in a UK hospital pharmacy, Beso et al., (2005) used semi-structured interviews with Pharmacy staff that made dispensing errors to explore the causes of errors. Being busy, short-staffed, subject to time-constraints and physical conditions of the individual (feeling tired or unwell) were the most commonly reported error producing conditions. Interruptions and look-alike/sound-alike drugs were also reported, as was lack of knowledge about the availability of different drugs or formulations of the same drug. Lack of focus on dispensing tasks, and latent factors were also identified during interview.

This highlighted the importance of information related to what interviewees had observed, and what they were thinking and doing when incidents occurred in identifying causes. However, while an interviewee will know what they were thinking, doing and observing at the time of an incident, they will not necessarily have all the information necessary to identify what Dekker (2006) referred to as the underlying systemic causes, or what Reason (1995) referred to as the latent factors.
associated with what they were experiencing. For example, do they know why they were particularly busy, short-staffed, subject to time-constraints or is it someone from a management or administration role that is likely to have the most accurate information about this?

This shows the need for thorough data collection for investigation including the need for interviewee information to be corroborated with (i) other interviewee information, and (ii) information from other sources, to get all of the information necessary to identify the underlying systemic causes of incidents.

1.4.2. Studies that focus on ‘surmised’ causes as opposed to actual causes

Another variation of this tendency to take a leap of faith to identify causes rather than leaving what Dekker (2006) referred to as an analytic trace for investigation findings was identified in some studies that focused on the ‘surmised’ causes of incidents as interviews did not focus on identifying specific causes of specific incidents (Cooper et al, (1984), ElBardissi et al, (2007), Brown et al, (2006)). Tully et al, (2009) emphasised this when they stated that it was unclear how best to prevent drug prescribing errors because recommendations were often based on ‘surmised’ causes rather than empirically collected data.

For example, Cooper et al, (1984) studied anaesthesia related human error and equipment failure. Interviews focused on errors staff observed directly that involved preventable human error or equipment failure. The interview did not require examples of any specific type of error or equipment failure. So what were identified were what the authors referred to as “conceivably” the causes as opposed to the actual causes.

Brown et al, (2006) found that diagramming patients’ views of root causes of adverse events in ambulatory care provided a broadly accessible planning tool for reducing ambulatory care adverse drug events (ADE) by showing a comprehensive picture of the ‘potential causes’. The authors highlighted that, to avoid predisposing informants to systemic biases, they avoided asking the patients whether they had
personally experienced an ADE. Thus, their findings were limited in that they did not distinguish between reports based on direct personal experience and speculative attributions for patient-related causes.

Based on the methodology used in these and other such studies, it is unlikely that the investigators could have learned what triggers in the environment were being observed and responded to by the real actors involved in incidents, nor the underlying systemic causes of these environmental triggers.

Many studies focused on learning from batches of incident report data (Barach & Small (2000 and 2002); Bechmann et al., (2003); Carson-Stevens et al., (2016); Catchpole et al., (2008); Dodds & Kodate (2012); Hibbert et al., (2015); Holzmueller et al., (2005); Hutchinson et al., (2010 & 2013); Needham et al., (2005); Skapik et al., (2009); Stavropoulou et al., (2015); and Walsh and Antony (2007)).

This generally involved analysis of data from incident report forms which were completed in the immediate aftermath of incidents and uploaded to national incident reporting and learning systems. These forms were completed prior to any thorough investigation of the incidents. So the information about causal factors included in these forms would be limited to the reporters’ understanding of the causes and not the causes that were identified after thorough investigation. Many of these studies referred to this causal information as “potential” causes (i.e. Brown et al., (2006); Carson-Stevens et al. (2015)) as opposed the actual causes identified by empirical study. Case study 4 in chapter 2 which relates to the National Miscarriage Misdiagnosis Review (Ledger et al., 2011) shows how the apparent causes of an incident in its immediate aftermath can be significantly different to the actual causes identified after more thorough investigation.

An example of a study that focuses on batches of incident report data is the large-scale study of incidents reported from general practice via the National Reporting and Learning System (NRLS) in England and Wales which was conducted to identify the most frequent and most harmful patient safety incidents, and relevant contributory factors (Carson-
Stevens et al., 2016). These researchers found that only one-third of incident reports included described ‘potential’ contributory factors and reporters did not routinely describe the organisational-level factors contributing to incidents. So this information tends to be incomplete. Furthermore, it is hypothetical in relation to causes as opposed to being based on empirical analysis to identify causes.

Morrison et al., (2009) put it clearly when they stated that the fundamental key to both understanding how a system worked and to being able to devise interventions to improve its functionality was a model of the system which incorporated the functional relationships between the elements of the system. They went on to state that what needed to be modelled was the real system – the objective dependencies and constraints operating in the real world independently of any one actor’s intentions. Thus, they conclude, what is modelled is not simply a mental construction of the actors in the system but the actual material and social structure within which action takes place, including social relations, co-ordination actions, information and communication (Morrison et al., 2009).

This emphasises the importance of using real information about causal factors – such as interviewing people that observed the actual events, and considering contemporaneous documented records of events - as opposed to hypothetical or speculative information about events.

1.4.3. Studies that focus on superficial cause as opposed to systemic causes

There was a tendency for studies to focus on superficial causes of incidents (For example, studies by Coté et al, (2000); & ElBardissi et al, (2007)) as opposed to focusing on the deeper underlying systemic causes.

In their study to identify factors that contributed to adverse sedation events in children undergoing procedures in the US, Coté et al, (2000) identified contributory factors including (i) inadequate resuscitation, (ii) inadequate and inconsistent physiologic monitoring, (iii) inadequate
pre-sedation medical evaluation, and (iv) inadequate recovery procedures. However, this study did not appear to identify the deeper, more underlying causes. For example, the reasons for the inadequate resuscitation, or the inadequate monitoring, or the inadequate pre-sedation medical evaluation were not described.

Similarly, a study by ElBardissi et al, (2007) described applying a human factors analysis classification system (HFACS) methodology adapted from aviation accident investigation - to the cardiovascular surgery operating room. They interviewed 68 healthcare professionals from a single operating room using semi-structured interviews. Questions focused on whether and how often interviewees observed what could be considered as superficial causes such as: “How often do members of the OR [Operating Room] team cut corners when performing their job, for example failing to perform needle counts? Can you provide examples of other situations?” Questions did not focus on ‘why’ the team cut corners when performing their jobs. So this study identified what happened, and how often it happened, but it did not focus on ‘why’.

Dekker (2006) emphasises the importance of identifying the underlying systemic causes of harm as opposed to superficial causes, in order to achieve meaningful organisation wide safety improvement.

At the same time – no literature clarified what was a sufficiently deep system/underlying cause, nor what was the stop-rule that indicated that you have reached a satisfactory answer.

A study by Cronin (2005) seemed to go some way toward a better understanding of causes compared to many others, by using the London Protocol for the systems analysis of clinical incidents (Taylor-Adams et al., 2004) to investigate eight incidents and then analysing patterns of factor types and influencing contributory factors that arose from the eight investigations. However, identifying that the contributory factors fell - for example - into the “task” or the “work environment” category in this study still seemed to incompletely answer the question about why incidents occurred, and what needed to be done to address the causes to prevent future harm occurring. For example, it was unclear
from this study what specific aspects of the “task” or “work environment” contributed to incidents, and what needed to be done to address these.

Furthermore, there were only eight investigations included in this study and all occurred in paediatric services. It seemed from reading the Cronin (2005) paper that it might be possible to get an even better understanding of the stop-rule for identifying satisfactory underlying systemic causes of incidents by (i) applying a systemic approach – such as the London Protocol to a larger number of serious incidents that occurred across a wider span of the health system, and (ii) some deeper analysis of further details of contributory factors.

1.4.4. Studies that focus on part of the health system and subsets of incident types

Examples of studies that were speciality-centred or incident-type focused included studies related to re-intubation incidents in intensive care units (Bechmann et al, 2001), anaesthesia-related human error and equipment failure (Cooper et al, 1984), adverse sedation events in children undergoing procedures (Coté et al, 2000), cardiovascular surgery (ElBardissi et al, 2007), the operating theatre (Catchpole et al, 2004), paediatrics (Cronin, 2005), errors in drug prescribing administration in acute hospitals (Beso et al, 2005; Edmondson, 2004; Coombes et al, 2008; Tully et al, 2009; Dornan et al, 2009), mis-transfusion (Elhence et al, 2010), child and adolescent psychiatry (Ammenwerth et al, 2002), and adverse drug events in ambulatory care (Brown et al, 2006).

Amalberti et al (2011) stated that the dominant approach to safety was often too process driven and too in-hospital and speciality-centred (“silo-driven”) when attributing causes to adverse events. They warned that an outlook that is confined to a single speciality (silo-driven outlook) is a pitfall that must be avoided. This is not to say that there is not value and legitimacy in focussing attention on specific procedures/units as there are likely specific causal patterns identifiable from these – e.g. reasons why the count fails in foreign object retention.
But, as shown above, published studies are often speciality and/or incident type focused. The point is, while it is accepted that some causes may be specific and considering these specifically is legitimate, it appears that there is additional value in also using a wider more systemic lens that considers as broad a range of incidents within as wide a span of the health system as is possible. It is important to explore this.

1.4.5. Studies that match types of incidents to a limited number of causes

Many studies endeavoured to match types of incidents with prescribed incident causes (ElBardissi et al., (2007); Elnicki et al., (1980), Eunhee et al., (2016)).

One example is the operating room study by ElBardissi et al, (2007) which is referred to above. In this study semi-structured interviews used questions developed to target each of the four broad categories and sub-headings with the HFACS (Human Factors Analysis and Classification System) framework namely (i) organisational influences, (ii) unsafe supervision, (iii) preconditions to unsafe acts, and (iv) unsafe acts. This empirical study found that many issues were identified within these four broad causal categories, but there were no statistical difference between the frequencies with which each broad category or sub heading were identified. Planning, problem correction, and skill based errors and routine violations were the most frequent causal sub headings identified. So, this methodology could not identify why these problems occurred.

A second example is an empirical study by Elnicki and Schmitt (1980) that reported using a simple prediction model to estimate the relationships between adverse incidents and selected patient and environmental characteristics in a large hospital. It focused on three types of incidents namely (i) falls, (ii) medication errors, and (iii) others. It found that, while some of the incident-characteristic relationships were significant, the findings did little to explain “why incidents occurred” and none of the estimated equations yielded results that could be logically translated into policy recommendations for the
hospital. They concluded that adverse patient incidents could not be predicted by observing the patient characteristic and hospital environment. This is a relatively old study, but its findings remain pertinent to this thesis.

Finally, a third example is an empirical study by Eunhee et al., (2016). This was a study of the relationship between nurse staffing levels and work environment with patient adverse events in a cross-sectional study using a combination of nurse survey data, facility data, and patient hospital discharge data in South Korea. This study found relationships between incidents and prescribed causes. Specifically, they found that a larger number of patients per nurse and poor work environment increased the incidence of patient adverse events, such as administration of the wrong medication or dose to the patient, pressure ulcers, and injury from falling after admission. Several limitations were highlighted by the authors. For example, the results of the study were based on cross sectional data; therefore, causal relationships among patient adverse events, nursing staffing levels, and nurse work environment could not be determined. Also, this study did not consider other nurse characteristics, such as stress (burnout), fatigue, or poor sleep quality due to shift work, which might be significantly related to patient adverse events and could increase the possibility of confounding effects by unmeasured or unknown factors.

So, a problem with trying to match incident types to incident cause is that (i) it is not possible to learn ‘why’ incidents occurred, and (ii) some causal factors may be omitted or overlooked.

1.4.6. Absence of Human Factors and system safety expertise in investigations

Doggett (2004) and Carroll et al., (2002) referred to the importance of aspects of rigor in information analysis in order to identify causal factors including skills in (i) critical thinking, and (ii) processes for categorising the quality of data used to establish causes. Many other studies identified that Human Factors and system thinking expertise were
important for this (For example: Cronin (2005); Drupsteen & Hasle (2014); & Peerally et al., (2016)).

The study by Cronin (2005) found that the complexity of human factors science required expertise to tease out contributory factors. Peerally et al (2016) identified that - despite the complexities, sensitivities and challenges of this work, investigations in healthcare are “typically conducted by local teams, not the expert accident investigators who are proficient in systems thinking and human factors, cognitive interviewing, staff engagement and data analysis that are characteristic of other high-risk industries”.

1.4.7. Limited research about the quality of investigations and how to evaluate this

Much literature was identified criticising the quality of investigations in healthcare (Anderson & Kodate, (2015); Bowie et al., (2008); Care Quality Commission, (2016); House of Commons, (2015); Kirkup, (2015); Parliamentary and Health Service Ombudsman, (2015); Wallace, (2006); Wallace et al., (2006); and Wallace et al., (2009); Cassins & Barrach (2012); and Kellog et al., (2017)).

Only four studies were identified that referred to the evaluation of the quality of investigations in healthcare (Bagian (2002); Wallace et al., (2006); Quality Care Commissions (2016); and Leistikow (2016)). A “Closure Checklist” which was designed to give assurance about the compliance of investigations with the NHS Serious Incident Framework was included in appendix 8 of that framework (NHS England, 2015). No studies were identified related to the development of this checklist, nor to empirical studies of its application. None of these studies related to investigations in non-acute services. None focused specifically on the systems analysis method of investigation. Only two of these studies predated the research reflected within this thesis (Bagian et al., (2002); Wallace et al., (2006)). Also, only two of these studies (Wallace et al., (2006) and Leistikow (2018)) went in to any detail about the method of evaluating investigation quality.
The four evaluation tools (Bagian (2002); Wallace et al., (2006); Quality Care Commissions (2016); and Leistikow (2016)) and the “Closure Checklist” (NHS England, 2015) are described in Chapter 3 of this thesis:

**Study 1: Developing a reliable tool to evaluate investigation quality.**

**1.4.8. Limited research about the factors that affect investigation quality**

As there was very little reference in the literature to methods of evaluating the quality of serious incident investigation reports, it is not surprising that there was even less literature referring to the factors that affect the quality of investigations. None of the four studies referred to above that related to evaluating the quality of investigations (Bagian et al., (2002); Wallace (2006); Care Quality Commission (2016); and Leistikow et al., (2016)) – referred to analysis to identify factors that affect investigation quality.

One paper which was published while the research was on-going (Drumpsteen and Hasle (2014)) referred to the following factors affecting investigation quality, which in turn the authors identified as detracting from the potential for organisations to learn from incidents:

- There was seldom sufficient time made available to do a thorough enough investigation of incidents. Investigations often stopped too early to have identified all causes, and selection of recommendations was done based on “expert opinion” of the investigators. This resulted in a strong focus on technical actions.

- Investigations tended to be conducted by employees of the organisations who had technical backgrounds, which resulted in a focus on technical issues in the incident investigations and a focus on technical actions for improvement whereas human factors and organisational issues were rarely addressed.

- There was a strong focus on direct causes and on the human error, and not on the context in which an error occurred and on the reasons for certain behaviours. As a result, structural measures for
improvement were not taken and follow-up actions consisted of reminders of existing rules and procedures.

- The investigators did not have the knowledge and experience to carry out a satisfactory investigation with investigations rarely addressing organizational causes, because there was a blind spot for organizational and cultural issues and technical factors were more easily identified.

Pertinent to this thesis, Drumpsteen and Hasle (2014) highlighted that factors that affect investigation quality might include (i) the time available to investigators to complete investigations; (ii) investigator knowledge and experience (the relative importance of technical expertise related to the matters under investigation compared with investigation expertise such as in human factors and organisational issues); and (iii) the importance of focusing on the underlying causal conditions in addition to the more obvious superficial causes.

1.4.9. Limited analysis of groups of investigation reports to identify patterns in causal factors

Only two studies were identified that related to the analysis of groups of completed investigation reports to identify themes in causal factors. One of these studies is a study of Root Cause Analyses (RCAs) of surgery-related adverse events by Cassin and Barach (2012). This study drew on the researchers own experience of facilitating “more than 100” RCAs. It describes themes identified from the data – but it does not specify the methodology used to generate these themes. The researchers refer to the difficulty drawing generalizations from the data because the issues were multifactorial and required a systemic response. They report that they were frustrated with the quality of information that emerged from the RCAs. They highlight the importance of considering alternative tools for the management of serious clinical adverse events such as analysing an event across all levels of an organisation by using the London Protocol (Taylor-Adams et al., 2004)). They suggested (as did Hollnagel, 2004; Rasmussen 1989, 1993, & 1997; and Dekker (2006)) that the overriding advantage of systemic models was their emphasis that
accident analysis must be based on an understanding of the functional characteristics of the system, rather than on assumptions or hypothesis about internal mechanisms as provided by standard representations.

The second study that was found to use a group of investigation reports to identify themes in causal factors was a study by Cronin (2005) which is referred to in section 1.4.3 above. This study includes eight completed incident investigation reports related to non-trivial occurrences in paediatric services at the Winnipeg Health Authority (WRHA). The eight investigations were conducted by the researcher herself and they followed the Systems Analysis method outlined in the London Protocol (Taylor-Adams et al., 2004). The study outlines patterns in the **factor types** and **influencing contributory factors** as per the London Protocol. The author stated that the London Protocol provided structure for interviews and the collateral search for information, but the complexity of human factors science required expertise to tease out contributory factors, root causes and the context in which they occurred. It is noteworthy that this study referred to root causes even though it used the London Protocol (Taylor-Adams et al., 2004) which, as shown above, considered the term **root cause** misleading. At any rate, this study described the following eight lessons learned from a review of a database of 30 reviews of critical occurrences and near misses involving children:

(i) Acute paediatric care is a tightly coupled system with multiple high-risk processes  
(ii) Critical occurrences usually have multiple contributory factors  
(iii) Medication error is the commonest category of active failure in acute paediatric care  
(iv) Most errors that reach the patient do not cause harm  
(v) The authority gradient is alive and well  
(vi) Accountability matters  
(vii) The learning organisation engages its partners  
(viii) Writing recommendations is easy. Implementation is challenging.
It is unclear from this paper whether these 30 cases include the eight cases used to identify the themes in causal factors referred to above. Some of the lessons learned described in (i) – (viii) above do not appear to relate to the deeper underlying systemic causes of harm. For example, medication errors were identified to be the commonest category of active failure. However, this does not add to learning about the causes of the medication errors. The step-by-step methodology of the analysis of the contributory factor data to generate these lessons was not described in the paper by Cronin (2005).

One study by Kellogg et al., (2017) considered 302 Root Cause Analyses (RCAs). But it focused on the quality of recommendations rather than on either (i) the quality of the individual investigations, or (ii) patterns of causal factors identifiable from the RCA data.

It found that multiple event types were repeated in the study period in the same organisation, including (i) retained foreign body incidents, (ii) medical administration errors, and (iii) wrong-site surgery incidents. The authors stated that, while recognising that some types of events were impossible to eliminate completely, they proposed that repeat events occurred despite repeat RCAs because of the quality and types of solutions that were proposed by RCA teams.

So, this study focused on categorising proposed solutions from completed RCAs and found them to be weak. This in turn was identified as an important factor in failing to learn from incidents culminating in recurrences.

Commenting on the recurrence of incidents in spite of repeated RCAs identified in the Kellog et al., (2017) study, Vincent et al., (2017) stated that: “…perhaps we have been too optimistic in assuming that a thoughtful analysis would lead naturally to reasonable and effective recommendations”.

But the examples of the RCAs in the Kellog et al., (2017) study, suggest that the RCAs were less than appropriately thoughtful analyses. For example, one RCA stated: “Analysis confirmed that our continuing policy is effective despite this occurrence. However, sponge was retained.”
Human error determined to be a factor”. This RCA proposed the following solution: “Re-emphasise policy and procedure at OR staff meeting and at next Perioperative Service Chiefs meeting”. So this RCA did not identify why the sponge was retained, nor the solution necessary to address the causal factors.

The phenomenon of isomorphism described by Toft & Reynolds (2005) is also probably very important, yet overlooked in the Kellog et al., (2017) and other similar studies. Isomorphism is the phenomenon whereby similar incidents may have different causes and different incidents may have similar causes. Applied to the Kellog (2017) and other studies, it would be important not to assume, for example, that two cases of retained swabs following surgery automatically have the same causes. Rather, isomorphism forces us to consider that two cases of retained swabs could have very different causes. So, while identifying the fact that the quality of recommendations was weak in the Kellog et al., (2017) study was a very important matter to be identified and addressed – analysis of patterns of causal factors would seem to be very important too.

So it appears that two separate issues may need to be addressed if we are to leverage incident investigations to better inform system safety – namely: (i) we need to conduct better individual investigations that generate better causal analyses of individual incidents to inform local actions that are more likely to have a greater impact on addressing local causes, and (ii) we need to conduct analysis of causal factors data from groups of high quality individual investigations to identify the patterns of underlying systemic causes from the range of incidents that occur throughout the system to inform better actions for organisation wide safety improvement.

1.5. Discussion

The overarching research question for this thesis relates to how we can effectively leverage incident investigations to better inform system safety.
This chapter emphasises the challenge of learning from incidents in healthcare for effective organisation wide safety improvement.

Such a complex challenge requires sophisticated research to understand and solve it.

This chapter also highlights gaps in the research related to methods for, and benefits and challenges of (i) evaluating the efficacy of various investigation methods; (ii) evaluating the quality of individual investigation reports; (iii) identifying factors that affect investigation quality; (iv) enhancing investigator competencies in areas such as human factors, systems thinking, critical thinking, processes for analysing data to identify causes, and producing investigation reports that leave a clear analytic trace for investigation findings; (v) considering the range of information necessary to accurately identify incident causes, (vi) focusing on identifying the underlying systemic causes as opposed to the ‘surmised’, ‘potential’, or superficial causes including what is a helpful stop rule for drilling down to identify systemic causes; (vii) investigating different ranges of incident types that occur in different spans of the health system; and (viii) identifying patterns of causal factors from groups of individual investigation reports.

The remainder of this thesis reports original ground-breaking research that addresses some of the research gaps highlighted above. It describes four studies designed to address the overall research question by reflecting a profound analysis of the problem space. It chronicles an action research approach to developing a reliable Investigation Quality Evaluation Tool (IQET) that thoroughly evaluates investigations including the quality of the analytic trace for investigation findings (Study 1). It applies the IQET to Serious Incident Investigation reports and determines the extent to which these meet stated investigation quality standards, and identifies areas for improvement (Study 2). It analyses data collected via the IQET and from training attendance records at investigation training to empirically identify factors that affect investigation quality (Study 3). It analyses further details of contributory factors to identify patterns in causal factors from a group
of investigation reports. In doing this, it explores how to overcome some of the difficulties of achieving a satisfactory causal analysis, including learning how to inform “stop-rules” for how deep the analysis of underlying systemic causal factors should go (Study 4). It delivers novel findings that make an innovative contribution to the body of knowledge about how to effectively leverage incident investigations to better inform system safety by answering the specific research questions outlined in table 1.1 below:

<table>
<thead>
<tr>
<th>Research Question</th>
<th>Where this research question is answered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is it possible to develop a tool to reliably evaluate the quality of investigation reports, including the quality of the analytic trace for investigation findings?</td>
<td>Study 1: (Chapter 3) Action research to develop a reliable tool to evaluate investigation quality</td>
</tr>
<tr>
<td>Can such a tool be applied to evaluate investigation quality in a healthcare system to identify areas where they are strong and areas for improvement?</td>
<td>Study 2: (Chapter 4) Application of the tool to HSE investigations to identify areas where they are strong and areas for improvement.</td>
</tr>
<tr>
<td>Can factors that affect investigation quality be empirically identified from information (i) about investigations collected using the Investigation Quality Evaluation Tool, and (ii) attendance at investigator training?</td>
<td>Study 3: (Chapter 5) Identification of factors that affect HSE investigation quality</td>
</tr>
<tr>
<td>Can clear patterns of causal factors be identified from a group of investigation reports that could inform better risk and safety management across a healthcare system?</td>
<td>Study 4: (Chapter 6) Analysis to identify patterns in causal factors from HSE investigations</td>
</tr>
<tr>
<td>What can the approach taken in this study offer Healthcare Systems? What value would be offered by on-going (i) application of the tool to evaluate the quality investigation reports, (ii) identification of factors affecting quality, and (iii) identification of patterns in causal factors? What are the implementation requirements?</td>
<td>Application: Chapter 7</td>
</tr>
<tr>
<td>What does this mean at the generic level of healthcare system safety? What can other healthcare systems and other domains learn from this? Should we change our conceptualisation of the role of incident investigations in system safety based on these data?</td>
<td>Discussion: Chapter 8</td>
</tr>
</tbody>
</table>

Table 1.1 Showing the research questions addressed in this thesis and where they are addressed.
Before the research reflected within this thesis commenced, the Health Service Executive (HSE) had developed incident investigation processes and training that attempted to both (i) build on, and (ii) address many of the gaps in the literature identified in this chapter. The investigation experience that informed these investigation processes and training - and details of the actual investigation processes and training derived are important aspects of the organisational context within which this research was conducted. Therefore, the organisational context for this thesis is described in Chapter 2.
Chapter 2

The organisational context - Learning from incidents in the HSE

Overview of chapter 2

2.1. Introduction

2.2. History and scope of the HSE

2.2.1. On-going restructuring of the HSE

2.3. History of investigation structures in the HSE

2.3.1. Investigation structures prior to the establishment of the HSE

2.3.2. Investigation structures following the establishment of the HSE

2.3.3. Cases that highlighted the need to improve investigation quality

2.3.4. Cases that highlight some progress in HSE investigation quality

2.4. Initiatives taken to improve investigation professionalism and quality

2.4.1. Updating investigation guidelines

- Move from the epidemiological model to the systemic model
- Evolution to the term “Key Causal Factor”
- Evolution of a tool to audit conformance with guidelines

2.4.2. Delivery of training to support implementation of the guidelines

- The evidence base for investigator training
- Evidence based investigator training design and delivery
- Findings of analysis of participants’ feedback about this training

2.5. Discussion

2.1. Introduction

As stated in Chapter 1, the overall aim of this research is to explore how to effectively leverage incident investigations to better inform system safety. Before the research reflected within this thesis commenced, the HSE had developed incident investigation processes and training that attempted to both (i) build on, and (ii) address many of the gaps - in the literature identified in Chapter 1. The investigation experience that
informed these investigation processes and training - and details of the actual investigation processes and training derived - are important aspects of the organisational context within which this research was conducted which are described here in Chapter 2.

Chapter 2 starts with the history of the HSE. It then shows that the HSE has been through multiple transformations resulting in changes in management structures and processes since it was established in 2005. It continues by outlining that these transformations continue and demonstrating that on-going transformations (albeit that they may be needed) pose a challenge for developing, maintaining and evaluating consistent high-quality investigation practices.

Incident investigation cases are presented within this chapter which develop the idea that learning from incidents is not straightforward or automatic and that effectively deriving the learning requires a level of professionalism and consistency in the investigation process. It also requires a paradigm shift from seeking to answer the question: “Why does this harm keep on happening?” before we have properly answered the question: “Why did this harm happen in the first place?”

Later, this chapter summarises interventions designed to improve the professionalism and consistency of investigations. Finally, this chapter concludes with a list of research questions that are important for considerations about whether this is achieved and whether it does or can result in more effective learning from incident investigations.

### 2.2. History and scope of the HSE

The Health Service Executive (HSE) was established under the Health Act, 2004, and commenced operation in January 2005.

It provides health and social care services to the population of Ireland. According to the 2016 census – this is approximately 4.7 million people (Central Statistical Office, 2016). The HSE is Ireland’s largest employer with over 67,000 direct employees, and another 40,000 in HSE funded health care organisations.
2.2.1. On-going restructuring of the HSE

As shown in table 2.1 below, the HSE has been in a more or less on-going process of structuring, restructuring, transforming, merging and dividing since it was established in 2005.

The information about the HSE’s vision, mission, values and objectives in table 2.1 below was sourced from (i) consecutive corporate plans, and (ii) from individuals who facilitated and supported the various transformation processes. It is noteworthy that, in 2011 in line with legislation, the HSE submitted the draft Corporate Plan 2011 – 2014 to the Department of Health (DoH) for consideration. At that time, due to the impending publication of the DoH Statement of Strategy 2011 – 2014 (Department of Health, 2012) which outlined the high level aims and objectives of the overall health system over the period, and the Programme for Government implementation plan (Department of Health, 2015), the DoH only considered this as a final “draft”. So, the Corporate Plan 2011 – 2014 was never in fact converted to a final document, nor was it published. This indicates a somewhat unstable period in the history of the HSE with (i) a change in Government, (ii) the economic crash and its consequences for the HSE, and (iii) the abolition of the board of the HSE, the establishment of the HSE directorate, and the return of the “vote” to the Department of Health.

Senge et al, (1994) defined a system as a perceived whole, whose elements hang together because they continuously affect each other over time and work towards a common purpose. As described in Chapter 1, Dekker (2006) described that the systemic approach to accident causation sees accidents as emerging from interactions between system components and processes. This means that accidents come from the normal workings of the system. That is to say, they are a systemic by-product of people and organisations trying to pursue success with imperfect knowledge and under the pressure of other resource constraints (scarcity, competition, time limits) (Dekker, 2006). Dekker (2006) described good systems investigations as an effective way of describing the causes of these systemic problems and of prescribing solutions to address these causes.
Translating this to the health system context - incidents in the health system are a systematic by-product of people and organisations trying to pursue success with imperfect knowledge and under the pressure of other resource constraints. The continuously changing structure and purpose of the HSE compounds this as it is difficult for staff to achieve clarity about the purpose and structure of the HSE if these change often. Consequently it is difficult to optimise the interactions between system components and processes to effectively achieve the purpose of the system.

To summarise, the more-or-less continuous organisational flux presented in table 2.1 below, including a period from 2011 – 2014 when the HSE’s vision, mission, values and objectives were never in fact formally finalised, poses significant challenges as follows:

- A challenge to effectively achieving the HSEs purpose when the purpose is constantly changing as are the elements of the system that need to be arranged to effectively work together to achieve that purpose, meaning potentially more incidents occurring, and

- A challenge to realising the power of systems analysis investigations to contribute to an accurate system-wide understanding of system performance in a context where the elements of the HSE are continuously changing, including the elements that were designed to drive investigation and learning from incidents.
<table>
<thead>
<tr>
<th>Years</th>
<th>Vision, Mission, Values and Goals/objectives</th>
<th>Main Structure and Structural Changes</th>
<th>Incident management and investigation structures</th>
</tr>
</thead>
</table>
| **2005 – 2008** | **Vision:** To consistently provide equitable services of the highest quality to the population we serve  
**Mission:** To provide high quality integrated health and personal social service built around the needs of the individual and supported by effective team-working  
**Values:** No values were articulated in the 2005 – 2008 corporate plan  
**Objectives/goals:**  
1. We will improve people’s experience of our services and their outcomes, through developing, changing and integrating our services, in line with best practice.  
2. We will work to protect, promote and improve the health and well-being of the population, based on identified need and with particular focus on measures to address social exclusion.  
3. We will empower staff to deliver responsive and appropriate services, making effective team-working a priority.  
4. We will develop the HSE as a dynamic, effective and learning organisation in partnership with service users, patients, staff, not-for-profit/Voluntary/Community sector and other stakeholders. |  
**2005**  
Three defined areas of operation:  
1. Health and personal social services divided into three service delivery units namely (i) Population Health, (ii) Primary, Continuing and Community Care (PCCC), and (iii) a National Acute Hospitals Office (NHO),  
2. Support Service including six corporate functions (i) Human Resources, (ii) Finance, (iii) National Shared Services, (iv) Information and Communication Technology (ICT), (v) Estate Management, and (vi) Procurement,  
3. Reform and innovation, responsible for driving the HSEs strategic and corporate planning processes. This comprised of (i) Strategic Planning, Reform, and Implementation (SPRI), (ii) Corporate Planning and Control Processes, and (iii) Expert Advisory Groups (EAGs).  
**2007**  
The 2007 Transformation Programme saw the dissolution of the SPRI group and unit. |  
2005  
The National Office of Quality and Risk was established within the Office of the CEO of the HSE. This office had a role in developing and supporting implementation of incident management and investigation policy throughout the HSE.  
2008  
The Serious Incident Management Team (SIMT) was established within the Office of the CEO of the HSE. This SIMT had a role in developing and supporting implementation of incident management and investigation policy throughout the HSE.  
Both the National Office of Quality and Risk and the SIMT were located within the Office of the CEO of the HSE at this time. While there were some common members of the SIMT and the Office of Quality and Risk – they were discrete and separate structures. |
| **2008 – 2011** | **Vision:** Easy access, public confidence and staff pride  
**Mission:** To enable people to lead healthier and more fulfilled lives  
**Values:** Respect, fairness and equity, excellence, leadership, accountability, responsibility.  
**Objectives/goals:**  
1. *Health and wellbeing:* We will invest in preventing illness; supporting, encouraging and empowering people to pursue independent, healthy and fulfilling lifestyles to reduce the likelihood of illness. We will ensure that early diagnosis, treatment and care options are available, if required.  
2. *Sustainable services:* We will reconfigure our services to develop sustainable hospital and community services that provide the care people need now, and in the future. By delivering the majority of care in the community, we will enable hospitals to focus on improving accessibility to deliver more efficient acute care. |  
**2009**  
1. The NHO and the PCCC were merged to form the Integrated Service Delivery Directorate (ISD).  
2. Services across the country were divided into four regions lead by Regional Directors of Operations (RDOs), who had full operational responsibility for the services delivered within their remit. RDOs were later referred to as Regional Directors of Performance and Integration (RDPIs).  
3. Each RDO area was divided geographically into Integrated Service Areas (ISAs).  
4. Each ISA lead reported to the RDO and provided acute and community and social care services to the geographical area within their jurisdiction.  
5. The support services of Estates, Legal Services, Contracts, Procurement, and ICT came together to support the ISD.  
**2009**  
1. The SIMT and the Office of Quality and Risk moved from the Office of the CEO to the Quality and Clinical Care Directorate (QCCD).  
2. An ISD/QCCD Review Group was set up with a role in helping the HSE to gain an understanding of the rate/type/level of investigation of serious incidents from PCCC, Hospitals, and Children’s Services.  
3. The ISD/QCCD Review Group became the National Incident Management Team (NIMT). The NIMT had two co-chairs, one from the ISD reporting to the National Director of the ISD, and one from the QCCD reporting to the National Director of QCCD. |  
3. **Operational excellence**: We will achieve operational excellence using processes and systems that are efficient, easy for service users to access and understand, evidence based and deliver value for money.

4. **Unlocking our potential**: We will actively support and encourage all staff to achieve their full potential and deliver quality care. In partnership, we will recognise and celebrate achievements and encourage staff to work responsibly, manage challenges and take pride in their contribution to the services they provide on behalf of the organisation.

5. **Quality and safety**: We will ensure the quality and safety of our services. By developing a transparent quality and safety culture and adapting our work practices, we will ensure that continuous quality and safety improvement is integral to all that we do.

6. **Trust and confidence**: We will build the public’s trust and confidence in our health services through the provision of timely, well integrated, professional and accessible services. We will make it easier for people to access the right service, in the right place, at the right time. 

---

<table>
<thead>
<tr>
<th>2011 – 2014</th>
<th>Vision: A world-class health system for all the citizens of Ireland</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Mission</strong>: To provide health and personal social services to the people of Ireland, within the resources allocated to us by Government</td>
</tr>
<tr>
<td></td>
<td><strong>Values</strong>: Respect, outcome focused, responsive, transparent, excellence &amp; quality, caring &amp; compassion.</td>
</tr>
<tr>
<td></td>
<td><strong>Objectives/goals</strong></td>
</tr>
<tr>
<td></td>
<td>1. Keeping people healthy</td>
</tr>
</tbody>
</table>

---

| | The programme for Government 2011-2016 identified that, over time, the HSE would be abolished. The Minister for Health announced the need for the urgent appointment of a new Directorate Team to prepare for the transformation of the health system to a Universal Health Insurance (UHI) model of healthcare, and which would run the health services as they existed. |

---

| 2011 | The title “National Director for Quality, Risk and Clinical Care” was changed to the National Director for the Quality and Patient Safety Division (QPSD). |
| | • The Office of Quality and Risk at this time located within the QPSD became the Office |

---

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>The HSE transitioned from the four regional structures to a divisional structure with National Directors appointed to (i) the Acute Hospital Division (AHD), (ii) the Mental Health Division (MHD), (iii) the Social Care Division (SCD), (iv) the Primary Care Division, (v) the Health and Well-being Division (H&amp;WBD), and (vi) the National Ambulance Service. A standalone National Cancer Control Programme (NCCP) emerged at this time.</td>
</tr>
</tbody>
</table>
| 2014 | 1. Frontline services that previously fell under divisions were further divided into seven Hospital Groups (HGs) which fell within the Acute Hospital Division (AHD); and nine Community Health Offices (CHOs) which delivered (i) mental health services, (ii) social care services, (iii) primary care services, and (iv) health and wellbeing services, to the population within their remit. CHOs were led by Community Health Officers.  
2. Each of the nine CHOs reported to the three National Directors for Mental Health (MHD), Social Care (SCD), and Primary Care (PCD).  
3. Each of the seven HGs was led by a HG CEO who reported to the National Director for Acute Hospital Services.  
4. Three Regional Ambulance Services reported to the National Director of National Ambulance Services (NAS). |

### Vision: A healthier Ireland with a high quality health service valued by all

**Mission:** That people in Ireland:
- Are supported by health and social care services to achieve their potential
- Can access safe, compassionate and quality care when they need it

### 2015 - 2017

need it, and can be confident that we deliver the best outcomes and value by optimizing our resources.

**Values:** Care, compassion, trust, and learning.

**Objectives/goals:**

1. Promoting health and well-being as part of everything we do so that people can be healthier
2. Providing fair, equitable and timely access to quality, safe health service so that people need
3. Fostering a culture that is honest, compassionate, transparent and accountable
4. Engaging, developing and valuing our workforce to deliver the best possible care and service to people who depend on them
5. Managing resources in a way that delivers best health outcomes, improves people’s experience of using services and demonstrates value for money.  

A new position of Chief Clinical Officer (CCO) was created. This position was to sit alongside the DDG for Operations and the DDG for Strategy and Planning creating a “triumvirate” reporting to the Director General (DG) of the HSE.

<table>
<thead>
<tr>
<th>Positions as follows:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. DDG for Operations which covered acute hospital operations and community operations, and</td>
</tr>
<tr>
<td>2. DDG for Strategy and Planning</td>
</tr>
</tbody>
</table>

Quality, Safety and Risk (QSR) who in turn reported to the National Director for QAVD.

2018 At this time, QAVD moved from reporting to the DG of the HSE to reporting to the newly appointed Chief Clinical Officer (CCO). Consequently, the NIMLT moved with QAVD into the newly formed CCO structure. The NIMLT reporting line was now via the Assistant National Director for QSR to the National Director for QAVD, to the CCO, and finally to the DG.

Table 2.1: Showing changes over time in the HSEs vision, mission, values, objectives, and structures, including incident management and investigation structures.

---

2.3. **History of investigation structures in the HSE**

This section outlines the history of incident investigation structures within the HSE. It emphasises how organisational structures for this were constantly changing in the context of wider organisational change and how this created challenges for developing, maintaining and evaluating consistent high-quality investigation practices.

2.3.1. **Investigation structures prior to the establishment of the HSE**

Processes, policies and guidelines for incident management and investigation were at varying levels of existence, development and maturity in the 10 former Health Boards and the Former Eastern Region Health Authority that existed prior to the establishment of the HSE in 2005. Some considered management of clinical and non-clinical incidents together, others considered these separately. Some considered complaints as service user reported incidents and considered these within their incident management and investigation structures and processes, others did not. Some included staff and families in investigation processes, others did not. Some sites delivered training for investigators, others did not.

For example, the author led the Healthcare Risk Management function of the former Midland Health Board which published its Healthcare Risk Management Policy in 2003 (Midland Health Board, 2003). This included guidelines for complaint and incident management and investigation which were based strongly on the ALARM Protocol for investigating clinical incidents (Clinical Risk Unit and ALARM, 1999). These guidelines encompassed the investigation of both clinical and non-clinical incidents in acute, community and corporate services, along with the investigation of complaints that could be defined as incidents. Investigator training was delivered for staff that would be conducting investigations under these guidelines.

2.3.2. **Investigation structures following the establishment of the HSE**

The structures and processes for incident investigation within the HSE were impacted by the continuous significant transformation and restructuring and consequent merging and division of local, regional and national structures reflected in table 2.1 above. This constant organisational flux posed
challenges to maintaining momentum for building investigator capacity and
capability and associated investigation quality.

**Establishment of an Office for Quality and Risk**

Towards the end of 2006, an Office for Quality and Risk was created within the
Office of the then CEO of the HSE. This Office had a role in developing and
supporting implementation of policy in relation to incident management and
investigation throughout the HSE. This Office moved to the Office of the
National Director for Quality and Clinical Care in 2009. It published the
“*Toolkit of Documentation to support the Health Service Executives Incident
Management*” (HSE 2009). This toolkit included investigation guidelines which
were largely based on the London Protocol (Taylor-Adams *et al* 2004). This
office delivered some investigation training in 2010 and developed an e-
learning investigation training module on HSEland\(^\text{13}\). As shown, investigation
structures and processes were in their infancy at this time. Consequently, the
need for any further comprehensive strategy to identify investigators, or to
develop and evaluate investigation professionalism, capability and capacity
within the HSE was not identified at this time.

**Establishment of a Serious Incident Management Team (SIMT)**

In the interim, the CEO of the HSE established a Serious Incident Management
Team (SIMT) in April 2008 in response to a number of high profile serious
incidents. These included (i) the Portlaoise Mammography Review (Health
Service Executive 2008) which identified nine cases of missed or delayed
diagnoses of breast cancer; and (ii) the investigation by the regulator, namely -
the Health Information and Quality Authority (HIQA) into the delay in
diagnosis of breast cancer related to Rebecca O’Malley (Health Information
and Quality Authority, 2008).

The SIMT consisted of senior clinical and management representatives from
community and acute hospital services who brought senior clinical and

\(^{13}\) HSEland is an online learning forum developed and run by the Health Service Executive. It provides
courses and learning resources for Healthcare workers in both the hospital and community health settings.
Access to hseland.ie is available over the internet, on a secure site. It is available to all Healthcare
Professionals in the Republic of Ireland, both within Health Service Executive (HSE), Voluntary Hospital
Sector, and associated Non-Government-Organisations (NGO’s). It is accessible via
https://www.hse.ie/eng/staff/leadership-education-development/onlinelearning/
general management experience to the SIMT table. The author was assigned from her role as General Manager for Quality and Safety in the Dublin Mid-Leinster Region where she reported to the National Office of Quality and Patient Safety - to the SIMT at the time it was established. The author was the sole member of the SIMT who had training and experience in serious incident investigation. The SIMT had a role in overseeing and/or directly managing a relatively small subset of serious incidents according to agreed criteria. Like the Office for Quality and Safety referred to in the previous section, the SIMT also had a role developing and supporting implementation of policy in incident management and investigation throughout the HSE. Also, as for the Office for Quality and Risk referred to in the previous section, the need for any further comprehensive strategy to identify investigators, or to develop and evaluate investigation professionalism, capability and capacity within the HSE was not identified as a role for the SIMT, as structures and processes for incident management and investigation were in their infancy at this time.

Establishment of a National Incident Management Team (NIMT)

In 2009, in an attempt to understand the rate, type, and level of investigation of serious incidents that were occurring within the Primary, Continuing, and Community Care (PCCC), Hospitals, and Children’s Services, a Quality and Clinical Care/Integrated Service Delivery (i.e. QCCD/ISD) Review Group was established. This group soon became known as the National Incident Management Team (NIMT) when it took on a role in overseeing the management of some serious incidents that fell outside of the scope of the subset of serious incidents that were managed or overseen by the SIMT. The NIMT had two co-chairs. One was nominated by and reported to the National Director for QCCD. This NIMT co-chair had a responsibility to inform incident management and investigation methodology. The other NIMT co-chair was nominated by and reported to the National Director of the ISD and this co-chair had a role around communicating - and supporting implementation of - learning from incidents within the ISD structures.

The SIMT was not involved in any consultation and engagement about the development of the NIMT. However, when SIMT members became aware of the establishment of the NIMT, it was identified that some members of the
SIMT needed also to become members of the NIMT to ensure that there would be no unnecessary overlap or omission in relation to the support and oversight of incident management and investigation, and to consider cases that should be referred from the NIMT to the SIMT. By the end of 2009, there were a number of common members between the SIMT and the NIMT including the author. As for the Office for Quality and Risk, and the SIMT referred to in the two previous sections, it was not identified that the NIMT needed to contribute to any further comprehensive strategy to identify investigators, nor to develop and evaluate professionalism, capability and capacity for investigations within the HSE as structures and processes for incident management and investigation were in their infancy at this time.

So, at this point in time, there were three national offices with a role in incident management and investigation within the HSE. But the need for any of them to contribute to a further strategy to build and evaluate professionalism, capacity and capability for incident investigation had not been identified.

**Merging the NIMT and the SIMT**

The author became the Director of the SIMT in April 2010 and sought to merge the SIMT and NIMT. This merger was completed at the end of 2011. The merged team was called the NIMT. The author’s former role as Director of the SIMT was abolished. The NIMT moved location from the Quality and Clinical Care Directorate to the newly formed Quality and Patient Safety Directorate. The NIMT continued to have two Co-chairs, one nominated by and reporting to the National Director for Quality and Patient Safety, and one nominated by and reporting to the National Director for Integrated Service Delivery. The author became an ordinary member of the NIMT and sought for her role to focus on advising on investigation methods and quality. In 2012, the author became the Co-chair of the NIMT nominated by and reporting to the National Director for Quality and Patient Safety.

**Moving the NIMT to the QAVD**

In autumn 2014, the Office of the Director of Quality and Patient Safety was divided into two National Division Offices namely:
• The Quality Improvement Division (QID)
• The Quality Assurance and Verification Division (QAVD).

The NIMT moved to the QAVD in September 2014. However, the author was the only member that moved with the NIMT. The NIMT was then repopulated with quality and safety staff that were being re-deployed from the Offices of the Regional Directors of Performance and Integration (RDPI), (formerly Regional Directors of Operations (i.e. RDOs)) which were being de-commissioned. At this time, the name of the NIMT was changed to the National Incident Management and Learning Team (NIMLT).

2.3.3. Cases that highlighted the need to improve investigation quality

In her role as a member of the SIMT, the author was aware of - or was directly involved in - a large number of serious incident investigations from which she derived much learning which informed subsequent interventions she led to contribute to improvements in investigation professionalism and quality, and which informed the research questions that underpin the current research.

The following cases are a small subset of published cases.

Case 1: HIQA Investigation into a delayed diagnosis of Breast Cancer (HIQA, 2008)
An example of:

• Failure by the HSE to conduct an investigation of a serious incident when it became apparent
• Failure of any investigation to identify the specific causes of this incident

This HIQA investigation (HIQA, 2008) identified that no investigation of this incident had occurred within the HSE at the time when it became apparent that a missed diagnosis had occurred. This highlighted the need for the HSE to have adequate structures and processes in place to thoroughly investigate all serious incidents when they occurred or became apparent.

The HIQA Report (HIQA, 2008) identified that a pathologist made an error by diagnosing a fibroadenoma from a Fine Needle Aspiration (FNA) specimen, that is - a non-malignant lump - when in fact the patient had breast cancer. However, the report did not explore why the pathologist made this error. That is to say, the report did not explore the causes of this error.

This HIQA report also stated that a subsequent multi-disciplinary team review was compromised by the fact that although the report of the FNA was
discussed at the meeting, no review of the slide took place nor was the reporting pathologist present. The report also noted that there was no arrangement in place for either the reporting pathologist, another pathologist, or the cytology slides to be present at this meeting. However, the report did not explore why this was the case. That is, it did not explore the causes of the unsatisfactory multi-disciplinary team review.

It is acknowledged that the terms of reference for the HIQA investigation did not require for the investigators to identify the causes of the original missed diagnosis. However, the fact of the matter is that the underlying causes of this incident do not appear to have been identified. The importance of identifying the causes of incidents did not seem to be broadly apparent at this time.

The fact that no investigation which focused on identifying the causes of this incident occurred meant that we had not learned whether the causes of this missed diagnoses:

- could re-occur at this hospital or elsewhere
- were limited to the pathological diagnosis of breast cancer
- could impact the pathological diagnosis of other conditions, or indeed
- could manifest in causing other types of harm at this hospital or throughout the health system

The learning from this case as it related to improving investigation practices was that:

- we need to be absolutely clear in policy and practice that all serious incidents should be thoroughly investigated when they occur/become apparent, and
- Incident investigations should focus on identifying causes of incidents

This case prompted the following questions:

- Can we develop and implement investigation guidelines to drive better identification of incident causes and consequently improve the potential to learn from incidents how to stop future harm arising from their causes?
- Can we develop a tool to evaluate investigation quality including evaluating how well investigations identify incident causes?

Case 2: Portlaoise Mammography Review (Doherty, 2007)

A second example of a review that failed to learn the specific causes of incidents

The Portlaoise Mammography issue related to concerns that had arisen when a nurse identified false positives in the diagnoses made by one consultant
radiologist. This meant that a radiologist was diagnosing cancer where in fact cancer did not exist. This in turn meant that patients were told they had cancer when in fact they did not. While this would have been very upsetting for patients, it was not as serious as a situation of false negative diagnoses whereby a patient would be informed that they did not have cancer when in fact they did, as this could result in a delay in starting treatment which in turn could result in significantly poorer outcomes for the patient.

The nurse in this case was concerned that if this radiologist was making false positive diagnoses - the radiologist might also be making false negative diagnoses. When this was reported to senior management, a decision was made to cease mammography services and to review the work of all of the consultant radiologists that were conducting mammograms at the hospital. When these mammograms were reviewed, nine cases of missed diagnosis of breast cancer were identified (Doherty, 2007).

The Portlaoise Mammography review involved a review of 3,037 mammography films. The rate of missed diagnosis for the radiologist about whom the concerns were originally raised was not significantly different compared with the rate of missed diagnosis for any of the other radiologists. Furthermore, the author of the review noted that the false negative rate identified within this review fell within the false negative rates published within other similar reviews (Doherty, 2007).

The learning from this case as it related to improving investigation practices was that:

- Firstly, if safety concerns are raised about an individual practitioner at one site, closer scrutiny may reveal similar issues in relation to other practitioners at the same site and possibly even at other sites throughout the system. This is particularly so where there is an absence of audit or other performance data to give assurance that this is not the case,

- Secondly, what may appear to be an issue of concern in relation to the performance of an individual practitioner (such as issues with performance related to diagnostic miss rates) may be revealed by closer scrutiny to be performance that is equivalent to the performance of other comparable practitioners at the same and other sites, and

- Finally, while this review had identified nine cases of missed radiological diagnosis of breast cancer, it did not thoroughly investigate the nine individual cases to identify the causes of the individual missed radiological diagnoses. Indeed, the author of the review stated that “Patients who have been diagnosed with breast cancer as a result of this review should be fully informed about the circumstances surrounding their initial misdiagnosis” (Doherty, 2007). While all nine patients were informed of the findings of breast cancer that arose from the investigations triggered by this review – they were not provided with a thorough individual
The latter point highlighted a missed opportunity to identify and learn from the causes of these missed diagnoses of breast cancer. While the Portlaoise Mammography Review did refer to the relatively high error rates in mammography cited in international mammography studies, and the fact that error rates in this case were within the expected error rates, it noted that standards require double reading and multidisciplinary assessments which were not in place at Portlaoise at this time which was prior to the establishment of BreastCheck\textsuperscript{14}. However, the word cause was not referred to once in this review. We had no idea following this review of the actual precise causes of the nine individual cases of missed radiological diagnoses of breast cancer. We did not know if the nine cases had the same causes, or if there were different causes for each of the nine cases. We did not learn whether the causes of these missed cancer diagnoses:

- could re-occur at this hospital or elsewhere
- were limited to the radiological diagnosis of cancer via mammography
- could impact the radiological diagnosis of other conditions using other diagnostic modalities, or indeed
- could manifest in causing other types of harm at this hospital or throughout the health system.

There were a lot of references in the literature at this time to the need to learn from incidents when they occurred, and answering the questions referred to in the bullets above is what learning from incidents means. However, it was not possible to find an example of a review that had occurred anywhere else in the world where the individual cases were investigated to identify specific individual causes of the specific individual adverse events. The Portlaoise Mammography Review itself had followed the methodology of a similar review conducted in Northern Ireland in 2005 (Wilson, 2005), which did not refer to the individual causes of the individual cases of missed cancer diagnosis either.

In response to this learning, the author advocated for the HSE’s first national guidelines and subsequent guidelines on conducting look-back reviews to include a clause that required for any serious incidents that were identified within such reviews to be subject to individual systems analysis investigations to identify the specific causes of the individual incidents (Health Service Executive 2008 & 2015).

In summary, the questions arising from this case that informed interventions the author led to attempt to improve investigation professionalism and

\textsuperscript{14} BreastCheck is a Government-funded programme that provides free mammograms to eligible women on an area by area basis every two years.
quality, and that informed the research reflected within this thesis are as for case 1 above as follows:

- Can we develop and implement investigation guidelines to drive better identification of incident causes and consequently improve the potential to learn from incidents how to stop future harm arising from their causes?
- Can we develop a tool to evaluate investigation quality including evaluating how well investigations identify incident causes?

Case 3: Review of Chest X-rays and CT scans in the North East (HSE, 2008)

A third example of a review that failed to learn the causes of the incidents that fell within the review

In May 2008 the SIMT took oversight of a major review of 5,835 chest x-rays and 67 CT scans in a total of 4,936 patients reported by an individual locum consultant radiologist at Louth/Meath Hospitals. The review was prompted by missed diagnoses in a small number of patients in two Louth/Meath Hospitals who later died from lung cancer. Nine cases of delayed diagnosis of lung cancer were identified from this review (HSE North East Radiology Steering Group, 2008).

This review differed from the Portlaoise Mammography Review (Doherty, 2007) referred to above in that it reviewed only the work of the individual radiologist about whom concerns were initially raised whereas the Portlaoise review considered the work of all the radiologists that did similar work at the particular site.

As for the Portlaoise Mammography Review, we did not learn from the North East Radiology Review about the specific causes of the individual missed diagnoses of lung cancer, or whether the causes of these missed lung cancer diagnoses:

- could re-occur at this hospital or elsewhere
- were limited to issues with the radiological diagnosis of lung cancer
- could impact the radiological diagnosis of other conditions, or indeed
- could manifest in causing other types of harm at this hospital or throughout the health system.

Again, the questions arising from this case that informed interventions the author led to attempt to improve investigation professionalism and quality, and that informed the research reflected within this thesis are as for cases 1 & 2 above.
The three cases referred to above all identified missed diagnosis rates that were within the so-called normal ranges of missed diagnoses identified in the literature and in similar studies internationally.

This meant that if missed diagnoses rates on X-ray, mammogram, CT, and pathology were reviewed at any other hospital in Ireland or at hospitals in other developed countries, similar rates of missed diagnoses would probably have been identified at these other sites.

These three reviews were conducted in a context of intense political and adverse media attention that appeared to view these cases as exceptional. However, the fact of the matter was that, while the individual cases of missed diagnosis were deeply tragic and sad, the missed cancer rates were not exceptional.

Dekker (2006) described accidents as arising from the normal workings of a system; and as a systemic by-product of people and organisations trying to pursue success with imperfect knowledge and under the pressure of resource constraints. If we consider accidents as arising from the normal workings of a system, and if we investigate the system thoroughly to understand the normal workings of that system that contributed to the accident, we can learn how to improve its normal workings to in turn reduce the rate of accidents.

Translating this logic to the healthcare context of cases 1, 2, and 3 above means that if we consider the so-called normal cancer misdiagnosis rate as part of the normal working of the system - and if we investigate the normally occurring misdiagnoses to identify their causes – we could learn much from such investigations about how to reduce the normal miss rate resulting in improved outcomes for our service users.

Yet, it seemed that these three reviews - and similar reviews in other jurisdictions, and the associated media coverage and political commentary – were not at all focused on this point of trying to learn from the so-called normal miss rate to reduce it even further. Rather they seemed to be focusing on simply counting the misses; they appeared to be surprised at the results; and they searched for someone to blame for it. There appeared to be more of a focus on asking emotionally “why does this keep happening?” and seeking to find people to blame for this - rather than focusing logically on asking “why did
this happen in the first place? “ to identify causes so as to address them to stop them resulting in future harm. Without a focus on identifying and addressing causes - there could be no assurance that the solutions that were put in place would address the underlying causes and consequently, would result in better outcomes for our service users. None of the reviews referred to above, nor indeed any other similar reviews - were focusing on identifying “why” these missed diagnoses were occurring in order to learn how we could prevent future harm to our service users from the causes of these specific adverse events.

These missed cancer diagnoses cases resulted in significant harm and tragic experiences for our service users and their families including lost opportunities for cure, and significantly poorer outcomes including reduced life expectancy and delays in accessing palliative care. A lot of time and energy was invested in case 2 and 3 in identifying the cases of missed diagnoses and in disclosing this to the service users and/or their loved ones and such disclosure was appropriate. However, after all that time and energy was expended in these reviews, we had not learned what caused these tragic events. The realisation of this stark reality was a major trigger in prompting the author to undertake the current research.

2.3.4. Cases that highlight some progress in HSE investigation quality

Cases 4 and 5 below describe cases which implemented the learning that was derived from cases 1 – 3 above and how this contributed to improved investigation professionalism and quality.

Case 5 shows that a high quality, reliable investigation can be completed in a very timely manner.

But first, case 4 below describes evidence that implementing learning about how to improve investigations contributed to judgements by the public that investigations were thorough and of reasonable quality.

Case 4:
National Miscarriage Misdiagnosis Review (Ledger et al, 2011)
An example of a review:
- That sought to identify the specific causes of individual cases of
That demonstrated that findings from clinical review of case notes did not identify any additional causes of incidents that were not identified by systems analysis investigations.

That demonstrated that the causes identified following thorough investigation differed from the apparent causes prior to thorough investigation.

Where the woman that the original concern was related to was quoted in the national print media as stating that she felt the investigation was “.... very thorough”.

On the 9th of June 2010, reports of two cases of miscarriage misdiagnosis were reported in the Irish news media. This meant that a diagnosis of miscarriage had been made in error for both of these women, and that medical or surgical intervention was recommended to the women, but subsequently it was found that the pregnancies were viable and the women went on to continue their pregnancies. Over the following weeks, several other women raised similar concerns with their hospitals.

This resulted in the commissioning of the HSE’s National Miscarriage Misdiagnosis Review in June 2010. At that time, the author was the Director of the Serious Incident Management Team (SIMT). The author was appointed to the role of Chair of the SIMT which was established to manage this incident. Professor Bill Ledger, then Head of the Academic Unit for Reproductive and Developmental Medicine at the University of Sheffield – was appointed as the External Independent Chair of the National Miscarriage Misdiagnosis Clinical Review Team.

The original proposed approach for the miscarriage misdiagnosis review was to assess the conformance of the 18 Early Pregnancy Assessment Units (EPAUs) across the country with accepted standards for the management of early pregnancy. Following the author’s reflections on the experience of the Portlaoise Breast Cancer Review (HSE 2007), the HIQA investigation of Rebecca O’Malley’s delayed diagnosis of breast Cancer (HIQA 2008), and the North East Review of Chest X-rays (North East Radiology Review Group, 2008) as referred to in cases 1, 2, and 3 above the author proposed that:

(i) in addition to conducting assessments of the conformance of the EPAUs with agreed standards, we should also consider individual investigations of each woman’s case to identify the causal factors of identified individual cases of miscarriage misdiagnosis.

(ii) that the women should get both their individual systems analysis investigation report and the overall National Miscarriage Misdiagnosis Review report which would be informed by the individual investigation reports.
It was acknowledged that what is set out in (i) and (ii) above was not an approach that had ever been used before. But the approach was agreed.

On this basis - the Terms of Reference for this review specifically included the following:

“The satisfactory investigation of cases (systems analysis) to determine the causes”

So, unlike the earlier reviews referred to in cases 1, 2, and 3 above, the purpose of this review was not only to identify cases, it was also to identify the causes of the miscarriage misdiagnoses and to recommend actions necessary to address these causes so as to prevent recurrences of future harm as far as possible.

The stated objectives of this review were:

1. “To review the hospital systems analysis investigations undertaken of the cases submitted to the review team and additional specific clinical information in relation to cases identified to identify the causes of specific cases and recommended actions to address them, and

2. To review the arrangements in the EPAUs and whether they adhered to acceptable standards”.

The National Miscarriage Misdiagnosis Review (Ledger et al, 2011) was published in April 2011.

The findings from each individual systems analysis investigation (N=24 in this case), together with the findings from the review of individual cases by the National Miscarriage Misdiagnosis Clinical Review Team, were used to develop a series of recommendations for improvement in services.

Although the report states that there was evidence of variation in how systems analysis investigation methodology was applied by different hospitals, overall the clinical review team noted that they were reassured that when the contributory factors and recommendations identified in each of the systems analysis investigation reports were aggregated, they supported the findings and recommendations made by the clinical review team following consideration of the clinical details from the healthcare records of the referred cases.

There were no causal factors identified within the clinical review of the healthcare records of the individual cases that had not been identified within the systems analysis investigation of the individual incidents.

A joint letter was sent by the Chief Medical Officer at the Department of Health and Children, and the National Director for Quality and Clinical Care (QCCD) within the HSE on the 10th of June 2010 (i.e. immediately prior to the commencement of the National Miscarriage Misdiagnosis Review), to all public and private obstetric and gynaecological facilities in Ireland. The letter
advised these facilities to immediately ensure that the decision to use drugs or surgical intervention in women who had a diagnosis of miscarriage was always approved by a Consultant Obstetrician. This was on the basis that there was a sense prior to the review that involvement of Consultant Obstetricians in the decision to use drugs or surgical intervention was necessary to prevent Miscarriage Misdiagnosis. However, analysis of the data collected within this review identified that the primary diagnosis of miscarriage was made by Registrar level doctors in 54% of cases (n=13), Consultant level doctors in 25% of cases (n=6), and by Senior House Officers in 21% of cases (n=5). So, Consultants were identified to make miscarriage misdiagnoses. Therefore, involving Consultants more in diagnoses of miscarriage was unlikely to be the optimum solution to favourably impact the rate of miscarriage misdiagnosis. On the other hand, the analysis within the Miscarriage Misdiagnosis Review did identify other causes of miscarriage misdiagnosis. For example, it identified that there was an apparent lack of awareness amongst clinicians that just because a clinician did not hear a baby’s heartbeat, did not necessarily mean that the heartbeat did not exist, and that it could mean that the heartbeat was too quiet to detect. Thus, interventions to raise the level of awareness about this amongst clinicians were likely to have a greater impact on improving the rate of miscarriage misdiagnosis than interventions to involve Consultants more in the diagnosis.

The learning from this was that the causes of incidents and the recommendations to address them as identified following thorough investigation could be quite different to what the causes and recommendations appeared to be before thorough investigation. This is not a criticism of the letter sent by the Chief Medical Officer and the National Director of QCCD in the HSE of the 10th of June 2010 as referred to above. Chapter 1 shows that many studies focus on quality improvements based on “surmised” causes of incidents reported to national incident reporting systems and which have not had thorough individual investigations. It seems reasonable to assume that diagnosis may be enhanced by senior clinical input. And it is important to put interim safety measures in place until investigations are completed. However, the experience of this case shows that it is also important to be aware that such interim safety measures are based on incomplete information and that more thorough data collection and analysis may reveal quite a different picture of incident causes and solutions.

Following publication of this report - the woman whose concerns triggered this national review was quoted in the national print media as stating the following about the Miscarriage Misdiagnosis Review report:

- “I feel they left no stone unturned…..I feel it is very thorough”.

So this investigation report was considered to be thorough by a woman that was affected by the incident.
However, the National Miscarriage Misdiagnosis Review also demonstrated that there was evidence of variable compliance with the principles of systems analysis investigation methodology. While the majority of the investigations were fully compliant with guidelines, in some, the chronology sections of the reports were lacking in detail. Other elements required of the systems analysis methodology were not included in some cases. For example, some individual investigations which had been completed prior to the commencement of the Miscarriage Misdiagnosis Review did not include interviews with the women concerned. So this was a lost opportunity to incorporate the voice and the experience of the women involved into the review process in some cases. The report sections that showed most evidence of variable compliance were those sections describing Care Delivery Problems and Contributory Factors. This was in line with the findings of Wallace et al., (2006).

The National Miscarriage Misdiagnosis Review report stated that experienced systems analysis investigators had confirmed that the most difficult aspect of conducting a systems analysis investigation was in the correct and appropriate identification of the Care Delivery Problems. The report considered that this may have accounted for the absence of a documented Care Delivery Problem in some of the reports reviewed, and the deficiencies in how these were described in others.

With hindsight, while it was a sign of progress that a National Review of this nature was for the first time focusing on identifying the causes of the adverse events within the review - it should not be surprising that deficiencies in systems analysis investigations were identified. The Toolkit of Documentation to Support the Health Service Executives Incident Management (Health Service Executive, 2009) was only published in early 2009. A HSELand training course was developed to support implementation of the Toolkit. However, beyond this, there was no strategic approach to identifying HSE investigators and to delivering formal support to build their capability and professionalism as investigators. There was no process to ensure that the investigators that conducted the investigations that fell within this review had attended the HSE training. There was no proactive mechanism of evaluating the quality of investigations to identify for investigators and the organisation whether investigation quality was satisfactory or whether aspects of investigation quality needed to improve and how this could be achieved – prior to

---

15 The Toolkit of Documentation to Support the Health Service Executive Incident Management (2009) referred to Care Delivery Problems (CDP’s) as follows: “CDP’s are problems that arise in the process of care, usually through actions or omissions by employees. Several CDP’s may be involved in one incident. CDP’s have two essential features:

(i) care deviated beyond safe limits of practice
(ii) the deviation had at least a potential direct or indirect effect on the eventual adverse outcome for the service user, employee or general public.”
The tool that was used to evaluate the quality of the individual serious incident investigations within the miscarriage misdiagnosis review after submission to the clinical review team in this case was developed from a tool previously commissioned by the Head of Quality and Risk and developed by the Quality and Patient Safety Office in the Dublin Mid-Leinster Region. This case showed that it was important to be able to evaluate the quality of investigations. Consequently the evaluation tool used in this case went on to be developed into the Audit Tool that was published within the 2012 Guidelines for the Systems Analysis Investigation of Incidents and Complaints. This in turn informed the Investigation Quality Evaluation Tool (IQET) developed as part of the research reflected in this thesis.

As stated, in this case, a woman harmed commented positively on investigation thoroughness which seemed to be an indicator of public confidence in investigation quality. This contributed to the evolution of the following questions which informed the research questions in this thesis:

- This review was referred to as “thorough” by a service user. Thoroughness would seem to be an important aspect of investigation quality for service users. What are the other important aspects of investigation quality?

- The service user voice and experience was captured in this review via interviews in the cases that were investigated by hospitals following the commencement of the National Miscarriage Misdiagnosis Review. Hospital investigators were supported in this by the National Miscarriage Misdiagnosis Review Team. The voice and experience of the women was important in contributing to the thoroughness and quality of the review. However, some hospital investigations which were completed before the commencement of the National Review did not include interviews with the women. This prompted the question as to whether the service user voice and experience was being captured in investigation interviews generally and what was the impact of this on investigation quality?

- What are the other factors that contribute to investigation quality?

- Can we develop a reliable tool to collect the data referred to in the previous bullets, and to evaluate investigation quality, and to identify the factors that affect investigation quality?

Case 5:
Investigation of the failure to transport a young patient for transplantation surgery (Health Service Executive, 2011)
An example of an investigation that:

- Was completed in a timely manner (i.e. within five weeks)
- Was found to be reliable

The first published HSE investigation report that followed the Toolkit of Documentation to Support Incident Management (Health Service Executive, 2009) related to the failure to transfer a young person to Kings College Hospital in London for Transplantation Surgery on the 5th of July 2011 (Health Service Executive, 2011). This investigation was commissioned by the HSE Serious Incident Management Team (SIMT). The author was the Director of the SIMT at the time and she was appointed as the Chair of the Investigation Team in this case. The second investigator was the lead investigator. This investigator had significant knowledge and experience of developing investigation guidelines, conducting investigations, and delivering investigator training.

The Health Information and Quality Authority (HIQA) have a policy of not investigating individual incidents. However, shortly after the HSE commenced this incident investigation, the Minister for Health announced that HIQA would also be conducting an investigation of this incident.

The lead investigator and the author were required to prioritise this investigation over our other work priorities. We were given protected time to do this. Our HSE investigation involved interviewing 19 individuals from both within and outside the HSE, in addition to exhaustive factual accuracy checking of the draft reports with all 19 interviewees including the patient’s parents. Both the HIQA and the HSE investigations of this incident were published on the same day namely the 12th of August 2011. This was approximately five weeks after the respective investigations commenced.

Only one recommendation differed significantly between the HSE and the HIQA report whereby the HIQA report stated that the “HSE, in collaboration with OLCHC16 and KCH17, should discuss with the parents/guardians of children who are escalated on to the KCH priority transplant list the consideration of relocation of the patient and their parents/guardians to Dublin or London. If this is deemed to be appropriate, and requested by the parents/guardian, then the HSE should, in conjunction with OLCHC and KCH, facilitate this”. This was not identified as necessary based on the data collected and analysed within the HSE investigation, as if all the recommendations of the HSE investigation were implemented, there should not be a recurrence of the failure to successfully transport a child for transplantation surgery in similar circumstances in the future. Therefore, the HSE investigation could not justify the relocation of children and their parent(s)/guardian(s), and possibly separating them from the rest of their families, and possibly taking them from

---

16 OLCHC: Our Lady’s Children’s Hospital Crumlin
17 KCH: Kings College Hospital (i.e. London)
their normal school/work environment etc., on the basis of the data collected and the causal factors identified. Subsequently, the HSE found that it was not appropriate to put in place a process for relocating families in this circumstance.

No other causal factors or contributory factors were identified within the HIQA investigation report which were not identified within the HSE investigation. This demonstrated that trained and experienced HSE investigators that followed HSE investigation guidelines and who were given protected time to prioritise investigation work were able to conduct a reliable investigation in a timely manner. It also demonstrated the potential for thorough HSE investigations to contribute important information for management decisions.

The learning from this case contributed to the evolution of the following research questions which informed the current research:

- How timely are HSE investigations; what factors contribute to the timeliness of investigations; and what impact does timeliness have on investigation quality?
- And again, can we develop a reliable tool to evaluate investigation quality (including timeliness and reliability) and to collect data from investigation reports about factors that affect investigation timeliness and quality?

2.4. Initiatives taken to improve incident investigation professionalism and quality

This section outlines some key initiatives which were undertaken in an effort to make the investigation process more consistent and more professional. These initiatives included the development of (i) updated investigation guidelines (Health Service Executive, 2012), and (ii) training for investigators. To a large extent, this research tests the assumptions of these improvement initiatives. The development and implementation of these initiatives was extremely challenging in the context of a health system that was in almost constant transformation as shown previously in this chapter.

2.4.1. Updating investigation guidelines

In 2009 when the author was the systems analysis investigation advisor to the SIMT, she was assigned to lead a process to develop enhanced systems analysis investigation guidelines. The author became Chair of the HSEs “Investigation Process Working Group” (IPWG) which used an action research approach culminating in the publication of the HSE’s guidelines for the
Systems Analysis Investigation of Incidents and Complaints (Health Service Executive, 2012).

Action research is defined by Stringer (2013) as solutions-oriented investigation leading to resolution of issues investigated. Stringer states that a basic action research routine includes repeated cycles of investigation based on a Look, Think, Act routine as follows:

(i) Look: Acquiring information
(ii) Think: Reflecting on the information gathered
(iii) Act: Planning practical steps toward resolution of the issue investigated

Stringer (1999 & 2013) goes on to state that applying participatory approaches to investigation stimulates feelings of pride, dignity, identity, control, responsibility, and unity.

In line with the approach to action research set out by Stringer (1999 & 2013) the author took the role of researcher as facilitator and catalyst, ensuring full participation of all relevant stakeholders encouraging all to contribute to the improvement of investigation guidelines. Work was done to ensure optimum (i) relationships (ii) communication (iii) participation, and (iv) inclusiveness in line with good practice in action research.

An exhaustive list of stakeholders was engaged in updating the investigation guidelines including the following:

- Service users who were harmed by healthcare and service user representatives
- Staff who commission investigations
- Staff who conduct investigations
- Staff who implement learning from investigations
- Staff who have a role in quality, risk and safety
- Staff who have a role in delivering community and acute hospital services
- Unions and partnership fora
- Health Intelligence experts
- Communications experts
- Advocacy practitioners
Human Resources representatives
- National and international general safety experts, and
- National and international patient safety experts

The IPWG conducted consultation and engagement with staff and service users and a range of other external stakeholders including the Department of Health and Children; HIQA; the Health and Safety Authority (HSA), and the Forum of Health and Social Care Professionals. A Technical Reference Group (TRG) and a Trade Union Reference Group (TURG) was also established.

A draft updated HSE Investigation Procedure was developed by the IPWG and a series of nine consultation and engagement workshops took place across the HSE in May and June 2010 including workshops in Galway, Kilkenny, Cork, Limerick, Tullamore, Ardee, and Dublin.

Eight out of nine of these workshops included HSE employees and service users together, and one of the workshops was held for service users alone. Over 320 staff and service users attended the workshops where participants made a highly positive contribution to the HSE investigation process work. The workshops used focus group and survey methods to gain participants (i) experience of and attitudes towards HSE investigation processes to-date, and (ii) their reaction to the proposed updated investigation procedure. Data collected from focus groups at these workshops, and evaluation of workshop questionnaires completed by workshop participants indicated that participants had a lot of views and experiences to offer and to inform the investigation process work, and that participants found the workshops to be helpful in ensuring that their views and experiences informed this work (Health Service Executive, 2010).

Specifically, 83% of participants indicated via workshop evaluation forms that they were satisfied or very satisfied with the proposed investigation procedure and 73.4% believed the procedure to be an improvement on existing procedures (Health Service Executive, 2010).

The IPWG finalised the updated investigation guidelines based on the feedback from:

- the consultation and engagement workshops with staff and service users referred to above
the Technical Reference Group (TRG)

the Trade Union Reference Group (TURG)

regulators

national and international general and patient safety experts.

Following legal review, the work of the IPWG culminated in the publication of the Guidelines for the Systems Analysis Investigation of Incidents and Complaints in November 2012 (Health Service Executive, 2012).

The five most significant changes in the updated investigation guidelines compared with the earlier version were as follows:

(i) It was explicit that the guidelines applied to the investigation of incidents that had been identified through the complaint management process

(ii) It was explicit that investigations should proceed even if other investigations were on-going or anticipated such as criminal investigations by An Garda Síochána (i.e. the Police Service of the Republic of Ireland); investigations by Professional Regulators such as the Irish Medical Council (IMC) or the Nursing and Midwifery Board of Ireland; investigations by General Regulators such as HIQA, the MHC or the HSA, and investigations arising from civil litigation managed by the State Claims Agency (SCA)

(iii) It moved from an “epidemiological” model of accident causation (i.e. Reasons Model of accident causation) to a “systemic” model of accident causation. Latent and active failures were not referred to in the updated guidelines. Further details of this are outlined below.

(iv) The term “Care Delivery Problems” was replaced with the terms “Key causal factors” and “Incidental Findings”. Further details of this are outlined below.

(v) The inclusion of an audit tool for use by investigators and investigation commissioners to assess compliance of investigation reports with the guidelines. Further details of this are outlined below.
Move from the epidemiological model to the systemic model

The HSE Toolkit (2009) referred to Reasons model of accident causation (1995, 1997, & 2000) including references to “active” and “latent” failures; layers of defence to prevent accidents; and how holes in these layers of defence lined up to cause an accident trajectory. Dekker (2006) described accident models such as Reasons Model of accident causation as the “Epidemiological model” which considered that accidents could be prevented by identifying and knocking out resident pathogens, or by making sure they did not get activated. Dekker (2006) stated that, though this model oversimplified accident causation, it had been helpful in portraying the imperfect organisational structures that let accidents happen. But this model did not specify much about the processes that created the holes in the layers of defence, nor how active and latent failure interacted (Dekker, 2006).

The experience of using the HSEs 2009 Toolkit, including using it in the National Miscarriage Misdiagnosis Review as per case 4 above - did seem to help investigators to focus more on the imperfect organisational structures that let incidents occur as opposed to overemphasising the errors made by the Healthcare practitioners at the so-called “cutting edge” of the system. However, there was no data generated from the application of this investigation approach that enhanced our understanding of the processes that created the holes in the layers of defence, nor how active and latent failure interacted.

As stated, based on learning from this experience - the 2012 Guidelines no longer referred to “latent” and “active” failures. Neither did they refer to Reasons Model of Accident Causation. However, reference to these continued in investigation training to support implementation of the guidelines as they were found to be helpful in encouraging investigators to consider all of the information gathered, including information related to organisational causes of harm in addition to information related to actions and decisions of individuals at the coal face of service delivery. In this context the two theories of accident causation, i.e. the systemic and the epidemiologic, were considered to be complimentary and useful when used in conjunction with each other.
Evolution of the term “Key Causal Factor”

As shown in case 4 above, there was evidence that investigators found the correct categorisation of data derived from investigations as “Care Delivery Problems” as per the London Protocols (Taylor-Adams, et al, 2004) to be challenging. This was in line with findings of Wallace et al., (2006 & 2009) and Percarpio et al., (2008). This triggered a process of evolution from the use of the term “Care delivery problem” to use of the term “key causal factors (KCF)” which is described in a paper by McCaughan et al (2013) as follows:

This paper described that there was a need to enhance investigation guidance particularly in relation to the definitions of “care delivery problems” and “service delivery problems” and to clarify the need for each problem to be analysed to find contributory factors to enable investigators to focus on specific incident causes and remedies as far as this was possible. It described that, in 2010, the Investigation Process Working Group (IPWG) proposed replacing the two terms “care delivery problems” and “service delivery problems” with a single term “deviation from safe/acceptable practice” which was defined as:

“Issues that arise in the process of delivering and managing health services, usually actions or omissions by members of staff”.

Deviations from safe/acceptable practice were further described as having one essential feature, namely:

“The deviation had a direct effect on the eventual adverse outcome for the individual(s) harmed”.

This paper described the consultation and engagement which culminated in further changes to the definition of “Deviation from safe/acceptable practice” to the following:

“Deviations from safe/acceptable practise are defined as issues that arise in the process of delivering and managing health services where the deviation(s) had an effect on the eventual adverse outcome”.

The rational for the changes are noted within this paper by McCaughan et al., (2013) as follows:
A difficulty was highlighted with the reference in the existing definition to "Acts or omissions by members of staff". It was considered that this might put an unhelpful emphasis on the "individual" factors that might contribute to incidents and an under emphasis on other factors which might contribute to incidents. It was highlighted that this in turn could contribute to a problem of an organisational tendency to unfairly blame individuals rather than considering incidents very impartially, methodically and systematically. It was also highlighted that the entire framework of contributory factors should be used in any incident investigation and a definition that focused on only one element of this framework (i.e. individual factors only) might be unhelpful.

Members of the IPWG Technical Reference Group (TRG) highlighted a difficulty with the following reference in the existing definition “The deviation had a direct effect on the eventual adverse outcome for the individual(s) harmed”. Specifically, the IPWG TRG highlighted that there could be deviations that could have an effect, albeit not necessarily a "direct" effect on the eventual adverse outcome - which would be important to include in investigations, hence the recommendation to delete the word "direct" from the definition.

Finally, the IPWG TRG identified that the reference in the definition to "individuals harmed" could be an obstacle to applying the investigation methodology to incidents that do not result in clear/direct harm to people such as a PPARS (i.e. Personnel Payroll and Related Systems) incident; data protection incidents etc.,. Hence, this reference was removed from the definition.

Further consultation and engagement on the updated draft guidelines occurred in May and June 2012. Changes based on feedback included replacing the term "deviation from practice" with the term "Key Causal Factor" which was defined in the final published version of the guidelines as:

“Key Causal Factors (KCFs): Issues that arose in the process of delivering and managing health services which had an effect on an eventual adverse outcome”
Evolution of a tool to audit conformance with guidelines

A report commissioned by the National Director for Quality and Patient Safety to identify any learning from serious incident investigation reports completed between 2009 - 2012 (Mullens and Crowley, 2013) identified that:

“The reports are variable in terms of whether or not they are in the standard HSE format. This improves in the latter reports from the time period. It is worth monitoring the use of standardised investigation methods and report formats as it results in a much clearer and more comprehensive picture and is much easier to draw conclusions from”

The investigation guidelines within the Toolkit (Health Service Executive, 2009) included a template investigation report to help ensure standardisation of investigation reports. The 2012 investigation guidelines included an enhanced template investigation report based on learning from the experience of using the template in the 2009 toolkit, and the consultation and engagement process referred to in the previous sections of this chapter. When the 2012 investigation guidelines were in development, it was identified that a tool to audit conformance with the guidelines should be included within the guidelines. For the first time in national HSE investigation guidelines - an audit tool was included in the 2012 investigation guidelines (Health Service Executive, 2012). As stated previously, the audit tool that was used to evaluate the quality of the individual serious incident investigations within the miscarriage misdiagnosis review (Ledger, et al, 2011) was developed from a tool previously commissioned by the Head of Quality and Risk in the HSE and developed by the Quality and Patient Safety Office in the Dublin Mid-Leinster Region. This tool went on to be developed into the Audit Tool that was published in the 2012 Guidelines for the Systems Analysis Investigation of Incidents and Complaints.

2.4.2. Delivery of training to support implementation of the guidelines

The evidence base for investigator training

At the time of publication of the HSE’s 2012 investigation guidelines (Health Service Executive, 2012) - very little literature was identified related to training healthcare incident investigators. Some literature referred to the need for
detailed cognitive human factors training (Bagian et al., 2001). One paper referred implicitly to the need for investigators training in areas such as critical thinking, and data collection and categorisation (Carrol et al., 2002). Other papers conveyed the need for on-going continuous development, support and feedback for investigators (Wallace, (2006); Wallace et al., (2006) & (2009)).

Bagian et al., (2001) stated that RCA (i.e. Root Cause Analysis) training material asked RCA teams to look for the sources of error in the system of care but did not equip RCA teams, beyond a rudimentary introduction to human factors concepts, with detailed cognitive human factors training needed to make practical recommendations that addressed the system complexity.

In a paper by Carroll et al., (2002), these authors referred to aspects of rigor in information analysis to identify causes of incidents such as (i) critical thinking, and (ii) processes for categorising the quality of data used to establish causes. Although these authors did not explicitly refer to investigator training, it seemed implicit in this that investigators should receive training in critical thinking skills and data categorisation.

One study considered the experience of healthcare professionals who attended Root Cause Analysis (RCA) training (Braithwaite et al., 2006). In this study, participants of RCA training reported improved skills and commitment to safety; and that the investigations they conducted had contributed to safety improvements. However, RCA trainees reported problems with having protected time and resources to conduct investigations, lack of feedback and, a need for additional training and greater support to maintain momentum.

The National Patient Safety Agency (NPSA) in the UK developed a 3-day RCA train-the-trainer programme which was delivered by pairs of the 34 Patient Safety Managers employed by the NPSA to work with local health boards in Wales and Strategic Health Authorities and their geographically associated NHS trusts in England. There were also internet-based self-study tools and materials to assist with the teaching of, and conduct of RCAs (http://www.npsa.org.uk ). The NPSA trained over 7000 staff in two years, offering at least eight fully funded places to each of the 607 trusts in England and Wales.
Wallace (2006) referred to a study which examined the application of RCA in eight case study sites. This study included interviews with staff who conducted RCAs, and a critical examination of their nominated “best” or “exemplar” RCA from seven Trusts involving a blind critique of submitted RCAs by a former Head of Investigations at the former National Patient Safety Agency in the UK. This reviewer produced a critique against the main elements of RCAs as taught in the programme, and a Strengths, Weaknesses, Opportunities and Threats framework against the standards and guidance of RCA in the NPSA materials (Wallace, 2006). This identified evidence of exemplary practice in two investigation reports, with less depth of analysis and thoroughness in implementation in three, and scant evidence of recognisable features of RCAs in the exemplar reports from two trusts (Wallace, 2006).

The full report of this study (Wallace et al., 2006) identified some weaknesses, for even the most complete RCAs, requiring more focus on use of Care/Service Delivery Problems or issues, contributory factors and root causes, as, the report highlighted: “…these are integral to understanding the causes and possible remedies and preventive actions”. This highlighted the importance of investigators having, and adhering to clear definitions of causal factors. The final comment and recommendation of this report included that: “…the NPSA can add to wider learning by ensuring that innovations in RCA ….are evaluated....”

Evidence based investigator training design and delivery

At the time of the publication of the HSEs Guidelines for the Systems Analysis Investigation of Incidents and Complaints (Health Service Executive, 2012), the author was the only member of the National Incident Management Team (NIMT) that had training and experience in conducting investigations and she was fully occupied in the role of deputy chair of a Maternal Death investigation referred to in Chapter 7, and other NIMT work. Immediately following the publication of the Maternal Death investigation report in June 2013 (Arulkumaran et al, 2013), the author commenced design and delivery of investigation training to support implementation of the newly published investigation guidelines. This training was based on:
(i) the experience the author and others had gained from delivering investigator training within the HSE (most notably being based on training that had been delivered in the former Dublin Mid-Leinster Region), since 2004, and

(ii) the evidence identified within the literature at that time and as outlined earlier in this chapter.

The target group for this training was individuals nominated from within services that would have a role in conducting serious incident investigations.

Training material was developed including (i) Reading material for participants, (ii) PowerPoint presentation, and (iii) Scenarios developed for role play and group work.

A systems analysis investigation training brochure was developed which outlined the purpose and content and other details of this training\(^{18}\).

The purpose of this training as stated in this brochure was:

“... investigators will learn and practice how to conduct systems analysis investigations of incidents and complaints in accordance with HSE guidelines (Health Service Executive, 2012).”

The stated objectives of this course were that participants would be able to:

- Organise the investigation and gather the data
- Determine the incident chronology
- Know when and how to seek external expert input
- Identify the key causal factors and incidental findings
- Identify the contributory factors
- Make SMART\(^{19}\) recommendations according to the hierarchy of preferred control measures
- Write and submit investigation reports that are valid, reliable and generalizable
- Know when and how to seek legal input/review

---

19 SMART: Specific, Measurable, Achievable, Realistic, and Time-bound.
The course duration was one full day plus two separate half days at approximately three month intervals. Following attendance at the first day of training, trainees were to be assigned a serious incident to investigate with a more experienced investigator - by the division that nominated them to attend the training. Trainees were to be mentored and supported in doing this by the lead for incident management in the area they were nominated to this training from. Details of the course content and how it was divided out throughout the three days is reflected in appendix 1.

**Trainers**

From June 2013 to October 2014, the author was the only NIMT investigation trainer and she had limited time to deliver this training. In October 2014, four additional trainers were added enabling for a greater number of investigation training sessions to be delivered.

These trainers had extensive training and experience in managing and investigating incidents at local and national level. They also had extensive experience of writing local and national incident management and investigation policies and guidelines.

**Course Award**

The NIMLT (and formerly the NIMT) collaborated with nursing and medical bodies to arrange the following accreditation for attendance at this investigator training course:

- Doctors who attended the one day systems analysis training received a certificate of attendance and 5 CPD (Continuous Professional Development) credits from the Royal College of Physicians of Ireland (RCPI); 3 CPD credits for attending the interim follow up and networking session; and a further 3 credits for attending the final networking and debriefing session.

- Nurses who attended for the entire course received 10.5 CEU (Continuing Education Units) from the Nursing and Midwifery Board of Ireland (NMBI, formerly An Bord Altranais).
Course Methodology

The course used a combination of training methodologies including (i) pre-course reading material, (ii) didactic presentations, (iii) discussions, group work, and role play, and (iv) a practical real serious incident investigation exercise.

Findings of analysis of participants’ feedback

Analysis of the completed Feedback Forms for investigation trainees that attended day 1, day 2, and day 3 training between June 2016 and June 2017 (Health Service Executive National Incident Management and Learning Team, 2013) is outlined below:

Day 1 training

- More than 83% of participants rated the segments of the training related to the six steps of carrying out a systems analysis investigation in line with HSE guidance as excellent or very good;
- 92% rated the practical session involving a role play interviewing exercise and follow up group discussion as excellent or very good
- 79% rated the pre-course reading information sent to them as excellent or very good
- The overall course content was rated by 89% of participants as excellent or very good,
- The trainer’s knowledge of the investigation process was rated as good or excellent by 97% of participants

Day 2 training

- 97% of participants strongly agreed or agreed that the training would help them to better fulfil their role as investigators
- 50% rated the opportunity to present the work of their Investigation team and the opportunity to get feedback from other participants as excellent or very good (Note: Some participants were not assigned investigations to conduct following day 1 training and so would not have had an investigation to present)

20 This training at this time had not changed from the time it commenced in 2013.
81% rated the opportunity to learn from other investigation teams about their investigation work as excellent or very good.

The pre-training information received was rated as excellent or very good by 75% of participants.

**Day 3 training**

98% of participants strongly agreed or agreed that the training would help them better fulfil their role in investigating an incident/complaint according to the HSE Guidelines for Systems Analysis Investigation

88% strongly agreed or agreed that they would feel confident to participate as an investigator of an incident/complaint investigation using the HSE Guidelines following training

60% rated the opportunity to present the work of their Investigation team as excellent or very good (Note: Not all participants were assigned an investigation to conduct and so these participants would not have had an investigation to present)

62% rated the opportunity for their investigation team to get feedback from other participants/mentors about their investigation to date as excellent or very good (As, above - not all participants were assigned an investigation to conduct and so these participants would not have had an investigation to present)

95% rated the opportunity to learn from other investigation teams as excellent or very good

74% rated the pre-training information provided as excellent or very good.

A table showing sample comments from participants of day 1, day 2, and day 3 training is included in appendix 2.

**2.5. Discussion**

This chapter presented the history of the HSE which was the organisational context within which this research was conducted. It showed that the HSE has been continuously significantly restructuring, dividing, merging and transforming since it was established in 2005, and the challenges this poses to developing, maintaining and evaluating consistent high-quality investigation practices.
Interventions to improve the professionalism and consistency of the investigation process were described.

Incident investigation cases were presented which developed the idea that learning from incidents is not straightforward or automatic and that effectively deriving the learning requires a level of professionalism and consistency in the investigation process. It also requires a paradigm shift from seeking to answer the question: “Why does this harm keep on happening?” before we have properly answered the question: “Why did this harm happen in the first place?” That is, a need to focus on identifying the causes of incidents.

Research questions arising from the investigation experience reflected within the case studies are as follows:

- In addition to thoroughness, reliability and timeliness, what are the other important aspects of investigation quality?
- Is the service user voice and experience being captured in investigation interviews and what is the impact of this on investigation quality?
- What are the factors that affect investigation quality?
- Can we develop a reliable tool to (i) evaluate investigation quality (including evaluating how well investigations identify incident causes), and (ii) which collects data from investigation reports about factors that may affect investigation quality?
- Can investigation guidelines and investigation training improve investigation quality including improve identification of incident causes and consequently improve the potential to learn from incidents how to stop future harm arising from incident causes?

To a large extent, the research reflected within the remaining chapters of this thesis focuses on determining whether the guidelines and training described in this chapter did or can result in better quality investigations and consequently - more effective learning from incidents to leverage system wide safety improvement.
Chapter 3 - Study 1

Developing a reliable tool to evaluate investigation report quality.

Overview of chapter 3

3.1. Introduction: Review of the literature to identify quality markers and evaluation tools

- VA NCPS\textsuperscript{21} Investigation Quality Evaluation Tool
- NPSA\textsuperscript{22} RCA\textsuperscript{23} Investigation Quality Evaluation Tool
- The Rationale for developing an exhaustive IQET\textsuperscript{24}

3.2. Method: The iterative action learning approach for developing IQET

- **STEP 1:** Checking the evidence base for developing IQET 1
- **STEP 2:** Qualitative inter-rater reliability testing of IQET 1
  - Reviewers • Method • Results
- **STEP 3:** Testing and enhancing IQET 1 through evaluation of 2013 reports to develop IQET 2
- **STEP 4:** Qualitative inter-rater reliability testing of IQET 2
  - Reviewers • Method • Results
- **STEP 5:** Development of IQET 3
- **STEP 6:** Application of IQET 3 to evaluate 2014 reports
- **STEP 7:** Quantitative inter-rater reliability testing of IQET 3
  - Reviewers • Method • Results

3.3. Discussion

As stated in the previous chapters, the overall aim of this research is to explore how to effectively leverage incident investigations to better inform system safety.

The research question underpinning study 1 is designed to contribute to the overall research aim and is:

"Is it possible to develop a tool to reliably evaluate the quality of serious incident investigation reports including the quality of the analytic trace for investigation findings?"

\textsuperscript{21} VA NCPS: Veteran Affairs National Centre for Patient Safety (i.e. in the USA)
\textsuperscript{22} NPSA: National Patient Safety Agency (i.e. in the UK)
\textsuperscript{23} RCA: Root Cause Analysis
\textsuperscript{24} IQET: Investigation Quality Evaluation Tool
3.1. INTRODUCTION: Review of the literature to identify quality markers and evaluation tools

As shown in Chapter 1, much literature criticises the quality of investigations in healthcare (Anderson & Kodate, (2015); Bowie et al., (2008); Care Quality Commission, (2016); Wallace, (2006); Wallace et al., (2006); and Wallace et al., (2009); and Cassins & Barrach (2012))

A review of the literature identified the following markers of investigation quality:

(i) Thorough data collection and analysis is vital (Bagian et al., (2002); Wallace et al., (2006); Dekker (2006)).

(ii) Conducting interviews with individuals that have information that is important for investigation purposes including healthcare professionals that observed events and the person that was harmed by the events (and/or their family members as appropriate) (Bagian et al., (2002)). Duchscherer et al., (2012) and Kahneman (2011) highlighted the importance of individual interviews. They emphasised that a principle of good investigation is that interviewees should be interviewed individually to avoid influencing memory and interpretation of events.

(iii) An investigation report should leave an analytic trace for investigation findings. This includes a detailed reconstruction/chronology of events leading up to the incident (Bagian (2002), Dekker (2006), Wallace et al., 2006)).

(iv) A robust process for categorising the quality of data used to establish causes is pertinent (Bagian, (2002), Wallace et al., (2006); Doggett (2004); Carroll (2002); and Drupsteen & Hasle, (2014)).

(v) Developing efficient recommendations to address the causes of the incident is key (Dekker (2006); Bagian et al., (2002); Kellog et al., 2017)).

(vi) Checking the factual accuracy of the investigation report with those that were involved in/observed the incident (Bagian, 2002).

(vii) Writing investigation reports so that systemic causes and generalizable learning is apparent is important (Rasmussen, (1989, 1993, 1997); Dekker, (2006)).
Investigation validity and reliability is important (Bowie et al., (2008)). According to Weiss (1998) validity has to do with the extent to which the indicator captures the concept of interest. That is to say, an indicator should measure what you intend to measure. This would imply that valid investigations are investigations that ask all the questions they need to ask, and get all the answers they need to get to identify all the correct safety problem causes (i.e. contributory factors) and solutions (i.e. recommendations). Reliability has to do with whether repeated efforts to measure the same phenomenon come up with the same answer (Weiss, 1998). Applying this definition of reliability to investigations implies that reliable investigations are investigations that identify all the correct safety problem causes (i.e. contributory factors) and solutions (i.e. recommendations), so that if another investigation team were to conduct a second investigation of an incident using a comparable methodology, they should not identify any other or different contributory factors or recommendations.

Only two tools to evaluate investigations in healthcare were identified prior to this research commencing namely (i) the Veteran Affairs (VA) National Centre for Patient Safety (NCPS) evaluation tool (Bagian et al., 2002), and (ii) the National Patient Safety Agency (NPSA) evaluation tool (Wallace et al., 2006). These are described in the following two sections.

3.1.1. VA NCPS Investigation Quality Evaluation Tool

Bagian et al., (2002) described how the Veteran Affairs (VA) National Centre for Patient Safety (NCPS) monitored the quality and completeness of Root Cause Analysis (RCA) investigations through an immediate review and feedback process. A copy of the RCA quality evaluation tool was sought and received from the authors of this paper. This tool evaluated 23 aspects of RCA investigations in line with NCPS Triage Cards and RCA Training Materials including:

- SAC (i.e. Severity Assessment Code) Potential
- whether the initial description was updated with a flow diagram that also indicated questions to be considered in relation to the event
• whether the brief description within the investigation provided the basic information received regarding the event so that it covered the who, what, when and where of the event

• whether people that could provide the clearest picture of the event and surrounding issues that may have led to the event were interviewed

• whether policies, procedures, reports, regulations, medical records, committee minutes related to the event were covered

• whether a final understanding of the event displayed a thorough understanding of events, incorporating answers to the questions asked in the initial flow diagram

• whether there is a Final Description which updated the narrative to include all related information

• whether each root cause involved a logical sequence that used the “25 rules of causation” as mentioned in the Triage Cards

• whether Key Human Factors questions delved deeply into the issues associated with each root cause (Communications, Training, Fatigue/Scheduling, Environment/Equipment, Rules/Policies/Procedures) as mentioned in Triage Cards

• whether narratives were fully de-identified regarding the patient, family, staff and facility

• whether incident reporters were consulted to ensure that root causes and subsequent actions taken by the team reflected accurate understanding of the event

• whether there were attachments, if applicable which reflected entries listed under “Methods and Tools”

• whether “Lessons learned” moved beyond root causes to a better understanding of the RCA process, team dynamics, impact of the event on the staff and the facility, etc.,

This evaluation tool asked the following two questions about each of the 23 aspects of investigations evaluated:
- Item completed? Answer options included: Yes, No or Not Applicable (N/A)
- Met intent (i.e. of the item)? Answer options included: Yes or No.

There was no published report of the findings following application of this evaluation tool.

**3.1.2. NPSA RCA Investigation Quality Evaluation Tool**

Wallace (2006) referred to a study which examined the application of Root Cause Analysis (RCA) in eight case study sites. This study included interviews with staff who conducted RCAs, and a critical examination of their nominated “best” or exemplar RCA from seven Trusts involving a blind critique of submitted RCAs by a former Head of Investigations at the former National Patient Safety Agency (NPSA) in the UK. This reviewer produced a critique against the main elements of RCAs as taught in the programme, and a Strengths, Weaknesses, Opportunities and Threats framework against the standards and guidance of RCA in the NPSA materials (Wallace, 2006). There was evidence in two of exemplary practice, with less depth of analysis and thoroughness in implementation in three, and scant evidence of recognisable features of RCAs in the exemplar reports from two trusts (Wallace, 2006).

The full report of this study (Wallace et al., 2006) identified some weaknesses, for even the most complete RCAs, requiring more focus on use of Care/Service Delivery Problems or issues, contributory factors and root causes, as, the report highlighted: “...these are integral to understanding the causes and possible remedies and preventive actions”. This highlighted the importance of investigators having, and adhering to clear definitions of causal factors.

The tool used to evaluate the investigations in this study considered the following:

- Executive summary
- A full chronology (e.g. tabular timeline, cause and effect chart, timeline, or narrative chronology, etc.)
• Investigation team membership (a multidisciplinary team composed of clinical, managerial & RCA experts – depending on the severity of the incident).
• Terms of Reference
• Variety and accurate application of RCA tools
• Adherence to standard RCA approach
• The data sources (there would be an expectation that a large and varied data set would have been collected and used e.g. medical records, statements, interviews, training schedules, staff rotas, equipment etc.)
  This list will vary depending on the type of incident being investigated.
• The findings Care/Service delivery problems or issues, contributory factors & root causes
• Recommendations (especially targeted solutions (owned by the team/organisation), which are sustainable)
• The use of national, standard NHS investigation guidance and process
• Adherence to standard RCA approach
• Action plan highlighting issues for local action and issues that have wide implications
• Good practice
• Appropriate appendices (List documentary evidence; copies of relevant documentation; methodology used and relevant diagrams e.g. fish bone, cause and effect chart etc. Full chronology/timelines etc., if not in the main report)

3.1.3. The rationale for developing an exhaustive IQET

The HSE NIMT had developed an audit tool to monitor compliance with the “HSE Guidelines for the Systems Analysis Investigation of Incidents and Complaints” (Health Service Executive, 2012) for use by investigators and by commissioners of investigations to ensure that investigations were conducted in line with the guidelines. The audit tool within these guidelines focused on collecting evidence that investigation reports complied with these guidelines. The format of the Audit tool required auditors to answer “Yes/No/Partial” to

---

25 IQET: Investigation Quality Evaluation Tool
questions about whether investigation reports reflected evidence of compliance with the guidelines and included a space for “Comments” in relation to each question. Users of the audit tool reported anecdotally that the tool could reflect that an investigation report was compliant with the investigation guidelines but that there could be issues with the quality of the investigation report which the audit tool was not sensitive enough to identify.

The learning from this experience was that - what was needed was a rich understanding of (i) the investigation, and (ii) how the investigation was represented within the report - rather than a superficial checklist of surface criteria.

So, for the purpose of the current research, an evaluation tool needed to be developed which not only collected data as to whether or not investigation reports complied with the guidelines - but which also collected detailed data in relation to the quality of each element of the investigation as reflected in the various sections of the investigation report. In particular, an important objective of this research was to develop an evaluation tool that would satisfactorily evaluate the quality of the “analytic trace for investigation findings” as referred to by Dekker (2006).

This tool also needed to collect data about causal factors for analysis to identify patterns in causal factors for study 4 of this thesis.

3.2. METHOD: The iterative action learning process for developing the IQET

An iterative action research approach was used to develop and test the Investigation Quality Evaluation Tool (IQET).

As stated in Chapter 2, action research is defined by Stringer (2013) as solutions-oriented investigation leading to resolution of issues investigated. Stringer states that a basic action research routine includes repeated cycles of investigation based on a Look, Think, Act routine as follows:

(iv) Look: Acquiring information

(v) Think: Reflecting on the information gathered
(vi) Act: Planning practical steps toward resolution of the issue investigated

Stringer (2013) goes on to state that applying participatory approaches to investigation stimulates feelings of pride, dignity, identity, control, responsibility, and unity.

In line with the approach to action research set out by Stringer (1999 & 2013) the author took the role of researcher as facilitator and catalyst, ensuring full participation of all relevant stakeholders encouraging all to contribute to the improvement of the IQET. Work was done to ensure optimum (i) relationships (ii) communication (iii) participation, and (iv) inclusiveness in line with good practice in action research.

Figure 3.1 below and the following sections outline the seven steps in this iterative action learning process for developing the IQET.

**Figure 3.1:** Design of this study to develop the Investigation Quality Evaluation Tool (IQET)

**STEP 1: The evidence base for developing the IQET 1**

The review of the literature outlined in section 3.1 above identified two tools for evaluating the quality of investigation reports which predated Investigation
Evaluation Tool Version 1 (IQET 1). These two evaluation tools were:

(i) Bagian et al., (2002)) referred to quality assuring root cause analyses. Direct contact was made with the authors of this paper seeking a copy of the tool used to quality assure the root cause analysis investigations. The tool received was entitled: “NCPS\textsuperscript{26} ROOT CAUSE ANALYSIS FACILITY REPORT”.


Both of the tools referred to in (i) and (ii) above are described in detail in section 3.1 above.

At the time of developing IQET 1, two National Incident Management Team (NIMT) colleagues and the author were the only three full time members of the NIMT. The three of us had a role in supporting the implementation of investigation guidelines, and the delivery of high quality investigations. Therefore, we considered the two tools referred to in (i) and (ii) above, and the audit tool in the “HSE Guidelines for the Systems Analysis Investigation of Incidents and Complaints” (Health Service Executive, 2012). Based on these considerations, we developed IQET 1 (See appendix 3).

IQET 1 collected data in relation to how the following were reflected in investigation reports which is based on (i) the literature about investigation quality markers outlined in 3.1 above, and (ii) followed the steps of conducting an investigation as per the Guidelines for Systems Analysis Investigation of Incidents and Complaints (Health Service Executive, 2012):

- Timeliness of investigations
- Quality of data and literature collection and review
- Quality of chronologies
- Quality of analysis of the chronology to identify key causal factors\textsuperscript{27},

\textsuperscript{26} NCPS: National Centre for Patient Safety (i.e. in the USA)
\textsuperscript{27} Key causal factors were defined as: “Issues that arose in the process of delivering and managing care that had an effect in the eventual adverse outcome” (HSE Guidelines for the Systems Analysis Investigation of Incidents and Complaints (2012)).
- Quality of analysis of key causal factors to identify contributory factors and incidental\(^{28}\) findings
- Quality of recommendations in relation to the use of a hierarchy of preferred control measures to develop recommendations; and in relation to how SMART\(^{29}\) recommendations were
- The generalizability of investigation reports

The audit tool within the "HSE Guidelines for the Systems Analysis Investigation of Incidents and Complaints" (2012) asked the following question in relation to key causal factors:

> "Are key causal factors identified and/or does the report state that none were identified following the analysis of the chronology?" (Yes?/No?/Partial. Comment)

In order to strengthen the evaluation tool in terms of assessing what Dekker (2006) referred to as "the analytic trace for investigation findings" IQET 1 (See appendix 3) asked the following question in relation to key causal factors and contributory factors:

---

\(^{28}\) Incidental Findings were defined as: "Issues that arose in the process of delivering and managing health services identified during the course of an investigation which the investigators consider did not impact on the outcomes but which serve to identify issues for system improvement e.g. issues relating to documentation, communication etc." (HSE Guidelines for the Systems Analysis Investigation of Incidents (2012 and 2015))

\(^{29}\) As per the HSE Guidelines for the Systems Analysis Investigation of Incidents (2015) SMART = Specific, Measurable, Achievable, Realistic, Time bound.
**STEP 2: Qualitative inter-rater reliability testing of IQET 1**

Prior to using the IQET 1 to evaluate the quality of serious incident investigation reports which were completed in 2013 – qualitative inter-rater reliability testing was conducted on four randomly selected investigation reports by three reviewers as follows.

**Reviewers**

In line with good practice in action research a decision was taken that the inter-rater reliability testers should be individuals who would have a future role in using the IQET. At the time, there were three individuals in the HSE that held this role including the author, and the only two other fulltime members of the National Incident Management Team (NIMT). The involvement of the authors’ two fulltime NIMT colleagues would enable for them as stakeholders in the process of evaluating investigation quality - to contribute constructively to the development of the IQET. This in turn would enhance the likelihood of their buy in to the use of the IQET in the future if this research identified that this was beneficial. These NIMT colleagues also had experience of developing investigation guidelines, delivering investigation training, and conducting investigations. Therefore, as reviewers, they brought knowledge and experience of investigating incidents to the process enabling a sophisticated critique of the first iteration of the IQET. Finally, these reviewers required less training and support to conduct the inter-rater reliability testing.

<table>
<thead>
<tr>
<th>Q: The investigation report shows appropriate analysis of the chronology to either: a) identify key causal factors or the equivalent b) establish that there were no key causal factors where applicable?</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Give details if necessary or if you give a score of 3 or less</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional comments</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Q: Where the equivalent of key causal factors have been identified, the investigation report shows appropriate analysis of the key causal factors or the equivalent to identify the underlying contributory factors or equivalent</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Give details if necessary or if you give a score of 3 or less</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional comments</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
compared with individuals that did not have knowledge and experience of incident investigation.

It was acknowledged that limitations of this action research approach included (i) potential issues with reliability, and (ii) with reproducing this research in other domains. However, this was considered a pragmatic solution necessary in order to answer the research question at hand, and to increase the likelihood of effective future implementation.

**Method**

The two other NIMT reviewers and the author met in February 2014 to discuss and plan the qualitative inter-rater reliability testing of IQET 1. The following actions were conducted/agreed at this meeting:

(i) The author demonstrated the IQET 1 in Excel to the two other reviewers

(ii) One of the other reviewers agreed to randomly select one investigation report from the investigation reports that were submitted for this research from each of the four HSE regions and to circulate these four investigation reports to each of the reviewers

(iii) All reviewers agreed to review all four investigation reports and complete the IQET 1 in Excel for each investigation report

(iv) All agreed to consider the following:

   a. The usability of IQET 1 in Excel

   b. For questions where Likert type scales were used, and where the responses by the reviewers varied by a magnitude of two or more, the reviewers would consider the questions with a view to enhancing the clarity and reducing the ambiguity of the question

   c. To check whether it was possible to get the answers for the questions from the completed investigation reports

(v) The time taken to review the investigation reports and complete IQET 1 would be recorded

(vi) A follow up, discussion, and debrief meeting was scheduled for the three reviewers later in February 2014.

**Results**

The three reviewers met again on the 25th of February 2014 to consider the
completed IQET 1s.

The results of this qualitative inter-rater reliability testing of IQET 1 are summarised below:

(i) It was identified that it might not be possible to answer some questions from the information available in the completed investigation reports such as the question about whether contributory factors that could occur elsewhere were communicated to the relevant senior managers. However, it was agreed that these questions should be retained on IQET 1 in case some investigation reports might include the information.

(ii) It was also identified at this meeting that the four reports that were randomly selected for this inter-rater reliability test varied significantly in structure and content. Based on this, it was anticipated that the structure and content of the remaining investigation reports might vary significantly. Therefore, it was considered that further review and enhancement of the IQET 1 might be needed as more investigation reports were evaluated.

(iii) The reviewers found the Excel Spread Sheet difficult to use. They recommended consideration of use of SPSS. This was because the reviewers had access to, and experience of using SPSS. Also, they anticipated that as the IQET evolved, there would be a lot of cases included for evaluation, and a large number of variables requiring data collection. They considered that SPSS would be easier to use in this context where there were large amounts of data possibly requiring sophisticated analysis. It was also noted that the data could be easily exported to Excel if needed.

(iv) It was identified that, in the absence of many published tools to evaluate the quality of investigation reports in the detail required for this study – that the “additional comments” section for each question would be very important to inform an improved IQET.

(v) The meeting recommended that consideration be given to the training, support and guidance that would be needed by future users of the IQET.

(vi) There were no questions where the responses by the reviewers varied by a magnitude of two or more.

(vii) The times to complete these reviews were recorded as follows:
<table>
<thead>
<tr>
<th>Investigation Report 1</th>
<th>Reviewer 1</th>
<th>Reviewer 2</th>
<th>Reviewer 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>100 minutes</td>
<td>90 minutes</td>
<td>120 minutes</td>
</tr>
<tr>
<td>Investigation Report 2</td>
<td>90 minutes</td>
<td>80 minutes</td>
<td>90 minutes</td>
</tr>
<tr>
<td>Investigation Report 3</td>
<td>105 minutes</td>
<td>90 minutes</td>
<td>90 minutes</td>
</tr>
<tr>
<td>Investigation Report 4</td>
<td>70 minutes</td>
<td>40 minutes</td>
<td>90 minutes</td>
</tr>
<tr>
<td>Total time</td>
<td>365 m (6hrs 5mins)</td>
<td>300 m (5hrs)</td>
<td>390 m (6hrs 30mins)</td>
</tr>
</tbody>
</table>

Table 3.1: Time taken by reviewers to review and input data from review of investigation quality onto Excel spread sheet

It was anticipated that it would be laborious to review the 2013 investigation reports. On this basis – it was agreed that the author would use IQET 1 to evaluate the quality of 2013 investigation reports and revert to the two other NIMT reviewers to discuss the learning from this process.

Based on the learning from this qualitative inter-rater reliability testing meeting, the author developed an SPSS database for data collected by IQET 1.

**STEP 3: Testing and enhancing IQET 1 through evaluation of 2013 reports to develop IQET 2**

**Method**

The author evaluated the 61 investigation reports which were completed in 2013 and which were submitted to the NIMT - using IQET 1. The data was entered onto the SPSS data base contemporaneously as the investigation reports were evaluated.

**Results**

**Time taken to conduct evaluation**

As predicted at the meeting related to the qualitative inter-rater reliability testing referred to in step 2 above – the structure and content of the 2013 investigation reports varied significantly. This posed challenges for the evaluation of reports such as when the sequencing of sections of some reports did not align to the sequencing of the sections of the IQET 1 requiring going back over sections of the tool when evidence of compliance or non-compliance was identified in a report, or re-reading sections of a report when an aspect of IQET 1 referred to an issue that was reflected previously in an investigation report.

The average amount of time taken to evaluate and enter data from each of the 2013 investigation reports was 74.45 minutes; with a minimum duration
of 18 minutes, and a maximum duration of 204 minutes. It is important to note that the IQET 1 collected data about causal factors for use in study 4 of this thesis in addition to data about aspects of investigation quality and this will have impacted the timelines for completing IQET 1.

**Learning which informed contemporaneous enhancements of IQET 1**

IQET 1 and the SPSS data base were enhanced contemporaneously as the 61 investigation reports were being evaluated as and when the evaluation revealed that these enhancements were needed to achieve the objectives of this study. These enhancements included refining the scales to better capture the differences between reports, and to collect more data about specific aspects of investigation quality as follows:

(i) Developing specific important quality criteria for evaluating each element of the report
(ii) Deleting questions where the information was not collectable from investigation reports
(iii) Including questions about the size and make up of investigation teams
(iv) Collecting data about causal factors.

Further details of (i) to (iv) above are outlined in the following four sections.

**Developing specific important quality criteria for evaluating each element of a report**

Analysis of the qualitative data collected in the “Additional Comments” sections of IQET 1 identified specific important criteria about each element of the investigation report. For example, the question on the IQET 1 related to the quality of data collection reflected in the investigation report was as follows:

```
<table>
<thead>
<tr>
<th>Strongly disagree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>
```

Some of the comments from the comments section of the IQET related to data collection were as follows:
“The report would benefit from inclusion of a reference section including refs for local, national and international literature and PPPG's reviewed and referred to”

“Interviews are not used as means of collecting data”

“…there is no reference … the literature specific to this case (fractures; extended A&E waits etc.)”

“…does not reference individual interviews”

“There are no references to review of PPPG's or relevant literature”.

“…refers to lit review, but there is no reference to any literature used in the investigation except for the Healthcare Record…”

“…refers to the fact that the investigation team reviewed the medical records and all relevant policies and guidelines, but it does not refer to what policies and guidelines were reviewed…”

“…refers to examining minutes of … meetings; protocols; interviewing a limited number of staff (does not say how many or what cadre of staff)…”

“Refers to interviews; review of HCR's and statements. Does not refer national and international PPPG’s and literature.”

“Would benefit from a list of the actual PPPG's collected and reviewed”

From the analysis of the entire data collected in the “Additional Comments” section, the following additional questions were added to the IQET 2 in a format that requested a yes/no response:

- Does the investigation report include a summary of the data collected and reviewed?
- Does the report reflect that the relevant records/healthcare records were collected and reviewed?
- Does the report reflect that the relevant local, national and international policies, procedures and guidelines were collected and reviewed?
- Does the report reflect a review of the relevant literature?
- Does the report reflect that individual interviews were conducted with individuals who observed the incident and/or had information pertinent to achieving the objectives of the systems analysis investigation?

This was then followed by a question to rate the quality of the specific section of the investigation, for example the section reflecting the data collected - as “Excellent”, “Very Good”, “Good”, “Fair”, or “Poor”: 
Questions about readability and fair procedures were also identified as important to be added to IQET 2.

Deleting questions where the information was not collectable from reports
Questions were deleted where it was identified that the information was not collectable from the investigation reports as follows:

- Date when decision to conduct investigation occurred
- Date when investigation report was released to those affected/harmed

Including additional questions about the investigation team
It was identified that it was important to collect data about the size and make up of investigation teams that undertook the investigations to help determine the impact of this on the quality of investigation reports.

Collecting information about causal factors
It was identified that the evaluation tool needed to be enhanced to collect data about key causal factors, contributory factors, and incidental findings to enable analysis to identify:

(i) The quality of the analytic trace for investigation findings as referred to by Dekker (2006)
(ii) Patterns in causal factors to help identify the most common causes of harm with a view to informing organisation wide safety interventions that were likely to have the greatest possible safety impact.

When all 61 investigation reports were reviewed and evaluated, the changes reflected above were made to IQET 1 to create IQET 2.

**STEP 4: Qualitative inter-rater reliability testing of IQET 2**
The IQET 2 was then qualitatively tested for inter-rater reliability by three reviewers in autumn 2015. These three reviewers used IQET 2 to evaluate four randomly selected serious incident investigation reports which were completed in 2014. The reviewers then met to discuss significant variations, findings and recommendations to enhance IQET as follows.

**Reviewers**
As for the qualitative inter-rater reliability testing of IQET 1 - and in line with good practice in action research - the inter-rate reliability testers for IQET 2
were individuals who would have a future role in using the IQET. In the time the elapsed since the qualitative inter-rate reliability testing of IQET 1 described above, the NIMT had changed as reflected in Chapter 2. The two previous reviewers had left the NIMT. They were replaced with four individuals that had extensive knowledge and experience of (i) conducting investigations; (ii) developing investigation PPPGs; and (iii) delivering investigation training. Two of the four other members of the National Incident Management and Learning Team (NIMLT) and the author conducted the qualitative inter-rater reliability testing of IQET 2. The selection of the two out of the four other members of the NIMLT was a pragmatic one on the basis of their availability in the context of the work-load of the NIMLT at the time.

Method
Forty five investigation reports that were completed in 2014 were submitted for the purpose of this research. These 45 reports came from four HSE Divisions namely (i) the Acute Hospital Division, (ii) the Mental Health Division, (iii) the Social Care Division, and (iv) the National Ambulance Service. For the purpose of this qualitative inter-rater reliability test of IQET 2, one investigation report was randomly selected from the reports submitted by each of these four divisions totalling four investigation reports selected for use in this test.

Each of the three reviewers (i.e. two NIMLT colleagues and the author) evaluated each of the four investigation reports and completed a hard copy of the IQET 2 for each report independently of the other reviewers.

Results
The three reviewers (i.e. two NIMLT colleagues and the author) met after we had reviewed each of the four investigation reports and completed a hard copy of IQET 2 for each one. The following learning from this inter-rater reliability testing was identified at this meeting:

(i) It was agreed that the questions that asked whether aspects of the investigation report were: “Excellent”, “Very good”, “Good”, “Fair”, or “Poor” were too subjective and that this would be replaced by a score for

---

key investigation quality elements that were identified in the report.

(ii) The section that collected information about Contributory Factors (CFs) for analysis to identify patterns in causal factors was developed to include guidance for reviewers in relation to specifying whether the CFs were observed in the investigation report; or whether they were deduced from the data available in the investigation report.

(iii) 41 key elements of investigation quality were identified under nine broad quality themes. These were informed by a) the steps of the investigation process as per HSE investigation Guidelines (Health Service Executive, 2012), b) the evaluation tools that predated the IQET, and c) the learning from the experience of using IQET 1 as described above - as follows:

→ Data collection (7 elements)
→ Quality of chronology (7 elements)
→ Analysis of chronology to identify Key Causal Factors (KCFs) (3 elements)
→ Analysis of KCFs to identify Contributory Factors (CFs) (3 elements)
→ Analysis of chronology to identify Incidental Findings (IFs) (5 elements)
→ Quality of recommendations (5 elements)
→ Generalizability (3 elements)
→ Plain English/Readability (4 elements)
→ Fair procedures/factual accuracy checking (4 elements)

(iv) A method of giving Investigation Quality Scores (IQS) for aspects of investigations that were considered important for a) “leaving an analytic trace for investigation findings” (Dekker, 2006), and b) for enabling analysis for generalizable learning from groups of investigation reports – was developed. This related to questions requiring yes or no answers as follows:

→ A score of 1 should be assigned where investigation reports reflected key elements

→ A score of 0 should be assigned where the investigation reports
did not reflect key elements

Question 8.4. was an exception to the above rule. Question 8.4. was:

“Are the key causal factors adequately supported by the evidence presented within the investigation report?”

This question was scored as follows:

a) A score of 2/2 was assigned if “All” key causal factors were supported by the evidence

b) A score of 1/2 was assigned if “Some” key causal factors were supported by the evidence

c) A score of 0/2 was assigned if “No” key causal factors were supported by the evidence

d) A score of 1/1 was assigned if the investigation report stated that no KCFs were identifiable, and this was adequately supported by the evidence presented

→ Sections should be assigned as “Not applicable or N/A” where that element did not apply to the investigation report. For example, if a report identified that there were no Key Causal Factors, then according to the “Guidelines for the Systems Analysis Investigation of Incidents and Complaints” (Health Service Executive, 2012) there would be no Contributory Factors. Therefore, the sections of the evaluation tool related to Contributory Factors would be considered “Not Applicable” in these investigation reports and scores from these sections would not be considered in the final score for these investigation reports.

The tool for tallying these scores is shown in table 3.2 below.
<table>
<thead>
<tr>
<th>Section number</th>
<th>Section heading</th>
<th>Maximum possible score (i.e. excluding N/A scores)</th>
<th>Score</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>Data collection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Quality of chronology</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Analysis of chronology to identify KCFs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Analysis of chronology to identify IF’s</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Analysis of KCFs to identify CF’s</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Quality of recommendations</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Generalisability</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Plain English/Readability</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>Fair procedures/factual accuracy checking</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Total actual score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Maximum possible score</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 3.2: Tool for tallying individual investigation report quality IQSs.

→ The total actual score for each investigation report should be calculated by adding the scores for each key section; then dividing this by the sum of the maximum possible scores for each section (i.e. excluding “Not Applicable” scores) and multiplying this by 100 to get the result in percentage format as per figure 3.2 below.

![Figure 3.2: Tool for calculating final IQS for individual investigation reports.](image)

(v) Questions about whether it was clear that investigators were not responsible for the incident and did not manage the service where the incident occurred were modified to include whether this was deducible from the data or not.

(vi) Guidance was developed in relation to questions about whether investigators could be considered subject experts or investigation experts.
(vii) Guidance was developed in relation to what constituted a relevant review of policies, procedures, protocols and guidelines.

(viii) Learning from using the IQET 2 for the evaluation of 2013 reports showed that some investigations did not refer to KCFs, CFs or IFs, and some that did, appeared not to adhere to the definition of these as per HSE Guidelines. Therefore, it was agreed that IQET 3 should include questions which asked whether the report defined KCFs, CFs and IFs in line with HSE guidelines.

(ix) Questions were added in relation to whether the KCFs, the CFs and the IFs identified (or the fact that they were not identified) were adequately supported by the evidence presented within the investigation report to help determine whether the report reflected what Dekker (2006) referred to as a satisfactory analytic trace for investigation findings.

The criteria shown in tables 3.3 and 3.4 below were used to underpin decisions about which sections of the evaluation tool were quality scored and which were not.
<table>
<thead>
<tr>
<th>Criteria for NOT quality scoring questions</th>
<th>Criteria for quality scoring questions</th>
</tr>
</thead>
</table>
| ▪ Traceability of investigations for checking purposes | ▪ Aspects of investigation quality which are important for leaving an “analytic trace for investigation findings” as referred to by Dekker (2006):
| ▪ Learning about the investigation quality evaluation process | ▪ Data collection (Excl., number of interviews) |
| ▪ Variables independent of quality, and important for analysis of correlation with quality such as: | ▪ Chronology (Excl., scope in time) |
| ▪ Demographics (i.e. Division/site/speciality where the incident occurred) | ▪ Analysis of chronology to identify KCFs |
| ▪ Timeliness of investigations | ▪ Identification of incidental findings |
| ▪ Investigator details | ▪ Analysis of KCFs to identify CFs |
| ▪ Scope in time of chronology | ▪ Recommendations |
| ▪ Number of people interviewed | ▪ Generalizability (Excl., investigation quality reviewers judgement about whether CFs appeared as though they may occur elsewhere, and whether recommendations may be applicable elsewhere).
| ▪ Legal review | ▪ Application of fair procedures |
| ▪ Methodology used | ▪ Aspects of investigation quality which are important in enabling generalizable learning from a group of investigations (i.e. Use of plain English/readability) |
| ▪ Data collected for analysis of causal factors | |
| ▪ Investigation quality reviewers judgements: | |
| ▪ Whether CFs appeared as though they may occur elsewhere (Q 12.1) | |
| ▪ Whether recommendations may be applicable elsewhere (Q 12.3) | |
| ▪ Impartiality of investigation report | |
| ▪ Safely sharing investigation reports for learning and improvement purposes (i.e. anonymisation) | |
| ▪ The need for investigations to be human and compassionate (i.e. apology and acknowledgement) | |

Table 3.3: Criteria used to underpin decisions about which sections of the evaluation tool were quality scored for investigation quality scoring (IQS) purposes and which were not.

Table 3.4 below shows the details of how the criteria referred to above were applied to each question within IQET to decide which questions would be scored for IQS purposes.
Table 3.4: Showing details of how the criteria referred to above were applied to each question within IQET to decide which questions would be scored for IQS purposes.

<table>
<thead>
<tr>
<th>Section number</th>
<th>Section title</th>
<th>No of Questions</th>
<th>Questions scored</th>
<th>Rational for scoring</th>
<th>Questions not scored</th>
<th>Rationale for not scoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Title, reference details, date of review and reviewer details</td>
<td>7</td>
<td>None</td>
<td>-</td>
<td>All 7</td>
<td>Questions in this section included questions that enabled traceability of the investigation, description of the incident by the quality reviewer, impact of the incident, time taken to evaluate the quality of the investigation report, etc... These were important to understand the demographics of the investigations and the time taken to evaluate quality - but were not directly related to the dependent variable i.e. the actual quality of the investigation</td>
</tr>
<tr>
<td>2</td>
<td>Timeliness of investigation</td>
<td>16</td>
<td>None</td>
<td>-</td>
<td>All 16</td>
<td>That investigations are completed as quickly as possible was considered an important aspect of investigation quality. However, it was considered that some good quality investigations could be completed very quickly, while some good quality investigations could be completed slowly either because the nature of the issues being investigated required more time to investigate, and/or because issues of availability of investigators contributed to delays in completing investigations. Conversely, some poor quality investigation could be done quickly, while some poor quality investigations could be completed slowly. Therefore, timeliness of investigations was considered separately from the quality scoring, and data was analysed to determine whether there was any correlation between timeliness and quality. Data about reasons for delays was also collected from investigations reports where this was available.</td>
</tr>
<tr>
<td>3</td>
<td>Details of division, site and speciality</td>
<td>5</td>
<td>None</td>
<td>-</td>
<td>All 5</td>
<td>Questions in this section included details of the part of the HSE the incident occurred within. This was considered independent of investigation quality and therefore, it was not scored for quality scoring purposes. This data was analysed to determine whether there was any correlation between investigation quality and the site/speciality the incident related to.</td>
</tr>
<tr>
<td>4</td>
<td>Investigator details</td>
<td>15</td>
<td>None</td>
<td>-</td>
<td>All 15</td>
<td>Details about whether investigators were subject experts and/or investigation experts, and whether they were involved in the incident and/or the service where the incident occurred were collected. This was not quality scored as this was considered an independent variable. This data was analysed to determine whether there was any correlation between investigator details and quality scores.</td>
</tr>
<tr>
<td>Section number</td>
<td>Section title</td>
<td>No of Questions</td>
<td>Questions scored</td>
<td>Rational for scoring</td>
<td>Questions not scored</td>
<td>Rationale for not scoring</td>
</tr>
<tr>
<td>----------------</td>
<td>--------------------------------</td>
<td>-----------------</td>
<td>------------------</td>
<td>---------------------------------------------------------------------------------------</td>
<td>---------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>5</td>
<td>Methodology (General)</td>
<td>4</td>
<td>None</td>
<td>Questions in this section collected details about whether the investigation methodology was described and if so, whether it indicated that a systems analysis methodology was used. If not a systems analysis, it enabled collection of details of alternative methodologies used. This was not scored - as it was considered important not to introduce bias into the process by assuming that only a systems analysis methodology could produce a reasonable quality investigation. So the methodology used was treated as an independent variable - enabling analysis of the relationship between this and investigation quality.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Methodology (Specific) Data collection*</td>
<td>8</td>
<td>All except 6.6</td>
<td>Questions in this section related to data collected via records, the literature, and interviews. It was scored for quality scoring purposes as it was considered that how well the details of the data collected and reviewed were reflected within an investigation report was an important element of the &quot;analytic trace for investigation findings&quot; referred to by Dekker (2006)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6.6 not scored</td>
<td>Q 6.6 related to the number of individuals that were interviewed. This was not quality scored as it was considered that some investigations may need a few interviews, whereas others may need many. Therefore, it was considered an independent variable, and it was analysed separately to determine whether there was any correlation between the number of interviews and quality score.</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Methodology (Specific) Chronology*</td>
<td>8</td>
<td>All except 7.1</td>
<td>Questions in this section were scored for quality scoring purposes as it was considered that how well the details of the chronology of events were reflected within an investigation report was an important element of the &quot;analytic trace for investigation findings&quot; referred to by Dekker (2006)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>7.1 not scored</td>
<td>Q 7.1 related to the scope in time of the investigation. This was not quality scored as it was considered that some investigations may need a long scope in time reflected within the chronology to achieve its purpose, whereas in others a short scope in time may be sufficient. Therefore, it was considered an independent variable, and it was analysed separately to determine whether there was any correlation between the scope in time reflected within the chronology and quality score.</td>
<td></td>
</tr>
<tr>
<td>Section number</td>
<td>Section title</td>
<td>No of Questions</td>
<td>Questions scored</td>
<td>Rational for scoring</td>
<td>Questions not scored</td>
<td>Rationale for not scoring</td>
</tr>
<tr>
<td>----------------</td>
<td>---------------------------------------------------</td>
<td>-----------------</td>
<td>---------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>8</td>
<td>Methodology (Specific) Key Causal Factors (KCFs)*</td>
<td>4</td>
<td>All except 8.3</td>
<td>Questions in this section were scored for quality scoring purposes as it was considered that how well the analysis of the chronology to determine KCFs (or to determine that none were identifiable) was reflected within an investigation report was an important element of the &quot;analytic trace for investigation findings&quot; referred to by Dekker (2006)</td>
<td>8.3 not scored</td>
<td>Q 8.3 was &quot;If the report identifies KCFs, please list the key causal factors&quot;. So this question related to the collection of data about key causal factors for thematic analysis. It did not relate directly to the quality of the investigation report. Therefore, this was not quality scored.</td>
</tr>
<tr>
<td>9</td>
<td>Methodology (Specific) Incidental Findings (IFs)*</td>
<td>4</td>
<td>All except 9.4</td>
<td>Questions in this section were scored for quality scoring purposes as it was considered that how well the analysis of the chronology to determine IFs (or to determine that none were identifiable) was reflected within an investigation report was an important element of the &quot;analytic trace for investigation findings&quot; referred to by Dekker (2006)</td>
<td>9.4 not scored</td>
<td>Q 9.4. was &quot;If the report identifies IFs, please list the IFs&quot;. So this question related to the collection of data about Incidental findings for thematic analysis. It did not relate directly to the quality of the investigation report. Therefore, this was not quality scored.</td>
</tr>
<tr>
<td>10</td>
<td>Methodology (Specific) Contributory Factors (CFs)*</td>
<td>5</td>
<td>All except 10.4</td>
<td>Questions in this section were scored for quality scoring purposes as it was considered that how well the analysis of the KCFs to determine CFs (or to determine that none were identifiable) was reflected within an investigation report was an important element of the &quot;analytic trace for investigation findings&quot; referred to by Dekker (2006)</td>
<td>10.4 not scored</td>
<td>Q 10.4. was &quot;Please complete for each key causal factor: (i) Factor type. (ii) Contributory factor, and (iii) Details&quot;. So this question related to the collection of data about contributory factors for thematic analysis. It did not relate directly to the quality of the investigation report. Therefore, this was not quality scored.</td>
</tr>
<tr>
<td>Section number</td>
<td>Section title</td>
<td>No of Questions</td>
<td>Questions scored</td>
<td>Rational for scoring</td>
<td>Questions not scored</td>
<td>Rationale for not scoring</td>
</tr>
<tr>
<td>----------------</td>
<td>---------------------------------------------------</td>
<td>-----------------</td>
<td>------------------</td>
<td>--------------------------------------------------------------------------------------</td>
<td>----------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>11</td>
<td>Methodology (Specific) Recommendations*</td>
<td>5</td>
<td>All 5</td>
<td>Questions in this section related to whether recommendations were linked to the CFs, and whether the hierarchy of preferred controls was used in developing recommendations. These were scored for quality scoring purposes as it was considered that how well this was reflected within an investigation report was an important element of the &quot;analytic trace for investigation findings&quot; referred to by Dekker (2006)</td>
<td>None</td>
<td>-</td>
</tr>
<tr>
<td>12</td>
<td>Generalizability*</td>
<td>5</td>
<td>All except 12.1 &amp; 12.3</td>
<td>Questions in this section were scored for quality scoring purposes as it was considered that how well investigations identified whether causal factors and recommendations may be applicable elsewhere were reflected within an investigation report was an important element of the &quot;analytic trace for investigation findings&quot; referred to by Dekker (2006) - particularly as this related to generalizable learning from investigations</td>
<td>12.1 &amp; 12.3 not scored</td>
<td>Questions 12.1 asked whether the investigation report identified CFs which seemed as though they could occur elsewhere. Question 12.3 asked whether the report included recommendations that appeared as though they may be applicable elsewhere. If the answer to these questions was yes, other questions related to whether this was reflected within the report and these other questions were scored for quality scoring purposes. But questions 12.1 and 12.3 were not scored as these related to the quality reviewers judgement and were not a direct measure of any aspect of investigation quality.</td>
</tr>
<tr>
<td>13</td>
<td>Legal Review</td>
<td>2</td>
<td>None</td>
<td>-</td>
<td>All 2</td>
<td>Questions about legal review were included to determine whether it occurred, if so, why, and if so, whether it had an impact on investigation quality. So it was considered independent of investigation quality, and therefore it was not scored for quality scoring purposes.</td>
</tr>
<tr>
<td>14</td>
<td>Anonymisation</td>
<td>5</td>
<td>None</td>
<td>-</td>
<td>All 2</td>
<td>Anonymisation was considered important in order to ensure that investigation reports could be safely shared for learning and improvement purposes and so data was collected to determine whether reports were anonymised or not. However, this aspect was not scored for quality scoring purposes as it was not considered as an important part of the &quot;analytic trace for investigation findings&quot; referred to by Dekker (2006)</td>
</tr>
<tr>
<td>15</td>
<td>Use of plain English/Readability was considered</td>
<td>4</td>
<td>All 4</td>
<td>Use of plain English/Readability was considered</td>
<td>None</td>
<td>-</td>
</tr>
<tr>
<td>Section number</td>
<td>Section title</td>
<td>No of Questions</td>
<td>Questions scored</td>
<td>Rational for scoring</td>
<td>Questions not scored</td>
<td>Rationale for not scoring</td>
</tr>
<tr>
<td>---------------</td>
<td>----------------</td>
<td>-----------------</td>
<td>------------------</td>
<td>-------------------------------------------------------------------------------------</td>
<td>---------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>16</td>
<td>Apology</td>
<td>3</td>
<td>None</td>
<td>The inclusion of/reference to an apology was considered important when KCFs were identified in the context of the need for investigations to be human and compassionate. However, how an apology was reflected within an investigation report was not considered as a part of the &quot;analytic trace for investigation findings&quot; referred to by Dekker (2006). Therefore, data was collected for analysis purposes - but this was not scored for quality scoring purposes.</td>
<td>All 3</td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>Acknowledgement</td>
<td>4</td>
<td>None</td>
<td>The inclusion an acknowledgement of the contribution of staff and/or those affected/harmed to an investigation was considered important in the context of the need for investigations to be human and compassionate. However, how an acknowledgement was reflected within an investigation report was not considered as a part of the &quot;analytic trace for investigation findings&quot; referred to by Dekker (2006). Therefore, data was collected for analysis purposes - but this was not scored for quality scoring purposes.</td>
<td>All 3</td>
<td></td>
</tr>
</tbody>
</table>

English/Readability* important for quality purposes as (i) it made reports accessible to those harmed/affected; and (ii) it made reports more accessible to quality evaluation and thematic analysis by researchers who may not have specialist knowledge in the area covered by the investigation. Access for this purpose is important for identifying generalizable learning from groups of investigation reports and so is related to an important purpose of investigations.
<table>
<thead>
<tr>
<th>Section number</th>
<th>Section title</th>
<th>No of Questions</th>
<th>Questions scored</th>
<th>Rational for scoring</th>
<th>Questions not scored</th>
<th>Rationale for not scoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>18</td>
<td>Application of fair procedures*</td>
<td>4</td>
<td>All 4</td>
<td>This section related to how well reports reflected a process of circulation of drafts to staff and those affected/harmed for factual accuracy checking purposes. This was scored for quality scoring purposes as it was considered that how well this was reflected within an investigation report was an important element of the “analytic trace for investigation findings” referred to by Dekker (2006) - particularly as this related to generalizable learning from investigations</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>19</td>
<td>Impartiality</td>
<td>1</td>
<td>None</td>
<td>-</td>
<td>1</td>
<td>This was not scored as this reflected the overall view of the quality reviewer about the impartiality of the investigation report. It was not an objective measure related to whether something was or was not reflected within an investigation report. It was analysed separately to determine whether there was any correlation between the quality reviewers’ judgement about the impartiality of the investigation report and objectively measured quality scores.</td>
</tr>
<tr>
<td>20</td>
<td>Investigation guidelines followed</td>
<td>1</td>
<td>None</td>
<td>-</td>
<td>-</td>
<td>This was not scored - as it was considered important not to introduce bias into the process by assuming that any one specific investigation guideline was more likely than others to produce a reasonable quality investigation. So the data about the investigation guidelines used was treated as an independent variable - enabling analysis of the relationship between this and investigation quality.</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>110</strong></td>
<td><strong>41</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**STEP 5: Development of IQET 3**

IQET 3 was developed based on the learning and recommendations from the qualitative testing of IQET 2 as outlined in the previous section. (Please see IQET 3 in appendix 5).

**STEP 6: Application of IQET 3 to evaluate 2014 reports.**

**Method**

The author used IQET 3 to evaluate the 45 investigation reports that were completed in 2014 - and one report which was completed in 2013 but was submitted to the NiMLT with the 2014 investigation reports – for the purpose of this research. That is to say, a total of 46 investigation reports were evaluated using IQET 3.

**Results**

The structure and content of the 2014 investigation reports did vary significantly, posing challenges for analysing the reports similar to the challenges for the 2013 reports referred to above. However, this was less challenging than it had been for the 2013 investigation reports as the 2014 reports were more standardised than the 2013 reports.

The average amount of time taken to review and enter data from the 2014 investigation reports was 102.32 minutes; with a minimum duration of 47 minutes and a maximum duration of 209 minutes.

The average time to review and enter data related to the 2014 investigation reports was greater than the average time taken for the 2013 reports. The fact that more data was being collected about each of the 2014 investigation reports contributed to this extended timeline. It is important to note that IQET 3 collected data about causal factors for use in study 4 of this thesis in addition to data about aspects of investigation quality and this will have impacted the timelines for completing IQET 3.

**STEP 7: Quantitative inter-rater reliability testing IQET 3**

**Method**

For the purpose of quantitatively testing inter-rater reliability of IQE 3, nine serious incident investigation reports were randomly selected from the 45
serious incident investigation reports that were completed in 2014 and which were not preliminary reviews or investigations using some other methodology other than a systems analysis methodology.

**Reviewers**

A second reviewer was appointed to review these nine investigation reports using IQET 3. In keeping with the action research approach adopted by this research, the second reviewer was selected from the HSE’s National Incident Management and Learning Team (NIMLT) as this individual had training and experience in incident investigation and they would have a future role in using the IQET. The second reviewer and the author independently evaluated the nine investigation reports and completed a hard copy of IQET 3 for each one. When this was done, the two sets of completed hard copy IQET 3s for the nine investigation reports were compared.

**Results**

The results of the analysis of this quantitative reliability testing within and across cases are outlined in the following sections.

**Inter-rater reliability within cases**

The reliability between reviewers for each case was tested using Cohen’s kappa coefficient - a statistic which provides coefficients of agreement between two raters for nominal scales (Fleiss *et al.*, 1969).

Fleiss (2003) proposes levels of agreement suggested by magnitudes of kappa as follows:

- Greater than 0.75 = “Excellent agreement”
- 0.40 – 0.75 = “Fair to good agreement” and
- Below 0.40 = “Poor agreement”

As shown in table 3.5 below, inter-rater reliability for 55.5% (N=5) was excellent (kappa value ranging from .756 – .859), and for the remaining 44.44% of cases (N=4) inter-rater reliability was fair to good (kappa value ranging from .418 - .587).
Inter-rater reliability for each question across cases

The reliability for each question across cases between reviewers was also tested.

For seven questions - namely questions 6.1, 6.2, 7.3, 11.1, 11.3, 11.5, and 12.6 - it was not possible to calculate the kappa statistic for inter-rater reliability as one of the raters had the same answer for all questions (i.e. nine yes’s or nine no’s) and SPSS could not compute this statistic as at least one variable in each 2-way table upon which measures of association were computed was considered a constant. In these cases, the crude percentage agreement was calculated and it is shown in appendix 6 that the percentage agreements for these seven questions were 88.89% for questions 6.1, 6.2, 7.3, 11.5, and question 12.5, and 100% for questions 11.1 and 11.3. The kappa score for other cases where there was the same number of agreements and disagreements, but where neither rater had consistently the same answer – was taken to be the kappa score for these cases also. Please see appendix 6.

Inter-rater reliability for 35.29% (N=12) of questions was categorised as excellent, for 32.35% (N=11) was fair to good; and for 32.35% (N=11) inter-rater reliability was poor (Please see details in appendix 6).

NIMLT meeting to discuss learning from quantitative inter-rater reliability testing

In line with the action research approach used in this study, a meeting to discuss learning from the inter-rater reliability testing was held with IQET 3 users including:

(i) the two NIMLT quantitative inter-rater reliability reviewers (i.e. the author and the second reviewer described above), and

(ii) the remaining three NIMLT members who used IQET 3 to evaluate reports completed in 2015 outside the scope of this thesis.

<table>
<thead>
<tr>
<th>Case</th>
<th>Case 100</th>
<th>Case 102</th>
<th>Case 104</th>
<th>Case 108</th>
<th>Case 110</th>
<th>Case 112</th>
<th>Case 118</th>
<th>Case 121</th>
<th>Case 125</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kappa</td>
<td>0.587 (Fair – good)</td>
<td>0.542 (Fair – good)</td>
<td>0.478 (Fair – good)</td>
<td>0.782 (Excellent)</td>
<td>0.846 (Excellent)</td>
<td>0.756 (Excellent)</td>
<td>0.784 (Excellent)</td>
<td>0.859 (Excellent)</td>
<td>0.418 (Fair-good)</td>
</tr>
</tbody>
</table>

Table 3.5: Reliability of IQSs between reviewers for each case
This meeting (referred to as the NIMLT meeting from here on) considered the data from the quantitative inter-rater reliability testing, and from the experience of NIMLT members using IQET 3 to evaluate investigation reports completed in 2015. Consequently, this meeting identified that, for six of the 11 questions where inter-rater reliability was identified as poor (i.e. for questions 6.3, 6.4, 9.1, 10.4, 11.2, 18.2), no further enhancements could be achieved to the wording, but that training of and communication between reviewers in the use of the tool to ensure a standardised approach – would be important. The meeting also identified that monitoring of inter-rater reliability would be important.

For the remaining five of the 11 questions where inter-rater reliability was found to be poor (i.e. questions 7.7, 12.1, 15.1, 15.3, and 18.1), enhancements were agreed by the NIMLT meeting as reflected in the following sections.

**Addressing inter-rater reliability issues related to question 7.7**

Question 7.7 in IQET 3 was:

“Does the investigation report specify the individuals that observed each chronological event?”

To address the issue of poor inter-rater reliability identified related to question 7.7, the NIMLT meeting agreed that the text “...or specify that events were unobserved” should be included in question as below:

<table>
<thead>
<tr>
<th>7.7. Does the investigation report specify the individuals that observed each chronological event or specify that events were unobserved?</th>
<th>Yes (1)</th>
<th>No (0)</th>
<th>N/A</th>
<th>Comments</th>
</tr>
</thead>
</table>

**Addressing inter-rater reliability issues identified related to question 12.1**

To address the issue of poor inter-rater reliability identified related to question 12.1, the NIMLT considered this question in the context of questions 12.1 – 12.5 in the IQET 3 as shown below:
The NIMLT considered that, in most circumstance, it would not be possible for investigators to determine from the information available to them whether contributory factors and recommendations could be applicable elsewhere (i.e. outside of the site where the incident occurred). The NIMLT also considered that it would not be possible for reviewers that were evaluating the quality of investigations to determine this either from the information available within investigation reports. On this basis, the NIMLT agreed that question 12.1 – 12.5 should be replaced with 12.1 only which read:

“Does the report state that nationally applicable recommendations should be communicated to relevant National Director(s) for implementation nationally within the body of the report (i.e. not just within the ToR)?
Addressing inter-rater reliability issues identified related to questions 15.1 and 15.3

To address the issue of poor inter-rater reliability identified related to question 15.1 and 15.3, the NIMLT considered these questions in the context of questions 15.1 – 15.4 in IQET 3. It was agreed that question 15.1. “Does the report consistently use every day words and avoid jargon?” would be deleted as elements of this were catered for in questions 15.2 – 15.4 which became 15.1 – 15.3 respectively as below:

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>15.1. Does the report use terms consistently e.g. heart attack v coronary event?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15.2. For abbreviations, are the terms always presented in full text with the abbreviation beside them the first time they appear in the report?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15.3. For technical terms, are they always explained; and/or is there a glossary of terms including the source of definitions referenced?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Addressing inter-rater reliability issues identified related to questions 18.1

To address the issue of poor inter-rater reliability identified related to question 18.1, the NIMLT agreed that question 18.1 in IQET 3 should be enhanced from: “Does the investigation report refer to the application of fair procedures?” by including the text: “…(i.e. not just ToR) as highlighted below:

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>18.1. Does the body of the investigation report (i.e. not just ToR) reflect the application of fair procedures?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Further enhancements to IQET 3 identified during the meeting with NIMLT quantitative inter-rater reliability reviewers and other NIMLT members that used IQET 3 to evaluate reports completed in 2015 - and solutions agreed to address these issues - are outlined in appendix 6.
A challenge for quantitative inter-rater reliability testing

A challenge emerged for quantitative inter-rater reliability testing of question 8.4 where the two reviewers (i.e. the second NIMLT reviewer and the author) interpreted this question differently as follows:

<table>
<thead>
<tr>
<th>8.4. Are the key causal factors adequately supported by the evidence presented within the investigation report?</th>
</tr>
</thead>
<tbody>
<tr>
<td>All (2)</td>
</tr>
</tbody>
</table>

The author interpreted this question to mean: Are the key causal factors or a finding that there were no key causal factors adequately supported by evidence presented within the investigation report? The second reviewer interpreted this question literally and did not answer this question in cases where the investigation did not identify any key causal factors.

Five of the nine reports (i.e. 55.56%) randomly selected for the quantitative inter-rater reliability testing did not identify key causal factors, with the result that there was very little data to compare for reliability testing purposes (i.e. only four cases).

In response to this issue, it was agreed by the NIMLT meeting that the following text “...or a finding that there were no key causal factors...“ should be added to question 8.4, and that the option “KFCs not referred to” would replace the option “N/A” in this question as highlighted below:

<table>
<thead>
<tr>
<th>8.4. Are the key causal factors or a finding that there are no key causal factors adequately supported by the evidence presented within the investigation report?</th>
</tr>
</thead>
<tbody>
<tr>
<td>All (2)</td>
</tr>
</tbody>
</table>

Related to this, it was agreed that the following additional question related to causal factor data collected for future analysis to identify patterns in causal factors - should be included as question 8.5:

“If there are no KFCs in the report or if there are and you believe based on the evidence in the report that they are incorrect; and if based on
The changes to IQET 3 as outlined above, and in appendix 6 (Results of quantitative inter-rater reliability testing of IQET 3) culminated in the creation of IQET 4 which went on to be used by the NIMLT for the evaluation of the quality of serious incident investigation reports completed in 2016 and onwards. A copy of IET 4 can be found in appendix 7.

3.3. Discussion

An emerging appreciation of the importance of evaluating and assuring the quality of investigations has occurred since the research reflected within this thesis was completed (Care Quality Commission, (2016 and 2016a); Department of Health, (2015); House of Commons, (2015); Kirkup, (2015); NHS Improvement, (2016); Parliamentary and Health Services Ombudsman, (2016); Leistikow (2016)).

The Morecambe Bay Investigation (Kirkup, 2015) found that the quality of investigations carried out into serious incidents in maternity services was poor and that this contributed to on-going failures to learn and improve. This was also found to have resulted in the system having an overly optimistic view of performance in the midwifery unit. Recommendation 23 of the Morecambe Bay Investigation stated that clear standards needed be drawn up for maternity serious incident investigations. However, there was no reference to the mechanism of evaluating compliance with these standards.

The Public Administration Select Committee Report “Investigating Clinical Incidents in the NHS” (House of Commons, 2015) found that the quality of most investigations fell far short of what patients, their families and NHS staff were entitled to expect, and that no single person or organisation was responsible and accountable for the quality of clinical investigations. This report recommended the establishment of an independent Health Services Investigation body that was primarily a centre of expertise and promoter of good investigatory practice and expertise with its own substantial investigative capacity, so that it could lead by example, oversee local investigations and conduct investigations when necessary. However, as for the Morecambe Bay
Investigation (Kirkup, 2015), there was no reference to the mechanism of evaluating that the quality of investigations was satisfactory.

The Parliamentary and Health Service Ombudsman’s Report (2015) expressed concerns that there was no national guidance for patient safety incident investigations which made clear how investigations should be independently quality assured and stated that investigations needed to “be independently quality assured”.

In its response to the Morecambe Bay Investigation (Kirkup, 2015), the Freedom to Speak Up Consultation (NHS Improvement, 2016), and the Public Administration Select Committee Report “Investigating Clinical Incidents in the NHS” (House of Commons, 2015), the English Government stated that it believed that there was further scope to improve the quality of investigations into serious incidents in the NHS; that there was much to be learned from other safety-conscious sectors such as the airline industry; and that clear standards should be drawn up for investigations of all serious incidents, not just maternity incidents. It announced that it would establish a new Independent Patient Safety Investigation Service that would conduct independent, expert-led investigations into patient safety incidents from the 1st of April 2016 (Department of Health, 2015).

Following this, NHS England published a revised Serious Incident Framework in March 2015 (NHS England, 2015). This framework did refer to quality assuring investigations. It stated that the investigation Commissioner should undertake a quality assurance review of the investigation report, and that the Commissioner must seek assurance that the report fulfilled the required standard for a robust investigation. In relation to quality assuring investigation reports, the framework referred the Commissioner to appendix 8 which included a closure checklist with 17 questions under the following six headings called “elements”: (i) Set up/preparation (i.e. of the investigation); (ii) Gathering and mapping; (iii) Analysing information; (iv) Generating solutions; (v) Throughout (i.e. Is there evidence that those affected have been appropriately involved and supported?); and (vi) Next steps (i.e. Is there a clear plan to support implementation of change and improvement and method for monitoring?).
This checklist asked whether the Lead Investigator was appropriately trained. What constituted appropriate training was not specified. The checklist also asked whether (i) national, standard NHS investigation guidance and process was used; (ii) interviews were conducted; (iii) care delivery problems were identified; and (iv) there was evidence that contributory factors were explored for each problem. Similar to the VA evaluation tool (Bagian et al., 2002), the NHS Serious Incident Framework Investigation evaluation tool required a yes or no answer to each of the 17 questions; and for questions that were answered “no” it asked whether there was a robust rationale that prevented this affecting the quality of the investigation.

Subsequently, the Care Quality Commission (2016) conducted a review of the quality of 74 serious incident investigation reports from 24 NHS acute hospital trusts related to incidents that had occurred between April 2013 and October 2014. The report stated that the assessment framework used for the evaluation of the quality of serious incident investigations was produced using guidance, tools and templates available on the NHS England website, including:

- The Serious Incident Framework March 2013, which was the guidance in place when trusts carried out the investigations included within the review.
- The revised Serious Incident Framework March 2015, to identify the impact of changed guidance on the findings of the review.

The specific tool used to evaluate the quality of these serious incident investigation reports was not available from these sources. This was sought and received through direct correspondence with the Care Quality Commission. The tool entitled “CQC Deaths in care review: The Quality of Serious Incident (SI) investigations of deaths” consisted of a total of 45 questions related to the following six aspects of investigation quality that were evaluated namely (i) Key facts about the investigation and its purpose (12 questions); (ii) Investigation team, methods and tools (6 questions); (iii) Depth
and breadth of information collected (16 questions); (iv) Conclusions of the investigation (3 questions); (v) Recommendations and learning from experience (8 questions); and (vi) Overall comment by the reviewer.

It is noteworthy that the CQC study referred to the term **Key Causal Factor**. This term did not appear in any of the guidance or supporting documentation related to serious incident investigation in the NHS at that time. This term was developed during the consultation and engagement process for the Irish Health Service Executives Guidelines for the Systems Analysis of Incidents and Complaints (Health Service Executive, 2012). The process that generated the term is described further in Chapter 2 of this thesis and in a paper by McCaughan et al., (2013).

Leistikow et al., (2016) described a tool used by the Dutch Health Inspectorate to evaluate the quality of sentinel event analysis reports. This evaluation tool included 29 questions related to the six aspects of investigation quality namely (i) Process (7 questions); (ii) Reconstruction (1 question); (iii) Analysis (5 questions); (iv) Conclusions (4 questions); (v) Recommendations (5 questions); and (vi) Aftercare (5 questions)

Unlike the VA NCPS Evaluation Tool (Bagian et al., 2002), the NPSA Evaluation Tools (Wallace et al., 2006); the NHS Serious Incident Framework Closure Checklist (NHS, 2015), and CQC Evaluation Tool (CQC, 2016) referred to above, questions in the Dutch Health Inspectorate evaluation tool were scored. Irrelevant questions did not obtain any score. The total score for each investigation report was calculated by dividing the total amount of points by the total amount of relevant questions, leading to a percentage which was the overall quality score of the sentinel event analysis report. This is in line with the scoring method for the IQET as described earlier in this chapter.

Appendix 8 details a comparison of IQET 3 developed as described in this chapter - with the other five evaluation tools (i.e. VA NCPS Evaluation Tool (Bagian et al., 2002); NPSA Evaluation Tools (Wallace et al., 2006); NHS Serious Incident Framework Closure Checklist (NHS, 2015); Dutch Health Inspectorate Evaluation Tool (Leistikow, 2016); and CQC Evaluation Tool (CQC, 2016)) showing where the other evaluation tools do and do not have questions that are equivalent to the IQET and vice versa.
The iterative action research approach to developing the IQET reflected in this chapter focused on developing the tool so that it would thoroughly and reliably evaluate the quality of serious incident investigations thereby answering the following question which underpinned this research:

“Is it possible to develop a tool to reliably evaluate the quality of serious incident investigation reports including the quality of the analytic trace for investigation findings?”

The resultant evaluation tool is time consuming to use. However, it should not be forgotten that this tool also collects data for analysis to identify patterns in causal factors (See Study 4) - in addition to data about the quality of investigations. The use of the IQET requires a high level of knowledge and experience of incident investigation. The future sustainable use of the tool requires buy in from future users. These three factors informed the decision to use NIMLT members to reliability test the evaluation tool as:

(i) they could be provided with protected time to conduct these tests,
(ii) they already had the high level of knowledge and experience of incident investigation necessary to use the tool, and
(iii) it was considered important to engage them in the development of the tool as they would be its future users.

Another important matter is the fact that the NIMLT was independent of the operations within which the incidents occurred. NIMLT was located within the HSE’s Quality Assurance and Verification Division (QAVD) and therefore, was well placed to conduct an independent and impartial evaluation of investigation quality.

That said, it is acknowledged that using NIMLT reviewers in reliability testing could detract from the rigor of the reliability testing. However, as described earlier in this chapter - this was considered to be a necessary and pragmatic compromise in this research in order to answer the research question and in order to increase the likelihood of the future use of this tool if this research identified that it was beneficial. In any event, the quantitative reliability testing described within this chapter identified that reasonable reliability was generally achieved.
The application of the evaluation tool in study 2, 3, and 4 as described in the next three chapters will throw light on whether the approach taken in this research was justified.
Chapter 4 - Study 2

Applying the IQET to evaluating investigation report quality

Overview of chapter 4

4.1. Introduction

4.2. Review of criteria for high quality investigations

4.3. Method

Sample
Application of the IQETs to evaluate 2013 and 2014 investigation reports
Method for Investigation Quality Scoring (IQS) 2014 investigations
Method for determining whether KCFs were adequately supported by evidence
Analysis of the quality of investigation reports

4.4. Result

Summary of quantitative results
Results from IQS process
Detailed results:
Investigation timeliness; Existence of “Summary of methodology”; Quality of data collection; Quality of chronologies; Quality of analysis to identify KCFs; Quality of analysis to identify CFs; Quality of analysis to identify IFs; Quality of recommendations; Readability of investigation reports; Fair procedures; Anonymisation; Apology; Impartiality; Guidelines followed

4.5. Discussion

Quality of data collected; Quality of chronology; Quality of analysis to identify KCFs; Quality of analysis to identify CFs; Quality of analysis to identify IFs; Recommendations; Generalizability; Readability, Fair procedures; Conclusion

4.1. Introduction

The overarching research question for this thesis considers how to effectively leverage incident investigations to inform system safety. This requires incident management and investigation policy that delivers measurable learning from incident investigations. This in turn requires consideration of both the HSE and the international investigation experiences and what we can learn from these to inform:
Chapter 2 described the HSE investigation experience and how learning from this and the international investigation experience informed (i) HSE criteria for high quality investigations, (ii) HSE investigation guidelines, and (iii) the delivery and evaluation of investigator training.

Chapter 3 described the process of developing a reliable tool to evaluate the quality of investigation reports in study 1. The research question underpinning this chapter is whether such a tool can be applied to evaluate investigation quality in a healthcare system to identify areas where they are strong, and areas for improvement. Study 2 endeavours to answer this research question by applying the tool to HSE investigations.

The discussion section of this chapter explores why HSE investigation reports did or did not meet particular standards. It identifies areas that need to be prioritised to improve investigation quality.

But first, this chapter reviews the criteria for high quality investigations and internal HSE investigation quality standards.

### 4.2. Review of criteria for high quality investigation

As detailed in Study 1 (Chapter 3), the following criteria were identified from the literature as important for high quality investigations:

(i) Thorough **data collection** and **analysis** is vital (Bagian *et al.*, (2002); Wallace *et al.*, (2006); Dekker (2006)).

(ii) Conducting **interviews** with **individuals that have information that is important for investigation purposes** including healthcare professionals that observed events and the person that was harmed by the events (and/or their family members as appropriate) (Bagian *et al.*, (2002)).

Duchscherer *et al.*, (2012) and Kanemane (2012) highlighted the importance of **individual interviews**. They emphasised that a principle of
good investigation is that interviewees should be interviewed individually to avoid influencing memory and interpretation of events.

(iii) An investigation report should leave an analytic trace for investigation findings. This includes a detailed reconstruction/chronology of events leading up to the incident (Bagian (2002), Dekker (2006), Wallace et al., (2006)).

(iv) A robust process for categorising the quality of data used to establish causes is pertinent (Bagian, (2002), Wallace et al., (2006); Doggett (2004); Carroll (2002); and Drupsteen & Hasle, (2014)).

(v) Developing efficient recommendations to address the causes of the incident is key (Dekker (2006); Bagian et al., (2002); Kellog et al., (2017)).

(vi) Checking the factual accuracy of the investigation report with those that were involved in/observed the incident (Bagian, 2002).

(vii) Writing investigation reports so that systemic causes and generalizable learning is apparent is important (Rasmussen, (1989, 1993, 1997); Dekker, (2006).

(viii) Investigation validity and reliability is important (Bowie et al., (2008)). According to Weiss (1998) validity has to do with the extent to which the indicator captures the concept of interest. An indicator should measure what you intend to measure. This would imply that valid investigations are investigations that ask all the questions they need to ask, and get all the answers they need to get to identify all the correct safety problem causes (i.e. contributory factors) and solutions (i.e. recommendations). Reliability has to do with whether repeated efforts to measure the same phenomenon come up with the same answer (Weiss, 1998). Applying this definition of reliability to investigations implies that reliable investigations are investigations that identify all the correct safety problem causes (i.e. contributory factors) and solutions (i.e. recommendations), so that if another investigation team were to conduct a second investigation of an incident using a comparable methodology, they should not identify any other or different contributory factors or recommendations.
4.3. Method

This section describes the application of the IQET as per steps 3 and 6 of the seven step process described in Study 1 and as shown in figure 4.1 below.

![Diagram](image)

**Step 1 (2013)**
Literature review and Investigation Quality Evaluation Tool 1 (IQET 1)

**Step 2 (2014)**
Qualitative inter-rater reliability testing of IQET 1
Random sample of 4 reports with 3 reviewers

**Step 3 (2014)**
IQET 1
Applied to 2013 reports to develop IQET 2
(n=62)

**Step 5 (2015)**
Developed IQET 3

**Step 6 (2015/16)**
Applied IQET 3 to 2014 reports (n=45)

**Step 7 (2016/17)**
Quantitative inter-rater reliability testing of IQET 3
Learning from this to inform IQET 4

**Step 4 (2015)**
Qualitative inter-rater reliability testing of IQET 2
Random sample of 4 investigations with 3 reviewers

Figure 4.1: Showing the application of the IQET as per steps 3 and 6

4.3.1. Sample

The National Director for Quality and Patient Safety (QPS) requested that reports of investigations of incidents that resulted in death and serious harm and which were completed between the 1st of January and 31st of December 2013 would be forwarded to the National Incident Management Team (NIMT) for review.

65 reports of investigations of serious incidents which were completed in 2013 were returned to the NIMT. Four were excluded (See footnote31).

---

31 One was a review of a service at a specific site and was not an investigation of a specific individual incident that resulted in death or serious harm.

---

One was a report of a Look Back Review in relation to a number of incidents; and not an individual investigation of a specific incident that resulted in death or serious harm.

---

One was a draft report of a healthcare record review related to an incident that resulted in serious harm and not a final report of a systems analysis investigation of that incident. This case was followed up to determine whether there was a final report of a full systems analysis investigation conducted in relation this incident and it was confirmed that a full investigation did not take place as safety recommendations were implemented based on the draft report of the healthcare record review.
Subsequently, the National Director for Quality Assurance and Verification (QAVD) wrote to the National Directors of the six Divisions of the HSE and requested that reports of investigations of incidents that resulted in death and serious harm and which were completed between the 1st of January and 31st of December 2014 would be attached to the Quality and Patient Safety Incident Information Management Systems (QPS IIMS) for review.

52 reports completed in 2014 were attached to the QPS IIMS. Seven were excluded (See footnote\textsuperscript{32}). See appendix 9 for further details of investigation reports that fell within this study.

4.3.2. Application of IQET to evaluate the 2013 & 2014 reports

IQET 1 was used to evaluate the quality of the 62 investigation reports completed in 2013. It was then enhanced to create IQET 2 based on learning from the process of evaluating the 2013 investigation reports in Study 1 as described in Chapter 3. Qualitative inter-rater reliability testing of IQET 2 was conducted following evaluation of the 2013 investigation reports culminating in the development of IQET 3. This was used to evaluate the 45 investigation reports completed in 2014. The main differences of IQET 1, 2, and 3 are outlined in Chapter 3 and the tools can be found in appendices 3, 4, and 5.

The data was inputted on an SPSS data base.

\textsuperscript{32} Of the 52 investigation reports that were attached to the QPS IIMS, one was an investigation of an incident that was completed in 2013. This investigation was not one that was returned with the 2013 investigation reports already received by the NIMLT. This investigation was reviewed using IQET 3. Of the remaining 51 investigation reports that were returned and which were completed in 2014, six were excluded from this study for reasons outlined as follows:

\begin{itemize}
  \item Two were investigations of incidents that were completed in 2015. These investigation reports were not included within this study.
  \item One submission was a report of a Look Back Review in relation to a number of incidents; and not an individual investigation of a specific incident that resulted in death or serious harm.
  \item One was a draft report of the investigation of a serious incident. Follow up occurred with the relevant division a number of times to determine whether there was a final report of the investigation of this incident. A final report was not furnished by the time the review and analysis took place. Consequently, the draft report was not included within this study.
  \item One report was not a systems analysis of an incident, but was rather an investigation of an allegation of abuse of a vulnerable adult under the HSE’s Vulnerable Adults Policy (2014), and so this was not included within this study.
  \item One report attached to the QPS IIMS was password protected. Follow up was made with the relevant division seeking the password. A password was not furnished by the time the review and analysis took place so this report could not be included in this study.
\end{itemize}
The structure and content of the 2013 investigation reports varied significantly. This posed challenges for evaluation. The average amount of time to evaluate and enter data from the 2013 investigation reports was 74.45 minutes; with a minimum duration of eight minutes, and a maximum duration of 204 minutes.

2014 reports were less variable but took more time to analyses because more data was gathered from them. The average amount of time for 2014 reports was 102.32 minutes; with a minimum duration of 47 minutes and a maximum duration of 209 minutes.

4.3.3. Method for Investigation Quality Scoring (IQS) 2014 reports

Study 1 (Chapter 3) details the Investigation Quality Scoring (IQS) process which was developed to score aspects of the 2014 investigation reports which were considered important for (i) “leaving an analytic trace for investigation findings” (Dekker, 2006), and for (ii) enabling analysis for generalizable learning from groups of investigation reports. Tables 3.3 and 3.4 in Study 1 in Chapter 3 show the criteria that underpinned decisions about which sections of the evaluation tool were used for quality scoring purposes and which sections were not.

4.3.4. Method for determining whether causal factors were adequately supported by evidence

After reading and evaluating the quality of the chronology and before reading and evaluating the Key Causal Factors (KCFs), KCFs were deduced from the evidence presented within the chronology. The KCFs deduced in this manner were then compared with the KCFs that were identified within the actual investigation report by the original investigators. Different and/or additional KCFs were deduced for some investigation reports from this process and these are illustrated via examples of cases in the results section of this chapter.

After reading and evaluating the quality of the analysis of the KCFs to identify contributory factors (CFs), the CFs were considered to determine whether they were adequately supported by the evidence within the investigation report. This included considering whether different and/or other CFs were
identifiable from the evidence presented within the investigation report. These are illustrated with examples of cases in a later section of this chapter.

4.3.5. Analysis of the quality of investigation reports

Data related to the quality of investigation reports for both the 2013 and the 2014 investigation reports were analysed together where possible. The data were analysed separately where joint analysis was not possible due to differences in the version of the IQET used. The results of this analysis are outlined in section 4.4 below.

4.4. Results

This results sections starts by summarising the quantitative analysis (i.e. analysis of questions with yes/no answers), followed by outlining the results of the Investigation Quality Scoring (IQS) process. Finally, the detailed findings of the evaluation of investigation quality are outlined including using cases of specific investigations to illustrate these findings.

4.4.1. Summary of quantitative results

Table 4.1 below shows the results of the analysis of the questions in the evaluation that elicited yes/no answers.

Note re table 4.1 below:
* and the green colour indicates that this question was used for IQS purposes
¥ Indicates that information from both 2013 and 2014 investigation was included in this analysis

<table>
<thead>
<tr>
<th>Question</th>
<th>Frequency</th>
<th>Valid Percent</th>
<th>N/A</th>
<th>Not possible to tell</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1. Does the report state the date the incident occurred?</td>
<td>102</td>
<td>96.2</td>
<td>3.8</td>
<td>1</td>
<td>106¥</td>
</tr>
<tr>
<td>2.3. Does the report state the date the investigation team was established?</td>
<td>4</td>
<td>8.9</td>
<td>91.1</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>2.6. Does the report state the date the investigation commenced?</td>
<td>54</td>
<td>50.5</td>
<td>49.5</td>
<td>-</td>
<td>107¥</td>
</tr>
<tr>
<td>2.9. Does the report state the date the investigation was completed?</td>
<td>93</td>
<td>86.9</td>
<td>13.1</td>
<td>-</td>
<td>107¥</td>
</tr>
<tr>
<td>2.14. Did the investigation achieve the target timelines?</td>
<td>7</td>
<td>19.4</td>
<td>80.6</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>2.15. If no, is a reason for the delay given in the investigation report?</td>
<td>7</td>
<td>24.1</td>
<td>75.9</td>
<td>-</td>
<td>29</td>
</tr>
<tr>
<td>4.1. Does the report state the names of the investigators?</td>
<td>40</td>
<td>88.9</td>
<td>11.1</td>
<td>-</td>
<td>45</td>
</tr>
<tr>
<td>4.2. Does the investigation report state the number of investigators?</td>
<td>101</td>
<td>94.4</td>
<td>5.6</td>
<td>-</td>
<td>107¥</td>
</tr>
<tr>
<td>4.3. If no, is it possible to deduce the number of investigators?</td>
<td>0</td>
<td>0</td>
<td>100</td>
<td>-</td>
<td>6</td>
</tr>
<tr>
<td>4.5. Does the investigation report state the job title of the investigators?</td>
<td>40</td>
<td>88.9</td>
<td>11.1</td>
<td>-</td>
<td>45</td>
</tr>
<tr>
<td>4.8. Does the investigation report state whether the investigators were internal and/or external?</td>
<td>11</td>
<td>24.4</td>
<td>75.6</td>
<td>-</td>
<td>45</td>
</tr>
</tbody>
</table>

33 Valid percent is the percent when not applicable cases/missing data are excluded from the calculations
<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>% Yes</th>
<th>% No</th>
<th>% Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.9. If not, is it possible to deduce whether the investigators were internal and/or external?</td>
<td>32</td>
<td>2</td>
<td>94.1</td>
<td>5.9</td>
<td>96.6</td>
</tr>
<tr>
<td>4.11. Does the investigation report state that the investigators were NOT responsible for the service within which the incident occurred?</td>
<td>1</td>
<td>44</td>
<td>2.3</td>
<td>97.7</td>
<td>96.0</td>
</tr>
<tr>
<td>4.12. If not, is it possible to deduce from the report that the investigators were NOT responsible for the service within which the incident occurred?</td>
<td>8</td>
<td>36</td>
<td>18.2</td>
<td>81.8</td>
<td>76.4</td>
</tr>
<tr>
<td>4.14. Does the investigation report state that the investigators were NOT directly involved in the incident being investigated?</td>
<td>1</td>
<td>44</td>
<td>2.3</td>
<td>97.7</td>
<td>96.0</td>
</tr>
<tr>
<td>5.1. Does the investigation report include the terms of reference (ToR) for the investigation?</td>
<td>30</td>
<td>15</td>
<td>66.7</td>
<td>33.3</td>
<td>66.7</td>
</tr>
<tr>
<td>5.2. If yes, does the ToR that is included adhere fully to the template ToR from the HSE Guidelines?</td>
<td>11</td>
<td>19</td>
<td>36.7</td>
<td>63.3</td>
<td>45.5</td>
</tr>
<tr>
<td>5.3. Does the report include a summary of the method used to conduct the investigation?</td>
<td>34</td>
<td>11</td>
<td>75.6</td>
<td>24.4</td>
<td>75.6</td>
</tr>
<tr>
<td>5.4. Does the summary of the investigation report state that a systems methodology was used for this investigation?</td>
<td>34</td>
<td>11</td>
<td>75.6</td>
<td>24.4</td>
<td>75.6</td>
</tr>
<tr>
<td>6.1. Does the investigation report state that the investigators were NOT responsible for the service within which the incident occurred?</td>
<td>1</td>
<td>44</td>
<td>2.3</td>
<td>97.7</td>
<td>96.0</td>
</tr>
<tr>
<td>6.2. Does the investigation report state that the relevant records/healthcare records were collected and reviewed?</td>
<td>37</td>
<td>8</td>
<td>82.2</td>
<td>17.8</td>
<td>82.2</td>
</tr>
<tr>
<td>6.3. Does the report reflect that the relevant local/national/international PPPGs were collected and reviewed?</td>
<td>15</td>
<td>29</td>
<td>34.1</td>
<td>65.1</td>
<td>34.1</td>
</tr>
<tr>
<td>6.4. Does the report reflect a search for and review of all relevant literature?</td>
<td>10</td>
<td>35</td>
<td>22.2</td>
<td>77.8</td>
<td>22.2</td>
</tr>
<tr>
<td>6.5. Does the report state the number of individual interviewees that were interviewed?</td>
<td>47</td>
<td>60</td>
<td>43.9</td>
<td>56.1</td>
<td>43.9</td>
</tr>
<tr>
<td>6.6. Does the report reflect that individual interviews were conducted with individuals that observed the incident and/or had information pertinent to the investigation?</td>
<td>47</td>
<td>60</td>
<td>43.9</td>
<td>56.1</td>
<td>43.9</td>
</tr>
<tr>
<td>6.7. Does the report reflect that those harmed/affected were given an opportunity to participate in an interview?</td>
<td>16</td>
<td>28</td>
<td>36.4</td>
<td>63.6</td>
<td>36.4</td>
</tr>
<tr>
<td>7.2. Was the scope in time reasonable?</td>
<td>35</td>
<td>*</td>
<td>79</td>
<td>25</td>
<td>80.3</td>
</tr>
<tr>
<td>7.3. Are events placed in chronological order?</td>
<td>40</td>
<td>5</td>
<td>88.9</td>
<td>11.1</td>
<td>88.9</td>
</tr>
<tr>
<td>7.4. Is the exact date and time of each event specified where this is known?</td>
<td>37</td>
<td>7</td>
<td>84.1</td>
<td>15.9</td>
<td>84.1</td>
</tr>
<tr>
<td>7.5. Where exact date and time is not known, is there evidence that investigators tried to determine this as well as possible from information available and from interviews in order to be able to place the event in chronological order including noting that the time is an approximation where relevant?</td>
<td>10</td>
<td>8</td>
<td>55.6</td>
<td>44.4</td>
<td>55.6</td>
</tr>
<tr>
<td>7.6. Is the chronology sufficiently detailed including details about reasons for, results of, and significance of tests/examinations and interventions?</td>
<td>6</td>
<td>39</td>
<td>13.3</td>
<td>86.7</td>
<td>13.3</td>
</tr>
<tr>
<td>7.7. Does the investigation report specify the individual that observed each chronological event?</td>
<td>22</td>
<td>19</td>
<td>53.7</td>
<td>46.3</td>
<td>53.7</td>
</tr>
<tr>
<td>7.8. Does the investigation report specify the source of the information referred to in the chronology?</td>
<td>20</td>
<td>21</td>
<td>48.8</td>
<td>51.2</td>
<td>48.8</td>
</tr>
<tr>
<td>8.1. Does the report refer to the definition of key causal factors in line with HSE investigation guidelines?</td>
<td>21</td>
<td>24</td>
<td>46.7</td>
<td>53.3</td>
<td>46.7</td>
</tr>
<tr>
<td>8.2. Does the report identify KCFs (or state that none were identified)?</td>
<td>39</td>
<td>6</td>
<td>86.7</td>
<td>13.3</td>
<td>86.7</td>
</tr>
<tr>
<td>8.4. Are the KCFs adequately supported by evidence presented within the investigation report?</td>
<td>29</td>
<td>78</td>
<td>27.1</td>
<td>72.9</td>
<td>27.1</td>
</tr>
<tr>
<td>9.1. Does the report refer to the definition of IFs in line with HSE investigation guidelines?</td>
<td>14</td>
<td>31</td>
<td>31.1</td>
<td>68.9</td>
<td>31.1</td>
</tr>
<tr>
<td>9.2. Does the report identify IFs or state that no IFs were identified?</td>
<td>24</td>
<td>21</td>
<td>53.3</td>
<td>46.7</td>
<td>53.3</td>
</tr>
<tr>
<td>9.3. Are IFs adequately supported by evidence within the investigation report?</td>
<td>12</td>
<td>32</td>
<td>27.3</td>
<td>72.7</td>
<td>27.3</td>
</tr>
<tr>
<td>10.1. Does the report reflect that each individual KCF was analysed separately to identify CFs?</td>
<td>11</td>
<td>16</td>
<td>40.7</td>
<td>59.3</td>
<td>40.7</td>
</tr>
<tr>
<td>10.2. Does the report clearly describe the factor type and the CF in line with HSE Investigation Guidelines (2012) stated that the scope in time of an investigation should be the shortest sufficient period of time necessary to be included to ensure the investigation proposes will be achieved.</td>
<td>10</td>
<td>78</td>
<td>27.1</td>
<td>72.9</td>
<td>27.1</td>
</tr>
</tbody>
</table>
10.3. In addition to the information referred to in 10.2. above, does the report include further details of each CF?*  
10.4. Are the CFs adequately supported by the evidence presented within the investigation report?*  
11.1. Does the report make recommendations?**  
11.2. Are the recommendations linked to CFs?*  
11.3. Are recommendations SMART?**  
11.4. Is there reference to the hierarchy of preferred control measures for developing recommendations?**  
11.5. Is there evidence that the hierarchy of preferred control measures was used in the development of recommendations?*  
12.1. Does the report identify CFs that seem as though they may occur elsewhere?  
12.2. If yes, does the report state that the CFs may occur elsewhere?*  
12.3. Does the report identify recommendations that seem as though they may be applicable elsewhere?  
12.4. If yes, does the report state that the recommendations are applicable elsewhere?*  
12.5. Also, if yes, does the report state that nationally applicable recommendations should be communicated to the relevant National Director(s) for implementation nationally within the body of the report?  
13.1. Does the report state that legal review of the report was undertaken?  
13.2. Does the report state that the investigation was carried out in accordance with the relevant legal framework?*  
13.3. Are recommendations SMART?  
13.4. For technical terms, are they always explained; and/or is there a glossary of terms including the source of definitions references?*  
13.5. For abbreviations, are the terms always presented in full text with the abbreviation beside them the first time they appear in the report?*  
14.1. Is the investigation report anonymised  
14.2. Is the investigation report anonymised in terms of the staff involved?  
14.3. Is the investigation report anonymised in terms of age?  
14.4. Is the investigation report anonymised in terms of gender?  
14.5. Is the investigation report anonymised in terms of the site where the incident occurred?  
15.1. Does the report state that a clear, specific, Measurable, Achievable, Realistic and state a Timeframe for completion (SMART)  
15.2. Does the report use terms consistently (i.e. heart attack v coronary event)?*  
15.3. For abbreviations, are the terms always presented in full text with the abbreviation beside them the first time they appear in the report?*  
15.4. For technical terms, are they always explained; and/or is there a glossary of terms including the source of definitions references?*  
16.1. Is an apology appropriate?*  
16.2. Where an apology is appropriate is an apology given/referred to in the report?  
17.1. Does the report reflect that those harmed/affected were given an opportunity to contribute to the investigation?  
17.2. If yes, did they contribute?  
17.3. If yes, was their contribution to the investigation acknowledged?  
17.4. Was the contribution of staff to the investigation acknowledged?  
18.1. Does the investigation report refer to the application of fair procedures?*  
18.2. Does the body of the investigation report reflect that interviewees received a draft report (or relevant excerpts) for factual accuracy checking purposes?*  
18.3. Does the report reflect that those affected received a draft chronology and any other relevant excerpts for factual accuracy checking purposes?*  
18.4. Does the report reflect that the draft was modified based on feedback to enhance factual accuracy and to enable the report to achieve its objectives?*  
19.1. Is the report written impartially (i.e. there is no evidence of bias such as hindsight bias, outcome bias or any other bias in the investigation report)?  

Table 4.1. Results of analysis of investigation reports related to yes/no questions on IQET

36 HSE Investigation Guidelines (2016) define SMART recommendations as Specific, Measurable, Achievable, Realistic and state a Timeframe for completion (SMART)
37 HSE Investigation Guidelines (2012) stated that it was appropriate for an apology to be given to the individual(s) affected if key causal factors are identified in the report.

137
4.4.2. Results from IQS process

Using the IQS process as outlined in Study 1 in Chapter 3, IQSs for the investigation reports completed in 2014 ranged from 13.79 - 78.13 with the average score being 45.17%.

Figure 4.2 below shows the percentage of the 2014 investigation reports that demonstrated satisfactory evidence in relation to each of the 41 elements of the IQS process under the nine main investigation quality themes.
Figure 4.2: Graph showing the proportion of investigations that demonstrated satisfactory evidence in relation to each of the 41 elements quality scored (IQS).
As shown in figure 4.2, 70% or more of the investigation reports reflected satisfactory evidence of:

→ **Summary** of data collected and reviewed

→ Relevant records/healthcare records were collected and reviewed

→ Investigation reports reflected that a reasonable **scope in time** was covered by the investigation, with events placed in chronological order within the chronology, and with exact date and time of events given where this was known

→ **KCFs and CFs were identified or** a statement that none were identified

→ **Recommendations** were made when appropriate, and these were linked to CFs

→ Terms were used **consistently** (i.e. heart attach v coronary event)

Conversely, 70% or more did not reflect satisfactory evidence of:

→ Search and review of the relevant **literature**

→ Sufficient details within the **chronology** including reasons for, results of, and significance of tests, examinations and interventions.

→ Adequate **evidence** to support identified KCFs, CF, and IFs or to support a finding that no KCFs, CFs, and IFs were identifiable

→ Clear **description of the factor type** and contributory factor in line with the framework of contributory factors in HSE guidelines.

→ Demonstrating that recommendations were **SMART**; and that the **“Hierarchy of preferred controls”** was referenced and used in developing recommendations.

→ That those affected received a **draft report for factual accuracy checking**.

→ **Generalizability** of investigation reports was a problem with only 5.9% of applicable investigation reports stating that CFs may occur elsewhere, only 5.3% of applicable investigation reports stating that recommendations may be applicable elsewhere, and none of the applicable investigation reports stated that nationally applicable recommendations should be
communicated to the relevant National Director(s) for implementation nationally.

4.4.3. Detailed results

4.4.3.1. Investigation timeliness

As shown in table 4.2 below, information about the timeframe from commencing to completing investigation reports was available for 35% (n=38) of investigation reports.\(^{38}\)

<table>
<thead>
<tr>
<th>Months from date investigation commenced to date completed</th>
<th>2013 Investigations</th>
<th>2014 Investigations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data available</td>
<td>18</td>
<td>20</td>
</tr>
<tr>
<td>Data missing</td>
<td>44</td>
<td>25</td>
</tr>
<tr>
<td>Mean</td>
<td>10.15</td>
<td>5.75</td>
</tr>
<tr>
<td>Median</td>
<td>6.00</td>
<td>5.00</td>
</tr>
<tr>
<td>Mode</td>
<td>6.00</td>
<td>1.00(^{a})</td>
</tr>
<tr>
<td>Std Deviation</td>
<td>8.57</td>
<td>3.52</td>
</tr>
<tr>
<td>Variance</td>
<td>73.74</td>
<td>12.38</td>
</tr>
<tr>
<td>Range</td>
<td>33.50</td>
<td>12.50</td>
</tr>
<tr>
<td>Minimum</td>
<td>1.75</td>
<td>1.00</td>
</tr>
<tr>
<td>Maximum</td>
<td>35.25</td>
<td>13.50</td>
</tr>
</tbody>
</table>

\(^{a}\) Multiple modes exist. The smallest value is shown

Table 4.2: Table comparing the timeframes for completion of investigation reports in 2013 and 2014.

The most common reason for delay cited in investigation reports related to issues of availability/competing priorities of investigation team members. Appendix 10 includes details of the reason for delays in completing investigations cited within investigation reports.

As shown in table 4.1 (i.e. 2.14), 19.4% (n=7) of applicable\(^{39}\) investigations achieved the target timeline of being completed within four months.\(^{40}\)

\(^{38}\) Specifically, this information was available for 16.82% (n=18) of 2013 reports; and for 44.44% (n=20) of 2014 reports.

\(^{39}\) In relation to investigations where timelines were categorised as “Not applicable”, all six were preliminary reports only and not a full systems analysis investigation (Case refs 84, 85, 86, 90, 91 and 101). The target timeline related to systems analysis
4.4.3.2. **Existence of the “Summary of the Methodology”**

HSE Investigation Guidelines (Health Service Executive, 2012) required that investigation reports included a methodology section. This, in-turn needed to include a summary of the systems analysis methodology used.

Table 4.1 (i.e. 5.3) shows that 24.4% (n=11) of investigations completed in 2014 did not include a summary of the investigation methodology used.

Appendix 11 gives further details of investigation reports that did not include a summary of the investigation methodology used and details from the comments section of the IQET - in relation to whether investigation reports included a summary of the investigation methodology used.

All of the 2014 reports that referred to a methodology (i.e. 75.6% (n=34)) stated that a systems analysis methodology was used. However, it was not unusual for investigation reports to state that they followed the systems analysis method, but for them not to actually follow the method either partially or completely as can be seen in the subsequent sections of this chapter. Further details related to this can be found in appendix 12.

4.4.3.3. **Quality of data collection**

Evaluation of the quality of the data collected was included in the IQS process and evaluated the following:

(i) the summary of the data collected and reviewed
(ii) whether relevant record/healthcare records were reviewed
(iii) whether relevant local, national and international PPPG’s were reviewed
(iv) whether all the relevant literature was reviewed

On the 23rd of May 2014, the HSE approved a Safety Incident Management Policy which included a target timeline for completion of investigation reports of four months, or less, from the day the investigation team was established. Two reports included in this study were commenced following the publication of this policy (Case refs 101 and 110). Both of these reports were completed within the four months target timeline. Case 101 was a preliminary report only. IQET 3 included a question related to whether investigation reports achieved the target timelines.

PPPG’s: Policies, Procedures, Protocols, and Guidelines
(v) data collected via interview

The results are shown in table 4.1 (i.e. 6.2 & 6.4) where it is apparent that there was a tendency to focus more on review of healthcare records and less on review of relevant PPPGs, and literature.

In relation to interviews:

→ 45.8% (n=49) of investigation reports did not refer to interviews
→ 43.0% (n=46) of investigation reports reflected that staff attended individual interviews
→ 0.9% (n=1) used interviews conducted for another process[^42]
→ 9.3% (n=10) referred to multidisciplinary team (MDT) meetings, and
→ 0.9% (n=1) referred to a combination of MDT interview and individual interviews

HSE investigation guidelines required that those that were harmed or affected by incidents, and/or their families, should be interviewed where appropriate. 36.4% (n=16) of 2014 investigation reports reflected that individuals affected by adverse events were given an opportunity to participate in an interview. Of these 16 cases where those affected/harmed were offered an opportunity to participate in an interview, 12 (75%) accepted the opportunity, and four (25%) declined.

Further details in relation to data collected via interview are included in appendix 13.

**4.4.3.4. Quality of chronologies**

The evaluation of the quality of the chronology involved the following seven elements all of which were included in the IQS process and further details of each are given in the following sections:

(i) Was the scope in time reasonable?
(ii) Were events placed in chronological order?
(iii) Was the exact date and time specified where known?

[^42]: This case used interviews conducted for a separate Trust in Care/Safeguarding investigation
(iv) Where this was not known, was there evidence that investigators tried to determine this from information available and from interviews?
(v) Was the chronology sufficiently detailed?
(vi) Was the source of information specified?
(vii) Were the observers of each event specified?

**Was the scope in time reasonable?**

For investigation reports completed in both 2013 and 2014, the scope in time was not specified in 2.8% (n=3) cases\(^{43}\). As seen in table 4.1 (i.e. 7.2), the scope in time was deemed to be reasonable in 76.0% (n=79) of investigations.

Analysis of the comments section of the IQET related to the scope in time of the investigation found that 16.8% (n=18) of chronologies did not include sufficient detail about the time immediately prior to the incident.

It arose in one case\(^{44}\) that the investigation related to the care delivered at one hospital, while care was actually delivered to the patient at two hospitals. The family’s complaint related to the failure to diagnose the patient’s condition at the first hospital. But it was not clear from the investigation report whether there were or were not issues in relation to the care delivered at the second hospital. It may have been helpful for this investigation to consider care delivered at both hospitals, unless there was some evidence at the outset that confirmed that there were no issues with care at the second hospital. If this was the case, it would have been helpful for this to have been explicitly stated within the investigation report. For example, it may have been helpful for the investigation report to outline whether the diagnosis was made within a reasonable timeframe at the second hospital.

**Were events placed in chronological order?**

This data was collected for 2014 investigation reports. As shown in table 4.1 (i.e. 7.3), events were considered to be placed in chronological order in 88.9% (n=40) of the 2014 investigation reports.

\(^{43}\) The scope in time was not specified for case refs 3, 80, and 130

\(^{44}\) Case ref 63
In one investigation report\(^{45}\) there were two different chronologies and the reason for this was unclear. It was also unclear what the difference between the two chronologies was. In another\(^{46}\), there was a summary chronology in the body of the report and a detailed chronology in an appendix. In one report\(^{47}\) there was one chronology derived from interviews; and a separate chronology derived from the healthcare records. Finally, in once case\(^{48}\) where retrospective notes were made, these were placed chronologically when the retrospective notes were made rather than at the time they referred to (albeit that the source of information was from a retrospective note made sometime later).

Was (i) the exact date and time specified, (ii) the chronology sufficiently detailed, (iii) the source of information specified, and (iv) the observer of events specified?

This data was collected for the 2014 investigation reports. As shown in table 4.1 (i.e. 7.4, 7.6, 7.7 & 7.8):

- Exact dates and times for each event were identified to be specified where this was known in 84.1% (n=37) of these investigation reports,
- Chronologies were deemed to be sufficiently detailed in relation to reasons for, results of, and significance of tests, and interventions in 13.3% (n=6) of investigation reports,
- Chronologies were considered to include sufficient detail about the source of information in 48.8% (n=20) of 2014 reports, and
- Chronologies were identified to include sufficient detail about who exactly observed events in 53.7% (n=22) of 2014 reports.

Further details from the comments section of the IQET related to the chronology can be found in appendix 14.

\(^{45}\) Case ref 131  
\(^{46}\) Case ref 122  
\(^{47}\) Case ref 120  
\(^{48}\) Case ref 115
4.4.3.5. Quality of analysis to identify Key Causal Factors

The process of evaluating the quality of analysis to identify Key Causal Factors (KCFs) included the following four elements which are described further in the next sections:

(i) checking whether the definition of key causal factor within investigation reports was in line with HSE guidelines

(ii) determining whether reports stated that KCFs were identified or stated that none were identifiable

(iii) determining whether KCFs (or a finding that none were identifiable) were adequately supported by the evidence reflected within investigation reports thus leaving what Dekker (2006) referred to as the analytic trace for investigation findings

(iv) A check to identify different/additional KCFs from the evidence

As shown in table 4.1 (i.e. 8.1), investigation reports completed in 2014 referred correctly to the definition of KCFs in 46.7% (i.e. n=21) of cases.

Did reports clearly identify KCFs or state none were identifiable?

Table 4.1 shows that 86.7% (n=39) of the 2014 reports stated that key causal factors were identified or that key causal factors were not identifiable. As shown in table 4.3 below, 56.4% (n=22) of these identified key causal factors.

<table>
<thead>
<tr>
<th>Key Causal Factor identified?</th>
<th>Does the report identify KCFs or state no KCFs exist?</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Yes</td>
<td>22</td>
<td>0</td>
</tr>
<tr>
<td>No</td>
<td>17</td>
<td>5</td>
</tr>
<tr>
<td>Report does not refer to KCFs</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>39</td>
<td>6</td>
</tr>
</tbody>
</table>

Table 4.3: Cross tabulation showing whether reports identify Key Causal Factors or state that no key causal factors were identified cross

<sup>49</sup>The case that did not refer to key causal factors was a review related to delayed access to psychiatric admission beds (i.e. case ref 98).
tabulated with whether reports identified key causal factors or not for 2014 reports

Were KCFs satisfactorily supported by evidence?

As shown in table 4.1 (i.e. 8.4)), evaluation deemed that KCFs (or a finding that no KCFs were identifiable) were adequately supported by the evidence within the investigation report in 27.1% (n=29) of reports completed in both 2013 and 2014.

Comparing 2013 reports with 2014 reports – it is apparent from table 4.4 below that 32.5% (n=20) of the 2013 investigation reports demonstrated adequate evidence to support KCFs (or a statement that no KCFs existed) while 20.0% (n=9) of the 2014 investigations demonstrated adequate evidence in relation to this.

<table>
<thead>
<tr>
<th>Is the identification of KCFs (or NO KCFs) adequately supported by evidence in the report?</th>
<th>2013 investigations</th>
<th>2014 investigations</th>
<th>2013 &amp; 2014 investigations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>17 (85%)</td>
<td>7 (70%)</td>
<td>24 (83%)</td>
</tr>
<tr>
<td>No</td>
<td>10 (43%)</td>
<td>15 (42%)</td>
<td>25 (42%)</td>
</tr>
<tr>
<td>Total</td>
<td>27 (15%)</td>
<td>22 (22%)</td>
<td>49 (17%)</td>
</tr>
</tbody>
</table>

Table 4.4: Cross tabulation for whether Key Causal Factors were identified or not with whether this was adequately supported by evidence in the report (for 2013 reports, 2014 reports, and both 2013 and 2014 reports).

Investigation reports that were found to have adequate evidence to support the identification of KCFs (or that no KCFs were identifiable) were more likely to identify KCFs, and this was consistent for 2013 and 2014 investigation reports as follows:

The Chi-Square test was done to determine if there was a statistically significant difference between the rates with which these two groups of reports (i.e. reports that demonstrated adequate evidence to support the KCFs identified versus reports that did not demonstrate adequate evidence of this) identified KCFs. The Pearson Chi-Square test showed that \( \chi^2(1)=11.603 \), \( P=0.001 \) meaning that reports that demonstrated adequate evidence to support the KCFs identified (or a finding that none were identifiable) were statistically significantly more likely to identify key causal factors.
**Deducing different/additional KCFs from the evidence**

After reading and evaluating the quality of the chronology and before reading and evaluating the KCFs, KCFs were deduced from the evidence presented within the chronology. The KCFs deduced in this manner were then compared with the KCFs that were identified within the actual investigation report by the original investigators. Different and/or additional KCFs were deduced for some investigation reports from this process. Table 4.5 below shows whether KCFs were identified by the original investigators within reports cross-tabulated with whether additional and/or different KCFs were deemed deducible by the author from the information available within investigation chronologies.

<table>
<thead>
<tr>
<th>Are different/additional KCFs deducible from the evidence within investigation reports?</th>
<th>Are Key Causal Factors identified within investigation reports by the original investigators?</th>
<th>2013 investigations</th>
<th>2014 investigations</th>
<th>2013 &amp; 2014 investigations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 4.5: Showing cross tabulation for whether Key Causal Factors were identified by the original investigators v whether they were deducible from the evidence within reports (for 2013 reports, 2014 reports, and both 2013 and 2014 reports).

As seen in table 4.5 above, for the 2014 investigation reports, the evaluation identified that different and/or additional KCFs were deducible in 24.44% (n=11) of cases. These 11 cases included four cases where the original investigation had not already identified Key Causal Factors; and seven cases where Key Causal Factors had been identified in the original investigation.

Below are some examples of cases where the evaluation identified that additional/different KCFs were deducible from the information available within the investigation reports.

**Important Note about the following cases:**

It must be emphasised that it is not possible for someone that is evaluating an investigation report without access to the original data (i.e. records and notes of interviews) to definitively determine whether the Key Causal Factors
identified within the investigation report are correct; or to identify new correct Key Causal Factors which were not identified in the original investigation report. It is accepted that even if Key Causal Factors appear to be incorrect or omitted, this may not in fact be the case. It may simply appear to be the case because there is insufficient information in the investigation report to either support the identified key causal factors or to support the finding that Key Causal Factors were not identifiable. In Dekker’s (2006) words, there is an insufficient analytic trace for investigation findings.

**Case 1: A case of suicide (Case Ref 84).**

This investigation stated that no KCFs were identifiable.

However, the quality of the chronology and analysis was not sufficient for the reader to be confident that no KCFs were identifiable.

Specifically:

a) The report identified that there was an issue related to the fact that a collateral history was not taken from a spouse on a named date. However, whether the spouse was there to give a collateral history on the named date was not stated. It appeared that the spouse may not have been present on that date but this was not explicitly stated. The issue of how well the service makes arrangements to ensure that collateral history givers are available to give collateral histories as soon as possible was not explored.

b) It was not clear what the diagnosis for the service user was and whether it was appropriate.

c) It was not clear whether the intervention in this case was appropriate i.e. the medication the service user was prescribed was known to cause feelings of agitation, restlessness, anxiety, aggression, feelings of being emotional, and feelings of not being like themselves or feelings that they may want to hurt themselves or others. This service user did express at their second visit that they wanted their medication changed due to worries related to their children. The literature stated that such side effects should be monitored closely. The service user was given an appointment for 11 days later, but sadly, died by suicide prior to this. It
was not clear what follow up occurred in relation to the service users concerns about their medication and whether the follow up would be considered appropriate in such circumstances.

Case 2:  Death of a service user living in a high support community residence by falling from a window (Case Ref 88)

This investigation identified the following two Key Causal Factors (KCFs):

**KCF 1:** Underlying condition of complex and enduring mental illness

**KCF 2:** Care management of a complex and enduring mental illness within the context of a community based recovery orientated service.

However, from the chronology it appeared that there may have been other key causal factors related to the need for increased monitoring which had been identified by clinical assessment; and issues related to compliance with medication. The investigation report did not include adequate detail about these issues.

On the basis of the evidence within this investigation report, the author deduced that the following may also have been Key Causal Factors in this case:

**Deduced KCF 1:** Failure to provide increased monitoring identified as necessary by clinical assessment

**Deduced KCF 2:** Issues in relation to monitoring compliance with medication

Additionally, the report recorded that the service user stated that they had been thinking of jumping out of a window shortly before they fell out of the window. The report also stated that it was not possible to conclude whether the patient fell out of the window or jumped out of it. It was not possible to tell from the report how it might be easy for the service user to have accidentally fallen out of the window as there were no details of the dimension of the window (i.e. whether it was very low with a very wide opening so that it would be understandable how someone could easily have accidentally fallen out of it).
Case 3: Death of a resident of a social care setting following a fall
(Case Ref 103)

The resident in this case had a falls risk assessment conducted by a Physiotherapist which identified that the resident had a high risk of falling and should be supervised when mobilizing using a Zimmer frame.

This report used the headings from the Contributory Factors Framework as Key Causal Factors which was not in line with the HSE’s systems analysis investigation guidelines (2012).

At the same time, it appeared from the evidence presented within the investigation report that there may have been an important key causal factor that was overlooked as follows:

→ The investigation report stated that the Physiotherapist recommended that this resident should be supervised when mobilizing using a Zimmer frame.

→ The investigation report showed that - both times the resident fell the resident was away from their bed and they appeared not to have been supervised as recommended by the falls risk assessment.

On the basis of the above evidence which was presented in this investigation report, the author deduced that the following may also have been a Key Causal Factor in this case:

→ Failure to comply with the recommendation of the falls risk assessment which stated that the resident should be supervised when mobilizing.

It seemed that it would have been very helpful for this Key Causal Factor to have been analysed using the framework of contributory factors to identify the underlying causes as to why it was that the recommendation of the falls risk assessment was not complied with in this case in order to help prevent future harm arising from the causes of this case i.e. Why was the resident not supervised when mobilizing?
Case 4: Serious attack of a nurse by a patient in an acute psychiatric service (Case Ref 110)

The following KCFs were identified within this investigation report:

1. The Service User suffers a Mental Disorder of such severity and resistance to treatment, that s/he remains a significant risk to others
2. The enactment of special 1:1 observation that placed the observer within arms-length of the service user and therefore at risk of assault.

The following was deduced as a Key Causal Factor based on the evidence presented within the investigation report:

1. Failure to access a Central Mental Hospital Bed for a section 21 part 2 patient

Case 5: Incident where a Resident who had been smoking in an area where smoking was prohibited - sustained burns caused by a cigarette which they had been smoking and which fell onto their clothing. (Case Ref 116)

This report stated that the Resident’s care plan stated that the Resident needed to be supervised when smoking. However, the Resident was not supervised when this incident occurred. But this is not listed as a Key Causal Factor. This is touched on in the Contributory Factors section and there is some good exploration in this section of the reason(s) why the Resident was not supervised when they were smoking. However, listing this issue as a key causal factor would have required that this be even more methodically done.

On the basis of the above evidence which was reflected within this investigation report, it was deduced that the following may also have been a Key Causal Factor in this case:

→ Failure to follow the Resident's care plan in so far as it stated that the Resident needed to be supervised when smoking.
Case 6: Death of a Residential Services client in an Acute Hospital setting and subsequent issues of malnutrition raised at Post Mortem. (Case Ref 121)

It appeared that the investigation may have focused on the concerns raised in the Post Mortem (i.e. related to malnutrition) and perhaps did not focus as much as was required on other issues such as issues related to the need to monitor in order to identify patient deterioration and the need to respond promptly and appropriately to signs of deterioration.

**Key Causal Factors listed in the report:**

1. Failure to seek dietetic intervention in the care of the patient for nearly two years
2. Not seeking GP to visit and attend patient until over 48 hours after previous GP visit even though there were on-going issues with the patient’s temperature; blood pressure; heart rate; respiratory rate and ? urinary output

Following evaluation it was deduced that KCF 2 above might more correctly be described as below based on the evidence presented in the investigation report:

→ Failure to monitor in order to identify patient deterioration and failure to respond promptly and appropriately to patient deterioration

### 4.4.3.6. Quality of analysis to identify Contributory Factors

The evaluation of the quality of the analysis of KCFs to identify Contributory Factors (CFs) involved the following five elements:

1. Was each KCF analysed separately to identify contributory factors?
2. Did reports identify CFs or state that none were identifiable?
3. Was the factor type and contributory factor described?
4. Were further details of CFs given?
5. Were CFs adequately supported by the evidence?
Table 4.6 above shows the cross tabulation of 2014 investigation reports that identified KCFs with reports that identified CFs.

In 40% (n=18) of 2014 investigation reports, analysis of KCFs to identify CFs was deemed “not applicable”. Of these 18 cases, one of these cases did not refer to key causal factors, and the remaining 17 cases related to cases where key causal factors were not identified.

Investigation reports completed in 2014 reflected that each individual KCF was analysed separately to identify CFs in 24.4% (n=11) of these reports.

When the “not applicable” cases are removed, 40.70% (n=11) of 2014 investigation reports reflected that each individual KCF was analysed separately to identify Contributory Factors as shown in table 4.1 (i.e. 10.1).

**Did reports identify CFs or state none were identifiable?**

It is important for investigations to be explicit about either identifying CFs or finding that none were identifiable in order for the reader to know that a satisfactory analysis was conducted to identify CFs, thereby leaving an analytic trace for investigation findings (Dekker, 2006).

As shown in table 4.1 (i.e. 10.x), when the “not applicable” cases were removed, 86.21% (n=25) of investigation reports completed in 2014 identified CFs or stated that none existed.

**Was the factor type and CF described?**

The Framework of Contributory Factors in the HSE Investigation Guidelines (Health Service Executive, 2012) is shown in table 6.1 in Chapter 6.

---

50 Case ref 98
The IQET checked whether investigation reports included details of the “Factor type” (i.e. the seven cells in the column on the left of this table) and whether the CFs were described (i.e. as per the seven cells in the column on the right side of this table).

When the “not applicable” cases are removed, 21.43% (n=6) of 2014 investigation reports identified Factor Type and CFs in line with the framework of contributory factors.

**Were further details of CFs given?**

Investigation reports completed in 2014 were found to include further details of CFs in 35.6% (n=16) of cases; this was not done in 20% (n=9) of investigation reports; and this was found to be “not applicable” in 44.4% (n=20) of investigation reports. When the “not applicable” cases are removed, 64.00% (n = 16) of 2014 reports included further details of contributory factors.

**Were CFs satisfactorily supported by evidence?**

The evaluation identified that the CFs were satisfactorily supported by evidence presented within the investigation report when the CFs were considered to be plausible underlying causes of the KCF identified. That is, there was an analytic trace from the KCFs to the CFs. As shown in table 4.1, this was considered “not applicable” in 44.2% (n=19) of reports. Evidence presented to support the CFs was identified to be unsatisfactory in 92.3% (N=24) of applicable 2014 cases. CFs were identified to be satisfactorily supported by evidence in 7.7% (n=2) of 2014 investigation reports.

Appendix 13 includes details from the comments section of the IQET related to this aspect of investigation quality and emphasises deficiencies with further detail provided about Contributory Factors.

---

52 Of the 20 cases that were recorded as not applicable, one of these cases (Ref 98) did not refer to key casual factors, and one case (Ref 101) was a preliminary report and not a full systems analysis. However, this investigation (Ref 101) did refer to elements of systems analysis (i.e. chronology and key causal factors) but it did not refer to CFs. The remaining 18 cases related to cases where key causal factors were not identified (i.e. case refs 84, 85, 86, 90, 91, 92, 96, 102, 104, 108, 111, 112, 113, 114, 115, 117, 118 and 127).
Case 122 below is an example of a case where it was considered that not enough evidence was included within the investigation report to give confidence about the CFs identified, and appendix 15 gives further details from the comments section of the IQET as to whether CFs were adequately supported by evidence.

Case 122 related to a delay in ambulance response to a 999 call where a pedestrian had been struck by a car.

This investigation report showed "what" happened well enough, but it did not show "why" it happened which is the focus of CF analysis.

For example:

→ The Contributory Factor section stated that the staff on duty at the hospital understood that it was a "level green" status; while the hospital bed management escalation plan indicated that it was a “level black”. However, this section did not address why this discrepancy occurred.

→ The Contributory Factor section stated that the escalation of the offload delay within the National Ambulance Service (NAS) hierarchy should have been more prompt. However, it did not refer to guidelines stating how and when this should occur; nor did it state "why" this did not occur. This prompts questions as to whether there should have been guidelines related to this which did not exist; or whether there were guidelines which were followed, but there was a problem with the guidelines; or whether there were guidelines but they were not followed and why; or whether some combination of these or other factors existed?

→ Also, the Contributory Factor section indicated that the communication about the offload delay was not communicated in a robust enough manner between ambulance and hospital personnel. However, it did not state "why" it was not robust enough. This also seemed somewhat subjective.

→ Finally, the Contributory Factor section stated that consideration should have been given to requesting aero-medical support but it did not specify the guidelines nor the evidence base where this was outlined to be the
correct course of action; or why this did not happen. Similar to a bullet above, this prompts questions as whether there should have been guidelines related to this which did not exist; or whether there were guidelines which were followed, but there was a problem with the guidelines; or whether there were guidelines but they were not followed and why; or whether some combination of these or other factors existed.

4.4.3.7. Quality of analysis to identify Incidental Findings

The process of evaluating the quality of analysis to identify Incidental Findings (IFs) included the following three elements:

(i) checking whether the definition of IF within investigation reports was in line with HSE guidelines

(ii) determining whether reports stated that IFs were identified or stated that none were identifiable; and

(iii) determining whether IFs were adequately supported by the evidence reflected within investigation reports.

As shown in table 4.1 (i.e. 9.1), 2014 investigation reports referred to the definition of IFs in line with HSE guidelines 31.1% (n=14) of the time. These reports identified IFs in 53.3% (n=24) of cases. No investigation reports stated that no IFs were identified. So, for the 46.7% (n=21) of investigation reports where no IFs were identified, it was unclear whether this was because none were identifiable, or because analysis was not undertaken to determine whether there were any IFs.

In relation to whether IFs were adequately supported by the evidence, one case was considered to be “not applicable”, because it was a preliminary report that related to an incident of a fall and not a full systems analysis investigation. It did refer to elements of a systems analysis (i.e. chronology and Key Causal Factors) but it did not refer to IFs. As shown in table 4.1 (i.e. 9.3), of the applicable 2014 reports, these were identified to have adequate evidence to support the IFs in half of the cases that identified IFs (i.e. 27.3% (n=12)). Therefore, 72.7% (n=32) of cases were considered not to have satisfactory evidence in relation to IFs. This included 11 cases which identified

\[53\] Case ref 101
IFs but which did not reflect satisfactory evidence to support the IFs; and 21 cases which did not refer to incidental findings so it was unclear whether this was because none were identifiable, or because analysis was not undertaken to determine whether there were any incidental findings.

4.4.3.8. Quality of recommendations

The process of evaluating the quality of recommendations included the following five elements:

(i) checking whether recommendations were made
(ii) determining whether recommendations were linked to CFs
(iii) determining whether recommendations were SMART
(iv) determining whether the “Hierarchy of preferred controls” was referred to, and
(v) determining whether the “Hierarchy of preferred controls” was used

SMART recommendations were considered to be recommendations where the recommendation was:

(i) Specific: The recommendation is clearly defined and identified
(ii) Measurable: The implementation of the recommendations is measurable
(iii) Achievable: It is possible to implement the recommendation
(iv) Relevant: The recommendation is closely connected to/appropriate to the contributory factor
(v) Time-bound: The timeframe within which the recommendation is to be implemented is clearly stated.

As per table 4.1 (i.e. 11.1 – 11.3):

a) Reports completed in 2014 made recommendations in 88.9% (N=40) of cases.
b) Recommendations were clearly linked to CFs and/or IFs in 80.0% (N=32) of applicable reports. (See further details of this in appendix 16).

c) Recommendations were considered to be SMART in 2.5% (N=1) of applicable reports.

**Hierarchy of Preferred Controls**

As shown in table 4.1 (i.e.11.1), recommendations were made in 88.9% (n=40) of 2014 investigations. According to HSE Guidelines (2012), the “Hierarchy of Preferred Control Measures” needs to be used in developing recommendations. The “Hierarchy of Preferred Controls” was referred to in 22.5% (n=9) of applicable investigations completed in 2014. It was not referred to in 77.5% (n=31) of these investigations.

None of the 40 investigation reports that made recommendations demonstrated any evidence that the “Hierarchy of Preferred Controls” was used in developing recommendations.

4.4.3.9. **Generalizability of investigation reports**

The process developed for evaluating the generalizability of investigation reports in this study included five elements namely:

(i) An assessment as to whether investigation reports identified Contributory Factors that seemed as though they may occur elsewhere (i.e. outside the site where the incident occurred)

(ii) A check as to whether reports identified as per (i) above stated whether CFs were applicable elsewhere

(iii) An assessment as to whether the report made recommendations that seemed as though they may be applicable elsewhere

---

54 Cases were classified as “Not Applicable (N/A)” in 11.1% (N=5) of cases including Cases ref 84, 85, 87, 101 and 104. More details from the comments section of the IET related to this question can be found in appendix 14

55 Cases were classified as “Not Applicable (N/A)” in 11.1% (5) of cases and including Case refs 84, 85, 87, 101 and 104. Cases 84, 85, and 87 stated that there were no KCFs, so it was reasonable that no recommendations were made. Case 101 was a preliminary review, and not a full systems analysis investigation. It did refer to elements of a systems analysis such as chronology and key causal factors, but it did not make recommendations. Case 104 referred to key findings, outcomes, implementation date and current status, but it did not refer to recommendations.

56 This hierarchy was considered “Not applicable” in five cases (i.e. Case refs 84, 85, 87, 101 and 104) which were described previously.
(iv) A check as to whether investigation reports identified as per (i) above stated that recommendations may be applicable elsewhere.

(v) A check as to whether reports that identified CFs and/or recommendations that were identified as possibly being applicable elsewhere – stated that nationally applicable recommendations should be communicated to the relevant National Director(s) for implementation nationally.

The results are summarised in table 4.7 below.

<table>
<thead>
<tr>
<th></th>
<th>Evaluation identified that report identified CFs that seemed as though they may occur elsewhere:</th>
<th>If yes, did report state this?</th>
<th>Evaluation identified that recommendations seemed as though they may be applicable elsewhere:</th>
<th>If yes, did report state this?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Frequency</td>
<td>Valid Percent</td>
<td>Frequency</td>
<td>Valid Percent</td>
</tr>
<tr>
<td>Yes</td>
<td>34</td>
<td>82.1</td>
<td>2</td>
<td>5.9</td>
</tr>
<tr>
<td>Total</td>
<td>45</td>
<td>100.0</td>
<td>45</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Table 4.7: Showing the results of the assessment as to whether CFs and/or recommendations appeared to be applicable outside of the site where the incident occurred, compared with whether reports stated this.

As shown in table 4.7 above, investigation reports that were completed in 2014 identified Contributory Factors that seemed - from the evaluation - as though they might occur elsewhere (i.e. outside of the site where the incident occurred) in 34 (i.e. 82.1%) of applicable cases.

Of the 34 investigation reports where the evaluation identified Contributory Factors that seemed as though they may occur elsewhere, 5.9% (n=2)\(^{57}\) stated that the Contributory Factors may occur elsewhere.

The investigation reports identified recommendations that seemed as though they may be applicable elsewhere in 38 (i.e. 84.4%) of cases.

Of these 38 investigation reports, 5.26% (n=2)\(^{58}\) stated that the recommendations may be applicable elsewhere.

\(^{57}\) Case refs 122 and 124
\(^{58}\) Case refs 117 and 122
None of the investigation reports stated that nationally applicable recommendations should be communicated to relevant National Director(s) for implementation nationally.

4.4.3.10. Readability of investigation reports

Use of easily readable plain English in investigation reports is important for:

(i) Accessibility and ease of reading and understanding by those affected/harmed by incidents, so that questions they have about what happened and why are easily answered from the investigation report

(ii) Ease of translation into safety improvements for staff and managers that have to implement safety improvements based on the learning from investigation reports

(iii) Those that are evaluating the quality of serious incident investigation reports who would likely have a research background, but may not have technical/clinical backgrounds, and

(iv) For those that are conducting analysis of groups of investigation reports to identify patterns in causal factors, who, as for the previous bullet, would likely have a research background, but may not have technical/clinical backgrounds.

Table 4.1 (i.e. 15.1 – 15.4) shows the results of the evaluation of the 2014 investigation related to their readability/use of plain English whereby 42.2% (n=19) of investigation reports avoided jargon and used every day words consistently; 93.3% (n=42) used terms consistently; 46.7% (n=21) used full text beside abbreviations the first time they were used; and 33.3% (N=15) always explained technical terms and/or included a glossary of terms.

4.4.3.11. Fair procedures

In relation to rights of individuals to be heard in investigations - section 4.4.3.3 above refers to data collection from interviewees.

The further evaluation of investigation reports in the context of fair procedures considered the following four elements:

(i) Did investigation reports refer to fair procedures?
(ii) Did staff interviewed receive draft investigation reports, or relevant excerpts, to factually accuracy check?

(iii) Did those affected/harmed receive relevant excerpts of draft reports to factually accuracy check?

(iv) Were reports modified based on feedback from interviewees?

Table 4.1 (i.e. 18.1 – 18.4) shows the results of the evaluation of 2014 reports related to the application of fair procedures and factual accuracy checking.

For the question: “Does the report refer to the application of fair procedures?” the case that was categorised as “Not applicable (N/A)” was case ref 125 which related to a power outage where no harm occurred.

For the question: “Does the investigation report reflect that those affected received a draft chronology and any other relevant excerpts for factual accuracy checking purposes?” - the two cases that were categorised as “Not applicable (N/A)” were Case ref 114 where sadly the relevant person that had been affected had passed away; and Case ref 125 which related to a power outage where no individual was harmed. Investigation reports reflected that those affected received a draft chronology and any other relevant excerpts of the draft report for factual accuracy checking in seven cases.

For the final question – 33.3% (n=15) of 2014 reports reflected that the draft report was modified based on the feedback received to enhance the factual accuracy of the final report.

4.4.3.12. Anonymisation

The evaluation of this aspect of investigation reports included a check as to whether the investigations were anonymised in terms of:

(i) The name, age and gender of the person harmed

(ii) The staff involved

(iii) The site where the incident occurred

The results of this evaluation are shown in table 4.1 (i.e. 14.1 – 14.5). The investigation that is listed as “N/A” was Case ref 125 which related to a power outage where no person was harmed.
4.4.3.13. Apology

The evaluation of this aspect of investigation reports included:

(i) A check as to whether it was appropriate for an investigation report to include an apology. Guidelines stated that it was appropriate for an investigation report to include an apology if KCFs were identified. Therefore, for the purpose of this evaluation it was deemed that it was appropriate for an apology to be included in the investigation report if KCFs were identified.

(ii) If an apology was appropriate, a check as to whether one was either given or referred to?

(iii) A count as to whether an apology was given or referred to.

The results of this evaluation are shown in table 4.1 (i.e. 16.1 & 16.2). As per table 4.8 below, of the 25 cases where an apology was appropriate - 24% (n=6) reflected that an apology was given/referred to. Of the six cases where an apology was given or referred to, five reports included a direct apology to the individual that was harmed\textsuperscript{59} while one report did not include a direct apology – but referred to an apology that had been given by some other source\textsuperscript{60}.

\textsuperscript{59} Case refs 97, 109, 110, 124 and 127

\textsuperscript{60} Case ref 95
Was an apology appropriate (i.e. KCFs were identified)?
Where an apology was appropriate, was one given/referred to?
Was an apology given or referred to?

<table>
<thead>
<tr>
<th></th>
<th>Frequency</th>
<th>Percent</th>
<th>Frequency</th>
<th>Valid Percent</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>25</td>
<td>55.6</td>
<td>6</td>
<td>24.0</td>
<td>Apology given</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>No</td>
<td>17</td>
<td>37.8</td>
<td>19</td>
<td>76.0</td>
<td>Apology referred to</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>N/A</td>
<td>3²¹</td>
<td>6.7</td>
<td>17</td>
<td></td>
<td>-</td>
</tr>
<tr>
<td>Total</td>
<td>45</td>
<td>100</td>
<td>45</td>
<td>100</td>
<td>6</td>
</tr>
</tbody>
</table>

Table 4.8: Showing results of evaluation of investigation reports related to the apology given/referred to.

4.4.3.14. Impartiality of investigation reports

In response to the question “Is the report written impartially (i.e. there is no evidence of bias such as hindsight bias, outcome bias or any other bias in the investigation report)?” table 4.1 (i.e. 19.1) shows that it was deemed that 2014 reports were written impartiality 40% (n=18) of the time.

Analysis of the comments section of the IQET related to this question indicated that methodological issues - such as problems associated with the quality of the chronology; the quality of references to relevant literature or PPPG’s; and the quality of analysis – were the most frequent factors that detracted from the apparent objectivity, rigor, and impartiality of investigation reports (identified as an issue for impartiality in 48.89% (n=22) of investigation reports).

Appendix 17 gives details of the comments captured via IQET about investigation report impartiality.

²¹ The three cases where the evaluation identified that it was not possible to tell from the report whether an apology was appropriate or not included the following cases:
→ Case ref 98 where the report did not refer to KCFs and it was not possible know whether KCFs were identifiable or not, so it was not possible to know if an apology was appropriate or not. It was also unclear whether the patient suffered any harm as a result of this incident
→ Case ref 101 which was a preliminary report and did not determine whether KCFs existed or not so it was not possible to know whether an apology was appropriate or not.
→ Case ref 125 which did not identify KCFs but did identify "issues". It was not apparent whether these were Contributory Factors or Incidental Findings, so it was not possible to tell from the report whether an apology was appropriate.
4.4.3.15. Guidelines followed

The investigations that were completed in 2013 and 2014 started in years ranging from 2010. Table 4.9 below shows whether investigations stated what investigation guidelines were used correlated with the year that the investigation was commenced. Investigation reports did not reflect the year the investigation commenced in 49.5% (n=53) of cases. The guidelines that were followed were stated in 91.7% (n=11) of investigations commenced in 2012; 87.5% (n=14) of investigations commenced in 2013; and 70.8% (n=17) of investigations commenced in 2014.

<table>
<thead>
<tr>
<th>Year investigation commenced</th>
<th>Report reflects guidelines used</th>
<th>Total</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>2011</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>2012</td>
<td>11</td>
<td>1</td>
<td>12</td>
</tr>
<tr>
<td>2013</td>
<td>14</td>
<td>2</td>
<td>16</td>
</tr>
<tr>
<td>2014</td>
<td>17</td>
<td>7</td>
<td>24</td>
</tr>
<tr>
<td>Not Shown</td>
<td>36</td>
<td>17</td>
<td>53</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>80</td>
<td>27</td>
<td>107</td>
</tr>
</tbody>
</table>

Table 4.9: Showing whether investigation reports reflected the investigation guidelines used correlated with the year the investigation commenced.

Table 4.10 below shows the investigation guidelines that investigators stated were followed for the 2013 and 2014 reports respectively. It is noted that the investigations completed in 2013 followed a greater variety of guidelines, whereas 71.1% (n=32) of the 2014 investigations followed the Systems Analysis Guidelines for the Investigation of Incidents and Complaints (Health Service Executive, 2012); 2.2% (n=1) followed the 2009 toolkit; and 26.7% (n=12) did not state what investigation guidelines were followed.
The report states that the following investigation guidelines were followed:

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Percent</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009 Toolkit of documentation to support incident management in the HSE</td>
<td>15</td>
<td>24.2</td>
<td>1</td>
</tr>
<tr>
<td>2012 Systems Analysis Guidelines for Investigation of Incidents and Complaints</td>
<td>17</td>
<td>27.4</td>
<td>32</td>
</tr>
<tr>
<td>No reference to guidelines followed</td>
<td>15</td>
<td>24.2</td>
<td>12</td>
</tr>
<tr>
<td>2007 Complaints Management Policy</td>
<td>2</td>
<td>3.2</td>
<td>-</td>
</tr>
<tr>
<td>ALARM or London Protocol</td>
<td>11</td>
<td>17.7</td>
<td>-</td>
</tr>
<tr>
<td>CDC HIQA Guidelines</td>
<td>1</td>
<td>1.6</td>
<td>-</td>
</tr>
<tr>
<td>Local Critical Incident Investigation and Trust in Care Guidelines</td>
<td>1</td>
<td>1.6</td>
<td>-</td>
</tr>
<tr>
<td>Total</td>
<td>62</td>
<td>100.0</td>
<td>45</td>
</tr>
</tbody>
</table>

Table 4.10: Showing what investigation guidelines were followed as reflected in 2013 and 2014 reports respectively.

More details of the investigation guidelines followed correlated to the year the investigation commenced can be found in appendix 18.

4.5. Discussion

4.5.1. Quality of data collected

In terms of the quality of data collection reflected within investigation reports, section 4.4.2 above shows that over 70% of 2014 reports reflected a satisfactory summary of data collected and reviewed, and of records collected and reviewed. However, less than 30% of investigation reports reflected an adequate review of the literature. The 2012 investigation guidelines referred to literature review in the definition of a systems analysis investigation as follows:

“A methodical investigation of a specific incident which involves collection of data from the literature, records (general records in the case of non-clinical incidents and healthcare records in the case of clinical incidents), interviews with those involved in delivering the care/service where the incident occurred and analysis of this data to establish the chronology of events that led up to the incident, identifying the key causal factors that had an effect on the eventual adverse outcome, the contributory factors, and recommended control
actions to address the contributory factors to prevent future harm arising as far as is reasonably practicable”.

These investigation guidelines also stated that the methods section should be explicit in explaining that the data used was from literature searches and review of documents. This is in line with investigation guidelines from other jurisdictions including the UK, the US, and the Netherlands.

The failure of most of the investigations to carry out literature searches could be for a number of reasons including but not limited to (i) lack of knowledge that this was needed, (ii) lack of appreciation of the value of a literature search in the investigation, (iii) lack of experience/expertise in literature searching, (iv) lack of access to resources and support to conduct literature searches, and (v) lack of time to conduct a literature search and review.

Anecdotally, trainees often state that they do not have the time, the skills, nor access to the resources needed to conduct robust literature searches and reviews. On foot of this, the National Incident Management and Learning Team (NIMLT) developed resources and supports for conducting literature searches and reviews including sharing information about library resources available to support this work. It would be important to monitor and evaluate the impact of these interventions on the quality of literature search and review reflected within investigation reports over time. In addition, research to explore the views of various stakeholders, including service users, about this aspect of investigation quality would be important.

4.5.2. Quality of chronology

Reports scored highly on all markers of the quality of chronology except for specifying the source of information and the reasons for and results of tests.

It is acknowledged that the need to detail these was not explicitly required by the 2012 investigation guidelines. Indeed, other jurisdictions such as the UK, USA, Australia, and the Netherlands do require detailed chronologies, but do not specifically identify this particular criterion. This was something that was identified in the processes of developing the IQET as described in Study 1 in Chapter 2 when it was determined that this was important for leaving what Dekker (2006) referred to as an “analytic trace for investigation findings”.

168
Investigation reports that do not give details of the source of information (i.e. from records, from interviews, etc.,) are likely to leave the reader (i) wondering about this, (ii) with a sense that the report is incomplete, and (iii) without a sense of the quality of the evidence that informs the report.

Similarly, not including the reasons for and results of tests are likely to leave a reader wondering (i) what the reasons were, (ii) whether they were justified, and (iii) whether they were related to the final outcome.

It is likely that the lack of emphasis on this in investigation guidelines contributed to lower scores on this aspect. And, similarly to failures to carry out a satisfactory literature search as described in the previous section, it may also be that these omissions are due to lack of time, training, and support. Further research to explore the reasons for this, the interventions to address them, and the impact of this on investigation quality, is warranted.

4.5.3. **Quality of analysis to identify KCFs**

Figure 4.1 shows that almost half of the 2014 investigation reports referred to a definition of KCFs in line with the definition in the 2012 guidelines, and 86.7% of these identified KCFs or stated that none were identifiable.

However, just over a quarter of 2014 reports were deemed to provide adequate evidence to support the identified KCFs, or the statement that KCFs were not identifiable.

Importantly, the results showed that reports that demonstrated adequate evidence to support the KCFs identified (or a finding that none were identifiable) were statistically significantly more likely to identify Key Causal Factors.

This is important because it indicates that investigation reports that did not demonstrate adequate evidence to support the KCFs identified (or a finding that none were identifiable) failed to identify KCFs that most likely should have been identifiable. This represents a lost opportunity to learn from incidents in spite of the fact that resources have been diverted to conduct these investigations. It emphasises the importance of ensuring that investigations follow a robust methodology and reflect adequate evidence to support the identification (or not) of KCFs.
This is also an important aspect of what Dekker refers to as **leaving and analytic trace for investigation findings**.

Other research also highlighted a difficulty with this, including Wallace et al., (2006).

It is heartening however, that the results from this study in this regard compare favourably with comparable research by the Care Quality Commission (CQC) (2016) in England. Table 4.11 below shows a comparison of the performance of the NHS England with the HSE in relation to common aspects of the quality of serious incident investigation reports that were evaluated.

| Proportion of investigations that included evidence of family involvement: | NHS England | HSE  |
|---|---|
| 12% | 36.4% |

| Proportion of investigations that included evidence of staff interviews: | NHS England | HSE  |
|---|---|
| 39% | 43.9% |

| Proportion of investigations that showed evidence of clearly structured methodology that identified KCFs: | NHS England | HSE  |
|---|---|
| 8% | 86.7% identified KCFs (or stated that none existed) 27.1% Reflected satisfactory evidence to support identified KCF (or a finding that no KCFs were identifiable) |

| Proportion of investigations that linked recommendations to contributory factors: | NHS England | HSE  |
|---|---|
| “A few” | 80% |

**Table 4.11:** Comparison of the findings of the evaluation of the quality of serious incident investigation reports between the NHS and the HSE

So, while **Study 2** identified that just over a quarter of HSE investigation reports reflected satisfactory evidence to support the KCFs identified (or that non were identifiable) this was considerably better than the investigations in the CQC study.

Even so, considerable improvement is needed if investigation reports are to leave a satisfactory analytic trace for investigation findings, and most importantly, to identify all pertinent KCFs. Chapter 7 describes sophisticated training for investigators that was developed in response to this learning from this research and which focuses intensely on this aspect of investigations. It is important for future research to consider the impact of this training on the quality of analysis to identify KCFs.
4.5.4. Quality of analysis of KCFs to identify CFs

As shown in figure 4.1, just under a half of 2014 investigations reflected analysis of individual KCFs to identify CFs while 86.2% of investigation reports identified CFs or stated that none existed. It is noteworthy that 10 reports which did not identify KCFs identified CFs. This went against HSE investigation guidelines and guidelines from other jurisdiction which required that KCFs be identified in the first instance, and that then each individual KCF be analysed separately to identify CFs (Health Service Executive (2012); Bagian et al, (2002); Wallace (2006); NHS (2015); Leistikow et al, (2016); Care Quality Commission, (2016)). Without first reflecting the KCF in the investigation report, and then showing the analysis of each of these to identify CFs, the reader cannot see what Dekker (2006) described as the “...analytic trace for investigation findings”. This indicates the importance of future research related to interventions to improve the rate with which reports reflect individual analysis of KCFs to identify CFs, and to eliminate the practice of identifying CF without first identifying KCFs.

4.5.5. Quality of analysis of KCFs to identify IFs

This was in general, the weakest part of the analysis of causal factors aspect of investigation reports in terms of lower compliance with the definition of IF (31.1%) and whether reports stated that IFs were identifiable or not (53.3%). However, IFs tended to be considered adequately supported by the evidence more often than KCFs or CFs. IFs are defined in the 2012 investigation guidelines as issues that were identified in the course of an investigation which did not impact on the outcome but which served to identify issues for system improvement. So these are not actual causes of the particular incident being investigated. The fact that (i) investigators may have been more focused on actual causal factors than incidental findings, (ii) investigators are under pressure to deliver the report of a particular incident investigation and identification of incidental findings may seem to be a luxury, and (iii) there may be a lack of understanding of the organisational learning value of incidental findings – may have contributed to these poor results. The author is aware that investigation trainees occasionally indicated that they
would categorise IFs as CFs as they felt management put a higher priority on CFs and ignored IFs.

Further research is required to determine the best interventions to improve the rate with which reports reflect analysis to identify IFs, and stakeholder’s views of the importance of this for investigation quality.

4.5.6. **Recommendations**

The majority of 2014 investigations (i.e. 80%) were deemed to link investigations to CFs satisfactorily. However, only 2.5% of reports reflected that recommendations were SMART\(^{62}\). It should be noted that investigation reports only received a score in relation to reflecting recommendations that were SMART when they reflected evidence of all five elements of this i.e. that the recommendations were specific plus measurable plus achievable plus realistic plus time-bound. Learning from this prompted a change in this aspect of the IQET for evaluations of the 2015 investigation reports and onwards. Specifically, the evaluation tool was modified to score these five aspects separately. So, for subsequent years, investigation reports received a score of one if recommendations were deemed specific, an additional score of one if they were deemed measurable etc., so that they could get a score of 5 if they were deemed to demonstrate all the elements of SMART recommendations. It would be important to determine what learning can be derived from the analysis of this into the future including whether or not some aspects of SMART recommendations are more likely to be well done compared with others, and if so, (i) the significance of this, and (ii) whether intervention to improve this is justified.

In relation to the hierarchy of control measures, just under a quarter (22.5%) referred to this hierarchy, and none reflected evidence that this hierarchy was actually used in developing recommendations.

This was a comparatively weak aspect of investigation reports. This prompts questions about whether investigators have a satisfactory understanding of risk management, system safety, and organisational learning. It also raises questions about the competence of investigators to propose design or

---

\(^{62}\) SMART: Specific; Measurable; Achievable; Realistic; Timebound
engineering changes. Is it appropriate to expect investigators to also be effective recommendation generators? In any case many recommendations never get implemented. Could this contribute to apathy by investigators in relation to recommendations?

Further research is indicated to consider all of these questions.

4.5.7.  Generalizability

This chapter identified that generalizability was the aspect of investigation quality that consistently scored the poorest. Investigation reports rarely referred to whether Contributory Factors (CFs) or recommendations were applicable elsewhere in the organisation.

It is arguable that this is something that may not be possible for investigators to do. For example, how would an investigator know if a CF or a recommendation is applicable elsewhere when they do not have information about the details of the structures, processes, or the socio-technical environment in other parts of the organisation, or indeed whether or not the recommendation has been satisfactorily addressed elsewhere?

This was also an aspect of investigation reports that reliability testers found particularly challenging to evaluate. This was because the IQET required them to determine if they thought the CFs or recommendations were applicable elsewhere if this was not stated explicitly in the investigation reports. Much discussion about this aspect of the IQET occurred in reliability testing meetings. This culminated in a consensus that generalizability was determined by measuring many of the other aspects of investigation quality such as whether definitions for KCF, CFs and IFs were adhered to, and whether there was satisfactory evidence to support the KCFs, CFs, and IFs identified. It was also identified that the analysis to identify patterns in causal factors from groups of investigation reports (as per study 4) should generate nationally applicable recommendations from the entire set of investigations evaluated – thus generalising from this data set.

In a thesis dedicated to exploring how to effectively leverage incident investigations to better inform system safety - generalizability is a most important aspect of investigation reports. It is important in order to derive
learning from groups of investigation reports about what is causing most harm to most people most often - and consequently to learn what interventions are required to improve safety and outcomes for the greatest number of people the greatest amount of the time. This is one of the most important reasons why investigations are conducted. Study 4 in chapter 6 explores this further.

4.5.8. **Readability**

Comparatively, this tended to be one of the stronger sections of investigation reports with over 90% using terms consistently, and over 40% using everyday words, and providing full text for abbreviations the first time they were used. Approximately a third of investigation reports provided explanations for technical terms. Readability is important to ensure that investigation reports are accessible to (i) services users and families that receive them; (ii) analysts that are evaluating the quality of investigation reports, and conducting analysis to identify patterns in causal factors - as such analysts may not have technical/clinical backgrounds; and (iii) managers that have to implement learning from investigation reports for safety improvement. So this is an important aspect of learning from investigation reports for more effective organisation wide safety improvement.

4.5.9. **Fair procedures**

Just under 40% of 2014 reports referred to fair procedures. Just over one third of 2014 reports reflected that those affected/harmed were offered an opportunity to attend an interview. Three quarters of these accepted this invitation. One third of 2014 reports reflected that they were modified based on feedback.

Checking and feedback from staff and those harmed/affected is important in ensuring the factual accuracy of investigation reports, and consequently for the analytic trace for investigation findings referred to by Dekker (2006). Further research related to stakeholders views about the importance of this aspect of investigation quality is warranted, as is research about how to improve the rate of engagement with staff and those affected/harmed in the interview and factual accuracy checking processes. Finally, research about interventions to improve the rate of modification of investigation reports
based on feedback from staff and those affected/harmed, and the impact of this on investigation quality, is indicated.

4.5.10. Apology

Of the 25 cases where KCFs were identified meaning that an apology was deemed appropriate - 76% did not refer to an apology. The reference to an apology in an investigation report is independent of the quality of a report as this relates to the identification of causal factors for safety improvement purpose. Never-the-less, an apology is an important aspect of a compassionate and humane investigation report.

It was not possible to determine from the investigation reports that identified KCFs but which did not refer to an apology – why this was not done. The “Toolkit of Documentation to Support Incident Management” (Health Service Executive, 2009) did not refer to the inclusion of apologies in investigation reports. The “Guidelines for the Systems Analysis Investigation of Incidents and Complaints” (Health Service Executive, 2012) stated that an apology should be included if KCFs were identified. Many of the investigations included within this study commenced prior to the publication of these guidelines. It is likely that these investigators may not have been aware of this requirement to include an apology. Further research to understand the reasons for this - and interventions to address this - is indicated.

4.5.11. Conclusion

The research question underpinning Study 2 asked whether IQET could be applied to evaluate investigation quality in a healthcare system to identify areas where investigations are strong and areas for improvement. Study 2 reflects the application of IQET to conduct a more thorough and comprehensive evaluation of serious incident investigation reports than has been previously achieved. It shows that certain aspects of quality tend to be better than others and considers some of the reasons for this. It gives examples to describe why specific investigation reports were considered not to meet particular quality criteria.

It goes some way to describing the challenge of understanding and representing a complex set of events in a structured report. It considers the
importance of accurately representing such complex sets of events in investigation reports in order to be able to glean data from groups of investigations for generalizable organisational learning and improvement. That said, it is acknowledged that the challenge is not getting a perfect account of events in an investigation report, but a strategic and pragmatic one that enables optimal organisational learning and improvement. It is about getting to a stage where investigators consider the questions that generate the answers necessary to enable (i) learning to answer service user and service provider questions about what went wrong and why, and (ii) how to really achieve organisation-wide learning and improvement from groups of well-structured investigation reports.

**Study 2** demonstrates that the quality of investigation reports included compares favourably with investigation reports completed in a similar timeframe within NHS England. This means that the HSE can be reassured that the interventions developed to improve investigation quality, including the development and delivery of evidence based investigation guidelines and training described in chapter 2 – have resulted in investigation quality that compares favourably with investigation quality in NHS England. However, the findings outlined in **Study 2** demonstrate that significant improvement in investigation report quality needs to continue if investigations are to achieve the high quality service users and service providers expect and deserve. This improvement in investigation is also necessary if they are to be of sufficient quality to contribute valid and reliable data for aggregate analysis to identify patterns in causal factors to in-turn contribute to effective organisation-wide safety improvement.

In order to achieve this improvement in investigation quality - and in order to achieve the potential consequent organisational safety improvement – we need to understand the factors that influence investigation quality.

**Study 3** in chapter 5 reflects analysis to identify factors that affect investigation quality.
Chapter 5 - Study 3

Analysis of factors predicting the quality of investigations

Overview of chapter 5

5.1. Introduction
  Review of the literature on factors affecting investigation quality
  Review of assumptions about what makes a better investigation team and process

5.2. Method

5.3. Results
  Attendance at NIMLT Investigator Training
  Timeliness of investigations
  Size and makeup of investigation teams
    Number of investigators
    Use of investigation experts on investigation teams
  The scope in time of the chronology
  The number of interviews
  Individual interviews
  Adherence to the definition of key causal factors
  Investigation method used

5.4. Discussion

5.1. Introduction
The overarching research question for this thesis considers how to effectively leverage incident investigations to better inform system safety. The previous chapters explored different aspects of this question by describing (i) the development and testing of a reliable tool to evaluate investigation quality in Study 1; and (ii) applying that tool to evaluate the quality of HSE investigations in Study 2. Study 3 in this chapter takes a third aspect of the overarching research question by exploring whether factors that affect investigation quality can be empirically identified from information (i) about investigations collected using the IQET, and (ii) attendance at investigator training. Specifically Study 3 focuses on the identification of factors that affect HSE investigation quality.
5.1.1. Review of the literature on factors affecting investigation quality

As there was very little reference in the literature to methods of evaluating the quality of serious incident investigations, it is not surprising that there was even less literature referring to the factors that affected the quality of investigations. One paper by Drumpsteen and Hasle (2014) referred to the following factors adversely affecting investigation quality, which in turn were identified as detracting from the potential for organisations to learn from incidents:

- There was seldom sufficient time made available to do a thorough enough investigation of incidents. Investigations often stopped too early to have identified all causes, and selection of recommendations was done based on “expert opinion” of the investigators. This resulted in a strong focus on technical actions.

- Investigations tended to be conducted by employees of the organisations who had technical backgrounds, which resulted in a focus on technical issues in the incident investigations and a focus on technical actions for improvement whereas human factors and organisational issues were rarely addressed.

- There was a strong focus on direct causes and on the human error, and not on the context in which an error occurred and on the reasons for certain behaviours. As a result, structural measures for improvement were not taken and follow-up actions consisted of reminders of existing rules and procedures.

- The investigators did not have the knowledge and experience to carry out a satisfactory investigation with investigations rarely addressing organizational causes, because there was a blind spot for organizational and cultural issues and technical factors were more easily identified.

HSE Investigation Guidelines focused on the need to address the issues highlighted in this paper by Drumpsteen and Hasle (2014). This research was important in determining whether addressing these issues was associated with improved investigation quality.
5.1.2. Review of assumptions about what makes a better investigation team and process

The assumptions about what makes a better investigation team/process reflected within the literature included that the team needed to be (i) multidisciplinary and include both investigation experts and all the relevant subject experts related to the topic being investigated, and (ii) independent of the service where the incident occurred.

The investigation quality evaluation tools used by Wallace et al. (2006), the Care Quality Commission (2016), and the Dutch Health Inspectorate (Leistikov et al., 2016) seemed to assume that it was important for the investigation team to be multidisciplinary. The Wallace et al., (2006) evaluation tool asked whether the investigation team was “a multidisciplinary team composed of clinical, managerial & RCA experts – depending on the severity of the incident”. The Dutch Health Inspectorate Evaluation Tool gave a score if the investigation report reflected that the investigation team was multidisciplinary. The CQC Evaluation Tool asked: Does the membership of the investigation team reflect the core knowledge and skills required to undertake this SI investigation in terms of: (i) investigation knowledge; and (ii) subject matter knowledge?”

However, even following direct contact with the authors it was not possible to identify any analysis of the data derived from these evaluations to determine the relationship between the constituency of investigation teams and investigation quality. No literature testing these assumptions was identified.

The IQET collected details about whether investigators were (i) subject experts and/or investigation experts, (ii) whether they were involved in the incident and/or service where the incident occurred, and (iii) whether they were internal and/or external. These variables were not quality scored as they were considered to be independent variables. These and other independent variables were analysed separately from the investigation quality scoring (ISQ) to determine whether there was any correlation between these investigator details and IQSs. See tables 3.3 and 3.4 in chapter 3 for further details of dependent and independent variables, including the independent variables that were analysed to determine their relationship with investigation quality.
5.2. Method

Three types of information were analysed to identify whether they had an effect on investigation quality as follows:

i. Information about whether investigators had attended National Incident Management and Learning team (NIMLT) training was collected from the NIMLT after the investigation reports were evaluated. Investigators names recorded on investigation reports were cross checked with attendance at NIMLT training to determine whether any of the investigators attended NIMLT training. This was subsequently analysed to determine whether there was a relationship between attendance at NIMLT training and investigation quality.

ii. Data about independent variables that were collected via the IQET as follows:
   a. Timeliness of investigations
   b. Size and make up of investigation teams including:
      i. Number of investigators
      ii. Whether teams were made up of investigation experts and/or subject experts
      iii. Whether teams were made up of internal and/or external investigators
      iv. Whether investigators were independent of the service where the incident occurred
   c. The scope in time of the chronology
   d. The number of interviews and whether individual interviews were conducted
   e. The use of the systems analysis method

iii. Individual dependent variables were analysed to determine whether they had an effect on investigation quality.

5.3. Results

5.3.1. Attendance at NIMLT Investigator training

Figure 5.1 below shows that 13.33% (n=6) of the 2014 investigation reports were conducted by investigation teams where one or more members had
attended one or more days of the HSE NIMLT three day systems analysis investigation training which is described in detail in chapter 2.

![Had Investigators attended HSE Systems Analysis Investigator Training (Day 1, 2, 3)?](image)

**Figure 5.1:** Showing whether investigators had attended 1, 2, or 3 days of the HSE NIMLT 3 day Systems Analysis Training.

Table 5.1 below shows a cross tabulation of Investigation Quality Score (IQS) with data about whether any investigators on investigation teams attended any HSE NIMLT Systems Analysis Investigation Training.
Using a t-test, this study found that investigations conducted by investigation teams where at least one of the investigators attended any of the HSE NIMLT investigation training, had statistically significantly higher Investigation Quality Scores (IQS) (61.71 ± 8.69%) compared to investigation teams where none of
the investigators attended any of this training (43.99 ± 17.19%), \( t(38) = 2.450, \ p < 0.05 \).

5.3.2. Timeliness of investigations

Only 20 of the 2014 investigations included details of both the start and finish date of the investigation so it was only possible to determine the time from start to completion of these 20 investigations. Figure 5.2 below shows a scatter plot diagram of the cross tabulation of the time taken to complete investigations with IQS.

![Figure 5.2: Scatter plot diagram of the cross tabulation of time to complete investigations with IQS.](image)

A Spearman’s Correlation test conducted to determine whether there was a non-linear relationship between time taken to complete investigations and IQS showed that there was no statistically significant relationship \( r_s(8) = .338, \ p = .145 \).

A Chi\(^2\) calculation on aggregated IQSs of less than 60 or 60 or more and timeframes of less than 5 or 5 or more months to complete investigations was statistically significant \( \chi(2) = 5.0505, \ p < 0.05 \) indicating that there was some correlation between longer timeframes and higher IQSs.

Many of the investigations within this study were started or completed prior to the publication of the 2012 investigation guidelines which required that investigators record reasons for delays. Only three investigations which
included details of timeframes for completing the investigation also included
details of reasons for delays. One investigation\textsuperscript{63} which was completed in 5
months cited the complexity of the systems analysis method as a reason for
delay. At the same time, this was a relatively short timeframe. One
investigation\textsuperscript{64} which was completed in 8.25 months cited the complexity of
the incident as the reason. Finally, one investigation\textsuperscript{65} which was completed in
7.5 months cited the limited availability of staff that were investigators in this
case as the reason for the delay.

So some investigations were completed within short timeframes and achieved
high IQSs, while others completed in short timeframes scored poorly. The
converse was also true. Please see the examples below which illustrate this.

\textbf{Example 1:}
An investigation that was completed within a \textit{short timeframe} and which
achieved a \textit{high IQS}.
Case ref 112 was an investigation of a patient suicide which was completed in
\textbf{5 months} and scored an IQS of \textbf{72.97}\% which was the joint second highest IQS
for 2014 investigations.
The investigation was conducted by \textbf{2 internal investigators}. None of the
investigators had attended HSE NIMLT investigation training, but one
investigator was known to have significant investigation training and
experience.
The investigation included 8 individual interviews, and the draft report was
circulated to all interviewees for factual accuracy checking prior to completion
of the report.

\textbf{Example 2:}
An investigation that was completed within a \textit{long timeframe} and which
achieved a \textit{high IQS}.
Case ref 112 was an investigation of a patient suicide within approximately 48
hours of discharge from Acute Psychiatric Services which was completed in \textbf{12
\footnotesize{\textsuperscript{63} Case Ref 117\textsuperscript{64} Case Ref 112\textsuperscript{65} Case Ref 127}}}
months and achieved an ISQ of 72.97% which was the joint second highest ISQ for 2014 investigations.

The investigation was conducted by 4 internal investigators. One investigator had attended HSE NIMLT investigation training.

The investigation included 12 individual interviews, and the draft chronology section of the report was circulated to all interviewees for factual accuracy checking prior to completion.

There was no discernible reason why this investigation should have taken so much longer than the previous example. One incident did not appear to be significantly more complex than the other. It may have been that (i) investigators were busy with their substantive positions, (ii) investigators were busy doing other investigations, or (iii) the fact that there were four investigators assigned to this incident and only two to the previous example could have meant that it was more difficult to diarise time for the four investigators to work together on this investigation than it was to do this for only two investigators as in the previous case.

Example 3:
An investigation that was completed within a short timeframe and which achieved a low IQS.

Case ref 129 related to an investigation of a delayed diagnosis of a myocardial infarction (STEMI\(^{66}\)) which was completed in 1.25 months and scored a relatively low ISQ of 34.15%.

The investigation was conducted by 3 internal investigators. One investigator had attended HSE NIMLT investigation training.

The investigation report did not refer to any interviews being conducted, or to any factual accuracy checking process. It is likely that the fact that interviews and factual accuracy checking appear not to have occurred contributed to both a shorter time frame for the investigation, but also to lower quality scores.

\(^{66}\) STEMI: ST-Elevation Myocardial Infarction
Example 4:

An investigation completed in the longest timeframe and which achieved an above average IQS.

Case ref 109 related to the investigation of the death of resident of a Care of the Elderly (COTE) site following a fall from a hoist where a sling was incorrectly attached which was completed in **13.5 months** and scored an ISQ of **56.10%**.

The investigation was conducted by **2 internal investigators**. None of the investigators had attended HSE NIMLT investigation training.

The investigation included 5 individual interviews, and the draft report was circulated to all interviewees for factual accuracy checking prior to completion.

There was no discernible reason as to why this investigation took so long to complete. The case did not appear significantly more complex than others. It was certainly a relatively thorough and detailed investigation and the investigators’ attention to this thoroughness including interviewing relevant individuals and factual accuracy checking may have contributed to the timelines. That said, a number of other investigations were equally thorough and involved at least as many interviews and as much factual accuracy checking – yet were completed in shorter timeframes. So, it is also likely that the extended time frame may have been caused by competing demands on the investigators’ time.

The investigation that achieved the highest IQS (78.13%) was completed in 4 months. Five out of the six highest quality scoring investigations (IQSs: 65.71%, 67.50%, 67.57%, 72.97%, and 78.13%) were completed between 4 and 6.5 months. However, as shown in example 2 above, the joint second highest quality scoring investigation (72.97%) took 12 months to complete.
5.3.3. Size and makeup of investigation teams

The IQET collected data about whether investigation teams were made up of
(i) internal investigators, (ii) external investigators, or (iii) a combination of
these.

The majority of investigation teams reflected in 2014 reports were made up of
internal investigators only (n=38 (84.44%)). The scores for these
investigations ranged from 13.79% - 78.13%, with a mean IQS of
44.69±17.81%. One (2.22%) investigation team consisted of a combination of
internal and external investigators. The IQS for this investigation was 41.67%.
Another one investigation team was made up of only external investigators.
The ISQ for this investigation was 41.03%. Two investigation reports did not
indicate whether the investigators were internal and/or external.

The number of investigation teams made up of a combination of internal and
external experts, and of external experts alone was too small to allow
statistical analysis of the relationship between these types of investigation
teams and IQSs.

**Number of investigators**

The number of investigators on investigation teams was not stated in 5.61%
(n=6) of 2014 investigation reports.

The pattern of the relationships between numbers of investigators on
investigation teams and IQSs was explored as per figure 5.3 below.
Figure 5.3: Box plot showing average and range of IQSs for different sizes of investigation teams.

This shows that investigation reports produced by teams of two and three had the highest mean IQSs. The data were then analysed to see if there was a statistically significant difference between the IQSs for reports created by investigation teams made up of two or three compared with the scores of investigation teams of other sizes. This revealed that investigation reports produced by teams of two or three (n=29) investigators had statistically significantly higher IQSs (50.96 ± 15.31%) compared to reports produced by teams that did not have two or three investigators (n=14), (36.84% ± 16.42%), t(41) = 2.812, p < 0.05.

Use of investigation experts on investigation teams

The expertise of members of investigation teams was not referred to in 7.48% (n=8) of reports and 1.8% (n=2) of reports related to investigation teams that were supported by a facilitator.

Table 5.2 below shows that investigation teams made up of investigation experts only were the least common type of investigation team (i.e. 11.34% of investigation teams (n=11)). No investigations completed in 2014 had teams made up of investigation experts alone.

Investigation teams made up of a combination of subject and investigation experts were the most common type of team (i.e. 60.82% of investigation teams (n=59)).
Investigation teams made up of **subject experts only** were the second most common type of team (i.e. 27.84% of investigation teams (n=27)).

<table>
<thead>
<tr>
<th>Were investigators subject experts, investigation experts, or a combination of subject and investigation experts?</th>
<th>Subject Experts</th>
<th>Combination of subject experts and investigation experts</th>
<th>Investigation experts</th>
<th>Not referred to in report</th>
<th>Facilitator</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are KCFs adequately supported by the evidence in the report?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>3 (11.11%)</td>
<td>19 (32.20%)</td>
<td>5 (45.45%)</td>
<td>2</td>
<td>0</td>
<td>29</td>
</tr>
<tr>
<td>No</td>
<td>24 (88.89%)</td>
<td>40 (67.80%)</td>
<td>6 (54.55%)</td>
<td>6</td>
<td>2</td>
<td>78</td>
</tr>
<tr>
<td>Total</td>
<td>27</td>
<td>59</td>
<td>11</td>
<td>8</td>
<td>2</td>
<td>107</td>
</tr>
</tbody>
</table>

Table 5.2: Showing whether investigations were conducted by investigation experts, subject experts or a combination of these compared with whether KCFs (or a finding that no KCFs were identifiable) were adequately supported by evidence within 2013 and 2014 reports.

Excluding investigation reports where investigator expertise was not referred to (n=8) and where investigation teams were supported by a facilitator (n=2), a Chi-square test showed that there was a statistically significant difference between the remaining three groups of investigation reports (i.e. Group 1: investigations by **subject experts**; Group 2: investigations by **investigation experts**; and Group 3: investigations by a **combination** of these experts) in relation to whether they demonstrated adequate evidence to support the KCFs identified (or that no KCFs were identifiable). Investigations by teams made up of investigation experts alone were the most likely to provide adequate evidence to support KCFs identified (or that none were identifiable). Teams made up of a combination of subject and investigation experts were the second most likely to provide adequate evidence of this. Teams made up of subject experts were least likely to provide this evidence. \( \chi^2(2) = 6.020, p < 0.05 \).

Investigations completed in 2014 which were conducted by subject experts alone (n=16) had statistically significantly lower IQS\(^{67} \) (39.28% ± 16.92)

---

\(^{67}\) IQSs were calculated for 2014 investigations. None of these were completed by investigation experts alone. Details of investigators were not given in 8.77% (N=4) of these reports.
compared to investigations conducted by a combination of subject and investigation experts (n=25), ((50.68% ± 15.82), t(39) = -2.157, p<0.05).

5.3.4. The scope in time of the chronology

The scope in time ranged from one day to 6933 days (i.e., a chronology that spanned approximately 19 years). The average scope in time was 290.66 days with a standard deviation of 1123.04. This data was skewed with 29.55% (n=13) of reports reflecting chronologies of 1 day duration, and 50% (n=22) reflecting chronologies of 7 days or less duration. This skewed data made meaningful statistical analysis challenging.

The relationship between IQS and the scope in time in days reflected within chronologies in the 2014 investigation reports is illustrated in figure 5.4 below.

![Figure 5.4.](image)

**Figure 5.4.** The relationship between IQSs and the scope in time in days reflected within chronologies in the investigation reports completed in 2014 (Two outliers of 3031 days and 6933 days removed)

A Pearson’s Correlation test identified that there was not a statistically significant correlation between the scope in time reflected within investigation chronologies and investigation quality scores ($r = -.197$, $n = 42$, $p = .212$ (two outliers removed) and $r = .212$, $n = 44$, $p = .361$ (including all outliers)).

HSE investigation guidelines (Health Service Executive, 2012) required for the scope in time covered in the chronology to be the shortest amount of time
necessary to achieve the objectives of the investigation. In other words, the scope in time covered in the chronology needed to be the shortest timeframe necessary to leave what Dekker (2006) referred to as a satisfactory “analytic trace for investigation findings”.

To check compliance with this aspect of the HSE Investigation Guidelines, Question 7.2 in the IQET asked “Is the scope in time of the investigation reasonable”\(^68\)? The timeframe was considered to be reasonable if it met the following two criteria:

(i) It was the shortest timeframe necessary to achieve the objectives of the investigation, and
(ii) It was the shortest timeframe necessary to leave a satisfactory analytic trace between the chronology and investigation findings.

Analysis was conducted of the relationship between the scope in time reflected within chronologies and whether this scope in time was determined to be reasonable. A statistically significant relationship was identified (\(U = 97, p = .05\)) with chronologies that covered shorter timeframes more likely to be judged as reasonable. However, the fact that 13 of the investigation reports reflected a scope in time of one day duration means that this statistical test may not be meaningful.

There were some investigation reports that had a short scope in time covered within the chronology where this was judged to be reasonable. There were others that had a short scope in time where this was deemed not to be reasonable. The converse was also true as shown in the examples below.

Example 5

Example of a case with a short scope in time covered in the chronology that was judged NOT to be reasonable

Case 109 related to the death of a resident of a Care of the Elderly (COTE) site following a fall from a hoist where a sling was incorrectly attached. The scope in time was one day duration (i.e. the day of the patient’s fall). However,

---

\(^68\) This question in the IQET included the following guidance footnote: “HSE Investigation Guidelines (2012) state that the Scope in Time of an investigation should be the shortest sufficient period of time necessary to be included to ensure the investigation purpose will be achieved.”
there was a reference in the analysis section of the report to the fact that a Multi-Task Attendant (MTA) gave information to a nurse about attaching the sling to the hoist two days prior to the incident which appears to have been incorrect but which the nurse appears to have followed on the occasion of this incident. This seemed to be pertinent to this case and therefore should have been reflected within the chronology. On this basis it is apparent that the scope in time covered in the chronology should have extended from at least this time two days prior to the incident to enable a focus on the details of what communications and actions occurred in relation to the safe moving and handling of this patient. The shorter scope in time in the chronology in this case was considered insufficient to allow the reader to see the analytic trace from the chronology to the investigation findings.

Example 6:
Example of a case with a long scope in time covered in the chronology that was judged to be reasonable
Case 96 related to the investigation of a death by apparent suicide of a patient in Community Mental Health Services. The duration of the chronology in this case was 330 days which was relatively long. However, this scope in time was deemed reasonable as it seemed important to consider the patient’s care over this duration to ensure that no potential key causal factors were missed. For example, it was important to be able to determine from the chronology the time that elapsed between medical reviews, and whether prescribing was in line with policy. The longer scope in time in the chronology in this case seemed necessary to allow the reader to see the analytic trace from the chronology to the investigation findings.

Example 7:
Example of a case with a long scope in time covered in the chronology that was judged NOT to be reasonable
Case 95 related to the investigation of an incorrect surgical site procedure which resulted in serious harm to the patient. The scope in time covered in
the chronology was 485 days. This was judged to be too long and therefore not to be reasonable. This was because the time from the booking for the surgery within the month before the incident - to the time the wrong site surgery actually occurred was considered to be the pertinent scope in time in order for the reader to see the analytic trace from the chronology to the investigation findings. The time up to the booking for the surgery was less pertinent to this and therefore not necessary to be covered within the scope in time of the chronology. HSE Investigation Guidelines (2012) allow for such additional information to be included within a section entitled "The background to the incident".

Example 8:
Example of a case with a short scope in time covered in the chronology that was judged to be reasonable

Case 15 related the HSE investigation of a maternal death. This investigation report was published in June 2013, and is referred to in chapter 7 also.

The scope in time covered in the chronology was seven days from the time the patient was admitted with a documented clinical impression of impending pregnancy loss to the time the mother tragically died. This short scope in time covered in the chronology was judged to be reasonable in order for the reader to see the analytic trace from the chronology to the investigation findings.

Analysis of the comments section of the IQET related to this question showed that it was often identified that there needed to be more emphasis on the details of the chronology in the timeframe closer to the actual incident. Additionally, the comments section of the IQET indicated that 17.78% (n=8) of 2014 reports had information within the chronology which might be better placed within either the “background to the incident” or the “aftermath of the incident” sections of the report if the chronology is to consist purely of the

---

69 Case refs 94, 97, 100, 105, 106, 117, 118, and 119
detail necessary for the reader to easily see the analytic trace from the chronology to investigation findings.

5.3.5. Number of interviews

The relationship between IQSs and the number of interviews reflected in the 2014 investigation reports is illustrated in figure 5.5 below.

![Figure 5.5](image)

**Figure 5.5.** The relationship between IQSs and the number of interviewees reflected in 2014 investigation reports

A Pearson’s Correlation test identified that there was not a statistically significant correlation between the number of interviews and IQSs ($r = -0.148$, $n = 23$, $p = 0.500$).

5.3.6. Individual interviews

Almost half of the investigations completed in 2014 (i.e. 48.89% ($n=22$)) stated that individual interviews were undertaken. Of the remaining 51.11% ($n=23$) of investigations, one stated that MDT (i.e. Multidisciplinary Team) interviews were undertaken; and the remaining 48.89% ($n=22$) did not refer to interviews.

Investigations that reflected that individual interviews occurred had statistically significantly higher IQSs (55.75% ± 14.96) compared to reports that did not reflect that individual interviews occurred (35.05% ± 12.16), [t(43) = 5.103, $p<0.001$].
5.3.7. Adherence to the definition of Key Causal Factor (KCF)

2014 reports used a definition of KCF that was aligned with HSE guidelines in 46.67% (n=21) of cases. The reports that used this definition of KCFs had statistically significantly higher IQSs (57.15% ± 11.45) compared to reports that did not (34.69% ± 13.99), \( t(43) = 5.838, p<0.001 \).

5.3.8. Investigation method used

Table 5.3 below summarises the proportion of investigation reports that were systems analysis investigations, preliminary reviews, or some other type of investigation.

<table>
<thead>
<tr>
<th>Year report complete</th>
<th>System analysis</th>
<th>Preliminary Review</th>
<th>Other</th>
<th>Chart Review</th>
<th>YSYS Review</th>
<th>Total</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>40</td>
<td>1</td>
<td>18</td>
<td>2</td>
<td>1</td>
<td>62</td>
<td></td>
</tr>
<tr>
<td>2014</td>
<td>35</td>
<td>6</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>45</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>75</td>
<td>7</td>
<td>22</td>
<td>2</td>
<td>1</td>
<td>107</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Table 5.3: Showing the proportion of reports that were systems analysis investigations, preliminary reviews or other per year and in total.

A statistically significantly greater proportion of 2014 investigations (n=35 (77.78%)), used the systems analysis method compared with 2013 investigations (n=40 (64.56%)) \( \chi^2(4) = 13.452, p= <0.01 \).

Preliminary Reviews were not referred to within HSE investigation guidelines. However, 13.33% (n=6) of the 2014 reports returned were referred to as “Preliminary Reviews”\(^{70}\).

Please see Appendix 19 for further details of the preliminary review by (i) Division; (ii) Brief description of incident; (iii) Number and type of investigators; (iv) Whether any of the investigators had attended any HSE NIMLT Systems Analysis Investigation Training; (v) Whether KCFs were identified or not; (vi) Whether there was satisfactory evidence to support identified KCFs; (vii) Timeliness of the investigations; and (viii) IQSs.

\(^{70}\) This included case refs 84, 85, 86, 90, 91, and 101
In four cases, the investigations were referred to as neither systems analyses nor preliminary reviews. Case refs 94 and 95 were entitled “Follow up analysis tool”. One of these four investigation reports referred to causal factors but it was unclear whether these were issues that the investigators considered contributed to harm (i.e. KCFs or contributory factors), or incidental findings. The investigation method was unspecified and unclear in sample ref 98. Please see Appendix 19 for further details.

All of the six preliminary reviews referred to KCFs. Three out of four of the “Other” type of investigations referred to causes. None of these 10 (i.e. Six preliminary reviews plus four other types of investigations) investigation reports used definitions of KCFs that were in line with the definition in HSE Guidelines, compared with 60% (=21) of the Systems Analysis Investigations which used a definition of KCFs that was in line with the guidelines.

In relation to whether investigation reports reflected satisfactory evidence to support the identification of KCFs, none of the preliminary reviews or the “Other” type of investigations were found to reflect satisfactory evidence of this while 25.7% (n=9) of systems analysis investigations were noted to provide satisfactory evidence of this as shown in table 5.4 below.

<table>
<thead>
<tr>
<th></th>
<th>Preliminary Reviews</th>
<th>“Other” investigations</th>
<th>Systems Analysis Investigations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Used definition of KCF’s in line with SA guidelines?</td>
<td>0/6</td>
<td>0/4</td>
<td>21 (60%)</td>
</tr>
<tr>
<td>Reflected satisfactory evidence to support identified KCF (or finding that no KCF’s identifiable)</td>
<td>0/6</td>
<td>0/4</td>
<td>9 (25.7%)</td>
</tr>
<tr>
<td>Average quality scores</td>
<td>24.82%</td>
<td>24.54%</td>
<td>51.02%</td>
</tr>
</tbody>
</table>

Table 5.4: Comparison between preliminary review, “Other” types of investigations, and Systems Analyses in relation to use of definition of KCF in line with Guidelines; whether reports reflected satisfactory evidence to support KCFs (Or a finding that none were identifiable); and average quality scores.

---

71 Case refs 93, 94, 95, and 98
72 Case ref 93
73 Incidental Findings (IFs) are defined in HSE Investigation Guidelines (2012) as important issues identified during the course of an investigation which the investigator did not consider contributed to the eventual harm, but which they identified as important for safety improvement
Although the numbers within some of these groups of investigations were too small to permit statistical analysis of the relationship between investigation method and IQSs, these scores tended to be better for systems analysis investigations compared with both Preliminary Reviews and “Other” types of investigations as shown in table 5.5 and figure 5.6 below.

<table>
<thead>
<tr>
<th></th>
<th>Range</th>
<th>Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>All 45 investigations (Incl., 35 systems analyses + 6 preliminary reviews + 4 (other))</td>
<td>13.79-78.13%</td>
<td>45.17%</td>
</tr>
<tr>
<td>35 systems analysis investigations only</td>
<td>23.68-78.13%</td>
<td>51.02%</td>
</tr>
<tr>
<td>6 preliminary reviews only</td>
<td>13.79-31.43%</td>
<td>24.82%</td>
</tr>
<tr>
<td>4 “other” investigations only</td>
<td>21.88-28.21%</td>
<td>24.54%</td>
</tr>
</tbody>
</table>

Table 5.5: Comparison between the range of scores and mean scores for (i) all 45 x investigations completed in 2014, (ii) 35 x systems analysis investigations, (iii) 6 x preliminary reviews, and (iv) 4 investigations that used some other method.

Figure 5.5: Box plot showing the average and range of scores for systems analysis investigations, preliminary reviews, and “Other” investigations completed in 2014.
5.4. Discussion

**Attendance at NIMLT investigation training**

Incident investigation is a challenging task requiring a range of skills including, but not limited to (i) project management, (ii) administration, (iii) interviewing, (iv) understanding technical and operational procedures and language, and (v) organising ideas and distinguishing between events and categories of data such as KCFs, CFs and IFs, etc. It may be that many of the problems of the quality of incident investigations referred to in the literature (Dixon-Woods & Provost (2016), Macrae (2016), Peerally et al.,(2016), van de Poel, et al (2012), and Vincent et al., (2017)) are due to their depending on inadequately trained investigators.

NIMLT implemented the learning from the Wallace et al., (2006) research in the delivery of its investigator training. The strong positive correlation between attendance at NIMLT training and IQSs demonstrates that the NIMLT investigator training made a positive contribution to investigation quality.

Further research is indicated to ensure that this positive correlation between attendance at NIMLT investigation training and IQSs is at least maintained and ideally - continuously improved.

**Timeliness of investigation**

No literature was identified that examined the effect of investigation timeliness on investigation quality.

This study found a lack of a statistically significant correlation between investigation completion timelines and IQS when all the 2014 investigation reports were considered collectively. Some investigations that were completed relatively quickly achieved relatively high IQSs, while others achieved relatively low IQSs. The converse was true also.

However, investigations that took five or more months to complete were statistically significantly more likely to result in IQSs of 60% or higher,
demonstrating that investigators may need more time to complete more high quality investigations.

At the same time, the fact that the highest scoring investigation was completed in 4 months - and 5 out of the 6 highest scoring investigations were completed in timeframes ranging from 4 to 6.5 months - demonstrates that it is possible to complete high quality investigations in relatively short timeframes.

There were examples of investigations of apparently comparable complexity that took both long and short times to compete. There were examples of investigations that included relatively large numbers of interviewees that took both long and short times to complete, and the converse was also true. Finally, there were examples of investigations with relatively small investigation teams that took both a long and short time to complete, and the converse was also true. Future analysis of the “reason for delay” section in delayed investigation reports would be important to gain insights into the reasons for these delays and to learn how to address them. Research using surveys and interviews with investigators may also be helpful in this regard.

In the interim, the evidence from this study indicates that it is important to make investigators and interviewees available so that investigations are completed as quickly as possible so that (i) service users and those affected get answers and closure as quickly as possible, and (ii) the HSE learns how to improve safety as soon as possible. At the same time, it is important to protect investigators from being rushed by internal or external pressure into producing lower quality investigations.

Size and makeup of investigation teams

As shown at the beginning of this chapter, investigation quality evaluation tools used in studies by Wallace et al., (2006), the CDC (2016) and the Dutch Health Inspectorate (Leistikow et al, 2016) seem to assume that it is important for the investigation team to be multidisciplinary and include subject matter knowledge. However, even following direct contact with the authors it was not possible to identify any analysis of the data derived from these evaluations to determine the relationship between the constituency of investigation
teams and investigation quality. No literature testing these assumptions was identified.

The findings of this thesis in relation to the size and make up of investigation teams are new and important. They challenge assumptions that investigation teams must include all of the multidisciplinary and subject experts related to the area being investigated. They identify that good investigations are more likely with teams of just two or three investigators, and that investigation experts alone are most likely to include adequate evidence to support key causal factors (or a finding that none are identifiable). None of the 2014 investigations which were quality scored were conducted by teams of investigation experts alone – but investigations conducted by a combination of subject experts with investigation experts were statistically significantly more likely to achieve higher quality scores than investigations conducted by investigation teams of subject experts alone.

For the purpose of this study “investigation experts” were identified as individuals that were in quality/safety/audit/risk management roles where they would likely have had training and/or experience in conducting investigations. These individuals would, in the main, have a healthcare background, usually coming from nursing or allied health professional cadres. They would at least be familiar with navigating healthcare records and the healthcare system in general.

The fact that the investigators are not subject experts does not mean that there is no subject matter expertise in the investigation since this typically resides in the interviewees who are clinicians or technicians.

This is not to say that subject experts should not be included on investigation teams. It is just to say that it is important to know that having a subject expert on an investigation team is not a pre-requisite to achieving investigation quality. However, this study shows us that having an investigation expert on an investigation team does seem to be a pre-requisite to achieving a high quality investigation.

This confirmation that relatively small teams of investigation experts can complete high quality investigations means that larger teams that would have
conducted investigations in the past can be divided up to deliver more investigations more efficiently in the future.

**Scope in time of the chronology**

Up to now, there have been no empirical studies of the relationship between the scope in time covered in investigation chronologies, and the quality of investigations. HSE investigation guidelines required for the scope in time covered in the chronology to be the shortest timeframe necessary to achieve the investigations objectives. This was because collecting the data for a chronology that is detailed enough to leave what Dekker (2006) referred to as an analytic trace for investigation findings – is laborious. For example, the chronology of the HSE investigation of the Maternal Death (Arulkumaran et al., 2013) referred to in example 8 in this chapter, and also in Chapter 7 - covered a scope in time of seven days and this was reflected in a 30 page chronology section in the final report. Similarly, the HSE investigation of the failure to transport a young patient to Kings College Hospital London for transplantation surgery in July 2011 which is referred to in chapter 2 (Health Service Executive, 2011) covered just under seven hours duration and was reflected in a 25 page chronology section in the final report.

The scope in time in chronologies in investigation reports included in this thesis were deemed to be reasonable if they were judged to be (i) the shortest possible timeframe to achieve the objectives of the investigation, and (ii) if they were sufficient for the reader to see what Dekker (2006) referred to as the analytic trace for investigation findings. On this basis, this research found no statistically significant correlation between the scope in time covered in chronologies, and IQSs. Some investigations that had a short scope in time were deemed to be reasonable, while others were not. And the converse was also true.

The findings of this study appear to support the notion that the scope in time covered in the chronology simply needs to be as short or as long as it needs to be based on the circumstances of the case. This in turn supports the notion that it is reasonable for HSE investigation guidelines to give investigators discretion to determine the shortest reasonable time frame that will achieve the objective of the investigation. This way, investigators are free to
determine the scope in time to be reflected in the chronology in a manner that will strike a correct balance between work load management (i.e. not considering too long a scope in time) - and the need not to compromise the ability of the investigation to achieve its objectives by over-restricting the scope in time covered. Determining the appropriate length of a chronology requires expertise and this is a key component that needs to be covered in investigator training.

HSE investigation guidelines (Health Service Executive, 2012) also provide for investigators to include details necessary to give good context to the incident but which are outside of the timeframe immediately before or after the incident - and which are not necessary to be within the chronology section to show the analytic trace for investigation findings - in the “background to the incident” section or the “aftermath of the incident section”. This study showed that some investigation chronologies included information that may be more well placed in the “background to the incident” section or the “aftermath of the incident section” if the chronology is to be as clear and concise as possible in terms of seeing the analytic trace between the chronology and investigation findings. This is another key component that needs to be covered in investigator training.

**Individual interviews**

To fully understand an incident we need to hear the multiple perspectives of the different people involved. Duchscherer et al (2012) and Kahneman (2012) highlighted the importance of individual interviews. They emphasised that a principle of good investigation is that interviewees should be interviewed individually to avoid influencing memory and interpretation of events. It is not surprising then that that there was a strong statistically significant correlation between IQSs and evidence within investigation reports that individual interviews occurred.

On-going training, research and evaluation focussed on ensuring that the rate of individual interviews in investigations is continuously improved – is important.
Adherence to the definition of Key Causal Factor

The definition of a Key Causal Factor (KCF) arose from an iterative process of intensive co-design, and consultation and engagement with stakeholders including (i) service users that were harmed by healthcare, (ii) investigation commissioners, (iii) investigators, (iv) managers that implement learning from investigations, (v) healthcare professionals, and (vi) national and international general and patient safety experts. Details of this process are referred to in chapter 2, and published elsewhere (McCaughan et al., 2013)).

Investigator trainees often report at investigation training that determining KCFs is the most difficult aspect of investigations. The task of determining KCFs is complex requiring (i) collection of the relevant data, (ii) knowledge and understanding of the definition of KCFs, and (iii) analytical skills to determine from the data whether KCFs exist, and if so, what they are. The process of identifying KCF is illustrated in detail in the maternal death investigation report (Arulkumuran et al., 2013) referred to in example 8 in this chapter and also in chapter 7 of this thesis. This was the first investigation to be published after the publication of the HSE Guidelines for the Systems Analysis Investigation of Incidents and Complaints (Health Service Executive, 2012). It adhered fully to the definition of KCF in those guidelines and identified that the KCFs were (i) failure to monitor to detect deterioration, (ii) failure to offer all management options, and (iii) failure to follow local sepsis guidelines when sepsis was diagnosed. In correspondence to the HSE following the publication of this investigation report, Professor Arulkumaran, External Independent Chair of the investigation, and President International Federation of Obstetricians and Gynaecologists stated:

“I found the guidelines to be very clear and detailed and they were helpful in enabling us to conduct our investigation in as methodical and robust a manner as was possible.”

The literature refers to the challenges investigators report related to identifying causal factors (i.e. Wallace et al., 2006), Anderson and Kodate(2015)). This study identifies a strong statistically significant correlation between adhering to the definition of KCF and IQSs. This is positive and important confirmation that having this definition helps investigators grapple
with one of the most difficult - and arguably probably one of the most important – aspects of the investigation task.

*The relationship between investigation methods and IQSs*

Section 5.3.9 shows that investigations using methodologies other than a systems analysis method took up significant time and resources but delivered investigations with consistently below average ISQs. In two (20%) of the cases that used other methodologies – it was not possible to determine whether any of the investigators had attended NIMLT investigation training. In the remaining eight (80%) of the cases that used other methodologies it was identified that none of the investigators had attended NIMLT investigation training. So it seems that there may be a correlation between lack of attendance at HSE NIMLT investigator training and use of other investigation methods. Similar incidents were investigated using both systems analysis and other methods so the use of different methodologies does not appear to be related to differences in types of incidents.

Section 5.3.9 also showed that a statistically significantly greater proportion of the 2014 reports used the systems analysis method compared with reports completed in 2013. This could be related to the fact that NIMLT investigation training commenced in mid-2013. Another factor that may have contributed to this increased use of the Systems Analysis Investigation method was the fact that the NIMLT also provided Incident Management Training to managers from 2013 onwards. This training promoted the use of the Guidelines for the Systems Analysis Investigation of Incidents and Complaints (Health Service Executive, 2012).

*Implications for theory and policy*

This chapter explores factors that affect investigation quality in a manner that has not been done before. The findings challenge existing notions about what is important in investigations including assumptions about the make-up and size of investigation teams. It shows that taking on board the recommendations of Wallace *et al.*, (2006) to focus more on causal factors - contributed to a measurable positive impact on investigation quality. All of this is important for developing the theoretical basis of investigation science.
This in turn is important for informing evidence based investigation policy that is likely to have an optimum impact on improving investigation quality to in-turn contribute to the greatest possible organisation wide safety improvement. These ideas will be picked up and developed further in the discussion in chapter 8.

But first, in order to remain focused on answering the overarching research question underpinning this thesis about how to effectively leverage incident investigations to inform system safety – Study 4 in chapter 6 will address another important aspect of this - namely: Can clear patterns of causal factors be identified from a group of investigation reports that could inform better risk and safety management across a healthcare system?
<table>
<thead>
<tr>
<th>Overview of chapter 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.1. Introduction</td>
</tr>
<tr>
<td>6.2. Method</td>
</tr>
<tr>
<td>Determining patterns of (i) Broad Contributory Factor Types, and (ii) Contributory Factors</td>
</tr>
<tr>
<td>Determining patterns from “further details of Contributory Factors”</td>
</tr>
<tr>
<td><strong>Step 1:</strong> Familiarise yourself with the data</td>
</tr>
<tr>
<td><strong>Step 2:</strong> Generating initial codes</td>
</tr>
<tr>
<td><strong>Step 3:</strong> Searching for themes</td>
</tr>
<tr>
<td><strong>Step 4:</strong> Reviewing themes</td>
</tr>
<tr>
<td><strong>Step 5:</strong> Defining and naming themes</td>
</tr>
<tr>
<td><strong>Step 6:</strong> Producing the report</td>
</tr>
<tr>
<td>6.3. Results</td>
</tr>
<tr>
<td>Patterns of Broad Contributory Factor Types</td>
</tr>
<tr>
<td>Patterns of Contributory Factors</td>
</tr>
<tr>
<td>Patterns identified from “further details of Contributory Factors”</td>
</tr>
<tr>
<td><strong>Theme 1:</strong> Rapid deterioration; <strong>Theme 2:</strong> Planning and monitoring;</td>
</tr>
<tr>
<td><strong>Theme 3:</strong> Communications; <strong>Theme 4:</strong> Access; <strong>Theme 5:</strong> Equipment, facilities and environment; <strong>Theme 6:</strong> Care pathways, PPPGs, other tools to support care delivery; <strong>Theme 7:</strong> Governance and risk management;</td>
</tr>
<tr>
<td><strong>Theme 8:</strong> Education, training and supervision; and <strong>Theme 9:</strong> Diagnosis</td>
</tr>
<tr>
<td>6.4. Discussion</td>
</tr>
<tr>
<td>The phenomenon of premature closure</td>
</tr>
<tr>
<td>Analysis over time</td>
</tr>
<tr>
<td>Analysis across the system</td>
</tr>
<tr>
<td>The need for investigators and analysts to have Human Factors knowledge</td>
</tr>
<tr>
<td>The importance of analysing groups of investigations to identify patterns in causal factors</td>
</tr>
<tr>
<td>A helpful pragmatic stop rule for identifying underlying systemic causes</td>
</tr>
<tr>
<td>The wicked problem of the complexity of patterns of causal factors</td>
</tr>
<tr>
<td>Addition to understanding of incident mechanisms</td>
</tr>
<tr>
<td>A clearer picture of patterns of causal factors for better system safety</td>
</tr>
</tbody>
</table>
6.1. Introduction

The overarching research question for this thesis relates to how to effectively leverage incident investigations to better inform system safety. The previous chapters explored different aspects of this question by describing (i) the development and testing of a reliable Investigation Quality Evaluation Tool (IQET) in Study 1; (ii) applying the IQET to evaluate the quality of HSE investigations in Study 2, and (iii) by exploring whether factors that affect investigation quality can be empirically identified from information collected using the IQET, and attendance at investigator training. Study 4 which is described in this chapter considers whether clear patterns of causal factors can be identified from a group of investigation reports that could better inform risk and safety management across a healthcare system.


Rasmussen (1993) stated that more focused generalization required careful consideration of the work processes that had been the source of adverse events. Compared with purely statistical analysis of accident reports, Rasmussen (1993) believed that such functional analyses added immensely to the understanding of the accident mechanisms and that more detailed and constructive suggestions for improvements could be derived from the identification of recurrent deviations from a joint analysis of a larger set of accident reports.

The patterns of (i) Broad Contributory Factor Types, and (ii) Contributory Factors from a group of incident investigations were described by Cronin (2005). However, knowing that the most common Broad Contributory Factor type referred to in investigation reports is, say, task and technology factors - does not help us to see a pattern of causal factors to inform better risk
management. This is because many questions remain outstanding. For example, which task and technology factors are most problematic, and why?

Similarly, knowing that, say, availability and use of PPPGs is the most common type of Contributory Factor - does not help us to see a pattern of causal factors to inform better risk management. Again, many questions remain outstanding. For example, is the problem that PPPGs are not available? Or is it that they are available but not disseminated, or evidence based? Or is it that they are available, and evidence based, and disseminated, but not used? And if so, why are they not used?

So, joint analysis to identify recurrent patterns in sets of thorough incident investigation reports is required for generalization. But it needs more than just analysis of the Broad Contributory Factor Type, and Contributory Factor.

No literature was identified describing the analyses of sets of thorough incident investigation reports to identify patterns of causal factors from data other than the analysis of (i) Broad Contributory Factor Types, and (ii) Contributory Factors by Cronin (2005). This thesis aimed to bridge this gap in the literature by addressing the following research question:

"Are there clear patterns of causal factors identifiable in the investigation reports that could inform better risk management across the HSE?"

As described in study 2 in chapter 4, the quality of the contributory factors information in the investigation reports that fell within this study was variable. This made analysis to identify patterns in causal factors challenging. However, attempting this meant that (i) reasonable thematic analysis was possible in order to answer the above research question, and (ii) actions were identified that – if taken - are likely to enhance the efficiency with which we can learn from incidents about how to improve system wide safety in the future.

6.2. Method

There were two main elements of the analysis for this study:

(i) Simple counting to determine patterns in Broad Contributory Factors Types, and Contributory Factors, and
Identification of patterns of causal factors from further details of Contributory Factors.

6.2.1. Method to determine the pattern of (i) Broad Contributory Factor Types, and (ii) Contributory Factors.

The HSE’s systems analysis investigation guidelines (Health Service Executive, 2012) required that the information in the chronology section of the investigation report be analysed to identify Key Causal Factors (KCFs). KCFs were defined in the guidelines as “Issues that arose in the process of delivering and managing care which contributed to the eventual adverse outcome”. The process of developing this definition is described in chapter 2, and elsewhere (McCaughan et al., 2013). Each identified KCF then needs to be analysed using the “Contributory Factors Framework” to identify (i) Broad Contributory Factor Type, and (ii) Contributory Factor. Please see a copy of the “Contributory Factors Framework” in table 6.1 below.
## Table 6.1: Framework of Contributory Factors from the Guidelines for Systems Analysis Investigation of Incidents and Complaints (2012, HSE) which in turn is from the London Protocol (Taylor-Adams et al., 2004).

The seven broad Contributory Factor types and the 28 Contributory Factors as per table 6.1 above were built into the pick-lists on the SPSS data base. The data about (i) Broad Contributory Factor Types, and (ii) Contributory Factors was entered into the SPSS database for each of the 107 investigation reports included within this study.

The (i) Broad Contributory Factor Type, and (ii) Contributory Factor data were counted to determine the resultant patterns in Contributory Factors.
The frequencies were analysed separately for 2013 and 2014. This was not to look for a trend over time. Rather, it was as a test of the stability of the pattern. If a very similar pattern is found in the two years it suggests that the determinants of that pattern (presumably the causal factors themselves, but possibly also the biases of the investigators) are stable. If a different pattern is found - it would suggest less stability and more variability meaning that causal factors of past events are less useful inputs to risk management as they may not be the relevant causes for future events. The results are shown in section 6.3 below.

6.2.2. Method to determine patterns from “further details of Contributory Factors”

The further details of Contributory Factors are necessary to understand the contributory/causal factors more fully. Thematic analysis of the further details of Contributory Factors was used to endeavour to answer the research question in this case, namely:

“Are there clear patterns of causal factors identifiable in the investigation reports that could inform better risk management across the HSE?”

Boyatzis (1998) describes thematic analysis as a method for identifying, analysing and reporting patterns within data. The six step guide for conducting a thematic analysis by Braun & Clarke (2006) was followed, using an inductive approach, to determine patterns from the further details of Contributory Factors as follows:

**Step 1: Familiarising yourself with your data**

The entire data set was read through once prior to actively re-reading searching for meaning and patterns in the data. Ideas for coding were noted during the first read for consideration during the subsequent steps of the thematic analysis.
Step 2: Generating initial codes

Coding was conducted manually by (i) considering the entire list of data items, (ii) identifying aspects of the data items that may form the basis of repeated patterns across the data set (i.e. the initial data code), and (iii) cutting individual data items and pasting them under initial data codes using Microsoft Word. At the end of this step, the data was coded and collated under a list of different codes identified across the data set.

Step 3: Searching for themes

The codes identified in step 2 above were analysed to consider how different codes may combine to form an overarching theme. This resulted in the codes being sorted into potential themes collating all the relevant coded data extracts within the identified themes. This phase ended with a collection of candidate themes, and sub-themes, and all extracts of data were coded in relation to them.

Step 4: Reviewing themes

This phase involved two levels of reviewing and refining themes. Level one involved reviewing at the level of the coded data extracts – that is - reading all the collated extracts for each theme, and considering whether they appeared to form a coherent pattern. If not, they were reworked by either (i) creating a new theme, (ii) finding a home in an already existing theme, or (iii) discarding them from the analysis. Level two involved a similar process, but in relation to the entire data set.

Step 5: Defining and naming themes

Efforts were made to give themes names which immediately gave the reader a sense of what the theme was about.

Step 6: Producing the report

The results of this process are reported in section 6.3 below.

---

74 The term “data item” refers to each individual piece of data collected, which together make up the data set or corpus (Braun and Clarke, 2006).

75 The term “data extract” refers to an individual coded chunk of data, which has been identified with, and extracted from a data item (Braun and Clarke (2006)).
6.3. Results

This results section is divided into three subsections with section 6.3.1 detailing the results of the analysis to identify patterns in Broad Contributory Factor Type; section 6.3.2 detailing the results related to Contributory Factors; and section 6.3.3 detailing the analysis to identify patterns from the further details of Contributory Factors data.

6.3.1. Pattern of Broad Contributory Factor Types

The pattern of Contributory Factors identified in the 2013 and the 2014 reports is almost identical as per figure 6.1.

![Figure 6.1: Showing the frequency of Broad Contributory Factor Types (Results for 2013 reports shown above in blue & 2014 reports below in red)]
As shown above, the pattern for 2013 and 2014 investigation reports is almost identical with the very minor exception of the relative position of “Team factors” and “Individual affected/harmed” which varies slightly between these two years. “Individual affected/harmed” is the second most common Broad Contributory Factor Type from the 2013 investigation reports occurring 15.38% (n=24) of the time; with “Team factors” the third most common broad contributory factor type occurring 14.74% (n= 23). “Team factors” is the second most common Broad Contributory Factor Type from the 2014 investigation reports occurring 15.60% (n=22) of the time; with “Individual affected/harmed” the third most common Broad Contributory Factor Type occurring 14.89% (n= 21).

As shown in table 6.2 below, of the total number of investigation reports within this study (N=107 i.e. 62 completed in 2013 and 45 completed in 2014), 54.21% (n=58) identified Broad Contributory Factors. Within these 54.21% of investigation reports, a total of 297 Broad Contributory Factors were identified.

By far the most common Broad Contributory Factor Type identified was “Task and technology factors” which was identified 37.04% (n=110) of the time. The two Broad Contributory Factor Types “Individual affected/harmed” and “Team factors” were the second most common Broad Contributory Factor Type with both occurring 15.15% (n=45) of the time. These were followed in frequency by “Work environment factors” which occurred 13.13% (n=39) of the time; “Individual (Staff) factors” which occurred 9.43% (n=28) of the time; “Organisational and Management Factors” which occurred 6.73% (n=20) of the time; and finally “Institutional Factors” which occurred 3.37% (n=10) of the time.
6.3.2. Pattern of Contributory Factors

The Contributory Factors Framework in the HSE’s 2012 systems analysis investigation guidelines required broad Contributory Factor types to be further categorised into Contributory Factors.

Of the investigation reports completed in 2013 (N=62), 53.23% (n=33) identified Broad Contributory Factors Types. Of these 33 reports, 66.67% (n=22) identified Contributory Factors.

Of the investigation reports completed in 2014 (N=45), 55.56% (n=25) identified Broad Contributory Factor Types. Of these 25 reports, 12.00% (n=3) identified Contributory Factors.

Please see the table 6.2 below showing the frequency of Contributory Factors for 2013 and 2014 investigation reports combined.
<table>
<thead>
<tr>
<th>Broad Contributory Factor Type</th>
<th>Contributory Factor</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individual affected/harmed:</td>
<td>Condition (complexity &amp; seriousness)</td>
<td>12</td>
<td>11.1</td>
</tr>
<tr>
<td></td>
<td>Language and Social Factors</td>
<td>3</td>
<td>2.8</td>
</tr>
<tr>
<td></td>
<td>Personality and social factors</td>
<td>2</td>
<td>1.9</td>
</tr>
<tr>
<td></td>
<td>Psychology, existing mental health condition, stress</td>
<td>2</td>
<td>1.9</td>
</tr>
<tr>
<td>Task and technology factors:</td>
<td>Availability and use of protocols, policies, standards</td>
<td>29</td>
<td>26.9</td>
</tr>
<tr>
<td></td>
<td>Policies etc., relevant, unambiguous, correct and realistic</td>
<td>4</td>
<td>3.7</td>
</tr>
<tr>
<td></td>
<td>Availability and accuracy of test results</td>
<td>5</td>
<td>4.6</td>
</tr>
<tr>
<td></td>
<td>Decision making aids</td>
<td>6</td>
<td>5.6</td>
</tr>
<tr>
<td>Individual (Staff) factors:</td>
<td>Knowledge and Skills</td>
<td>5</td>
<td>4.6</td>
</tr>
<tr>
<td></td>
<td>Competence - education, training and supervision</td>
<td>6</td>
<td>5.6</td>
</tr>
<tr>
<td>Team factors</td>
<td>Verbal communication</td>
<td>6</td>
<td>5.6</td>
</tr>
<tr>
<td></td>
<td>Written Communication</td>
<td>6</td>
<td>5.6</td>
</tr>
<tr>
<td></td>
<td>Supervision and seeking help</td>
<td>3</td>
<td>2.8</td>
</tr>
<tr>
<td></td>
<td>Team Structure (Leadership, congruence, consistency etc.)</td>
<td>1</td>
<td>0.9</td>
</tr>
<tr>
<td>Work environmental factors:</td>
<td>Staffing levels and skills mix</td>
<td>8</td>
<td>7.4</td>
</tr>
<tr>
<td></td>
<td>Environment - Physical and Cognitive</td>
<td>2</td>
<td>1.9</td>
</tr>
<tr>
<td></td>
<td>Design, availability and maintenance of equipment</td>
<td>3</td>
<td>2.8</td>
</tr>
<tr>
<td>Organisational and Management Factors:</td>
<td>Organisational Structure</td>
<td>1</td>
<td>0.9</td>
</tr>
<tr>
<td></td>
<td>Policy, standards and goals</td>
<td>1</td>
<td>0.9</td>
</tr>
<tr>
<td></td>
<td>Quality and Safety Culture and Priorities</td>
<td>1</td>
<td>0.9</td>
</tr>
<tr>
<td>Institutional Context Factors:</td>
<td>Economic and Regulatory Context</td>
<td>2</td>
<td>1.9</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>108</td>
<td>100.0</td>
</tr>
</tbody>
</table>

**Table 6.2:** Showing the frequency of Contributory Factors (2013 and 2014 reports combined)

Please see figure 6.3 below showing the frequency of Contributory Factors for 2013 and 2014 investigation reports shown separately.
6.3.3. Patterns identified from “Further details of Contributory Factors”

When investigators expanded on the Contributory Factors they identified, these details are described within this thesis as **further details of Contributory Factors**. HSE investigation guidelines (2012) did not explicitly state that **further details of Contributory Factors** should be included in investigation reports, but investigator training did highlight that such further details should be included in reports. **Further details of Contributory Factors** were included in 37.10% (n=23) of 2013 reports, and in 77.77% (n=35) of 2014 reports. That is, 54.2% (n=58) of the total 107 reports included within this study.

A total of 286 data items were identified from the **further details of Contributory Factors** data.

An **inductive approach to thematic analysis** as described by Braun and Clarke (2006) was used to identify patterns in further details of Contributory Factors.
This culminated in the identification of nine main themes and related sub-themes as shown in figure 6.4 below.

Figure 6.4: Thematic map showing the nine main themes and their sub-themes

As predicted by Braun and Clarke (2006) for this type of analysis, some data items fitted within a number of codes and themes. Where this occurred, for example with issues related to EWS, they were placed within **Theme 6: Care pathways, PPPGs, and other tools to support care delivery** when they made specific reference to the need for PPPGs. They were categorised to **Theme 7: Governance and risk management** when they referred specifically to, for example, the need to audit the EWS PPPGs. And they were categorised under **Theme 8: Education, training, and supervision** if they referred specifically to the need for training related to EWS.

Similar examples could be given for linkages with all other possible combinations of themes and sub-themes as shown in the figure 6.5 below.
Initially, a small number of data items did not seem to fit cohesively under any themes. As recommended by Braun and Clarke (2006) a theme “miscellaneous” was created to house these temporarily. After a number of reiterations of the thematic analysis process, all but two of these data items were eventually rehoused within existing themes. One of these related to case ref 100 and stated that there was a:

“need to finalise & implement guidelines for the management of patients with challenging behaviour”.

This was different to the data items related to specific clinical areas within theme 6. Ultimately, this was assigned to Sub-Theme 6l) “miscellaneous”.

The second was the following data item related to case ref 49:

“Need to implement National ACS [i.e. acute coronary syndrome] programme in the [redacted area initial]; Clinical Governance for critical care”.

This was considered under sub-category 1a) Recognising and managing rare conditions/unusual/time critical situations. However, it seemed somewhat different to the other two data items within this Sub-Theme in that it referred
to a programme of care, and also in its reference to clinical governance. 

Finally, it was divided into two items and categorised as follows:

(i) "Need to implement National Acute Coronary Syndrome programme" was assigned to sub-theme 6a) "miscellaneous", and

(ii) "Need for Clinical Governance for critical care" was assigned to sub-theme 7a) Broader Governance.

During the thematic analysis process, the following criteria emerged as helpful in determining whether data items should be included in or discarded from the analysis:

(i) The data tended to give a better/clearer understanding of the causal factor, and

(ii) The data tended to give a sense of the action necessary to prevent future harm arising from the causal factor.

Data items included in the thematic analysis satisfied either one or both of the above criteria.

It was considered that these criteria could form the basis of a helpful pragmatic stop rule for identifying systemic causal conditions in investigations to inform credible preventative measures. This idea is taken up and developed further in the discussion section of this chapter.

As stated, there were some (n=39) further details of Contributory Factors data items that appeared not to fit cohesively within any of the identified themes. These did not tend to give a better/clearer understanding of the causal factors, nor did they give a sense of the action necessary to prevent future harm arising from the causal factor. These were discarded from the analysis. Further details of these 39 data items and the broader thematic analysis can be found in Appendix 20 b).

Table 6.3 below shows the results of the thematic analysis to identify patterns in causal factors - and the following sections describe each Theme and its Sub-Themes. Further details are also available in Appendix 20 a).
<table>
<thead>
<tr>
<th>Themes</th>
<th>Sub-Themes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Theme 1:</strong> Responding to rapid deterioration&lt;sup&gt;76&lt;/sup&gt; (12)</td>
<td>1a) Recognising and managing rare conditions/unusual presentations (2)  &lt;br&gt; 1b) Managing complex patients +/- multiple co-morbidity (10)</td>
</tr>
<tr>
<td><strong>Theme 2:</strong> Planning and monitoring care&lt;sup&gt;77&lt;/sup&gt; (8)</td>
<td>2a) Initial assessments (4)  &lt;br&gt; 2b) On-going monitoring (4)</td>
</tr>
<tr>
<td><strong>Theme 3:</strong> Communications (50)</td>
<td>3a) Between services (3)  &lt;br&gt; 3b) Between agencies (1)  &lt;br&gt; 3c) With patients/families (7)  &lt;br&gt; 3d) Between multidisciplinary teams, and between shifts (18)  &lt;br&gt; 3e) Via healthcare records (21)</td>
</tr>
<tr>
<td><strong>Theme 4:</strong> Access (21)</td>
<td>4a) Access to Emergency Departments (ED) (2)  &lt;br&gt; 4b) Access to emergency surgery (1)  &lt;br&gt; 4c) Access to High Dependency Unit (HDU)/Intensive Care Unit (ICU) (3)  &lt;br&gt; 4d) Resource demand mismatch&lt;sup&gt;78&lt;/sup&gt; (15)</td>
</tr>
<tr>
<td><strong>Theme 5:</strong> Equipment, facilities &amp; environment (18)</td>
<td>5a) Design of facilities (3)  &lt;br&gt; 5b) Commissioning of equipment&lt;sup&gt;79&lt;/sup&gt; (1)  &lt;br&gt; 5c) Maintenance of equipment (2)  &lt;br&gt; 5d) Availability of/access to equipment (9)  &lt;br&gt; 5e) Risk assessment (3)</td>
</tr>
<tr>
<td><strong>Theme 6:</strong> Care pathways, PPPGs&lt;sup&gt;80&lt;/sup&gt;, and other tools to support care delivery (54)</td>
<td>6a) Planning and monitoring (including use of EWSs) (8)  &lt;br&gt; 6b) Communications (10)  &lt;br&gt; 6c) Access&lt;sup&gt;81&lt;/sup&gt; (10)  &lt;br&gt; 6d) Mental Health (7)  &lt;br&gt; 6e) Maternity/Neonatal care (3)  &lt;br&gt; 6f) Medication management (3)  &lt;br&gt; 6g) Nutrition management (2)  &lt;br&gt; 6h) Prevention and management of choking (2)  &lt;br&gt; 6i) Prevention and management of rapid deteriorating (3)  &lt;br&gt; 6j) Prevention and management of falls (2)  &lt;br&gt; 6k) Prevention and management of pressure ulcers (2)  &lt;br&gt; 6l) Miscellaneous (2)</td>
</tr>
<tr>
<td><strong>Theme 7:</strong> Governance and risk management (40)</td>
<td>7a) Broader governance (including developing and disseminating PPPGs) (7)  &lt;br&gt; 7b) Lack of clarity about roles and responsibilities (3)  &lt;br&gt; 7c) Issues related to risk and incident management (4)  &lt;br&gt; 7d) Need for audit (26)</td>
</tr>
</tbody>
</table>

<sup>76</sup> This theme includes detecting and responding to time critical situations  
<sup>77</sup> See also references to use of EWSs (Early Warning Scores) in Theme 6 (Care pathways, PPPGs, and other tools to support care delivery)  
<sup>78</sup> This Access sub-theme Resource demand mismatch included (i) referral and transfer, and (ii) demand/resource matching  
<sup>79</sup> This sub-theme referred to training of all relevant staff in the use of newly procured/commissioned equipment.  
<sup>80</sup> PPPGs: Policies, procedures, protocols, and guidelines
Theme 8: 
Education, training, and supervision (28)

8a) Training needs assessment (TNA) (1)
8b) Training for night staff (1)
8c) Induction/support/supervision for new/junior staff (5)
8d) Detection and management of rapid deterioration (4)
8e) Training related to specific clinical risks (13)
8f) Training related to equipment (3)
8g) Training related to communication (1)

Theme 9: Diagnosis (2)

9a) Premature closure (2)

Table 6.3: 
Showing key Themes identified from the thematic analysis of the further information about Contributory Factors data. The number in parenthesis beside the Theme indicates the number of data items that fell under that Theme. The number in parenthesis beside the Sub-Theme indicates the number of data items that fell under that Sub-Theme.

Theme 1: Responding to rapid deterioration:

The longer title for this Theme as per Appendix 20 a) is detecting and responding to rapid deterioration/time critical situations/complex patients.

It is shortened here as Braun and Clarke (2006) recommend identifying titles for themes that are:

“...concise, punchy, and immediately give the reader a sense of what the theme is about”.

This theme contained 12 data items which went across both acute and community services.

Analysis of this Theme identified two further sub-themes. Sub-Theme 1a) related to recognising and managing rare conditions/unusual/time critical presentations. These included a case of iGAS\footnote{IGAS: Invasive Group A Streptococcal Infection} which is a rare condition with high mortality rates, and a case of “warm shock” on a general ward which would more commonly occur in high dependency and intensive care settings.

Sub-Theme 1b) related to managing complex patients with or without multiple co-morbidities.

Links were identified between this theme and each of the other eight themes. For example, issues with (i) planning and monitoring care, (ii) communications

\footnote{Specific clinical risks referred to included (i) safe moving and handling, (ii) doing observations, (iii) prevention and management of falls, (iv) suicide prevention, (v) prevention and management of pressure ulcers; and (vi) management of nutrition.}
between agencies, services, healthcare professionals, with patients/families, (iii) access to emergency services, (iv) monitoring/diagnostic equipment, (v) compliance with early warning score systems (EWS), (vi) learning from audit of compliance with EWS, and (vi) training in the use of EWS, were considered to contribute to issues with detecting and responding to rapid deterioration.

**Theme 2: Planning and monitoring care**

Like Theme one, Theme two went across acute and community services.

This theme contained 8 data items which were divided into two sub-themes. Sub-Theme 2a) related to initial patient assessment, including reference to the importance of complete clinical systems review on admission. Sub-Theme 2b) related to on-going patient monitoring including reference to the importance of conducting and following up on test results, and the use of early warning scoring systems (EWS).

As stated previously, there were linkages between all themes, but there were particularly strong linkages between this theme and the availability of EWSs, and training in EWS.

**Theme 3: Communications**

The *communications* Theme was the second biggest Theme with 50 data items.

Like Theme one and two, Theme three went across acute and community services.

Analysis of this theme identified five Sub-Themes.

Sub-Theme 3a) related to communication between services including reference to the importance of verbal communication between senior primary care team clinicians and the laboratory team when there is recognition that an urgent blood sample needs to be sent to the laboratory.

Sub-Theme 3b) related to an issue with communication between the Department of Health (DoH) and the HSE in a case where there had been recent deaths from iGAS in two Paediatric Hospitals notified to the DoH, but where clinicians in other paediatric hospitals were not aware of this.
Sub-Theme 3c) related to communication with patients and families. This theme included reference to (i) the absence of information leaflets about the risk of vaginal birth after caesarean section (VBAC), (ii) communication about continence issues, (iii) communications where a patient is reserved, or where there are language issues, (iv) lack of information about access to services if problems arise following surgery, and (v) issues with information provided to families of critically ill infants.

Sub-Theme 3d) related to communication between healthcare professionals, between multidisciplinary teams members (MDTs), and between shifts. This was the third largest sub-Theme and comprised of 17 data items. Full details of these data items can be found in Appendix 20 a).

Sub-Theme 3e) related to communications via healthcare records. This was the second largest Sub-Theme comprising of 21 data items. These ranged from issues with documenting the exact planned surgical procedure in consent forms to general issues with nursing and medical documentation. These are detailed in Appendix 20 a).

As stated, there were linkages between all Themes, but there were particularly strong linkages between this Theme and communications Sub-Themes of both Theme 6: Care pathways, PPBGs, and other tools to support care delivery, and Theme 8: Education, training, and supervision.

Theme 4: Access
This Theme contained 21 data items. It differed from the other Themes in that the data items came predominately from investigations of incidents that occurred in acute services with only two data items arising from investigation of incidents in community services.

Analysis of this Theme identified four sub-themes as follows.

Sub-Theme 4a) related to access to emergency departments (EDs), including reference to issues with moving clinically stable patients from the ED to inpatient or AMAU (Acute Medical Assessment Unit) beds for admission to create space in ED to address the problem of ambulance offload delays.
Sub-Theme 4b) related to access to emergency surgery specifically when emergency and elective surgical teams are one and the same meaning that teams may need to leave elective surgery when a need to conduct emergency surgery arises.

Sub-Theme 4c) related to access to Paediatric Intensive Care Units (PICU), High Dependency Units (HDU) and cardiac intervention services including catheterisation laboratories.

Sub-Theme 4d) related to resource demand mismatch ranging from problems due to sudden surge in ED activity, to overcrowding. This was the third largest Sub-Theme containing 15 data items which are detailed in Appendix 20 a).

There were linkages between Theme 4 and all other Themes. However, there were particularly strong linkages between this Theme and the access Sub-Theme that fell under Theme 6: Care pathways, PPPGs, and other tools needed to support care delivery.

**Theme 5: Equipment, facilities, and environment**

Like the previous Themes, this Theme went across acute and community services.

This Theme contained 18 data items which were divided into the following five Sub-Themes.

Sub-Theme 5a) related to design of facilities including (i) the need for a seclusion room to be segregated to provide a small psychiatric intensive care unit, (ii) the need for an ambulance control room to facilitate communication and supervision, and (iii) the need for antenatal wards to be conducive to the efficient use of midwifery staff.

Sub-Theme 5b) related to commissioning of equipment, specifically a critical care trolley.

Sub-Theme 5c) related to maintenance of equipment including personal alarms, and foetal monitors.
Sub-Theme 5d) related to availability of and access to equipment ranging from foetal blood sampling equipment to access to torches during power outages.

Sub-Theme 5e) related to risk assessment particularly as it related to equipment, facilities, and the environment for the prevention of suicide.

There were linkages between Theme 5 and all other Themes. However, there were particularly strong linkages between Theme 5 and the equipment Sub-Theme that fell under Theme 8: Education, training, and supervision.

**Theme 6: Care pathways, PPPGs, and other tools to support care delivery**
This was the largest Theme with a total of 54 data items. This Theme also went across acute and community services.

Analysis of this Theme identified 12 Sub-Themes including the miscellaneous Sub-Theme referred to previously. Details of this Theme and its Sub-Themes can be found in Appendix 20 a). There were strong connections between Theme 6 and all other Themes, particularly the audit Sub-Theme within Theme 7: Governance and risk management, and Theme 8: Education, training, and supervision.

**Theme 7: Governance and risk management**
This was the third largest Theme with a total of 40 data items falling within it. It contained the biggest single Sub-Theme namely Sub-Theme 7d) need for audit. This contained 26 individual data items suggesting the need for various audits which are detailed in Appendix 20 a).

There were strong connections between Theme 7 and all other Themes, particularly Theme 6: Care pathways, PPPGs, and other tools to support care delivery, and Theme 8: Education, training, and supervision.

**Theme 8: Education, training, and supervision**
This Theme contained 35 data items divided into 7 Sub-Themes as per table 6.3 above and Appendix 20 a).
There were strong connections between Theme 8 and all other Themes, particularly **Theme 6: Care pathways, PPPGs, and other tools to support care delivery**, and **Theme 7: Governance and risk management**.

**Theme 9: Diagnosis**

This Theme contained a single sub-theme, namely **premature closure in diagnosis**, which in turn contained two data items. One was related to a case which was prospectively diagnosed as a miscarriage, but which was retrospectively considered to be either a case of miscarriage misdiagnosis, or a case of a surviving twin. The other related to a patient who had a previous diagnosis of lung cancer, but sadly went on to die of a burst duodenal ulcer while clinicians considered that the symptoms of the duodenal ulcer were related to a worsening of the patients lung cancer pain.

The identification of this Theme was somewhat different to the identification of the other eight Themes and this is described further in the discussion section below.

**6.4. Discussion**

The patterns of (i) Broad Contributory Factor Types, and (ii) Contributory Factors identified in this study were generally in line with what was previously published in the literature (Cronin, 2005), and what would be expected based on other sources of risk information in the HSE such as the Risk Register. The pattern was also almost identical for 2013 and 2014. The stability of the pattern suggests that the determinants of that pattern (presumably the causal factors themselves, but possibly also the biases of the investigators) are stable. This means that the causal factors of past events are useful inputs to risk management as they are likely to be the relevant causes for future events.

While this is very important, this chapter shows that knowing this does not go the whole way to answering the research question underpinning **Study 4** namely:

"Are there clear patterns of causal factors identifiable in the investigation reports that could inform better risk management across the HSE?"
And so, this chapter goes on to reflect what appears to be the first analysis to identify patterns in further details of Contributory Factors resulting in nine main Themes and 42 Sub-Themes. While this brought us a little further along the path to answering the research question, there is an outstanding need for a systemic causal enquiry that looks for deep systemic causes as opposed to just general associative themes if the research question is to be answered fully. This led to a consideration of what Braun and Clarke (2005) refer to as the need for thematic analysis to be “applied flexibly” to fit the research question. This in turn led to consideration of important causal patterns that could only emerge by considering the data from within this study with other data as described below.

The phenomenon of premature closure

Premature closure in diagnosis is the tendency to accept the first answer that comes along that explains the facts at hand, without considering whether there might be a different or better solution (National Academy of Science, Engineering and Medicine, 2016). Premature closure in medical diagnoses is well described in the literature (Voytovich et al., (1985); Eva et al., (2006)).

The phenomenon of premature closure had previously been observed by the author in at least four cases of delayed diagnosis of lung cancer that were outside of the scope of the cases included within the current study. These other cases were observed in the author’s role on the HSE Serious Incident Management Team (SIMT) and later on the National Incident Management Team (NIMT). They related to investigations that were completed before January 2013 and so were not included in this study. They involved four cases where patients had atypical presentations of lung cancer. That is, they did not present with the typical symptoms such as rib pain or coughing, including coughing up blood. Routine tests did not show markers for lung cancer. Chest X-rays were not reported to identify lung cancer. These patients complained of abdominal pain. Clinicians made diagnoses related to these abdominal symptoms. In all cases the patients re-presented on multiple occasions with worsening pain; and eventually further tests such as CT scans showed that the patient had lung cancer. When the original chest X-ray films were reviewed the lung cancer could be seen. The lung lesions were of the type that are
described in the literature as being difficult to identify prospectively without clinical information that is suspicious of lung cancer, such as being 1cm in diameter or less; having jagged edges; or being located in the hilar region. But these lesions are described as easy to see retrospectively when the diagnosis of lung cancer is suspected or known (Woodring, (1990); Heelan et al., (1984)).

Braun and Clarke (2006) state that:

“Ideally, there will be a number of instances of the theme across the data set, but more instances do not necessarily mean the theme itself is more crucial... researcher judgement is necessary to determine what a theme is... the “keyness” of a theme is not necessarily dependent on quantifiable measures – but rather on whether it captures something important in relation to the overall research question”.

They also recommend that during step one of the thematic analysis process - familiarising yourself with your data – the analyst should note ideas for coding for consideration during subsequent steps of the analysis process.

Premature closure in diagnosis was noted as an idea for coding during step one of the thematic analysis process although it was only referred to implicitly in two out of the 107 investigation reports, namely case refs 48 and 76.

Case ref 48 related to the death of a patient following failure to diagnose a duodenal ulcer prior to its perforation. This patient had a previous correct diagnosis of lung cancer with metastases. When the patient represented with worsening pain, this was attributed to a worsening of the lung cancer pain i.e. premature closure of diagnosis. The patient was treated for this and sadly died of a burst duodenal ulcer.

The second example of premature closure identified within the cases included in this study was case ref 76. This related to a woman who presented at a maternity unit at just under six weeks gestation. She complained of bleeding and thought she had miscarried her foetus at home. Examination indicated classic features of spontaneous on-going miscarriage. An ultrasound scan

---

84 Metastases refers to the development of secondary malignant growths at a distance from a primary site of cancer
showed some products of conception and blood in the uterus which the investigation report stated “detracted from the visibility of the scan”. A miscarriage was diagnosed and the patient was administered cytotec vaginally. The patient re-presented for follow up 10 days later. She indicated that the cytotec had fallen out when she toileted. A pregnancy test at this time was positive. An ultrasound scan showed a foetus aged 7 weeks and a heart-beat was identified. The investigation concluded that this was either a case of a miscarriage mis-diagnosis, or a case of a surviving twin.

The phenomenon of premature closure in diagnosis was not explicitly stated within any of these six investigation reports (i.e. case refs 48 and 76 from within this study, and the four cases of delayed diagnosis of lung cancer referred to above that the author had previously observed outside of the scope of the current study). Braun and Clarke (2006) highlight the role of thematic analysis in making what is implicit in the data explicit and the examples above of premature closure illustrate just this. However, it is likely that the important pattern of premature closure in diagnosis may not have been identified had only the two cases (i.e. case refs 48 and 76) within this study which implicitly referred to the phenomenon – been considered. Importantly, it was probably only possible to identify this theme because the two cases that implicitly described premature closure from within this study were considered by the author who had observed the phenomenon of premature closure described implicitly in at least four other investigation reports outside the scope of this study. This shows that the authors past knowledge and experienced of data outside of the scope of this thesis, was important in influencing the “researcher judgment” that Braun and Clarke (2006) highlight is “necessary to determine what a theme is” and that “the keyness of a theme is not necessarily dependent on quantifiable measures – but rather on whether it captures something important in relation to the overall research question”.

The important point is that limiting the analysis to the data that fell within the scope of this study would not have fully answered the research question in this study. This research question required a more powerful and robust inference process directed in part by the data that fell within the scope of this
study, but also in part by the experience and specific in-depth expertise of the author culminating in a hybrid methodology that was tailored to solve the particular problem at hand – building more powerful causal models. The observation of patterns of causal factors over time and across the system was also important. These matters are elaborated upon in the following sections.

**Analysis over time**

The cases of premature closure in diagnosis outlined in the previous section related to six cases that spanned seven years between 2006 and 2013. Only two were cases that were included within the 107 cases within this study. Both of these cases related to 2013 investigation. No cases involving premature closure in diagnosis were identified in the 45 investigation reports completed in 2014. That is not to say that this phenomenon did not exist in any of these cases. It is simply to say that this was not identifiable from the information included within these investigation reports. It should be noted that all cases of premature closure that resulted in death or serious harm may not have been investigated; all related investigations may not have been submitted to this study; and the author only had access to a small subset of cases in her former role of on NIMT and SIMT, so it is likely that cases of premature closure are occurring more frequently than these available figures suggest. Five out of six of the cases of premature closure in diagnosis were cases where this related to a delay in diagnosis that likely contributed to the patient’s death, or earlier death - so the problem is serious.

The National Academies of Science, Engineering and Medicine (2016) publication entitled “Improving diagnosis in healthcare” includes recommendations for improving diagnosis in healthcare to address the problem of premature closure – so the problem is considered solvable.

This pattern of serious and preventable premature closures in diagnosis would not have been identified if only the 2014 investigation reports had been considered. This highlights the importance of conducting analysis of patterns of causal factors from groups of investigation reports over time.
Analysis across the system

The two cases of premature closure identified within the 2013 investigations occurred within the maternity services and emergency services respectively highlighting the need to consider patterns of causal factors across services.

Even stronger evidence to support the need to consider patterns of causal factors across the system relates to failure to detect and respond to rapid deterioration. Table 6.4 below shows nine cases of failure to respond to rapid deterioration across divisions and services identified from the cases included within this study.

<table>
<thead>
<tr>
<th>Ref</th>
<th>Division</th>
<th>Service</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Acute Hospital Division</td>
<td>Emergency Services</td>
<td>Death</td>
</tr>
<tr>
<td>57</td>
<td>Acute Hospital Division</td>
<td>Medical Services</td>
<td>Death</td>
</tr>
<tr>
<td>79</td>
<td>Acute Hospital Division</td>
<td>Medical Services</td>
<td>Death</td>
</tr>
<tr>
<td>64</td>
<td>Acute Hospital Division</td>
<td>Surgical Services</td>
<td>Death</td>
</tr>
<tr>
<td>113</td>
<td>Social Care Division</td>
<td>Elderly Residential Service</td>
<td>Death</td>
</tr>
<tr>
<td>120</td>
<td>Acute Hospital Division</td>
<td>Children’s Acute Services</td>
<td>Death</td>
</tr>
<tr>
<td>121</td>
<td>Social Care Division</td>
<td>Adult Intellectual Disability Services</td>
<td>Death</td>
</tr>
<tr>
<td>124</td>
<td>Acute Hospital Division</td>
<td>Emergency and Medical Services</td>
<td>Serious Harm</td>
</tr>
<tr>
<td>131</td>
<td>Social Care Division</td>
<td>Child Intellectual Disability Services</td>
<td>Death</td>
</tr>
</tbody>
</table>

Table 6.4: Cases of failure to detect and respond to rapid deterioration per service, and outcome.

As seen in table 6.4 above, these nine cases spanned emergency, medical, surgical, acute children’s services, intellectual disability, and care of the elderly residential services. Sadly, the patients died in eight of these cases. In the remaining one case, the patient suffered serious harm.

It is reasonable to assume that more cases of failure to detect and respond to rapid deterioration occur than are investigated. Furthermore, it is reasonable to assume that not all investigations were submitted to this study. The author has observed cases of failure to detect and respond to rapid deterioration in other services - including Mental Health Services - in serious incident investigation reports outside of the cohort that fell within the current study. As stated previously, the author would only have sight of a subset of investigation reports. Even so, it is clear that the issue of failure to detect and
respond to rapid deterioration is one that goes across services. This highlights the need for conducting analysis of patterns in causal factors from groups of investigation reports from across services also.

The need for investigators and analysts to have human factors knowledge

Case ref 48 where clinicians attributed the patient’s symptoms to an existing lung cancer diagnosis and did not diagnosis a duodenal ulcer before it perforated; and case 76 where there was either a miscarriage mis-diagnosis or a failure to identify a twin surviving a miscarriage – have been referred to previously in the context of the phenomenon of premature closure in diagnosis. This was not identified explicitly within either of these investigation reports. It was identified by the author who has knowledge of the phenomenon and had encountered it previously in investigation reports that were outside of the scope of the current study as referred to previously.

This highlights the need for investigators and analysts deployed to identify patterns in causal factors from groups of investigation reports to have knowledge of human factors including knowledge of phenomena such as premature closure.

If investigators have the knowledge to identify such phenomena when they occur, they will also know to categorise these under the Cognitive Contributory factors section of the Contributory Factors Framework. It should also improve the likelihood that this phenomenon will be explicitly described in the further details of contributory factors. Thus, having investigators with enhanced human factors knowledge will contribute to the easier identification of these phenomena when they arise. It will also contribute to the usability of this data for the purposes of identifying patterns in causal factors.

The importance of analysing groups of quality investigations to identify patterns in causal factors

This chapter demonstrates, that as Rasmussen (1993) and Dekker (2006) predicted - if we want to gain an understanding of patterns of causal factors to inform better risk management across an organisation – we need to thoroughly analyse groups of high quality investigations done in a standardised way from across the system.
It also demonstrated that:

- We have gained a clearer understanding of a helpful pragmatic stop rule for identifying underlying systemic causes
- The pattern of causal factor causation is extremely complex posing an intractable (wicked) problem to solve,
- We have gained what Rasmussen (1996) described as: “...an immense addition to understanding accident mechanisms...”
- We have a clearer picture of the patterns of causal factors identifiable in investigation reports than ever before meaning these can better inform safety and risk management across the HSE

The above four points are elaborated on further in the next sections.

**A helpful pragmatic stop rule for identifying underlying systemic causes**

During the thematic analysis process, the following criteria emerged as helpful in determining whether data items should be included in or discarded from the analysis:

(i) The data tended to give a better/clearer understanding of the causal factor, and

(ii) The data tended to give a sense of the action necessary to prevent future harm arising from the causal factor

Data items included in the thematic analysis satisfied either one or both of the above criteria.

It was considered that these criteria could form the basis of a helpful pragmatic stop rule for identifying systemic causal conditions in investigations to inform credible preventative measures. This should inform (i) investigation PPPGs, (ii) investigator training; and (iii) the process for evaluating the quality of investigations. Further research related to the impact of these interventions on the quality of investigations, and on the quality of data derived from the analysis to identify patterns of causal factors to better inform system safety – is warranted.
The wicked problem of the complexity of patterns of causal factors:
Wicked problems in healthcare are defined as problems that (i) resist easy formulation, (ii) cannot be easily isolated from the system of care, (iii) have no clear causal relationship, (iv) are not exhaustive descriptions of the problem, and (v) can be explained in many ways (Rittel & Webber, 1973). Cassin & Barach, (2012) outline that wicked problems are related to other problems, have no simple fix, but require a specific response that only makes sense in the context of the unique characteristics attached to the problem described.

Blackman et al, (2006) describe wicked problems in healthcare as problems that cut across traditional service and organisational boundaries and that demand a whole system perspective. They go on to describe that the reality is often non-linear changes that arise from complex interactions, with outcomes that depend on the local context and may emerge over long periods of transition.

The thematic map reported in this chapter illustrates the intractable and wicked problem of the complexity of patterns of causal factors along the lines of a wicked problem as described above. It is the first evidence based illustration of a healthcare example of what Dekker (2006) described as dense patterns of causes, with contributions from all parts and corners of the system, and typically depending on many subtle interactions. It highlights that the same contributory factors are occurring across multiple services and sites behaving like superbugs that have already resisted many attempts to address them. It puts a spotlight on problems that are embedded vertically and horizontally across multiple layers of the system so that addressing them is like weeding out bindweed.

This will not be a popular finding in a context where politicians, health service managers, and the public wish to find a so called magic bullet to address the rate of harm that occurs in healthcare. The fact that there is no such magic bullet is eloquently described by Dekker (2006) as follows:

“Putting one countermeasure in place somewhere along (what you thought was like) a linear pathway to failure may not be enough...In general, it is extremely unlikely that the precise sequence of events, or
confluence of factors, will repeat itself, whether you put a barrier there or not. Complex systems have many parts that interact and are tightly coupled to one another. They can generate unfamiliar, unexpected interactions that are not immediately visible or comprehensible. Just slicing through one sequence of interactions you have now understood by looking at it in hindsight, leaves the door wide open for others to develop” (Dekker, 2006 Page 85-86).

For example, case 54 described a maternal death where a contributory factor related to the fact that the mother’s old notes were not retrieved for the current antenatal care episode. If the problem of access to notes from earlier episodes of care is resolved for maternity services only – this will not prevent an incident related to the failure to retrieve earlier notes for a patient in services other than maternity services. So, interventions need to be system wide - where applicable - to prevent future harm arising from the same causes.

By way of another example, case 49 relates to the death of a patient in ICU following collapse at home. The further details of contributory factors in this case identified that the recently procured critical care trolley needed to be put into operation including provision of training for all clinical staff. This highlights that simply procuring equipment is not sufficient. Training and support is also required to prevent incidents from occurring.

**Addition to understanding of incident mechanisms**

While the previous section describes the complexity and non-linearity of incident causation which poses an intractable or wicked problem to solve, this is an important addition to the understanding of incident causation in healthcare.

Kahneman (2011) refers to our tendency to answer a hard question with the answer to an easier one in spite of the importance of answering the right question when attempting to solve a problem. For example, it could be tempting to think that we can prevent incidents related to the failure to detect and respond to rapid deterioration by implementing EWS. However, based on the learning from the thematic map in this chapter and the further details in
appendix 20 a), we will not prevent these types of incidents unless we enable the development and implementation of PPPGs related to the detection and management of (i) rare conditions, (ii) unusual presentations, (iii) complex patients with multiple co-morbidities, and (iv) time critical conditions that address:

→ thorough planning and monitoring of these patients
→ appropriate communication between MDT’s, services, agencies, with patients/families
→ Access to services including Ambulance, Emergency Department, Emergency Surgery, HDU and ICU
→ Resource demand mismatches
→ Governance and risk management including the dissemination and audit of compliance with PPPGs related to improving the detection and response to rapid deterioration, and implementing learning from this, clarity about roles and responsibilities, and proper risk and incident management and implementing learning from this
→ Training, education and supervision

A clearer picture of the patterns of causal factors for better risk management across the HSE

Dekker (2011) reckoned that similarities between accounts of different adverse events pointed to common conditions that helped produce the problem under investigation. Both the examples of (i) the phenomenon of premature closure in diagnosis, and (ii) issues related to detecting rapid deterioration in patients described earlier in this chapter highlight similarities between seemingly disparate events and even application areas. This, Dekker (2011) pointed out – was the whole point of having an investigation contribute to organisation wide learning: so that it was not only about putting out the fires of individual events, but so that it was also helping with gaining an understanding of the underlying systemic factors that kept producing adverse events – and so paving the way to change them.

This study demonstrated that, by following the advice of Dekker (2011) as above, it has identified patterns in causal factors that are in line with what was
previously published in the literature (Cronin, 2005), and what would be expected based on other sources of risk information in the HSE such as the Risk Register. It also identified a range of causal factors types from what Reason (1995) referred to as the more proximal (failure to detect and respond to rapid deterioration, and premature closure in diagnosis) to the more latent (i.e. broader governance issues).

More importantly however, this study has identified that (i) improving further details of contributory factors, (ii) analysing causal factors over time, and (iii) analysing contributory factors across the system - improves the capability of the HSE to better identify and understand patterns in causal factors from investigation reports to inform better safety and risk management across the HSE.

The complex patterns of incident causation illustrated in the thematic map in this chapter is the closest illustration of the reality of incident causation in the HSE that we have to date. While it is not perfect it should help to focus minds on the reality of the incident causation problem. It is also now possible to build on this research to improve our picture of the reality of incident causation in the HSE. That way, we are better able to answer the following question than we were before:

"Are there clear patterns of causal factors identifiable in the investigation reports that could inform better risk management across the HSE?"

The answer based on this research is that the patterns of causal factors are clearer now than they were before and this should inform better safety risk management across the HSE. However, if the quality and quantity of further details of causal factors improves, we should identify an even clearer pattern of causal factors from investigation reports that could inform even better risk management across the HSE.

With the exception of writers such as Rasmussen (1993) and Dekker (2011), the literature is relatively silent on the importance of detailed descriptions of the underlying causal conditions within investigation reports. It is not surprising then that “HSE Guidelines for the Systems Analysis of Investigation..."
of Incidents” (2012) and equivalent investigation guidelines from other jurisdictions - did not emphasise the importance of including further details of contributory factors within investigation reports to illustrate why the contributory factor occurred - nor did these guidelines emphasise the importance of this for organisational learning purposes.

In response to learning from this study, the subsequent version of the “HSE Guidelines for the Systems Analysis of Investigation of Incidents” did refer to the need to include further details of contributory factors within investigation reports.

It would be important for future research to consider the impact this has on improving the capability of the HSE to better identify patterns in causal factors from investigation reports in order to better inform safety and risk management across the HSE.

But above all - this chapter has shown a way though the problem of the mismatch of single investigations that can only focus on ‘a linear pathway to failure’ to a predictive model of complex system functioning that is sufficiently robust to support credible preventive interventions – in three logical stages:

(i) Identifying causal factors in a single investigation provides a retrospective account of a specific causal pathway;


(iii) Use of system expertise to identify emergent systemic factors (which may not even be mentioned in original investigations). These define the system state that needs to be transformed. The causal pathways can then be reorganised in order to enable that systemic transformation.

This is an iterative process. The implementation of the control measures based on the systemic analysis provides an opportunity to test their efficacy empirically.

It also improves the investigation process – as we now have systemic antecedents of events to identify in specific investigations. This moves the
investigation process a step away from simple linear causation to generic emergent systemic factors. Antecedents of these more generic factors can then be explored in subsequent investigations (which was not possible before, such as if premature closure is identified, why did it occur?).

Again, analysis of multiple investigations will show more complex patterns of systemic causal factors.

More mature system expertise will identify second order emergent systemic factors and more powerful leverage over transforming the system.

Thus, incident investigation is not a bounded process, leading from problem analysis to implementing solutions. Analysis of multiple incident investigation reports to identify patterns in causal factors is essential to build an on-going process of progressive learning about the system. Each iteration of this extended process builds a deeper analysis, and more importantly, a deeper understanding of the system. This deeper analysis moves the original generic causal and contributory factors framework to specific systemic factors that give leverage over this particular type of system (i.e. they are generic within this specific focus of application, based on in-depth understanding of causal pathways in this type of system).

In summary, this chapter demonstrates that we have improved - and that we can continuously improve - our visibility and our understanding of the pattern of causal factors that result in harm to our service users and staff to in turn optimise how learning from incident investigations informs better safety and risk management across the HSE. In other words, we are learning, and we can continuously improve how we learn from serious incidents for more effective organisation wide safety improvement.

Chapter 7 now considers what value the approach taken in this thesis can offer Healthcare Systems.
Chapter 7 - Application

To effectively leverage investigations to better inform system safety

Overview of chapter 7

7.1. Introduction

7.2. What can the approach taken in this research offer healthcare systems?

7.3. Implementation requirements
   - Training of individuals to use the IQET
   - Resourcing people to use the IQET
   - The need to have a single person identifying patterns in causal factors
   - Effective communication and training

7.4. Cost benefit of the approach taken for healthcare systems
   - Smaller investigation teams
   - Good quality investigations don’t necessarily require more resources
   - The benefits of evaluating quality
   - The benefits of analysing patterns in causal factors
   - Cost benefit analysis

7.5. What happened to the approach in the interim?
   - Handover of learning from identification of patterns in causal factors
   - Investigation quality evaluation & analysis of causal patterns continued
   - Audit priorities are informed by patterns in causal factors
   - Additional training for investigators

7.6. Application for HSE policy and other jurisdictions
   - Application for HSE policy
   - Application for other jurisdictions and domains

7.7. Conclusion

7.1. Introduction

The overarching research question for this thesis considers how to effectively leverage incident investigations to better inform system safety. The previous chapters explored different aspects of this question by (i) describing the development and testing of a reliable Investigation Quality Evaluation Tool (IQET) in Study 1; (ii) applying the IQET to evaluate the quality of HSE investigations in Study 2, (iii) demonstrating that factors that affect investigation quality can be empirically identified from information collected using the IQET, and attendance at investigator training in Study 3, and (iv)
identifying patterns of causal factors from a group of investigation reports to
better inform risk and safety management across the healthcare system in
Study 4.

This chapter considers what the approach taken in this study has to offer
Healthcare Systems. It goes on to appraise what value would be offered by
on-going (i) application of the IQET to evaluate the investigation quality, (ii)
identification of factors that affect investigation quality, and (iii) identification
of patterns of causal factors from groups of investigation reports.
Subsequently, this chapter reviews the implementation requirements for this;
what happened to the approach in the interim, and application opportunities
for HSE policy and other jurisdictions and domains.

7.2. What can the approach taken in this research offer health systems?

Study 3, described in chapter 5, referred to the HSE investigation of the tragic
maternal death of Savita Halappanavar (Arulkumaran et al., 2013). This was
the first published HSE investigation to follow the HSE investigation guidelines
(Health Service Executive, 2012). Evaluation of this investigation using the
IQET within the current study showed that this investigation report complied
well with HSE investigation guidelines, and that it demonstrated what
Dekker(2006) referred to as a satisfactory analytic trace for investigation
findings. The solicitor representing Savita’s husband stated that implementing
the recommendations of that report would be important for improving the
safety of maternity services. The CEO of Patient Focus85 stated on national
radio the morning after the report was published that it was “an excellent
investigation by any standard”.

A second investigation that was included in this study, and which was (i)
identified by IQET to comply well with HSE investigation guidelines, and (ii)
which was stated to be good by patient advocates was the investigation
related to the tragic death of baby Mark Molloy in 2012. This investigation
was completed in 2013 and was subsequently published (Health Service
Executive, 2013). This incident triggered a public hearing at the House of the
Oireachtas (i.e. the Irish House of Parliament) Joint Committee on Health and

85 Patient Focus is a patient representative charity organisation.
Children. At this hearing, the CEO of Patient Focus stated the following on the public record in relation to this investigation report:

“When Mr. Mark Molloy said he and Róisín Molloy got a good review, they were correct. In fact, they got a spectacular review in comparison to any other patient that we in Patient Focus have ever dealt with.”

Such positive public response to HSE investigation reports is an important and positive outcome of an investigation for the HSE.

But equally important is the fact that implementing recommendations is resource intensive. Managers that have to implement recommendations must be confident that (i) the causal factors are accurately identified, and (ii) recommended actions will have the greatest possible impact on improving safety for the future.

It is important to mention here that there is a whole different challenge related to how to effectively implement recommendations which is beyond the scope of this study. This study looks at whether the recommendations are:

(i) Based on sound analysis to identify all the correct incident causes
(ii) Linked to actual causes (i.e. contributory factors)
(iii) SMART\(^\text{86}\), and
(iv) Use the hierarchy of controls to develop the most effective recommendations.

But even recommendations that meet these criteria may not be implemented well or at all due to:

(i) Resource constraints
(ii) Limitations in the investigators’ understanding of the operational context meaning the recommendations are not workable
(iii) Recommendations conflicting with recommendations from other investigations, audits, etc.

However, the IQET used in this study was found to measure the factors that generate the best quality recommendations well. Investigation with higher Investigation Quality Scores (IQSs) are more likely to reflect causal factors

\(^{86}\text{SMART: Specific, Measurable, Achievable, Realistic, Time-bound.}\)
more accurately and actions that are most likely to have the greatest possible safety impact. Continued use of the IQET, and continued improvement in IQSs over time means that the completeness and accuracy of causal factors are likely to improve, and the effectiveness of actions to address them should improve over time culminating in a significant improvement in safety.

The discussion related to Study 4 in chapter 6 related to the potential of the analysis of patterns in causal factors to contribute reciprocally to improved causal models and investigation methods, is particularly relevant in any discussion about what the use of the IQET can offer the HSE. The benefits can be summarised as follows:

(i) Use of the tool to identify high quality investigations with a strong analytic trace for investigation findings should contribute to the confidence that HSE managers and the public can have that causal factors are complete and correct. It will also contribute to confidence that the recommended actions to address them will have an optimum impact on safety. By the same token, when high quality scoring investigations state that key causal factors are not identifiable, the HSE and the public can be confident that this is correct, that no important causal factors have been overlooked and unaddressed, and that the investigation is not a so called ‘cover up’.

(ii) Conversely, when investigations score poorly, HSE managers and the public can know that the causal factors and recommendations are likely to be incorrect and incomplete. If the report states that no key causal factors are identifiable – we can know that some causal factors may have been overlooked, and the report is vulnerable to being criticised as a so-called ‘cover up’.

(iii) As illustrated in Study 4 in chapter 6, conducting analysis to identify patterns in causal factors from as big a group of high quality investigations as is possible over time and across the system will improve our understanding of patterns of causal factors. This will bring us to the common underlying systemic conditions that generate the greatest amount of harm to the greatest number of people the
greatest amount of the time. Efficiently addressing these underlying systemic causal factors is likely to have a significantly greater impact on improving safety than the current incident-investigation-recommendation approach.

(iv) Information from the analysis to identify patterns in causal factors will provide high quality information to inform the HSE Risk Register, and the schedule of Healthcare Audits. In fact, information from the analysis to identify patterns in causal factors to date informed the HSE Healthcare Audit Schedule for 2018/19.

(v) Related to (iv) above, real time analysis to identify patterns of causal factors will ensure that the causal factors identified by investigations are continually adding to information about the activity of existing risks and alerting the organisation about the emergence of new risks in a timely manner.

(vi) Individual feedback to investigators arising from the evaluation will be helpful in (i) confirming what investigators have done well, and (ii) identifying areas for improvement. Investigation training and investigation methods will also be improved based on feedback from evaluation of investigation reports and analysis to identify patterns in causal factors.

7.3. Implementation requirements

7.3.1. Training of individuals to use the IQET

In this study, six individuals used the evaluation tool for the inter-rater reliability testing. These individuals had a strong background in (i) conducting investigations, (ii) developing investigation PPPGs, and (iii) training investigators. Four of these individual have continued to use the tool for the evaluation of quality of investigations completed in the interim (i.e. from 2015 to 2017). One of the individuals has continued to conduct analysis to identify patterns of causal factors.

As shown in Study 4 in chapter 6, it is important that those that are evaluating the quality of investigations and/or conducting analysis to identify patterns in
causal factors - have a high level of investigation, human factors, and systems safety knowledge and experience. This is in order to be able to achieve the optimum iterative process whereby there is continuous reciprocal learning between and for:

(i) individual investigation quality,
(ii) investigation guidelines,
(iii) investigation training,
(iv) the process of evaluating the quality of individual investigations
(v) the process for identifying factors that affect investigation quality, and
(vi) analysing groups of investigation reports to identify patterns in causal factors.

Based on the experience of the use of the IQET for inter-rater reliability testing in this study, it is recommended that effective training in the use of the IQET by individuals with significant knowledge and experience of conducting investigations and training investigators involve the following:

(i) The trainer should be an individual that has significant knowledge and experience of (a) conducting investigations, and (b) using the IQET.

(ii) At least two weeks prior to IQET training - trainees should receive a copy of the IQET, and an investigation report that will be evaluated using the IQET during the training. They should be encouraged to familiarise themselves with both in advance of the training.

(iii) The initial training session is of four hours duration. The trainer and the participants use the IQET to evaluate the sample investigation report that was circulated in advance of the training with the trainer addressing any questions the trainees have about using the IQET.

(iv) The trainees leave training with two further investigation reports and an assignment to complete an IQET for each of these reports prior to the next training session. This course work is estimated to take approximately four hours.
(v) The trainees attend a second four hour training session approximately two weeks after the first one. During this session the participants get an opportunity to go through their two completed IQETs comparing findings and discussing where there are inconsistencies in responses compared with responses by other participants. The trainer facilitates this and addresses any questions the trainees have.

(vi) Users of the IQET should have access to the support of a more experienced user for their first six investigation report evaluations using the IQET.

(vii) Suitable inter-rater reliability testing should be built into the investigation evaluation process using IQET and this should be documented appropriately.

(viii) A learning network should be established where evaluators can engage with investigators, investigation trainers, investigation guideline developers, and analysts working to identify patterns in causal factors to ensure that learning is shared between these groups to inform continuous improvement of their respective processes.

Service user engagement in all of the above should be considered and encouraged.

7.3.2. **Resourcing people to use the IQET**

Currently, approximately 85 serious incident investigation reports are submitted annually for quality evaluation and analysis to identify patterns in causal factors. According to current NIMLT members, it takes two hours to evaluate a single investigation report which equates to approximately 23 working days for a single individual.

It took a single individual from the NIMLT approximately 17 days to conduct the analysis to identify patterns in causal factors from the 79 investigation reports that were submitted in 2017.

Extrapolating from this, the annual whole time equivalent required to (i) deliver training in the use of the tool, (ii) evaluate the quality of investigation reports using IQET, (ii) to conduct inter-rater reliability testing, and (iii) to
conduct analysis to identify patterns in causal factors is approximately 45 days or approximately 0.2 of a whole time equivalent staff member. It is acknowledged that other staff would need to be involved in administering the system, and attending training etc.

However, the cost of these interventions to improve system safety and to prevent incidents are dwarfed by the cost of incidents - given that Klazinga (2017) estimates that 15% of total hospital activity and expenditure is a direct result of adverse events, and the Irish National Adverse Events Study (INAES) (Rafter et al., 2016) estimates the annual cost to the Irish Exchequer of adverse events in adult inpatients in acute hospital services at over €194 million.

7.3.3. The need to have a single person identifying patterns in causal factors

Study 4 in chapter 6 showed the importance of identifying patterns in causal factors from as large a group of standardised investigation reports as possible, including all incident types from across the entire system, and over time.

It follows from this that it is important for at least one person to have read as many of the investigation reports as possible to gain the whole picture necessary to develop an accurate understanding of patterns in causal factors. This person should have a sufficient technical and clinical background to understand the technical and clinical aspects of the causal factor data. They should also have a background in qualitative data analysis, system safety and Human Factors in order to be able to tease out the Human Factors and systems safety aspects of the data. Ideally, a second individual should do this also to ensure optimum contingency and succession planning, should one individual become unavailable.

7.3.4. Effective communication and training so that investigators view evaluation positively

Consultation and engagement should occur with investigators and investigation commissioners and other stakeholders to develop a process for providing feedback about individual investigation report quality to individual investigators and investigation commissioners. This should be implemented as soon as possible and should include processes for:
(i) acknowledging high quality investigations,

(ii) sharing high quality investigations with investigators as practical examples of the standard that needs to be achieved, and

(iii) providing positive support to investigators where areas for improvement in investigation quality are identified.

Careful consideration should be given to the risk that an investigation report that has been released to a person that was harmed and/or their family is subsequently identified through the evaluation with IQET to be of poor quality. Engaging with investigators, commissioners, and service users is necessary to consider and identify control actions to manage this risk. This could include actions such as - but possibly not limited to - the following:

(i) Investigation training continues to emphasise the importance of adhering to investigation guidelines, and encourages investigators to refer to the IQET continuously throughout the processes and to conduct a self-assessment of compliance when they complete their investigation

(ii) At least one investigator (and ideally all investigators) should have attended the investigation training referred to in (i) above

(iii) Commissioners seek evidence that the investigators have completed a self-assessment of compliance with the IQET and possibly arrange for another investigator that was not involved in the investigation to evaluate the investigation using the IQET prior to officially accepting the final report.

Senior managers, the Board, and the Risk Committee of the HSE need to show leadership in relation to this by (i) highlighting the importance of the use of the IQET for safety for our service users and staff, and (ii) encouraging and supporting managers and investigators to engage in the evaluation process.
7.4. Cost-benefit of the approach taken for healthcare systems

7.4.1. Smaller investigation teams

Study 3 in chapter 5 identified that investigations conducted by teams of two or three investigators were statistically significantly more likely to have higher IQSs compared with investigations conducted by larger groups of investigators. This opens up an opportunity for a cost-benefit where smaller investigation teams deliver higher quality investigations freeing up valuable resources for (i) non-investigative purposes, (ii) using them to deliver additional investigations so that more high quality investigations can be provided on a cost neutral basis, (iii) or using freed up resources to resource the application of the IQET to analyse investigation quality and to conduct analysis to identify patterns in causal factors.

7.4.2. Good quality investigations don’t necessarily require more resources

This research showed that poor quality investigations often took as long or longer, and used as much or more resource compared with high quality investigations. National Incident Management and Learning Team (NIMLT) investigation training had a particularly significant impact on investigation quality. It is HSE policy that investigator training is delivered. So, implementing structures and processes that require that all serious incident investigation teams have at least one investigator (and ideally all) that has attended NIMLT training would be another cost neutral way of ensuring both high quality investigations and compliance with HSE policy on this.

7.4.3. The benefits of evaluating quality

Evaluating the quality of investigation reports using IQET does require significant time and energy. However, this thesis has made clear that poor quality investigations also take a lot of time and energy. They can do more harm than good both in terms of damaging public confidence in our investigation processes and the organisation in general, and also in terms of failing to identify the true causal factors and actions necessary to address them. This means the causal factors can remain unaddressed and available to cause harm to service users and staff in the future.
In this context, the IQET developed and tested in Study 1 and applied in Study 2 is important for providing assurance to the HSE and the public that investigations are of a satisfactory quality. It is also important for giving feedback to investigators on their investigation performance. This will be encouraging to investigators when high quality is identified. It will present an opportunity for learning and improvement for investigators when quality issues are identified. Evaluating the quality of investigations will highlight areas for on-going improvement in investigation processes, including investigation PPPG’s and training. Finally, using IQET to determine the quality of investigations delivers a proxy indicator of the confidence we can have that the data from investigations is of satisfactory quality to accurately identify patterns in causal factors to inform system wide safety improvement. Not evaluating the quality of investigations would mean that the HSE would invest in developing PPPGs, delivering training, and conduct investigations without checking whether this investment made any difference to the outcomes and outputs of the investigation process, including making a meaningful difference to system wide safety improvements.

7.4.4. The benefits of analysing patterns in causal factors

The analysis to identify patterns in causal factors also requires significant time and energy. But increasing evidence in the literature indicates that effective learning from past experiences in order to improve safety performance has proven to be difficult (Le Coze, 2013; Drupsteen and Hasle, 2014). This, and the evidence presented in Study 4 in chapter 6 of this thesis indicates that something different to the current incident-investigation-recommendation approach is required. Study 4 shows that analysis to identify patterns in causal factors is the different but pivotally important action that is necessary if we are to overcome the difficulty of effectively learning from past experiences to improve future safety performance.

7.5.4. Cost benefit analysis

A cost benefit analysis of the on-going (i) application of the IQET to evaluate investigation quality, and (ii) analysis of groups of investigation reports to identify patterns in causal factors - would need to consider costs and benefits as shown in table 7.1.below.
<table>
<thead>
<tr>
<th>Costs</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Developing PPPGs for incident investigation</td>
<td>▪ These PPPGs need to be developed anyway, and developing them based on the learning from this research means they will have a greater impact on safety performance</td>
</tr>
<tr>
<td>▪ Training and supporting investigators</td>
<td>▪ Investigator competence continuously improving</td>
</tr>
<tr>
<td>▪ Training and supporting investigation quality evaluators</td>
<td>▪ Competent investigation quality evaluators</td>
</tr>
<tr>
<td>▪ Reliability testing investigation quality evaluation</td>
<td>▪ Confidence that investigation quality evaluation is reliable</td>
</tr>
<tr>
<td>▪ Conducting high quality investigations</td>
<td>▪ Important information which is helpful to - and trusted by - those harmed/their families</td>
</tr>
<tr>
<td></td>
<td>▪ Local staff and managers see that investigations clearly identify correct causal factors and recommendations to address them. This should inform effective local improvements</td>
</tr>
<tr>
<td>▪ Evaluating the quality of investigations</td>
<td>▪ Assurance to the HSE and the public that the quality of investigations is satisfactory</td>
</tr>
<tr>
<td></td>
<td>▪ Identification of opportunities to improve investigation quality</td>
</tr>
<tr>
<td>▪ Analysis to identify factors that affect investigation quality</td>
<td>▪ Identification of factors necessary to maintain and improve investigation quality</td>
</tr>
<tr>
<td>▪ Analysis to identify patterns in causal factors</td>
<td>▪ A continuously improving understanding of the key systemic conditions that cause the most harm to the most people the most often. These should inform effective systemic/organisation wide improvements.</td>
</tr>
<tr>
<td>▪ Channelling learning from all of the above to improve (i) investigation PPPGs, (ii) investigator training, (iii) the process for evaluating the quality of investigations, and (iv) analysis to identify patterns in causal factors</td>
<td>▪ Continuous improvement in how we learn from incidents how to improve the safety performance of the organisation.</td>
</tr>
</tbody>
</table>

Table 7.1. Showing what a cost benefit analysis of the on-going (i) application of the IQET to evaluate investigation quality, and (ii) analysis of investigation reports to identify patterns in causal factors - to enhance incident investigations and how we learn from them – would look like.
7.5. What happened to the approach in the interim?

7.5.1. Handover of learning from identification of patterns in causal factors

In an effort to address the gap between identifying patterns in causal conditions from the set of investigation reports included in this study and implementing the learning from this research – two workshops were facilitated by the author in November and December 2015.

Attendees included Divisional Leads for Quality and Patient Safety in each of the six Divisions of the HSE, namely: (i) The Acute Hospital Division; (ii) The Social Care Division; (iii) The Primary Care Division; (iv) The Mental Health Division; (v) the Health and Wellbeing Division; and the (vi) The National Ambulance Service.

Attendees considered a spread sheet where columns represented each of the six Divisions; and rows represented the details of the issues identified in the report “Results of a systematic analysis of the quality of serious incident investigation reports which were completed in 2013 with trend analysis of the key causal and contributory factors” (Health Service Executive, 2015).

All participants considered each issue and decided whether or not the issue related to their respective Division. In making these decisions, participants considered the following:

(i) That the issues identified had emerged from aggregate analysis of serious incident investigation reports and were issues considered to have contributed to death or serious harm in the past

(ii) The issues may have been related to incidents that occurred in other Divisions and not in their respective Division. Participants accepted that the point of sharing learning from incidents in other Divisions was to consider whether the factors that contributed to harm in other Divisions existed within their respective Divisions so that these factors might be addressed before they actually contribute to harm. Participants accepted that this should be done in the context of good risk assessment and management.
It was agreed that individual Divisions would take the completed spread-sheet and consider the following within their own division and in collaboration with other divisions as required to ensure that learning from the analysis of patterns of causal factors was satisfactorily implemented:

(i) What actions were already in place to address each relevant issue?

(ii) Whether existing actions were satisfactory to address all relevant issues?

(iii) What work was on-going to implement the recommendations of other reports and how could work arising out of the learning from the analysis to identify patterns in causal factors and these other reports be aligned to prevent duplication/omission?

(iv) To develop and monitor implementation of action plans to address any outstanding/additional actions required to address all relevant issues

(v) Develop a mechanisms to identify whether actions satisfactorily addressed all relevant issues (i.e. audits; performance indicators; use of risk registers, etc.,)

Two interesting features emerged from these workshops which are relevant to the research questions underpinning this thesis as follows:

(i) Unlike work previously done related to learning from incident investigations – these workshops did not focus on recommendations. Rather, they focused on information about causes of incidents from across the entire organisation clumped into themes which they considered in the context of whether they were or were not hazards that posed risks for their respective areas of responsibility, and then managed accordingly.

(ii) The Divisional Leads for Quality and Patient Safety were curious about the quality of the investigations that generated the data that they were considering for action. They indicated that they were happier to take action when they had confidence in the integrity of the process that generated the data and consequently the integrity of the data generated. They stated that, prior to this
process, they were clear that investigations needed to be of satisfactory quality both in terms of providing answers to questions for those affected/their families, and for implementing improvement locally. However, this process caused them to appreciate the importance of high quality investigations for learning how to improve safety at the organisation wide level and they now saw more clearly the importance of structures and processes for continuously improving investigation quality. This is an important driver of improvement in investigation quality.

7.5.2. Investigation quality evaluation and analysis of patterns of causal factors continued

The National Incident Management Learning Team (NIMLT) continued evaluating the quality of investigation reports and conducting analysis to identify patterns in causal factors in the interim i.e. for the investigation reports that were completed from January 2015 to December 2017.

It would be important for this to continue into the future, and to (i) monitor trends in improvement or deterioration in aspects of quality over time, (ii) endeavour to identify the factors that affect this, and (iii) monitoring patterns in causal factors over time to inform the HSE risk register and risk management processes.

7.5.3. Audit priorities are informed by patterns in causal factors

One important impact of the newly available information about patterns in causal factors from this process is that it informs the HSE’s Healthcare Audit Schedule (Health Service Executive, 2018). The Healthcare Audit End of Year Report for 2018 (Health Service Executive, 2019) states that Healthcare Audit (HCA) is an objective, internal assurance activity designed to add value and improve the safety and quality of health and social care services.

Up to 2017, the HCA schedule was developed based on requests for audits from (i) National Directors including the National Director for Quality Assurance and Verification, (ii) the HSE Risk Committee, and (iii) from the National Clinical Excellence Committee (NCEC) in the Department of Health (DoH). Following a rapid appraisal of the HCA function (McCaughan, 2017) a
decision was taken that the HCA Schedule would in future be developed based on key risk information from the following five sources:

1. Patterns in causal factors from analysis of serious incident investigation reports
2. Risk register
3. National Patient Experience Survey
4. Analysis of complaints, and
5. Gaps in the Controls Assurance Process

The Healthcare Audit Schedule for 2017/18 is published on the HSE website and indicates that audits of the following topics were informed by information from the analysis of patterns in causal factors from serious incident investigation reports:

- Detecting and responding to patient deterioration
- Clinical handover
- Managing complex patients with multiple co-morbidities
- Discharge planning
- Medication safety
- Continence and toileting
- Hydration and nutrition
- Falls
- Pressure ulcers
- Emergency department off load delays
- The prevention and management of violence and aggression

Using information about the patterns emerging from the analysis of causal factors to inform audit priorities is important because it ensures that the HSEs audit resources are focused on the key risks that are associated with the most harm to the most people the greatest amount of the time. By the same token, identifying compliance with standards designed to address these risks – gives assurances about important aspects of organisational safety performance. Conversely, identifying gaps in compliance with these standards puts a spotlight on important areas requiring improved compliance for optimum safety performance.
7.5.4. Additional training for investigators

In response to the learning from Study 2 about the challenges identifying key causal and contributory factors the following training was developed to support investigators to improve how they do this:

(i) Trainers take a real investigation and modify it just enough to protect the confidentiality of the individual(s) involved but not so much as to detract from the real world learning opportunity of the case.

(ii) The chronology of the investigation is circulated to trainee investigators at least two weeks in advance of the training. Trainees are required to consider the chronology and complete a survey monkey questionnaire about what they believe the Key Causal Factors and Contributory Factors to be.

(iii) The trainers analyse the responses in advance of the training.

(iv) At training, the range of responses, and the correct Key Causal Factors and Contributory Factors are considered.

Anecdotal evidence suggests that this training is contributing to improvements in this aspect of investigation quality but this should be empirically evaluated through further research.

Subsequently, NIMLT members published a paper in the Proceedings of the Irish Ergonomics society Conference (Macken et al, 2018) related to the findings of their on-going analysis to identify patterns in causal factors as these related to human factors issues including cognitive biases. The evidence base outlined in this paper underpinned additional training in human factors that was developed and delivered to investigators focusing on human factors, including in the following cognitive biases which were identified in the causal factors analysis:

- **Authority bias**: The tendency to attribute greater accuracy to the opinion of an authority figure (unrelated to its content) and be more influenced by that opinion (Milgram, 1963).
- **Attribution bias**: A cognitive bias that refers to the systematic errors made when people evaluate or try to find reasons for their own and others behaviour.

- **Confirmation bias**: The tendency to search for, interpret, favour and recall information in a way that confirms one’s pre-existing beliefs or hypotheses (Plous, 1993)

- **Premature closure**: The premature closing of the decision making process before it has been fully verified (Mitchell, 2013).

- **(Loss of) situational awareness**: Situational Awareness is the idea of our mental picture of what is happening around us, as well as the implications of what is happening and what is about to happen (Mitchell 2013).

This training emphasises the importance of identifying and describing these cognitive biases in incident investigations - where they are identifiable. But most importantly, it focuses on the need for the investigators to explore with interviewees **why** these cognitive biases occurred, by questioning interviewees about what was going on in the environment, and what they were thinking at the time they experienced these biases. Thus, this will bring us further along the road to gaining a clearer understanding of the underlying systemic causal conditions of harm. For example, **Study 4 in chapter 6** identified that the cognitive bias of premature closure in diagnosis existed and was identifiable, albeit that this was implicit in the data. The learning from this research has informed investigation training so that in the future, investigation reports will not just explicitly state that such cognitive biases exist where they are identifiable – but they will also explore the causal conditions that contributed to them.

### 7.6. Application for HSE policy and other jurisdictions

**Application for HSE Policy**

A new HSE Incident Management Framework was published in January 2018 (Health Service Executive, 2018). This Framework states that the Quality Assurance and Verification Division will continue to monitor the quality of investigations (referred to as reviews in the framework). This is very
important, and the learning from this research should be helpful in ensuring that this is done as rigorously as is possible.

This framework also states that the “process for the aggregate analysis of the information will involve relevant stakeholders e.g. clinical and care programmes. This will inform the planning and design of initiatives aimed at improving quality and safety”. This is important also, in that it refers to engagement with relevant stakeholders, and initiatives to improve quality and safety. However, it does not specifically state that there will be on-going analysis to identify patterns in causal factors. It is acknowledged that the importance of analysis to identify patterns in causal factors was not known at the time the Framework was published, as this research was not complete at that time. However, the important findings of this research will be vital in informing effective incident management and learning structures and processes in the future.

The Framework refers to “aggregate analysis or meta-analysis of multiple incidents that are identified by a particular theme”. Within this, the Framework refers to both (i) multidisciplinary team (MDT) review of a group of apparently similar incidents (i.e. appear to be similar types of incidents and/or have similar causes), and (ii) review of a group of completed investigation reports. Both of these are considered separately in the following paragraphs.

In relation to MDT review of a group of apparently similar incidents, this refers to analysis of incident information other than information derived from a group of thorough individual incident investigation reports. A number of assumptions are made in relation to this process within the Framework.

Firstly, it assumes that it is possible to tell the causes of incidents before they are investigated in order to be able to categorise them into groups of similar incidents with similar causes for aggregate analysis purposes. The case related to the Miscarriage Misdiagnosis Review (Ledger et al., 2011) in chapter 2 highlights that the apparent causes of an incident before thorough investigation can be significantly different from the actual causes of the incident identified after thorough investigation.
Secondly, it assumes that a MDT that is given information other than information from thorough individual investigations of a group of incidents that are common in type and/or cause – will be able to identify from this information the causes of the incidents and consequently what actions are necessary to achieve safety improvement. Chapter 1 highlights many examples from the literature where this was identified to be problematic (Barach & Small (2000 and 2002); Bechmann et al., (2003); Carson-Stevens et al., (2016); Catchpole et al., (2008); Dodds & Kodate (2012); Hibbert et al., (2015); Holzmueller et al., (2005); Hutchinson et al., (2010 & 2013); Needham et al., (2004); Skapik et al., (2009); Stavropoulou et al., (2015); and Walsh and Antony (2007).

In relation to the reference in the HSE Incident Management Framework (Health Service Executive, 2018) to the review of a group of completed investigation reports - Study 4 described in chapter 6 of this thesis describes an innovative and effective solution to the problem of how to learn from a group of incident investigation reports to contribute effectively to safety improvement. Again, it is acknowledged that this thesis was not complete when the HSE Incident Management Framework was published in January 2018. However, the learning from this thesis should be immensely helpful in informing incident management and investigation structures, processes and policy that will drive more effective safety improvement throughout the HSE, especially as this relates to learning from groups of completed incident investigation reports.

**Application for other jurisdictions**

The basic principles identified in this thesis as important for continuously enhancing learning from serious incident investigations to better leverage improved system safety should be as applicable in health systems in other jurisdictions as they are here in Ireland. Further research is warranted to explore application in other jurisdictions.

The Healthcare Safety Investigation Branch (HSIB) conducts independent investigations of patient safety concerns in NHS-funded care across England. It has indicated that it is interested in the learning derived from this research.
It is particularly interested in learning about the factors affecting investigation quality derived from Study 3 as its second remit is to improve the quality of local investigations throughout the NHS. But it has indicated that it is also interested in learning from the analysis to identify patterns in causal factors from groups of investigation reports as per Study 4.

7.7. Conclusion

This chapter describes the practical details of training and resourcing individuals to use the IQET and to continue to conduct analysis to identify patterns in causal factors. It details the costs and benefits, and demonstrates that the cost of on-going application are minuscule compared with the costs of incidents. It highlights the benefit of improving staff and public confidence that investigation processes correctly identify all the causes of harm to inform improvements that should have the greatest possible safety impact for the greatest amount of people the greatest amount of the time. It summarises what has happened to the approach since this research was completed including how information from the analysis to identify patterns in causal factors now informs the HSEs audit priorities and schedules. Finally, it considers the applications for the HSE policy and for other jurisdictions.

In short, this chapter addresses the application of (i) the IQET, and (ii) the process of identifying patterns in causal factors from a group of investigation reports - to effectively leverage incident investigations to better inform improved system safety.

Chapter 8 now brings the discussion back to the generic level of healthcare systems safety including considering (i) how this research advances the state of the art, and (ii) implications for theory. It presents a model for continuously learning from incidents investigations to leverage more effective organisation wide safety improvement based on the evidence generated by this thesis.
Chapter 8: Discussion

Overview of chapter 8

8.1. Introduction

8.2. How has this thesis advanced the state of the art?

8.2.1. Learning for the HSE, other health systems, and other domains

- Need for investigation stability, consistency, professionalism and focus on causes
- Investigations from the whole system can be evaluated to improve investigation quality
- Data about investigation quality can be used to identify determinants of investigation quality
- Identifying patterns in causal factors from groups of investigations can inform better system wide safety management

8.2.2. Implications for theory

- Changing the concept of how we generalise from investigations for system wide learning
- The fallacy of preventing similar incidents recurring based on learning from one incident
- Continuously improving how we generalise from investigations for system wide learning

8.2.3. Implications for policy and implementation

- Investigator training
- Investigation team size and make up
- Investigation quality evaluation feedback to investigators
- Identification of factors that affect investigation quality
- Analysis of groups of investigation reports to identify patterns in causal factors

8.3. Reflections about the role of the author in this thesis

8.4. Strengths and limitations of this thesis

8.5. Next steps (Unfinished business)

8.1. Introduction

This thesis aimed to explore how to effectively leverage incident investigations to better inform system safety. This chapter examines how far the findings of this research go towards achieving this aim, how they fit with the existing literature, their applied and theoretical implications, and directions for future research.
8.2. How has this research advanced the state of the art?

The following sections demonstrate how this thesis advances the state of the art related to (i) learning for the HSE, other health systems, and other domains, (ii) implications for theory, and (iii) implications for policy and implementation.

8.2.1. Learning for the HSE, other health systems, and other domains

Need for investigation stability, consistency, professionalism and focus on causes

While the literature assumes that incident investigations are an important part of the safety management system (Woloshynowych et al., 2005; McEachan et al., 2014; Macrae & Vincent, 2014), there is little focus on how the quality of these investigations affects their ability to make this contribution.

Chapter 2 shows that stability in incident investigation processes is required amid often changing organisational structures in order to ensure sustained learning. The cases in chapter 2 show that limited investigations represent lost opportunities to learn from incidents. Furthermore, it shows that the quality of investigations is both an important safety issue, and important for gaining public trust in our investigation processes. Importantly, chapter 2 shows that learning from incidents is neither straightforward nor automatic and that effectively deriving the learning requires (i) a level of investigative professionalism, (ii) consistency in investigation processes, and (iii) a paradigm shift from asking “why did this happen again” to “why did this occur in the first place” – that is, the cause of incidents.

Investigations from the whole system can be evaluated to inform improved investigation quality

As shown in Chapter 1 - much literature criticises the quality of investigations in healthcare (Anderson & Kodate, 2015; Bowie et al., 2008; Care Quality Commission, 2016; House of Commons, 2015; Kirkup, 2015; Parliamentary and Health Service Ombudsman, 2015; Wallace, 2006; Wallace et al., 2006; and Wallace et al., 2009; Cassins & Barrach 2012;
and Kellogg et al. (2017). However, only four studies were identified that evaluate the quality of investigations in healthcare (Bagian (2002); Wallace (2006); Quality Care Commissions (2016); and Leistikow (2016)). None of these relate to investigations in non-acute services. None focus specifically on the systems analysis method of investigation. Only two of these predate the research reflected within this thesis (Bagian (2002) and Wallace (2006)). And neither of these focuses on evaluating the quality of the analytic trace for investigation findings which Dekker (2006) refers to as vitally important in investigations.

So this thesis addresses an important gap in the literature by demonstrating in Study 1 (Chapter 3) that it is possible to develop a comprehensive Investigation Quality Evaluation Tool (IQET) to rigorously evaluate the quality of individual serious incident investigation reports, including the quality of the analytic trace for investigations findings, across the whole span of the health system, against accepted criteria of investigation excellence. Related to this, Study 2 (Chapter 4) evidences that the IQET can be used to reveal the strengths and weakness of investigations. Chapter 7 outlines that learning from this informs interventions related to investigation PPPGs and training to maintain the strengths and address the weaknesses in investigation quality.

Data about investigation quality can be used to identify determinants of investigation quality

Study 3 (Chapter 5) outlines that some of the determinants of investigation quality are assumed rather than empirically determined (Bagian (2002); Wallace (2006); Quality Care Commissions (2016); and Leistikow (2016)).

As outlined in Study 3, this research is the first to show that data from the evaluation of investigation quality can be used to empirically test hypotheses about the determinants of investigation quality such as (i) investigator training, (ii) investigation team make up and expertise, (iii) whether and how interviews are conducted, (iv) definitions of causal factors used, and (v) investigation methods used. The findings from these empirical tests provide strong evidence for informing evidence based decisions about investigation
PPPGs and training in order to deliver the best quality investigations and the best quality data for system wide safety improvement purposes.

**Identifying patterns in causal factors from groups of investigations can inform better system wide safety management**

Rasmussen (1993) highlights the importance of identifying the underlying causal conditions from groups of investigations. Dekker (2011) states that:

> “Achieving context independent descriptions of adverse events is critical to pull out the systemic factors that went into creating them, and learning lessons that can be shared and distributed across other contexts as well.” (Dekker, 2011, Page 151)

Cronin (2005) analyses the contributory factors from eight incident investigation reports from a paediatric setting to identify the frequency distribution of contributory factors, and goes on to identify themes in lessons learned from a data base of 30 reviews of critical occurrences and near misses involving children.

**Study 4** (Chapter 6) demonstrates the analysis to identify the frequency distribution of contributory factors of the investigations included within this study. It goes on to detail the analysis of further details of contributory factors to identify patterns in causal factors at a deeper level in a larger batch of investigations from a wider span of the health system than done in the previous research by Cronin (2005). This brings us closer to identifying: “the systemic factors that went into creating them [i.e. the incidents]...” as referred to by Dekker (2011). Most importantly, **Study 4** shows that an incidental outcome of this analysis is the identification of criteria for a pragmatic stop rule for how deep we need to go in unearthing causal conditions to inform credible interventions. It also identifies emergent system features which (i) add to information about existing risks, (ii) identify newly emerging risks, and (iii) are important for informing system wide safety improvement. Issues with the quality of the further details of contributory factors are identified. This contributes to learning about policy and training interventions to address the quality of further details in contributory factors which are described in chapter 7.
8.2.2. Implications for theory

*Changing the concept of how we generalize from investigations for system wide learning*

Generalizability is the extent to which the findings of an enquiry are generally applicable outside the specifics of the situation studied (Robson, 2002). So, from the perspective of incident investigations, generalizability refers to the extent to which the findings of an individual incident investigation are generally applicable to the wider system outside the site where the incident occurred.

The literature recognises that generalizable lessons are often neither generated nor implemented from incidents in healthcare, and that learning often remains confined to the organisation where the incident occurs (Macrae, 2016). The literature also identifies that the tendency for healthcare organisations to develop multiple methods of investigating incidents reduces comparability, and renders the possibility of system level learning problematic (Cassin & Barach, 2012, Mullen *et al.*, 2013, Healthcare Safety Investigation Branch Expert Advisory Group (2016)).

Dekker (2011) highlights that the final step of an investigation goes beyond the mandate of an individual investigation, and that it must be done in a manner that facilitates identification of similarities between accounts of different adverse events in order to point to common conditions that helped to produce the problem under investigation. He stresses that the whole point of having an investigation contribute to organisation wide learning is so that it is not only about putting out the fires of individual events, but so that it is also helping to gain an understanding of the underlying systemic factors that keep producing adverse events – and so paving the way to change them (Dekker, 2011).

Rasmussen (1993) states that more focused generalization requires careful consideration of the work processes that are the source of adverse events, thus emphasising the importance of thorough investigations of individual incidents. He believes that such functional analyses add immensely to the understanding of the accident mechanisms. He continues to say that *more*
detailed and constructive suggestions for improvements can be derived from the identification of recurrent deviations from a joint analysis of a larger set of accident investigations (Rasmussen, 1993).

As outlined above, the literature implies that (i) investigations need to be conducted and written up in a manner such that learning that is generalizable to the wider system is accurately identified and clearly described (Robson, 2002), and (ii) investigations need to be conducted and written up in as standardised and thorough a manner as is possible so that analysis can be conducted to identify systemic patterns in causal factors from larger sets of investigation reports (Dekker (2011), Cassin & Barach (2012), Rasmussen (1993)).

On a broad level, the HSE Guidelines for Systems Analysis Investigation of Incidents and Complaints (Health Service Executive, 2012) and subsequent versions – is the tool to guide HSE investigators to (i) conduct and report investigations in a standardised manner, and (ii) produce generalizable data of a satisfactory standard to allow analysis of larger sets of investigation reports to identify patterns in causal factors for system wide learning purposes. The evaluation of the quality of investigation reports as per Study 2 (Chapter 4) – and as it continues into the future – enables the HSE to measure how well this standardised approach to conducting investigations is achieved. This is a proxy indicator of the generalizability of data generated from investigations, and of how confident the HSE can be of the quality of data for system wide learning purposes.

Notwithstanding this, this thesis identifies that generalizability is the aspect of investigation quality that consistently scores the poorest. As seen in Study 2 (Chapter 4), investigation reports rarely refer to whether Contributory Factors (CFs) and/or recommendations are applicable elsewhere in the organisation. It is arguable, that this is something that may not be possible for investigators to do. For example, how can an investigator know if a CF or a recommendation is applicable elsewhere when they do not have details about the structures, processes, or the socio-technical environment in other parts of the organisation, or indeed whether or not the recommendation has already been addressed elsewhere?
Case ref 15 related to a maternal death investigation (Arulkumaran et al., 2013) - which is also referred to in chapter 7 - is an exceptional case in relation to this matter. This is the only investigation report within the study that refers to a process of checking to see whether the recommendations are applicable to the wider organisation outside of the site where the incident occurred. It describes a process whereby the investigation team circulated draft recommendations for review and feedback to representatives of the National Clinical Care Programmes for Anaesthesia and Critical Care, the National Early Warning Score Project, The Neonatal Mortality Group, The Neonatal Perinatal Epidemiology Centre, The Obstetrics and Gynaecology Clinical Care Programme, and The Quality and Patient Safety Directorate. Each of these was asked to review the draft recommendations and provide feedback as to whether they were appropriate from their respective organisations perspective, and whether they were SMART\textsuperscript{87}.

This culminated in the development of recommendations that arose from what Dekker referred to as the \textit{context specific} situation where the incident occurred, yet were applicable to the \textit{context independent} wider system.

A specific example of this within this investigation report relates to a junior doctor that made a correct early diagnosis of possible sepsis and sent a blood lactate test sample to the laboratory to check this. However, the doctor was not aware that the particular hospital had a process of bedside blood lactate testing and delays occurred while the blood was in the laboratory. The solution at the site where the incident occurred was to ensure that interventions to address the reasons for non-compliance with the process for bedside blood lactate testing were implemented and checked. However, bedside blood lactate testing may not have been feasible or possible at other sites. Therefore, in order for the recommendation related to this contributory factor to be generalizable out to the wider system it was worded as follows:

“...there is a need for development, implementation and audit of compliance with guidelines.....These guidelines should emphasise clear

\textsuperscript{87} SMART: Specific, Measurable, Achievable, Realistic, and Timebound
pathways for most efficient access to blood gas and lactate testing (preferably at point of care), along with appropriate training.”

So this is the only example of an investigation within this study that left an analytic trace from the context specific data related to where the incident occurred through to checking to make it applicable to the context independent wider system.

Related to this, generalizability was an aspect that the IQET reliability testers in Study 1 found particularly challenging. This was because the IQET required them to determine if they thought the CFs or recommendations were applicable elsewhere if this was not stated explicitly in the investigation reports. Much discussion about this aspect of the IQET occurred in reliability testing meetings. This culminated in a consensus that generalizability is determined by measuring many of the other aspects of investigation quality such as whether definitions for KCF, CFs and IFs are adhered to, and whether there is satisfactory evidence to support the KCFs CFs and IFs identified (i.e. there is an analytic trace for investigation findings). This ensures that the data from individual investigation reports is collected and presented in as standardised and comprehensive a manner as is possible lending itself better to analysis to identify systemic patterns in underlying causal factors. On this basis, Study 1 identified that the analysis to identify patterns in causal factors should generate nationally applicable recommendations from the entire set of investigations evaluated – thus generalising from this data set.

Therefore, the evidence from this thesis supports a change in the concept of how to generalise from investigations for system wide learning. Specifically it moves the emphasis from generalising from individual investigation reports, to rather conducting individual investigations reports that generate data of sufficiently high quality and consistency to enable analysis to identify patterns of underlying causal factors from multiple incidents from across the whole system and over time - to inform system wide safety improvements that are likely to make the greatest possible safety impact.
The fallacy of preventing similar incidents recurring based on learning from one incident

Many polices related to incident management and investigation, and much of the literature refers to the need to investigate incidents to learn how to prevent similar incidents recurring (For example: Behr et al., (2015); Kellog et al., (2017)), NHS England (2015); Wrigstad, et al., (2017); Sujan, et al., (2017); and Peerally et al., (2016)).

However, changing our concept of how to generalise from investigations - as outlined in the previous section - forces us to re-consider the notion that we can prevent similar incidents recurring based on learning from one incident.

The phenomenon of isomorphism described by Toft and Reynolds (2005) is pertinent to these considerations. Isomorphism means that similar incidents can have very different causes, and very different incidents can have common causes.

For example, two maternal deaths may have different causes where one may relate to the failure to monitor and respond to rapid deterioration, and the other may be due to a medication event. However, two different types of incidents such as a maternal death and the death of a person in an intellectual disability residential service may both have a common cause such as failure to monitor and respond to rapid deterioration.

As Dekker (2006) described - incidents can have dense patterns of causes, with contributions from all parts and corners of the system, and typically depend on many subtle interactions. These causes can interact with any combination of themselves or other factors in the environment. Hence, any one cause of one incident can potentially contribute to an infinite number of different types of incidents. Conversely, any one incident type can potentially have an infinite number of causes.

Therefore, it is not helpful to refer to attempting to prevent future similar incidents recurring on the basis of learning about the causes of one specific type of incident. For example learning how to address the problem of failure to monitor and respond to rapid deterioration that causes one maternal
death, will not help with learning how to help prevent recurrence of a maternal death that is caused by a medication incident. Referring to the prevention of the recurrence of similar incidents creates a false expectation that it is possible to prevent future similar incidents recurring by implementing the learning from an investigation of one incident of a certain type. So, it is more helpful to refer to **effectively identifying and addressing the causes of individual incidents so as to prevent any type of future harm arising from these causes**.

Adopting this frame, allows us to go one step further. Namely, we can learn by understanding causes, rather than just simply identifying them. This sets the stage for how incident investigations can effectively leverage better system safety.

In summary, the literature is clear that (i) there is no point in doing investigations if they are not generalizable, (ii) standardised ways of conducting and writing up investigations are necessary for generalizability, and (iii) investigations need to include rich narratives providing the analytic trace to enable the identification of common causes of apparently distinct incidents, and distinct causes of apparently similar incidents – thus addressing the phenomenon of isomorphism (Toft and Reynolds (2005)).

*Continuously improving how we generalize from investigations for system wide learning*

Changing the concept of how to generalize from incident investigations for system wide learning as outlined in the previous sections enables us to focus on how to continuously improve how we do this.

Figure 8.1 below is a model of how we can continuously improve how we generalize from investigations for system wide learning based on the evidence generated from this research.
Figure 8.1: Model of how to continuously improve how to generalize from investigations for system wide learning. Items in blue ovals are processes that were part of this research (i.e. study 2, 3, & 4). The diagram shows how they fit in with and relate to items/processes that were in place and on-going prior to this research commencing.

Figure 8.1 shows that the evidence from this research supports that there are six elements of the model with the purpose of continuously improving how we learn from groups of investigation reports namely (i) investigation PPPGs, (ii) investigation training, (iii) individual investigations, (iv) evaluation of individual investigation quality, (v) identification of factors affecting investigation quality, and (vi) analysis of groups of investigation reports to identify patterns in causal factors.

The two other elements reflected in figure 8.1, namely (i) the risk register, and (ii) the audit schedule, enable organisational assurance that the controls identified to address the causes of individual incidents, and to address the patterns in causal factors identified from the analysis of groups of investigation reports, are in place, and having the desired effect. This model is important in enabling the HSE to achieve its purpose (i.e. of improving the health of the population (Health Service Executive, 2018)).
The model shows that all eight elements are interconnected signifying that, like any system, each element of the system influences the other.

As indicated by figure 8.1, the content of investigation PPPGs influences investigation training. Conversely, investigation training influences investigation PPPGs. For example, if investigator training participants highlight aspects of PPPGs that they find to be ambiguous or unclear - this informs improvements in investigation PPPGs and investigation training. Implementing these improvements also improves the capability of the system to continuously improve how to generalize from incident investigations for system wide learning.

Investigation PPPGs and investigator training also influence the quality of investigations. Monitoring and evaluating how exactly investigation PPPGs and training affect investigation quality is important for learning how to leverage these to further improve investigation quality.

The quality of investigation reports has an influence on the quality of the analysis to identify patterns in causal factors. So, enhancing factors found to improve investigation quality, and managing factors found to detract from investigation quality, improves the quality of investigations, and the quality of the analysis of groups of these to identity patterns in causal factors.

To complete the loop, learning from (i) evaluating the quality of investigation reports, (ii) identifying factors that affect investigation quality, and (iii) analysis to identify patterns in causal factors informs improvements in both investigation PPPGs, and investigation training.

For continuously improving learning from incident investigations – there is communication between the model for continuously improving how we learn from investigation reports and risk management processes both from (i) causal factors of individual investigation reports, and (ii) patterns in causal factors from groups of investigation reports.

In relation to the former (i.e. the relationship between the Risk Register and causal factors identified in individual investigation reports) the HSE Integrated Risk Management Policy (Health Service Executive, 2017) already requires that
the causes of incidents would be one source of risk that populates the risk
register. To effect this - based on the learning from this thesis – it is proposed
that there should be a clear process to ensure that when an investigation
identifies a Contributory Factor that may occur elsewhere, that it is
communicated to all relevant local and national risk registers to check
whether it is a risk at the other sites, and if so, whether it has already been
identified and satisfactorily managed, or whether further controls are
required. In this way, it adds to the information about an existing hazard on
the risk register. If not already identified, but deemed a risk for other sites – it
becomes a newly identified hazard that should be assessed and managed in
line with the HSE Integrated Risk Management Policy (Health Service
Executive, 2017). This ensures that there is an auditable trail from the original
incident to verified improvement, both locally at the site where the incident
occurred, and throughout the wider system.

In relation to the latter (i.e. the relationship between the Risk Register and
patterns in causal factors identified from groups of investigation reports)
Chapter 7 reflected a process for handing over the findings of this research
which included that Divisions would consider the patterns in causal factors in
their risk register processes as appropriate. Based on the learning from this -
it is proposed that the HSE Integrated Risk Management Policy (Health Service
Executive, 2017) is updated to reflect that patterns in causal factors identified
by analysis of groups of investigation reports are considered as additional
important sources of risk that populate the risk register. This again ensures
that there is an auditable trail from the original incident to verified
improvement, but this time the focus is at the level of system-wide
improvement.

The profile of a risk register that is informed by (i) data from better quality
individual investigations, and (ii) patterns in causal factors identified from
groups of better quality investigations is likely to be transformed. A risk
register transformed in this way is likely to evidence better verifiable
improvement in response to incidents compared with the period prior to the
transformation. Further research to explore this is important.
The final element of the model in diagram 8.1 relates to the audit schedule. It is considered that the audit schedule drives continuous improvement in how to generalize from investigations for system wide learning and improvement by having communications with two other elements of the model namely (i) the analysis of groups of investigation reports to identify patterns in causal factors, and (ii) the risk register process. Each of these is explained separately in the following two paragraphs.

In relation to (i) - based on learning from this thesis, the HSE Healthcare Audit schedule is now informed by information about patterns in causal factors identified from analysis of groups of investigation reports. This is reflected in the 2018/2019 Healthcare Audit Plan (Health Service Executive, 2018) which includes audits of - for example - compliance with PPPGs developed to address the issue of failure to detect and respond to rapid deterioration. This is described in further detail in Chapter 7.

In relation to (ii) it is proposed that the audit schedule should include audits of the implementation of control actions identified on risk registers in response to both (a) causal factors identified by individual investigations, and (b) patterns of causal factors identified by analysis of groups of investigation reports.

This model signifies a change from a focus on recommendations. Recommendations continue to be important to address the specific causes of the incident at the site where the incident occurred. However, these recommendations are what Dekker referred to context specific. What Dekker referred to as the context independent information is the further details of Contributory Factors that are produced for (i) analysis to identify patterns in causal factors, and (ii) management via the risk register process to drive both local and systemic safety improvement.

Like any system, detracting from the quality of any aspect of the model for continuously improving how to learn from investigations reflected in figure 8.1 above will detract from all other elements of the model and its overall ability to achieve its purpose. Conversely, improving any aspect of the model
will have a positive impact on all other elements of the model and its ability to achieve its purpose.

On the broadest level, this relates to how the HSE responds to and learns from incidents, so as to demonstrate verifiable assurance of compliance with controls that are developed to achieve optimum safety and risk management, to in turn achieve its overall objective of improving the health of the population of Ireland.

So it is important to keep a clear view of all aspects of the model at all times to ensure that all elements are functioning optimally in their own right – and in communication with other elements of the system. Doing this will make the process of learning and improving safety based on incident investigations resilient and less vulnerable to the risks associated with organisational flux referred to in Chapter 2.

In short, the model in figure 8.1 delivers credible data about patterns in causal factors from higher quality serious incident investigations that recipients can have confidence will drive an efficient agenda for auditable and verifiable improvement. Feedback mechanisms embedded within the model (namely (i) the evaluation of individual investigation quality, and (ii) identification of factors that affect investigation quality) behave as an internal model of learning within the investigation process. Analysis to identify patterns in causal factors effectively identify emergent system features which (a) add to information about existing risks, (b) identify newly emerging risks, and (c) are important for informing safety improvement across the organisation. Finally, monitoring compliance with controls on the risk register identified to address causes of incidents leaves an auditable trail from incident occurrence to implementation of improvement, including system wide improvement where appropriate.

It is helpful to refer to the example used in Chapter 6 here again. This example related to the problem of detecting and responding to rapid patient deterioration. It is easy to think that simply implementing EWS should curb this problem. However, the thematic map in Study 4 puts a spotlight on the numerous underlying causes of this problem which are embedded vertically
and horizontally across multiple layers of the health system like the roots of bindweed. Seeing the map of the bindweed roots throughout the system in the thematic map in Study 4 we learn that – in order to address the problem of detecting and responding to rapid deterioration - we need to develop and implement PPPGs related to the detection and management of (i) rare conditions, (ii) unusual presentations, (iii) complex patients with multiple comorbidities, and (iv) time critical conditions that address:

→ thorough planning and monitoring of these patients
→ appropriate communication between MDTs\textsuperscript{88}, services, agencies, with patients/families
→ Access to services including Ambulance, Emergency Department, Emergency Surgery, HDU\textsuperscript{89} and ICU\textsuperscript{90}
→ Resource demand mismatches
→ Training, education and supervision
→ Governance and risk management including the dissemination and audit of compliance with PPPGs and implementing learning from this, clarity about roles and responsibilities, and proper risk and incident management and implementing learning from this

Thus, the thematic analysis in Study 4 generated data that informed the above sophisticated yet comprehensive and credible solution to address the apparently intractable problem of detecting and responding to rapid patient deterioration. So, while the problem may be intractable, it is not impossible to solve – and clearly seeing all aspects of the problem in the thematic map helps to inform a comprehensive and credible solution to the problem which is likely to have a far greater impact on improving patient outcomes than less sophisticated and less comprehensive solutions. This appears to be a practical illustration of what Rasmussen (1993) meant when he said that more detailed and constructive suggestions for improvements can be derived from the identification of recurrent deviations from a joint analysis of a larger set of accident investigations.

\textsuperscript{88} MDTs: Multidisciplinary Teams
\textsuperscript{89} HDU: High Dependency Unit
\textsuperscript{90} ICU: Intensive Care Unit
To close the loop, monitoring compliance with controls on the risk register identified to address the causes of incidents related to detecting and responding to rapid deterioration - leaves an auditable trail from incident occurrence to implementation of improvement.

The above reflects an important achievement of this thesis. It demonstrates that it is possible to overcome the apparent lack of generalizability of systems analysis investigations, as the emergent themes identified from the group of systems analysis investigations included in study 4 are by definition generalizable. It is accepted that some of these themes describe what Reason (1995) refer to as more proximal causes (i.e. issues with detecting and responding to rapid deterioration, and diagnosis issues), while others are more in line with what he referred to as latent causes (i.e. Issues related to governance). Achieving this credible map of systemic causal status initiates a process of further investigation that can continue to reach back to systemic root causes that are the equivalent to Reason’s latent factors. Thus, a ‘platform’ of knowledge about these emergent factors makes it possible for well-informed investigators (and perhaps event deep systemic audits) to construct credible causal pathways through further investigations. There are plenty of plausible antecedents of premature closure in diagnosis, and failure to detect and respond to rapid deterioration. Serious incident investigations are not the only source of evidence about these.

It will take more than one thesis to solve the problem of generalizing from serious incident investigations for system wide safety improvement. But this thesis has taken the logically necessary first step. Once we can identify generalizable systemic proximal causes – we can progress to identify the systemic latent/root causes.

This highlights the importance of putting this thesis in the context of an extended implementation of the investigation guidelines that initiated it. Continued systems analysis investigations (and other sources of evidence) will serve to validate the analyses and conclusions of this thesis. They will deepen and extend the analysis, so that the system is enabled to learn about itself as a system. From this, the system learns to do what is necessary to improve its deep system functionality.
8.2.3. Implications for policy formation and implementation

**Study 3** (Chapter 5) showed that there was a statistically significant correlation between attendance at HSE investigation training and investigation quality. There was also a positive correlation between use of HSE investigation guidelines and investigation quality.

Chapter 7 showed that learning from this thesis informed both (i) investigation training, and (ii) investigator guidelines. There is anecdotal evidence that this is contributing to further improvement in investigation quality and further research is warranted to evaluate this objectively.

The evidence generated in this research should inform incident management and investigation PPPGs generally by ensuring that these PPPGs are underpinned by the model of **continuously improving how to generalise from investigations for system wide improvement** as outlined in section 8.1.2 above. Structures and processes for maintaining a clear view and optimal functioning and communication of all eight elements of the model at all times should be explicit in incident management and investigation PPPGs.

Specifically the learning generated by this these should inform investigation PPPGs in relation to (i) – (v) as follows:

**(i) Investigator training**

Chapter 2 showed that HSE investigation training was underpinned by learning from earlier studies related to investigator training (For example: Wallace (2006), Wallace *et al.*, (2006), and Wallace *et al.*, (2009)).

As stated, **Study 3** in chapter 5 showed that there was a strong statistically significant correlation between attendance at HSE investigation training and investigation quality. Specifically, investigation teams that had at least one member that had attended at least one of the three days of HSE investigation training scored significantly higher IQSs than investigation teams where no investigators attended any of this training. At the same time, the vast majority of investigation teams did not have any members that attended any of this training. Given the strongly positive correlation between attendance at
this training and investigation quality, consideration should be given to making it policy that at least one - and perhaps all – investigation team members must attend HSE investigation training. Future research exploring the implementation and impact of this on the elements of the model shown in figure 8.1 is indicated.

(iii) Investigation team size, and makeup

Chapter 3 showed that there was a tendency for the literature to assume that subject experts related to all relevant issues under investigation needed to be included on investigation teams (Bagian et al., (2002), Leistikow et al., (2016), and Care Quality Commission (2016)).

As shown in Study 3 (Chapter 5) there was a statistically significant positive correlation between investigation quality and:

- having not less than two, and not more than three investigators
- having at least one investigation expert on the team

Further research focused on understanding the dynamics of investigation teams, how expertise is recognised or not, and the impact of this on investigation quality and the other elements of the model shown in figure 8.1 is warranted.

(iii) Investigation quality evaluation feedback to investigators

Leistikow (2016) describes how providing feedback to hospitals about the quality of their investigations contributes to improvements in how hospitals learn from their own serious incidents.

Study 2 (Chapter 4) shows that evaluation of the quality of investigation reports gives important assurance to the health system and the public about the compliance of investigations with investigation quality standards of excellence and highlights areas for improvement. However, a process for providing feedback about the quality of investigation reports to sites or investigators has not yet been tried and tested in the HSE. Further research is required related to providing such feedback as has been done by Leistikow (2016). To ensure the buy in of investigators, it is important that this is done
in a positive and supportive manner focusing on what is done well, and opportunities for improvement. Further research related to the impact of this on the elements of the model shown in figure 8.1 is also indicated.

(iv) Identification of factors that affect investigation quality

As stated previously, no empirical studies of the factors that affect investigation quality were identified.

Study 3 (Chapter 5) goes some way towards addressing this gap in the literature by demonstrating that data from the evaluation of investigation quality can be used to empirically test hypotheses about the determinants of investigation quality. The findings from these empirical tests provide strong evidence for informing evidence based decisions about investigation PPPGs and training.

Further research is required to identify other determinants of investigation quality and the impacts of these on (i) investigation quality, and (ii) the quality of data derived from investigations for safety improvement purposes.

(v) Analysis of groups of investigation reports to identify patterns in causal factors

As shown above in this chapter, analysis of groups of investigation reports to identify patterns in causal factors is important to identify what Dekker (2006) refers to as the systemic underlying causes of harm.

Study 4 (Chapter 6) reports the analysis of investigation reports to identify the frequency distribution of Contributory Factors of the investigations, and patterns in causal factors at a deeper level in a larger batch of investigations from a wider span of the health system, bringing us closer to identifying: “the systemic factors that went into creating them…” (Dekker, 2011) than previously done. This also helped to identify a stop rule for how deep to dig to identify and better understand underlying causal conditions so as to inform credible preventive strategies.

However, issues with the quality of the further details of contributory factors were identified and described in Study 4. Further research related to
interventions to address these issues, and the impact of these interventions on the elements of the model shown in figure 8.1 is required.

8.3. Reflection about the role of the author in this thesis

This section reflects the role of the author in this research.

As shown in chapter 2, the author was a protagonist in developing investigation PPPGs, training to support their implementation, and considerations about structures and processes for (i) evaluating the quality of investigations; (ii) identifying factors that affect investigation quality; and (iii) identifying patterns in causal factors from groups of investigation reports to better inform system safety reflected in this thesis.

The author was also:

(i) The Chairperson of the Serious Incident Management Team that oversaw the HSE Miscarriage Misdiagnosis Review (Ledger et al., 2011) referred to in chapter 2

(ii) The Chairperson of the HSE investigation related to the failure to transplant a young patient to Kings College Hospital London for transplantation surgery (Health Service Executive, 2011) also referred to in Chapter 2

(iii) The Deputy Chairperson of the investigation team that conducted the HSE Maternal Death Investigation related to Savita Halappanavar (Arulkumaran et al., 2013) referred to in Chapters 5 and 7. This investigation was completed in 2013 and was included in the 2013 investigation reports in the research reflected within this thesis

(iv) The NIMT overseer of the investigation of the death of baby Mark Molloy (Health Service Executive, 2013) also referred to in Chapter 7. This investigation was also completed in 2013 and was included in the 2013 investigation reports in the research reflected within this thesis.

In addition to the above, the author has both a clinical background (allied health professional), and a background in human factors and systems safety.
The author’s expertise informed the research reflected within this thesis - and the learning from the research was important in informing the investigation PPPGs and training reflected in Chapter 2. This enabled rich repeated cycles of exploration of the problem space addressed in this thesis in a manner that is in line with the “Look, think, act routine” of action research described by Stringer (2013).

The analysis of contributory factors by Cronin (2005), demonstrates the importance of the role of expert judgement in analysing causal factors. Cronin was a clinician who identified the need to bring in a human factors expert to help to tease out the human factors aspects of the data in the analysis. No process for achieving consensus between Cronin and the human factors expert was described in this paper demonstrating that it is expert judgement and not consensus that is most important in this work.

Like the Cronin (2005) study, the 4 studies reflected within this thesis required expert judgement based on explicitly clear criteria to answer the specific research questions more than it needed consensus decisions.

The approach taken in this study, and the role of the author in it - enabled a sophisticated and nuanced exploration of the problem space. It is acknowledged that this may be at some cost to reliability and repeatability. However, a trade-off between reliability and validity is considered necessary in order to answer the research questions in this case. For example, it would have been possible to design a very reliability IQET that focused on simple criteria, such as the length of investigations and the number of interviewees only. But these would not have provided for exploring more advanced and subtle criteria such as whether the investigation reflected satisfactory evidence to support the identification of Key Causal Factors (KCFs) and Contributory Factors (CFs) which required expert judgement on the part of the evaluator.

A number of checks and balances were designed into this research to counter potential issues with reliability and repeatability. The first countermeasure was the qualitative and quantitative reliability testing of IQET that is described in Study 1. This confirmed reasonable inter-rater reliability. The second countermeasure was to include examples and case studies throughout the
thesis so that the reader can clearly see the logical process and criteria used for expert judgement on the part of the author. A third countermeasure is that all the raw data related to the analysis to identify patterns in causal factors as per Study 4 is included in Appendix 20. Again, this means that the reader can clearly see the logical processes and criteria used for expert judgement on the part of the author. A fourth countermeasure is that investigations were not quality scored based on the investigation methodology they used. This was considered an independent variable and analysed separately to determine if there was a correlation between the investigation method and investigation quality. This was in light of the authors awareness of the importance of not assuming that the systems analysis method promoted in Investigation Guidelines (Health Service Executive, 2012) was automatically the best method of investigation. Rather, it was important for this research to be conducted impartially in a manner that was open to the possibility that other methods of investigation may lead to better investigation quality. All of this and the fact that all of the data is coded for traceability back to the original investigation reports means that other researchers can access the original data to further test reliability and repeatability.

But the ultimate test will be the on-going evaluation of the model reflected in figure 8.1 which was created from learning derived from this thesis. Key to this will be (i) audit of compliance with risk controls created to achieve system wide safety improvement in response to learning from serious incident investigations, and (ii) evaluation of the safety impact of these.

8.4. Strengths and limitations of this thesis

Strengths

As discussed in Chapters 1 and 6, the problem of determining how to continuously improve how to generalize and learn from incident investigations to leverage organizational learning and improvement is a wicked problem (Rittel and Webber (1973 & 1974); Blackman et al, (2006); Cassin & Barach, (2012)).
This thesis reflects work done which brings us a long way towards achieving a solution to this wicked problem.

It achieves this firstly by addressing an important gap in the literature and demonstrating that it is possible to develop a reliable Investigation Quality Evaluation Tool (IQET) to comprehensively evaluate the quality of investigation reports, including the quality of the analytic trace for investigations findings, across the whole span of the health system, against accepted criteria of investigation excellence. It also evidences that the IQET can be used to reveal the strengths and weaknesses of investigations to inform investigation PPPGs and training.

Secondly, it is the first research to show that data from the evaluation of investigation quality can be used to empirically test hypotheses about the determinants of investigation quality such as (i) investigator training, (ii) investigation team make up and expertise, (iii) whether and how interviews are conducted, (iv) definitions of causal factors used, and (v) investigation methods used. The findings from these empirical tests provide strong evidence for informing investigation PPPGs and training in order to deliver the best quality investigations and the best quality data for system wide safety improvement purposes.

Thirdly, it reflects analysis at a deeper level of causal factors - specifically analysis of further details of Contributory Factors - to identify patterns in causal factors in a larger batch of investigations from a wider span of the health system and in more detail than done in previous research.

Fourthly, this thesis shows that the outcome of the analysis to identify patterns in causal factors effectively identifies emergent system features which (i) add to information about existing risks, (ii) identify newly emerging risks, and (iii) are important for informing safety improvement across the system. Most importantly, this aspect of the thesis achieves a resolution of the contradiction between the complexity of the system and the need to identify sufficient cause to implement prevention.

But above all, the approach used in this thesis brings us beyond the (i) over simplification of the sequence of events model of accident causation (i.e.,
(i) lack of specificity of the latent causes identified in the epidemiological model (i.e. Reason, 1995), and (iii) lack of generalizability of the systemic model. Importantly, the approach (a) respects complexity, (b) gives specificity to latent factors, and (c) demonstrates how to learn generalizable lessons to leverage system wide safety improvement from groups of system analysis investigation reports and how to continuously improve this.

**Limitations**

One limitation of this study relates to the fact that the analysis of patterns in causal factors reflected in Study 4 in Chapter 6 related to the 107 investigations that were included within this study, and specifically, the subset of these that included further details of Contributory Factors. As stated previously, it is reasonable to assume that not all serious incidents that should have been investigated were investigated. It is also reasonable to assume that not all available serious incident investigation reports were submitted to this study. Therefore, a limitation of this study relates to the fact that the investigation reports included may not be representative of the incidents that occur or of the incidents that are investigated. In order to minimise the impact of this limitation on the results of this study, a decision was taken not to select a sample of the investigation reports submitted for inclusion in this study, but rather to include all investigation reports that satisfied the study eligibility criteria. For the future, this highlights the importance of (i) conducting thorough investigations of all serious incidents, and (ii) submitting these for inclusion in on-going quality evaluation and thematic analysis processes. Structures and processes should be set up to drive and assure that this happens and this should be reflected in incident management and investigation PPPGs and evaluated in future research.

A second limitation which requires reflection relates to the fact that reliability testing of the investigation quality evaluation tools was conducted by small groups of individuals, including the author. As shown in chapter 3, three individuals (including the author) were involved in qualitative reliability testing of IQET 1, four individuals (including the author) were involved in the qualitative reliability testing IQET 2, and two individuals (including the author)
were involved in the quantitative reliability testing of IQET 3. This was done in a context where the work to evaluate the quality of investigations was very laborious, and required significant knowledge and experience, of (i) investigation PPPGs, and (ii) conducting investigations. There was only a small pool of available individuals with sufficient knowledge and experience to do this work and all of these were involved in the action research approach to developing, testing and implementing the IQET. So while this presented problems for reliability and repeatability – it was a pragmatic approach adopted in order to answer the specific research question. It also enabled real world learning where those involved in the reliability testing were individuals that were likely to continue the work of investigation quality evaluation into the future - and - in fact, they did.

A third limitation is associated with the fact that this research was conducted in the Health Service Executive, which is the Irish Public Health System. Other healthcare organisations and domains will have different investigation PPPGs, training, structures and processes so this may limit generalizability to other healthcare systems and domains.

Finally, the correlational nature of the analysis of factors influencing investigation quality means the direction of causation cannot be taken for granted. However, a counter argument is that other explanations of the causal connections, e.g. that easier cases were assigned to better trained investigators – are not very credible.

8.5. Next steps (unfinished business)

Areas for further research that are identified throughout this chapter include research related to structures and processes for providing feedback about investigation quality to sites and investigators in a supportive manner that enables improvement.

Further research examining the impact of different investigation methods on investigation quality – and the quality of data derived for analysis to identify patterns in causal factors - is also important. This should consider research outside of healthcare by Salmon et al., (2012) which compared three accident investigation methods namely (i) Accimap (Rasmussen (1997), (ii) CAST (i.e.
Causal Analysis using Systems Theory) (Leveson, 2004), and (iii) HFACS (Human Factors Analysis and Classification System) (Wiegmann and Shappell, 2003).

Salmon et al., (2012) judged that HFACS was limited to only identifying causal factors from within the organisation, and also limited in terms of the negative language used which focused on error and failure. They deemed CAST to be resource intensive and limited in terms of describing the relationship between contributory factors. However, they judged Accimap more favourably both in term of (i) not using a framework of Contributory Factors freeing investigators to identify any causal factors from within and outside the organisation, and (ii) enabling description of the relationships between causal factors.

The systems analysis method described in the London Protocol (Taylor-Adams et al., 2004) and used in HSE Investigation Guidelines uses a framework of Contributory Factors. But this framework is not limited to identifying only Contributory Factors that arise from within the organisation. Rather, it prompts identification of Contributory Factors from both within and outside the organisation. At the same time, the system analysis method does not focus on the relationships between Contributory Factors. This means that research comparing the Accimap method (Rasmussen, 1997) with systems analysis method (Taylor-Adams et al., (2004) & Health Service Executive (2012))and their respective effect on investigation quality is worthy of further study. This is particularly important for determining (i) the impact descriptions of the relationships between Contributory Factors have on investigation quality, and (ii) the impact having or not having a Contributory Factors framework has on analysis to identify patterns of causal factors from groups of investigation reports.

In relation to the generation of data for analysis of patterns in causal factors, Salmon et al., (2012) and Goode et al, (2019) consider the strengths and weaknesses of the absence of a classification scheme to describe the contributory factors in the Accimap. As stated above, the fact that investigators are not limited by a framework for the identification of contributory factors from any part of the system including from within and outside the organisation is considered a strength by Goode et al, (2019). However, they consider that the fact that identification of contributory factors
is entirely dependent on the analyst’s subjective opinion means reliability is likely to be limited and analysis of groups of investigations problematic (Salmon et al., (2012) and Goode et al, (2019)).

So, while comparison of systems analysis with Accimap, and indeed other investigation methods is indicated – such future research must not underestimate the importance of the learning from this thesis about the value of the systems analysis method in deriving generalizable learning from analysis to identify patterns in causal factors from groups of investigation reports.

Following on from this, there is a need to be mindful of the impact any research related to different investigation methods is likely to have on the process for identifying patterns in causal factors from groups of investigation reports that have used different investigation methods. Such research needs to endeavour to ensure that the quality of data for analysis to identify patterns in causal factors improves, and does not deteriorate over time.

Finally, this thesis focused on investigation quality through the lens of how well causal factors are identified which is important for improving system wide safety, risk management and incident prevention. However, future mixed methods research which considers the views of service users, those affected/harmed by incidents, investigators, managers that implement learning from investigations and other stakeholders, is required. Specifically, the views of those affected by incidents about investigation quality are important, as are the views of investigators about why certain aspects of PPPGs are difficult to follow. All of this is important to progress the agenda of continuously learning how to leverage incident investigations to better inform system safety.
References


Care Quality Commission. (2016). Briefing. Learning from serious incidents in NHS acute hospital; A review of the quality of investigation reports (pp. 8).


generate learning from patient safety incidents reported from general practice. *Bmj Open*, 5(12), e009079.


Committee report "Investigating Clinical Incidents in the NHS", and the Morecambe Bay Investigation (pp. 103). United Kingdom: Department of Health Williams Lead Group on behalf of the Controller of Her Majesty's Stationary Office.


Health Information and Quality Authority (HIQA). (2008). Report of the investigation into the circumstances surrounding the provision of care to Rebecca O’Malley, in relation to her symptomatic breast disease, the Pathology Services at Cork University Hospital and Symptomatic Breast Disease Services at the Mid Western Regional Hospital, Limerick. Ireland: HIQA.

Health Information and Quality Authority (HIQA). (2011). Report of the Inquiry into the circumstances that led to the failed transportation of Meadhbh McGivern for transplant surgery and the existing inter-agency arrangements in place for people requiring emergency transportation for transplant surgery (pp. 80). Ireland.


Health Information and Quality Authority (HIQA). (2013). Investigation into the safety, quality and standards of services provided by the Health Service Executive to patients, including pregnant women, at risk of clinical deterioration, including those provided in University Hospital Galway, and as reflected in the care and treatment provided to Savita Halapannavar (pp. 253). Ireland.


Health Service Executive (2019) Healthcare Audit End of Year Report 2018


Wilson, R. (2005). Report on a review of breast imaging at Altnagelvin, Belfast City Hospital and Antrim Area Hospital for the Permanent Secretary, DHSSPS Northern Ireland. (pp. 26). Northern Ireland.


300