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To err is human: an exploration of the implementation of the Duty of Candour

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“To err is human, to cover up is unforgivable, to fail to learn is inexcusable” Sir Liam Donaldson (2003:1)

Table of Contents

Title Page **1**
Table of Contents **3**
List of Figures **6**
Acknowledgements **7**
Abstract **8**
Chapter 1: Introduction **9**
Thesis Structure 9
The Statutory Duty of Candour 9
Grading of Patient Safety Incidents 11
Patient Stories 13
Purpose 15
Research Title and Aim 16
Conclusion 16
Chapter 2: Literature Review **18**
Introduction 18
Methodological Approach to Literature Review 18
Search Strategy 19
Empirical Literature on the Duty of Candour 23
Policy and Practice Literature 25
Hybrid Professional – Managerial Roles 35
Professional Hierarchies 38
Human Factors Theory 40
Critiques of Human Factors Theory 42
Models for Incident Investigation 43
Psychological Safety 45
Organisational Culture 47
Just Culture 50
Sociological Theories 52
Weberian Theory of Rationalisation 52
McDonaldization of Contemporary Society 54
Neoliberalism and the Impact of Market Forces 56
Conclusions from Literature 58
Chapter 3: Research Methods **60**

Introduction 60
Overview of the Study 60
Research Site 61
Methodological Approach 61
Classical Grounded Theory 62
Constructivist Grounded Theory 63
The Research Process and Rigour 64
Alternative Research Methods 65
Sampling 66
Interviews 69
Recruitment and Data Collection 71
Conducting Research on Sensitive Topics 73
Positionality 75
Methodological Journal 77
Data Analysis Methods 78
Memos 78
Coding 79
Categories 81
Confidentiality 83
Informed Consent 84
Procedure for Selecting Participants 85
Sample Size 86
Sample Characteristics 87
Conclusion 90
Chapter 4: Discussion 91
Introduction 91
Hybrid Professional - Managerial Roles 94
Organisational Culture 98
Organisational Practice 104
Methods of Communication: Written Letters 104
Standardised Template Letters 106
Standardised Letters – Using Human Factors Lens 110
Organisational Change 113
Organisation Change – Impact on Professional Identity 117
Additional Theme: Candour with Patients and Families 120
Additional Theme: Impact of Voice Recording of Interviews 123

Chapter 5: Conclusion ... 124
Introduction ... 124
Review of Research Aim ... 124
Conclusions ... 126
Strengths of the Research ... 131
Limitations of the Research ... 131
Implications for Healthcare ... 133
Recommendations for NHS organisations ... 134
Implications for Future Research ... 135
Chapter 6: Impact on Professional Practice ... 137
References ... 141
Appendices ... 154
Appendix A: Risk Assessment Form (Approved Version) ... 154
Appendix B: Participant Invitation Letter (Approved Version) ... 158
Appendix C: Participant Information Sheet (Approved Version) ... 159
Appendix D: Consent Form (Approved Version) ... 162
Appendix E: Interview Guide (Approved Version) ... 164
Appendix F: Overview of Participants ... 166
Appendix G: Example of initial and focused coding from interviews ... 169
Appendix H: Venn Diagram ... 181
Appendix I: Policy and Practice Literature – timeline ... 182

List of Figures

Figure 2.1: Initial literature review process

Figure 3.1: Research process

Figure 3.2: Data analysis and feedback cycle

Figure 3.3: Duty of Candour incidents by care group for the reporting timeframe of 1st April 2017 and 31st March 2018

Figure 3.4: Duty of Candour incident by type of reported incident

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Abstract

Aim of the study: to conduct qualitative research that considers the impact of the Duty of Candour legislation within healthcare.

Background: the concerns and complaints raised by a persistent group of patients and families, linked with increased mortality rates led to the Mid Staffordshire Inquiry (Francis Report, 2013). This inquiry found a catalogue of failings that included preventable deaths, incidents that had led to patient harm, and a culture that did not foster open and honest discussions with patients and families when something had gone wrong within the services provided at Mid Staffordshire NHS hospitals. The findings from this inquiry led to Sir Robert Francis recommending a statutory 'Duty of Candour' (Health and Social Care Act, 2008 amended 2014) across all healthcare services in England.

The Duty of Candour is the formalisation of the processes of being open and honest when a notifiable safety incident has occurred. Dalton and Williams (2014: 2) state that "put simply, candour means the quality of being open and honest".

Methods: a grounded theory methodology was used to help guide the research design and process. Specifically, the grounded theory developed by Kathy Charmaz (2012) became the theoretical framework used to analyse findings. 5 in-depth interviews were conducted with clinicians who had reported a patient safety incident that met the criteria for the Duty of Candour to be applied.

Findings: a number of key categories emerged from the analysis of interviews, these were hybrid professional – managerial roles, organisational culture, organisational practice and organisational change.

Conclusions: a number of key categories emerged from the analysis of the interview transcripts. Each of these key categories could be seen in isolation, however it is a much more powerful to see these findings as a collective discourse that links to the impact of the neoliberalist narrative on public healthcare provision in the UK. The need for the Duty of Candour is seen as the necessary response to ensuring NHS Trusts are responsive and transparent when things go wrong. However when a human factors theory lens is applied to the responses given in interviews it is apparent that issue such as lack of time, fear of reprisal, dual and often conflicting roles lead to dialogue with patients and families that is sometimes not personalised. From the interviews with the participants in this study there was a sense that they felt that in fulfilling their professional duty to enact the Duty of Candour requirements that they were simply fulfilling a bureaucratic task; rather than being enabled to take a person centred approach and an opportunity to learn from incidents and events.

Chapter 1: Introduction

This chapter provides an introduction to the thesis, and an overview of the evidence base and literature relating to the Duty of Candour and incident reporting. It also sets out the research focus and aim of this study. A number of relevant patient stories have been used in this section to illustrate the researcher's personal and professional rationale for choosing this subject. This chapter also introduces grounded theory as the chosen research methodology for this study. Finally, this chapter provides a brief overview of the structure and content of this thesis.

Thesis Structure

This thesis partly fulfils the requirements for the award of Professional Doctorate (DProf) in Health and Social Care. The thesis is presented over six chapters. Chapter 1 provides an introduction to the thesis, overview of the research and personal and professional rationale for choosing this research area. Chapter 2 provides a narrative review of the existing evidence and research and identifies gaps within the body of established knowledge. This chapter concludes with a synthesis of the literature to identify key themes. Chapter 3 considers the methodological approach that was employed and the research methods used. This chapter also covers sampling and the ethical considerations of the research. Chapter 4 critically explores the data analysis process, which was applied following data collection. The data coding process is explicated using the analytical process advised by Charmaz (2014). The key categories that emerged from the analysis process are highlighted. Chapter 5 covers the conclusions drawn from the data collected, while finally Chapter 6, presents some personal reflections, recommendations, and considers the impact of this research on professional practice.

The Statutory Duty of Candour

The Francis Report (2013) stated that the Duty of Candour should become a statutory requirement under the Health and Social Care Act (2008, amended 2014) and that this statutory requirement should be monitored through the healthcare regulatory body, Care Quality Commission (CQC). As a result of this recommendation, there was a requirement for all healthcare organisations in

England to have policies and procedures in place by April 2015 that described how local healthcare organisations would enact the Duty of Candour requirements.

The Duty of Candour regulation has two key components that need to be fulfilled prior to healthcare organisations being required to enact this legislation. The first requirement is that an incident is reported and that this incident meets the criteria for a notifiable safety incident (that the incident was deemed as unintended and or unexpected). Secondly that the reported notifiable safety incident has been graded as causing moderate or above harm. The Duty of Candour applies to all incidents which are reported and are graded as causing (or likely to cause) moderate harm or above or prolonged psychological harm.

The CQC states as part of the Duty of Candour, Regulation 20, Health and Social Care Act (2008, amended 2014 (2014: 1) that moderate harm can be defined as "harm that requires a moderate increase in treatment and significant but not permanent harm". The application of this regulation in clinical practice means that examples of incidents that meet the classification for notifiable patient safety incident (unintended and/ or unexpected) and moderate harm includes:

- A patient arrives for surgery but has not been given the correct advice to discontinue their Warfarin treatment, the patient's surgery was therefore postponed;
- A patient develops a grade 2 pressure ulcer during a hospital admission, although they are now well, they needed additional district nursing visits post discharge from hospital;
- A distressed and aggressive patient required physical restraint and anti-psychotic medication to be administered. During the restraint the patients arm was broken. The patient's arm was in plaster for 6 weeks but they made a full recovery.

Grading of Patient Safety Incidents

The level of harm that is applied to each incident is based on a professional view and therefore very open to issues around subjectivity and bias, as often the view of an individual clinician can impact on whether an event is reported as an incident at all. Dalton and Williams (2014: 3) state that, "there are a number of definitions of 'harm' that are used for different purposes. This can lead to confusion and some of the language of definitions can be positively unhelpful for talking to patients". For example one study found that "only 42% of the staff surveyed believed that medication near misses should always be reported" (Evans et al., 2006: 41). Without an incident being reported there is no chance of open and honest discussions with patients and families. There is also no opportunity to learn from an incident.

The literature surrounding the grading of incidents is of importance to this study as it is a key strategy in terms of how potential participants have been selected to take part in this research. Only incidents that are graded as moderate or above harm meet the criteria for enacting the Duty of Candour. For this research only participants that have reported an incident which has been graded as moderate harm have been selected.

In an attempt to reduce any possible subjectivity in the grading of incident, a scoring matrix was developed by the National Patient Safety Agency (NPSA), this was introduced in 2014. The risk matrix is often referred to as the 5 x 5 grid as there are two sections which each have 5 possibilities. On the x axis of this grid there are 5 possible options to score the 'consequences' of an incident, this ranges from insignificant to catastrophic. The y axis lists the possible options for the 'likelihood' of the incident, ranging from rare to almost certain. A total score of the incident is calculated by multiplying the 'likelihood' figure and the 'consequences' figure to calculate the grade score. For example, if the likelihood was graded as 4 (likely) and the consequences were graded as 3 (moderate), the grading would be 4 x 3 = 12. A score of 12 would result in a patient safety incident being categorised as moderate harm and therefore Duty of Candour would need to be enacted.

The National Reporting and Learning System (NRLS) (2019) was implemented in 2003 as a national large scale monitoring and reporting function, to collate all patient

safety incidents, and to review and share learning. This learning is disseminated through national alerts and bulletins.

Based on the Duty of Candour regulation, healthcare organisations should undertake a number of mandatory steps to ensure that patients and families are aware of the incident and have the opportunity to contribute to the ongoing investigation.

From an organisational perspective following the findings from the Francis Report (2013) there was widespread public pressure to ensure that there was a legal framework to enforce that healthcare organisations inform and involve patients and families when an incident had occurred.

From an organisational culture perspective there is a growing evidence base (Hutchinson et al, 2009) (Mahajan, 2010), that indicates that proactive incident reporting cultures (organisations with a high rate of reported, low harm incidents), including an organisational focus on being open and honest when an incident has occurred plays an important part in ensuring learning and improvements to services. Furthermore, proactive incident reporting can also help towards an organisational culture which enables members of staff to feel able to safely raise concerns (often before they become an incident or issue). This is often referred to as organisational psychological safety (Colley et al., 2013).

A detailed literature review, is set out in Chapter 2, highlights gaps in the current evidence base regarding the exploration of the application and impact of the Duty of Candour. However, it is important to note here that the existing evidence base on the Duty of Candour or 'Open Disclosure' (as it is often referred to internationally) (Iedema et al., 2008) identifies a clear and significant gap in our understanding of the workings of this regulation at a professional practice level. Specifically, there is a gap in the current evidence base in terms of the application of the statutory requirements by clinicians within healthcare services; as O'Connor et al. (2010: 376) state that: "much of the research also derives from use of hypothetical scenarios, focus groups, simulations or surveys rather than genuine adverse events". A similar point was also made by Birks et al. (2014: 25) who highlight that "there is relatively little work exploring real accounts of disclosure and error". The research described throughout this thesis adds to the current limited evidence base. This is due to its focus on

capturing the perspective from staff members who have been involved in an incident that triggered the statutory Duty of Candour.

From a personal and professional practice perspective one of the main drivers for the focus on this area of research is due to a number of key patient and family stories that are linked to when incidents occur within healthcare services, which illustrate the need for, and the development of, the principles of openness and the introduction of the Duty of Candour. Some of these stories are set out below.

Patient Stories

From a professional practice perspective, there are also a number of professional motivators that have enabled and driven a continued focus on this area of research throughout the researcher's Professional Doctorate journey. The researcher's professional role includes the oversight of investigations and learning from serious incidents; and a keen interest in terms of the exploration of how we use staff and patient stories to lead to improvements in practice. Two of the key stories that link to this research are described here. First is the story of Elaine Bromiley (Reid and Bromiley, 2012). Elaine had a re-occurring sinus problem and was admitted to hospital for an elective procedure. However, during this procedure, once Elaine had been sedated, it was very quickly apparent that there was an issue with being able to intubate her. In the operating theatre there were two anaesthetists, an ear, nose, and throat surgeon who had more than 30 years' experience, two operating department practitioners, two recovery nurses, and all of the emergency equipment that would normally be required. In addition to the standard equipment, once the complications of the procedure arose, one of the nurses brought in a tracheostomy kit. The tracheostomy kit was the piece of kit that, if it had been used, could have saved Elaine's life. However, this was not considered and for another 15 minutes the physicians continued in their failed attempts to intubate Elaine. Elaine remained unconscious and died some 13 days later. The inquiry from Elaine's death highlighted a number of issues including many that linked to human factors; including relationship /hierarchy within the operating theatre that created a barrier to the medical staff being accepting of the suggestion of the solution (tracheostomy kit) that was presented by the theatre nurse. Following the avoidable death of Elaine, Elaine's husband, Martin, who was an airline pilot at the time of Elaine's death used

his background in aviation and his knowledge of human factors to develop the national Clinical Human Factors Group. This is a network that brings together healthcare professionals in order to use human factors theory to understand why incidents and events occur within healthcare and essentially, how healthcare organisations can learn from these incidents.

The second story to highlight is that of Robbie Powell. Robbie was 10 years old when he died on 17th April 1990 of Addison's disease, a rare, but very treatable illness which stops the adrenal glands pumping vital hormones. There was an extended timeline of events that led to Robbie's death, which started approximately four months before his death. In December 1989 Robbie had suffered a bout of stomach pains and vomiting that was so bad that he was admitted to Morriston Hospital, Swansea, where he later recovered, following the administration of intravenous fluids. Robbie became unwell again on 1st April 1990, suffering from stomach pains, sickness and weight loss. Over the next two and half weeks Robbie was seen seven times by five different GPs. The investigation into Robbie's death highlighted that four of the GPs that had seen Robbie, did not read the previous medical notes. On the 15th and 16th April 1990 Robbie was taken again to the GP practice; he was so weak that he had to be carried into the GP surgery by his father. The GPs that assessed Robbie failed to complete a referral for him to be seen at hospital. On 17th April Robbie collapsed at home, Robbie's family called out the GP and Robbie was taken to hospital. Robbie died in hospital later that day.

The Powell family had to then campaign tirelessly for an open and honest investigation into the death of their son, this them led them to taking his case to the European Court of Human Rights in 1998. Due to the tenacity of Robbie's parents and particularly Robbie's dad, Will Powell, to strive for justice for Robbie, the now known as Duty of Candour was previously described as 'Robbie's Law' (Walsh, 2014).

Over a similar time period, Lord Donaldson (senior British Judge) had been campaigning for a law that required health services to provide information and medical records when an incident occurred within healthcare services as far back as 1985. This focus from Lord Donaldson was triggered due to a Court of Appeal case. In this case the information from a health authority was not shared with the mother of

the patient (her son) who had died. Lord Donaldson continued with his lobbying in terms of the requirement for not only a professional but also a statutory Duty of Candour for many years. As part of the positive changes that were made during this period, this included the introduction of the Data Protection Act (1999). The Data Protection Act (1999) gave patients a right to request and access their own health records however this was still some way from the requirements that are now in place as part of the Duty of Candour.

In 2003 Sir Liam Donaldson (the then Chief Medical Officer) proposed the statutory Duty of Candour, highlighting in the consultation document, Making Amends (2003) that, “to err is human, to cover up is unforgivable, and to fail to learn is inexcusable” (2003:1). It would not be until several years later (and numerous public inquiries and healthcare scandals) that the statutory Duty of Candour would start to become common terminology within healthcare.

The start of the policy momentum from the Making Amends report (2003) to the statutory Duty of Candour being enshrined under the Health and Social Care Act (2008) amended (2014) was the findings of the Mid Staffordshire Trust Inquiry (Francis Report 2013). This inquiry found that at Mid Staffordshire Hospitals there had been more than 1,200 more deaths than expected. The Francis Report (2013) highlighted that a number of these deaths had occurred due to contributory factors that were linked to patient safety failings and incidents.

These types of individual stories, which often sit (and can become lost) within larger inquiries, are the driving force behind this study. It is important to focus on how we can learn from individual stories, which can then impact on learning and improvement from patient safety incidents.

Purpose

The research set out within this thesis seeks to understand whether by introducing statutory regulation to be open and honest when an incident occurs, that this leads to a greater focus on learning from incidents and events.

There are many occasions in healthcare services where the Duty of Candour has been applied and the steps, as set out in the legislative framework, have been

followed; however, there is currently a gap in the evidence base in terms of what the impact of this activity was from a staff and patients/ family perspective. For example, this research actively seeks to understand whether the Duty of Candour is able to penetrate organisational culture to enable learning and improvement following a healthcare incident? Or, whether in fact the organisational culture dominates whether an incident is reported and responded to?

Through the research interviews that have been conducted, this study aims to develop new understanding and theory based upon the emergence of key categories of the experiences and stories from participants.

This study focuses on the professional practice and exploration of the responses from healthcare professionals during interviews. Throughout this thesis there are two main staff groups that are considered these are grouped into doctors, nurses and Allied Health Professional (AHPs); when these groups are being discussed simultaneously the term ‘clinicians’ will be used to signify all registered healthcare professionals.

Research Title and Aim

Title of study:

To err is human: an exploration of the implementation of the Duty of Candour

Aim of study:
To conduct qualitative research that considers the impact of the Duty of Candour legislation within healthcare

Conclusion

This chapter has provided a broad introduction into the focus and background of this research and its aims, and more specifically setting out some of the patient stories that were pivotal in the introduction of the Duty of Candour and have inspired this research. These experiences include the stories of Elaine Bromiley and Robbie Powell, who both died unexpectedly due to avoidable patient safety incidents and

errors. On a much larger scale similar stories and events are shown from the findings of the Francis Report (2013), which, ultimately led to the introduction of the Statutory Duty of Candour requirement for all healthcare organisations.

The next chapter of this thesis is the literature review. This chapter offers a synthesised view of the literature associated with the subject of Duty of Candour, incident reporting, and professional practice. As suggested by Charmaz (2014) the literature review has been reviewed and updated throughout the research process, in an iterative cycle of review, as and when any new areas emerge from the data analysis process.

Chapter 2: Literature Review

Introduction

The purpose of this chapter is to provide an overview of the key existing literature and evidence base that is relevant to the Duty of Candour. As part of the development of this chapter a search strategy was initially considered to support the early identification of existing research related to this study. This chapter provides a review of the research linked to the following areas: (a) empirial literature on the Duty of Candour (b) policy and practice literature (c) Human Factors Theory (d) organisational culture (e) sociological theories. These areas of interest have emerged through a iterative approach and review of relevant literature and how this links back to the the conclusions from the interviews conducted for this research. A basic, skeleton of the literature review was developed initally to meet the needs of the researcher understanding the current evidence base and also as a requirement for the ethical approval process. Using grounded theory methodology the literature review has been further developed and refined based on the catergories and themes from the research interview.

As this study has been conducted utilising a grounded theory lens, a discussion of the literature review process is considered in more detailed below.

The conclusions from this literature review have then been grouped into three main topics: organisational culture, ensuring learning lessons from incidents, and preparations for Open Disclosure/ Duty of Candour discussions.

Methodological Approach to Literature Review

As outlined in the introduction to this thesis, this study employs methods of analysis that are aligned with the grounded theory lens. There are several different methodologists within grounded theory. The seminal text, *The Discovery of Grounded Theory* (1967) by Glaser and Strauss is often referred to as classical grounded theory. There have been several subsequent adjustments and variations of the classical grounded theory, these are considered in more detail within the methodology chapter of this thesis.

At the outset of conducting any literature review it is important to understand the areas where this literature may come from (i.e., academic papers, grey literature) in order that they can be rigorously reviewed and explored. New literature is always appearing but it is important to be able to demonstrate that a detailed and structured approach to a literature review has been undertaken.

Throughout this study Charmaz's (2014) approach and framework related to grounded theory is highlighted as the preferred methodological approach. Charmaz (2014) suggested a more pragmatic approach to the process of the development of literature reviews and theoretical frameworks; linking it with the key grounded theory concept of constant comparison. Charmaz (2014) suggests that the literature review should not be seen as an isolated task but one which is re-reviewed throughout the research process, and particularly when completing coding for the analysis stage of the process. Charmaz (2014: 305) states that, "through comparing other scholars' evidence and ideas with your grounded theory, you may show where and how their ideas illuminate your theoretical categories and how your theory extends, transcends, or challenges dominant ideas in your field".

Search Strategy

In terms of the literature review undertaken for this research a five stage grounded theory model proposed by Wolfswinkle, Furtmueller and Wilderom (2013) has been utilised. These five stages are as follows: define the criteria, undertake the search, choose or select the relevant sources, analyse the information and finally present the information.

An initial literature review was conducted in years one and two as part of the Professional Doctorate journey, which initially provided the evidence required to seek and obtain ethical approval for this study to be conducted. However once the interviews and analysis stages were completed, the literature review was reconsidered on the basis of any new and emerging categories and theories based on the findings from the research

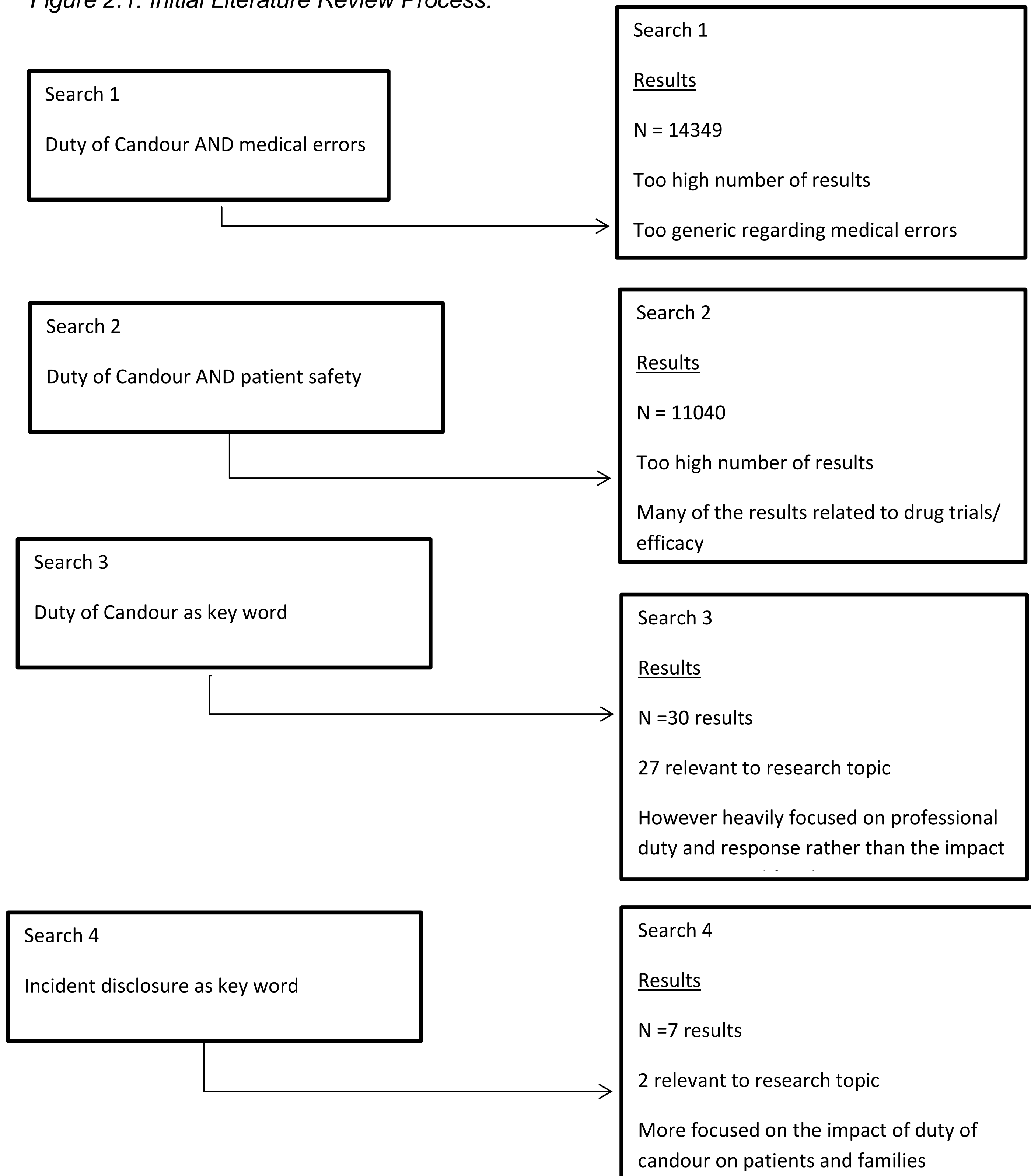
This literature review draws on a range of sources including, white papers, policy documents, inquiries and various academic sources, such as academic journals. The

literature review has been arranged thematically, based on the results of various literature searches. The initial literature review search took place in July 2017.

The Ovid Database was used to search for relevant articles and studies, key words searches included the terms, ‘incidents’, ‘candour’, ‘honesty’, and ‘patient safety’.

In order to support the evaluation of research papers the CASP tool (Cottrell 2011) was used in the early stages of this literature review. Once all relevant individual papers had been reviewed, an inductive interpretive approach of meta – ethnography (Noblit and Hare, 1998) was utilised to support the synthesis of a small number of research papers. This method of literature analysis tends to be used to support researchers to analyse and understand responses to qualitative research methods. A key element to this method of synthesis is comparison, constant comparison, similar to the analysis used within grounded theory. Other methods of synthesis have been explored including the critical interpretive method outlined by Dixon-Woods, (2006). However this method was discounted as it has been designed to support the review of multiple, diverse literature sources which use multiple methods, whereas meta – ethnography is more suited to literature reviews that produce smaller samples.

Figure 2.1: Initial Literature Review Process:



A subsequent review of the Ovid Database was conducted in July 2019. A similar, systematic approach to the initial literature search was utilised to undertake this additional search. This search focused on the use of the key words search of ‘duty’ and ‘candour’, published in the time period from 2017 to 2019. This search resulted in 5 additional sources (articles/ research papers), as follows:

- 2 research papers that focused on reviews of the methodology used when investigating patient safety incidents (Banham-Hall and Stevens, 2019 and Motuel et al (2017).
- 1 paper related to medical revalidation and remediation (Price and Archer, 2017).
- 1 paper related specifically to research that explored the safety of paediatric orthopaedics (Augustithis, Ensor, and Huntley, 2017).
- 1 research paper related to the exploration of patient safety events and how organisational values and engagement impact on the patient experience (Price-Davey, 2017).

The research by Price – Davey (2017) considers the recommendations from the Kirkup Report (2015) and subsequent investigations into the avoidable deaths of babies in NHS services. This research paper focuses specifically on the impact that organisational values and culture can have on patient experience and quality of care. Due to the focus of this research paper, this has been considered further in the sections of this thesis that focus on organisational culture. The remaining 4 papers identified above have been discounted as not being relevant, for the research described within this thesis.

Further to the detailed and specific searches conducted through the Ovid database, a number of additional searches were also undertaken during and post the research interviews being conducted. These additional focused searches highlighted the importance of literature associated with the neo liberalist narrative, including Weber’s theory of rationalisation (Ritzer, 1998) and the impact that neo liberalist policies, such as the concept of McDonaldization (Ritzer and Chen (2015)) have on publically funded healthcare services. Importantly these additional searches also highlighted further studies which related to the impact of, and barriers to, the implementation of the Duty of Candour (Hooper, 2019 and Harrison et al, 2019).

Empirical Literature on the Duty of Candour

Through the initial literature review process two linked studies (in terms of the research teams and location – Australia) were highlighted (Iedema et al., 2008, and Iedema et al., 2011). A further two studies were highlighted through additional searches (Hooper, 2019 and Harrison et al, 2019).

The study by Iedema et al (2008) related to research that was conducted as part of a national pilot research into the impact of the statutory requirements of Open Disclosure (the international term for Duty of Candour (Iedema et al., 2008). The research used a grounded theory approach to generate themes from the 23 interviews conducted with patients and families. The study by Iedema et al., (2008) was identified a number of years ago as part of an initial literature review conducted earlier on in the research design phase of the Professional Doctorate programme. Initially, it had been intended that a very similar study to the one conducted by Iedema et al. (2008), would be completed with patients and family members as participants. However, as part of the literature review it was highlighted that there had already been some studies that considered the impact of the Duty of Candour from a patient perspective (Iedema et al., 2008 and 2011). There were also some case studies used within a report commissioned by the CQC (Learning, Candour and Accountability, 2016). Hence, in terms of the potential emergence of new theory and the impact on the gap in the current evidence base, it was more appropriate for the research conducted to focus on a healthcare professional's perspective. Also as the study by Iedema et al. (2008) highlighted, there are significant ethical issues for any research project that focused on interviewing patients and families who have, in some way been involved or impacted on by a patient safety incident. It is noted that the number of participants in the study by Iedema et al. (2008) is low, due to the issues around ethical approval, a number of the ethics committees from the national pilot sites chosen did not agree ethical approval for this research to be conducted.

In the research conducted by Iedema et al. (2008) the potential participants were selected by the hospital sites themselves; the research team did not have access to incident information or clinical records. This type of research design can increase the potential for research issues such as organisations self-selecting the incidents or participants that they wish to be involved in the research study.

This is clearly a limiting factor in the research conducted by Iedema et al. (2008).Therefore in terms of the research described within this thesis a research design has been developed and implemented to ensure that the only role that the host organisation has in terms of the data is the initial request for a list of the incidents that meet the data selection criteria. The host organisation has not been informed of the names of staff that were linked to patient safety incidents or those who subsequently became research participants. The host organisation for this research confirmed at the point of ethical approval that they had no concerns in terms of the dual lead role of the researcher (professional role within the host organisation and leading this research project).

In the study by Iedema et al. (2008) interviews were conducted either over the telephone or face to face and the transcripts were analysed by four team members who independently reviewed information and tabulated this into themes. An iterative method was used to achieve constant comparison. Constant comparison is one of the standards deemed as being required to fulfil grounded theory analysis. Constant comparison has been described as "a process of maintaining a close connection between data and conceptualisation" (Bryman 2015: 568).

The second linked study (Iedema et al., 2011) was conducted by members of the same research team as the 2008 study and was based in a similar geographical area of Australia. The aim of this follow up study was to test whether Open Disclosure had become embedded into practice. This study was a qualitative study, which used 100 semi-structured interviews with patients and families to develop themes from interviews, analysed through grounded theory methodology.

In this study the research team had direct access to hospital records of those patients who met the inclusion criteria; this research design was implemented in order to address the limitations found in the 2008 study. The research team chose to run a national advertising campaign to promote this research and encourage patients and families that were not identified via the hospital records review, to take part in this research study. This recruitment method helped to identify patients and families who may have been involved in an incident but the incident had not been recorded on the hospital incident system. Unlike the pilot study no ethical approval issues where identified, with ethical approval being granted via the associated university.

One of the limitations that was identified by the research team was the relatively small sample for a national study. This concern is understandable in terms of the national basis of this research; however, it should be noted that this was a qualitative study, which focused on the experiences and stories of patients and families. Therefore the 100 narrative accounts that were gathered through this study are likely to generate key categories and therefore meet the requirements of a grounded theory qualitative study. Qualitative research tends to focus on the depth of engagement within participants rather than the breadth or extensiveness of the number of participants.

In the additional literature searches and reviews that were conducted in June 2019, highlighted two additional studies that were of relevance to the research described within this thesis. In the research by Harrison et al (2019), they conducted 12 semi structured interviews with individuals who were closely involved in the implementation of Open Disclosure (this research was conducted in Australia). The responses from the interviews conducted for this research highlighted three main conclusions, firstly that the serious incident investigation process needed to be more clearly linked with the requirements for Open Disclosure. Secondly, staff needed to be supported through appropriate training in regards to breaking bad news, risk management and regulation. Thirdly, that there needed to be further clarification in terms of if Open Disclosure relates to no or low harm incidents.

The article by Hooper et al (2019), focuses specifically on the implementation of the Duty of Candour in community nursing in the UK, which is therefore pertinent to the research described in this thesis. The article highlights that the barriers that still exist in regards to the implementation of Duty of Candour, include that members of staff still worry, that giving an apology to a patient/ family when an incident has occurred tantamount to the admission of guilt. This article highlights the fact that these concerns are linked to organisations where a culture of blame exist.

Policy and Practice Literature

There are numerous events, inquiries and incidents that could be used to populate this section of the literature review. For the sake of brevity, key events have been selected to illustrate the timeline that led to the implementation of the statutory Duty

of Candour. An overview of the timeline that relates to these literature sources is shown in Appendix I.

For the early part of the 20th Century, the medical profession were mainly self-regulating in terms of their professional medical practice, patients were unlikely to challenge the medical profession or raise concerns when something had gone wrong. As Yeung and Dixon-Wood (2010: 503) highlight “until late in the 20th century, assuring patient safety was considered largely a responsibility of medical professionals, and those professionals were often controlled through systems of professional self-regulation”.

However, from the late 1960’s onwards, there started to be a number of change in the way in which the NHS, including doctors, were regulated. This was driven by a number of high profile cases, these cases included the findings from *hospitals in trouble* by Martin (1984). In this text Martin (1984) highlighted a number of key inquiries including the appalling standards of care found at Ely Hospital, Cardiff (1969). The Ely Hospital was a long-stay hospital for people with learning disabilities, the inquiry found inhumane and threatening behaviour from a number of staff to the patients, general disregard for the patients care and treatment on the ward and a lack of care from senior managers when patient and members of staff raised concerns and complaints. During the 1970s, there were several public reports which highlighted systematic abuse, and the poor quality of care provided to, people with severe learning difficulties and mental health illnesses Rivett (1998). Into the late 1990’s and early 2000 these inquiries included the Bristol Inquiry (2001), which investigated the high mortality rates of children receiving heart surgery. However this inquiry also identified that this hospital trust had also removed and retained a large number of organs from deceased children, without the prior consent being gained from their parents. The findings from the Bristol Inquiry (2001) led to a closer review of the removal and organ retention practices across a number of hospitals. This uncovered that a large number of organs that had been removed and retained from deceased children at Alder Hey Childrens Hospital. The findings from the Royal Liverpool Childrens Inquiry (2001) sighted that there had been a paternalistic approach taken to the removal of organs from children without prior consent, sighting that organs had been removed in the “belief that parents or relatives would not wish to know about the retention of organs and the uses to which they are put” (2001:8).

At a similar time there was also the Harold Shipman case. Shipman, a GP, was convicted of the murders of 15 of his patients in January 2000 (Smith 2004); however it is thought that the actual number of people that Shipman murdered was over 200. This criminal investigation, along with other NHS 'scandals' such as the Bristol Inquiry (2001) and Royal Liverpool Inquiry (2001) led to a public eroding of the trust between patients and doctors. It is thought that these cases signalled the change in focus to a 'bad apple' discourse around healthcare professionals. Cooke (2012) highlights that these cases fit into two areas, firstly where there are issues of 'conduct', for example the murderous crimes of Harold Shipman and secondly issues of 'competence' i.e., the concerns raised regarding the professional practice of doctors involved in the Bristol and Royal Liverpool Inquiry (2000).

Further to this there was also a shift in the general acceptance of the, previously paternalistic relationship and mode of communication that doctors often held with patients. Patients were now demanding the need for more open dialogue to increase their ability to understand and choose their care and treatment. This change in the narrative from acceptance to informed choice, led to a change in the healthcare regulatory model from self to state regulatory models.

At this time, internationally there were also significant changes taking place in healthcare provision, with a focus on the impact of healthcare in terms of patient safety. In the US, the seminal text, *To Err is Human* (2000), was commissioned by the Institute of Medicines in the US in response to the need to consider the serious issues around patient safety. This report signalled a clear change within healthcare organisations, initially in the US in terms of building safer healthcare systems, which concentrated on the quality improvement movement. Part of this movement came from facts that were highlighted through the publication *To Err is Human* (2000) which stated that: approximately 44,000 people died in America each year as a result of medical errors, indicating that "more people die in a given year as a result of medical errors than from motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516)" (Kohn et al., 2000: 26).

To Err is Human (2000) put forward a number of recommendations, that required in order to improve patient safety, these include the development of a national (US) centre for patient safety. This centre was focus on setting national goals are

improvements for patient safety and also, importantly collating evidence on patient safety incident and learning from these incidents. The second recommendation was development of national mandatory reporting system for incidents and adverse events. This is similar to the national incident reporting system that is in place in England, National Reporting and Learning System (2003). The third recommendation was the requirement for the national incident reporting system to be used solely for the purposes of learning and improving and therefore it was recommended that the information held within system would be exempt from legal discovery. Clearly this was an important issue for the US system which is primarily insurance and see a higher proportion of legal claims. It was necessary to make it clear to clinicians that reporting of incident was not automatically result in a patient making a claim. Without this legal exemption clinician maybe less likely to report incidents, which results in a lack of learning and increased likelihood of reoccurrence. A further recommendation from this report related to the need to ensure that there were performance measures that not only considered waiting times and finance but also focused on patient safety. The final recommendation was that all healthcare organisations should have patient safety programmes in place, which had an executive sponsor and associated training programme for staff.

Following the publication of *To Err is Human* (2000), the Institute of Medicine released a follow up report, *Crossing the Quality Chasm* (2005). Although this report was less sensational than To Err is Human (2000) it aimed to give a longer term approach and guidance to the implementation of improvements, which improved patient safety and clinical outcomes. Don Berwick is often described as the architect of the 2005 report, however Berwick (consultant paediatrician and former Chief Executive of the US Institute for Healthcare Improvement) has had a much broader reach into improvements in patient safety both in US and UK. Berwick tends to not only focus on developing frameworks and methods that support improvement in healthcare. Berwick also had an interest in understanding the organisational culture and behaviours that must exist in order for improvements in healthcare to be introduced and embedded into practice.

Crossing the Quality Chasm (2005) recommended 6 domains of healthcare that required improvement: healthcare should be safe (avoidance of avoidable injury or

harm), healthcare should be effective (evidence based healthcare), patient – centred (focused of the needs and wishes of the individual patient, timely (reduction in waiting times and harmful delays to treatment), efficient (the avoidance of waste, including supplies), and finally healthcare should be equitable (no variation on the provision of healthcare that is linked to age, gender or geographical location). These domains were based on the premise that healthcare worked on 4 different levels, level A; patients and their experiences. Berwick (2002) described patients in this context as the organisational, "true north" Berwick (2002: 80). Level B was the smaller network of health services; the microsystems; Level C was the organisation that house the microsystems, therefore in the UK these would be NHS Trusts. Finally Level D was the political and regulatory structures and behaviours that impacted on the way that healthcare was delivered at Level C.

Crossing the Quality Chasm (2005) is an important piece of literature to note as the study considered within this thesis is understanding what the impact of a politically driven, legislative focused requirement has had on those implementing this requirement (clinical staff) and those who receive this information (patients and families). In Berwick's categorisation the Duty of Candour is understanding how something that is agreed at Level D (governmental level) impacts at other levels within the wider healthcare system.

Also, in 2000, in the UK the Department of Health published the report, *An Organisation with a Memory* (2000), this highlighted that more than one in ten patients had experienced an adverse event whilst in hospital and up to 70% of these events were preventable. Key recommendations from this report, including the requirement for the NHS to have unified mechanisms in place for the reporting of incidents, that there remained a need for further attention and work to be undertaken to ensure that the NHS had a more open culture and in turn creating more opportunities to learn and improve from incidents.

An Organisation with a Memory was published in 2000, however there was still widespread issue within the NHS as the findings from the Francis Report (2013) demonstrated. The Francis Report (2013) found a catalogue of failings at Mid Staffordshire Hospital Trust, many of which relating to a lack of incident reporting, learning from incident and an organisational culture which focused on blame.

The recommendations from the report An Organisation with a Memory (2000) also recommended the need for a systems based approach to the investigation of incidents and events.

This report highlighted the link between patient safety incidents and errors to other safety critical industries such as aviation. It introduces the concept of system thinking and human factors theory, which is considered in detail, later in this literature review.

In light of the investigation into the unexpected and avoidable death of Robert Powell, and several other high profile inquiries (including the Bristol Inquiry, 2001, Liverpool Hospitals Inquiry, 2001), the *Being Open Framework* (2009) was developed. This framework provided guidelines in relation to being open, honest and ensuring transparency when a patient safety incident or event had occurred. Importantly this framework provided detailed steps and actions to ensuring that the investigation process focused on opportunities for learning and improvement.

This framework stated that patients and families should “receive a meaningful apology and explanation when things go wrong” (National Patient Safety Agency 2009: 6). *The Being Open Framework* (2009) focused on the organisational cultural conditions that are required to ensure that high quality Open Disclosure discussions with patients and families take place, “promoting a culture of openness is vital to improving patient safety and the quality of healthcare systems” (National Reporting and Learning Service 2009: 7). However several years and inquiries later (including the Mid Staffordshire NHS Trust Inquiry, 2013) highlighted that the guidance within this framework was not being adequately followed.

The inquiry into Mid Staffordshire NHS Trust (Francis, 2013) found evidence of significant and catastrophic failings, many of which centred on patient safety incidents and lack of subsequent investigations. This inquiry also highlighted a lack of candour with patients and families when incidents had occurred. Following these findings Sir Robert Francis made hundreds of recommendations for all corners of health provision (primary care[1], community[2] and acute providers[3], Department of

[1] Primary care services include the services provided through general practice.
[2] Community health services are services such as district nursing, which are provided within or near to where a patients resides.
[3] Acute healthcare services tend to be provide on a larger, traditional hospital site and provide services such as Accident and Emergence Departments.

Health, Coroners and the Care Quality Commission). There were 14 recommendations that specifically related to the concept and principles of 'being open', with patients and families when an incident or event has occurred. In regards to the statutory Duty of Candour (Francis 2013) highlighted this through recommendation 181, which detailed the enforcement and regulation of the statutory Duty of Candour. This recommendation was split into two areas, firstly the organisational requirement to be open and honest when organisations believed that the care or treatment provided (or omitted) had resulted in a moderate or above patient safety incident. Secondly the professional Duty of Candour that specified the requirements for all registered healthcare professionals as part of their professional codes of conduct. Francis (2013:1) stated that "every healthcare professional must be open and honest when something goes wrong with the treatment or care which causes, or has the potential to cause harm or distress". The recommendations from the Francis Review (2013) clearly signalled a change in the way in which healthcare organisations were to be regulated. The Duty of Candour was made a statutory requirement in April 2014 for all health care organisations in England to adhere to under the amended Health and Social Care Act (2014). The duty of monitoring compliance with this requirement fell to the healthcare regulator, the Care Quality Commission, to monitor through their framework of regulatory inspections.

The findings from the Mid Staffordshire Trust inquiry (2013) prompted the commissioning of the report *Improving the Safety of Patients in England* (Berwick Report) (2013), which considered the culture of patient safety within the NHS. Berwick in his 2013 report attempted to bring some of the learning from the US in terms of improvement to patient safety to the NHS. This report highlighted the need for further research to better understand the impact of the disclosure of serious incidents on patients and families. Also the Berwick Report (2013), maintained consistency with Berwick's focus on the impact of the multiple levels that were outlined in the publication, *Crossing the Quality Chasm* (2005). Berwick's concerns in terms of organisational culture were also highlighted, he indicated that he had concerns that the Duty of Candour had the potential to become an overly bureaucratic system that had no impact on learning or improvement following an incident. This report returned to the principles of the *Being Open Framework* (2009) in terms of ensuring that it is necessary that attention is placed on organisational

culture, rather than simply using a regulatory approach and expecting the organisational culture to follow.

There are a number of papers and articles including Scammell (2015) and Glasper (2015) that were published prior to the full implementation of the Duty of Candour. These articles focused on the potential on professional registration this included joint guidance and statements from the Royal Colleges (General Chiropractic Council et al., 2014) on how registered health care professionals should respond to incidents and the Duty of Candour regulation. The research conducted by Scammell (2015) and Glasper (2015) highlighted the level of caution that some healthcare professionals had prior to the implementation of the Duty of Candour. Firstly, there was a general set of concerns that linked with the issues that Berwick (2013) had highlighted, that the Duty of Candour would become another arbitrary performance measure, which would not impact on the organisational safety culture. Secondly, concerns were also levied by clinicians through their respective professional councils (General Medical Council, Nursing and Midwifery Council) that there may be a reduction in incident reporting. This was due to the fact that the Duty of Candour legislation states that a letter should be sent to the patient describing the incident. This letter should also include an apology for the incident occurring. Professional councils initially raised concerns in regards to a written apology being provided and the link between this and the admission of legal liability; "while understanding that this is the right thing to do, practitioners may feel concerned that an apology could be interpreted as an admission of legal liability" (Scammell 2015: 237).

More recently there has been the publication of an independent review of deaths of people who accessed learning disability and mental health services in Southern Health NHS Foundation Trust from April 2011 to March 2015 (Mazars, 2015). This review found disparity in terms of the investigations of deaths of patients who had a learning disability or mental health condition, compared with patients who are seen within healthcare services for physical health conditions. In terms of Duty of Candour this report found that: "radically more effort needs to be made to develop the right culture across the Trust to engage with families when deaths occur and the Trust must continue to ensure systems to monitor Duty of Candour and increase meaningful involvement" (Mazars 2015: 33).

The purpose of meaningful involvement of patients and families in discussions that involve the disclosure, involvement and learning from incidents is a key category that has been highlighted by a number of the reviewed studies (Birks et al., 2014, Ledema et al., 2011, O'Connor, et al., 2010). Specifically, these studies stated that one of the main themes from their research was the issue of whether patients and families felt that staff had spent the time to prepare for the meeting to discuss an incident. Birks et al., (2014: 53) describes this theme as "good disclosure". The detailed findings from these studies, highlights a number of factors that could have been improved, these included that the clinician conducting the Open Disclosure meeting should know the patient/ family and understand what happened in the incident. Also that the clinician should have prepared the initial basic facts and be able to outline to the patient and family what the next steps were and how they could be involved in any subsequent investigation. The impact of the well-publicised pressures on NHS services and staff could be part of the rationale for staff not having adequate time to undertake considered and patient focused meetings with families.   However, one patient story describes the sometimes stark reality of Open Disclosure; 'Beth's' story is described, where a 5 year old child died following a routine operation. When one of the doctors came to tell the family what had happened during the operation, all the mother remembered was that the doctor still had on his surgical scrubs, which had her child's blood on them (Patient Stories.Org. 2012).

The findings from the Southern Health Report triggered a response from the Care Quality Commission, who had commissioned a system wide review in 2016. The 2016 review (Care Quality Commission, 2016) focused on the way in which healthcare trusts investigate and respond to deaths. This report, published in December 2016, highlighted that there was still much more work to do in terms of Duty of Candour and the involvement of patients when incidents occur, citing that, "some trusts reported feeling nervous about involving families, in some cases deciding not to involve families in an attempt to avoid adding to their distress" Care Quality Commission (2016:17). However this finding highlights the concerns and caution that Berwick (2013) raised in terms of the potential negative impact there could be from applying a top down, statutory requirement to something that requires a personal, individualised approach.

Following the findings of the Care Quality Commission report (2016) NHS Improvement published a new framework (NHS Improvement, 2017) to support improvements to the system wide learning from patient safety incidents. This framework also aimed to synthesise the learning and ideas from previous reviews and inquiries. This report reiterated that "in particular, bereaved families and carers should be asked if they had concerns about the quality of care received by the deceased to inform decisions about the need to undertake a case record review or investigation" (NHS Improvement 2017: 16).

The findings from this latest report highlight the issues that *Improving the Safety of Patients in England* (2013) report predicted. This report highlighted that it was necessary to have *both* the cultural climate within an organisation and a regulatory framework which provides the necessary safeguards to both clinicians who report and raise concerns and incidents and importantly, a commitment to patients and families to learn from these events.

One of the most recent high profile cases is that of Dr Hadiza Bawa-Garba (Cohen 2017). This is a case of a trainee paediatrician who was convicted of the manslaughter due to mistakes made in the care of six-year-old Jack Adcock, from Leicestershire. Jack died of sepsis in 2011. Dr Bawa-Garba was originally suspended from the medical register for 12 months. The General Medical Counsel (GMC) then took this case to the High Court, this resulted in Dr Bawa-Garba being permanently removed from the medical register. Dr Bawa-Garba, came forward and spoke to her line manager, recorded the events that had occurred, that had ultimately contributed to Jack Adcock's death. These events included rota gaps that meant on the day of the incident, Dr Bawa-Garba was covering the work of 2 doctors; the on call consultant was off site plus there was an IT issue. This is an example of, in healthcare, where we continue to respond to an incident by focusing on the person rather than the system issues. James Reason (2000) stated that "another serious weakness of the person approach is that by focusing on the individual origins of error it isolates unsafe acts from their system context" (Reason 2000: 769). High profile cases such as this one could lead to clinicians becoming less likely to report an incident due to fear of reprisal, which clearly has an impact on the opportunities for both meaningful engagement with patients and families and the opportunities to learn and improve.

Hybrid Professional – Managerial Roles

As this research focuses on the experiences of clinicians working in a healthcare environment, a key consideration is the evidence base that relates to professional identity and the concept of professionalism.

Within the research undertaken and outlined within this thesis, the concept of professional identity and the impact that dual and hybrid roles has on the management and learning from incidents was highlighted. In a paper by O'Reilly and Reed (2011), it highlighted three core concepts that impact on organisational agency: professionalism, which prioritises on professional expertise; managerialism, with a focus on managerial control and leaderism, which prioritises leaders in order that they can inspire others. These three narratives, hold different meanings dependent on the role that a person inhabits, for example managerialism and the element of control, may be seen as necessary in order to 'get the job done', whereas a person receiving direct instructions down through an organisational hierarchy may feel that this is a unnecessary level of control and that their role lacks autonomy. The research undertaken by O'Reilly and Reed (2011:1094) indicates that, "the discourse of managerialism has clearly been both the dominant and the assumed policy discourse of public service modernisation". Elements of managerialism linked to the overarching concept of New Public Management, which focuses primarily on effectiveness and efficiency, often leading to organisational cultures, which focus on the achievement of performance targets, above all else.

The tension between the three narratives of professionalism, managerialism and leaderism is easily identifiable with the NHS and across health and social care services/ sectors. Within the NHS there have been a number of different phases in terms of dynamics, differing levels of accountability and autonomy, and the numbers of clinicians and managers. In terms of the NHS and the role of managers. There is a general consensus through the literature that one of the most significant changes in the NHS was the inclusion and the increase of what were seen as financial rather than clinical managers. This change was signalled through the Griffiths report (1983). Roy Griffiths is often associated with heralding the managerial age of the NHS. The Griffiths report highlighted the requirement for general management within the NHS.

Prior to the Griffiths report (1983) nurses had long before been seen as part of the senior management team within the ward environment, with the high point in terms of levels of involvement of nurses as managers coming from the 1974 NHS restructure, which enshrined the principle of ‘consensus management’ (Ackroyd, 1996). However, the Griffiths report signalled a significant change in direction, with an overriding focus on financial and performance management; “planning, implementation and control performance” (Griffiths, 1983: 11). The increase of non-clinical, corporate managers caused some tensions within healthcare services, not least due to the fact that often managers and clinicians had different sets of competing priorities and pressures, which influenced their behaviours towards each other. For example, corporate managers were required to have a significant focus on the financial elements of service delivery, whereas clinicians would focus more on effectiveness and experience of care. In research by Breit, Fossestøl, and Andreassen (2018: 42) they suggests that “professional managers are able to use their expertise, legitimacy and social capital to transform established professional practices, values, and identities in ways that non-professionals are incapable of” . This quote clearly articulates some of the challenges of ‘non- professionals’, particularly when working with professionals who have a very strong professional grounded, like healthcare professionals/ clinicians.

With the recommendations of the Griffiths Report 1983, there came increased tensions between those who were traditionally seen as professionals in healthcare for example, doctors, nurses and allied health professionals and the new era of management. The concept of who is seen as a professional is ever evolving, through the development of new ‘professional’ roles and professional associations (Noordegraaf, 2007). These views, however were based on a traditional definition and meanings of professionalism, which focused on technical rationality. Evetts (2003: 4) states that “the meaning of professionalism is not fixed”; “different interpretations are now needed in order to understand the appeal of professionalism in new and old occupations, and how the concept is being used to promote and facilitate occupational change”.

From 2000 onwards, within the NHS there were attempts to bring together the two competing discourses of clinical (professionalism) and managerial, through multiple national and local nurse leadership courses. In the early 2000s in particular the

introduction of the ‘modern matron’ role as first introduced in the NHS Plan (2000). The NHS Plan (2000) “set out the government’s strategy for modernising all aspects of the National Health Service, improving the quality of care, and making the service more responsive to the needs of patients and their families” (Read et al., 2004: 6). With the NHS Plan (2000) the Labour government appointed in the 1997 General Election stated that the modern matron roles should be appointed into middle management role but retain clinical credibility; through visible, clinical leadership on the wards. The level of power associated with the modern matron role was highlighted through the autonomy given to these roles, not only in terms of operational management but also financial control. For example, it was proposed within the NHS Plan (2000) that every modern matron should have access to £5000 that could be spent in their service area, to improve quality. This additional ring fenced money has long since been removed. This policy changes linked to the academic literature around the attempts to reinterpret professionalism, as Noordegraaf (2007) highlighted the contemporary notions and definitions of professionalism, “do not just focus on distinctive work categories and workers, like managers versus professionals, who perform their work—they try to turn professionalism into a much more relational concept” Noordegraaf (2007: 774).

Nurse leadership roles are important to note as the research conducted for this study resulted in all of the same level of nurses i.e., sister or ward manager being interviewed. This in itself highlighted the dichotomy and conflict between clinically focused and managerial roles. For example when an incident has occurred on a ward sister’s place of work, in their managerial role they are required to review and sign this incident off, often resulting in a conflict of interest. However in a study by Sartirana (2019) he state that for those roles that often have both managerial and professional elements to them, for example medical director, that there is a need for effective recruitment processes in order the candidates who possess both sets of skills are appointed to these roles. Sartirana (2019: 634) “it is clear that a careful selection of candidates for hybrid positions is of paramount importance, and whenever possible, it is vital to find management-oriented professionals”.

The research described within this thesis, explores this internal conflict of roles and duties of the development of dual clinical and managerial roles and the impact that

this has had in terms of incident reporting, response to incidents and also embedding the learning from incidents and events.

Professional Hierarchies

Considering again the impact of organisational culture and leadership, it is necessary to explore the impact of organisational and professional hierarchies and the impact that this can have on incident reporting and learning. Focusing on the case of Elaine Bromiley (Bromiley, 2015) it is important to consider, the situational factors, specifically why the nurse who ultimately has the piece of kit, which could have saved Elaine's life, chose not to speak up. This case highlights the impact of medical hierarchies, which, are often amplified within a surgical theatre setting but exist throughout the NHS. In the case of Elaine, it is possible that due to the expertise in the operating theatre at that time that the nurse felt reassured (falsely) that the surgeons and anaesthetists understood what the issue was and how to resolve it. In a similar case study where a patient who was not fit for surgery but the surgeon chose to operate and the patient subsequently died, the medical oncologist and surgeon reflected that, "we realize that, each of us unsure, we gained confidence from the perceived assurance and expertise of the other" Srivastava (2013: 304). As part of the learning from the case outlined by Srivastava (2013) the two doctors worked together to develop a check list to ensure open communication across specialities, to navigates professional hierarchies based on experiences, ensure an holistic approach to patient care and the ability to raise concerns that are often based on gut instincts.

In the case described by Srivastava (2013) the issue was across medical specialities whereas in the Elaine Bromiley case (Bromiley, 2015) the issue was across professions i.e., doctors and nurses. The issue of cross professional hierarchies, the nurse – doctor relationship, authority and control is likely to be even further pronounced in the environment of the operating theatre. It is possible that there is still a sense of the traditional bias within the operating theatre; that nurses in this environment are there to simply support the surgeon, rather than the experience that they bring to the surgical team. With surgical multi-disciplinary teams in place for several years within the NHS, this issue may not feature as much as it previously

did, however one study personified this issue as, “traditionally, operating room nurses have been portrayed as ‘handmaidens’ to the surgeons, a position which implies that nurses’ bodies and the knowledge they use in practice are sites of discursive control by others” Riley and Manias (2006: 1541).

There is a sense that in the case of Elaine Bromiley (Bromiley, 2015) that the nurses present in the operating theatre were not an active part of the surgical team. The narrative of the ‘handmaiden’ (Riley and Manias 2006) that is there to aid the surgeon, in this case it may have been that in the midst of this incident that the surgeons reverted back to the traditional hierarchies, through focusing on the other doctors who they felt held the solution to the clinical issue. However considering a more contemporary model of command and control and power within the operating theatre, operating nurses now inhabit a different space, a different power – knowledge (Foucault, 1991). From a fiscal position operating nurses are now often the gatekeepers of the type and amount of equipment used within theatre. Medical equipment sales people tend to target theatre nurses, as do NHS managers. Managers tend to focus on requiring theatre nurses to ensure effective stock control and equipment usage to reduce the cost of surgery, whereas surgeons target operating nurses to try and influence the ability to access new pieces of equipment (Riley and Manias 2006). This dual identity provides operating nurses with increase power within the environment or space of the operating theatre.

The operating theatre example has been used to demonstrate the impact that professional hierarchies can have in terms of incidents and incident reporting, this is important in this research as an incident is required to be reported before any acknowledgement and apology can be given and any opportunities to learn sought out. In the research conducted within this thesis the across professional discourse is not as apparent as the participants are all nurse leaders who manage wards and services. However similar to the operating nurse example, the issue that participants have highlighted through this study is the impact of dual identity.

Human Factors Theory

Within the introductory chapter the link between patient stories and human factors was noted in terms of the impact that incidents and errors have on patients and families. Human factors theory is therefore of significant importance to the evidence base for the research described within this thesis. Human factors theory is also often referred to as 'high reliability theory'.

The basic premise of human factors theory is to understand how the human impacts on the system and processes in healthcare and how can we build safer systems to try and reduce incidents occurring in the future. Human factors theory focuses on understanding why incidents occur. Prior to human factors theory penetrating the healthcare organisational consciousness, risk factors associated with surgical procedures were only identified through patient factors (such as age or weight and the progression of a disease), and there was no consideration of the impact of the environment or equipment.

The origins of human factors theory dates back to 1940 and World War II, this focus was due to a number of design issues/ errors within cockpits that led to an increase in aircraft crashes. From this point onwards the aviation industry has led the way in terms of human factors focused investigations. This is demonstrated in the way that rapid investigations are conducted and the learning spread across aviation (often across multiple countries and airlines) to ensure that any faults or defects are addressed or else aircrafts are grounded until such a time as when the safety issue is resolved.

Within healthcare human factors theory started to penetrate thinking within healthcare organisations in the UK from the mid- 2000 onwards; however there was in fact papers and research completed in certain healthcare specialities (specifically anaesthesia) from the 1960's onwards. A paper by Chapanis and Safren (1960) was one of the first papers to consider the complex multi factorial reasons/ issues that often result in incident occurrence. A documented transcript from a conference proceeding in 1985 Chapanis provided this definition of human factors theory, "a discipline that discovers and applies information about human behaviour, abilities,

limitations and other characteristics to the design of tools, machines, systems, tasks, jobs, and environments for productive, safe, comfortable and effective human use" (Chapanis 1985: 1). The definition provided by Chapanis (1985) starts to outline how the human factors theory translates into the healthcare environment and these complex environments can impact on the occurrence of patient safety incidents.

From the period from 1960s, human factors thinking within healthcare continued to develop alongside other safety critical industries such as aviation. The evidence base and the broader understanding of the conditions that incidents can occur within healthcare has grown. In a study by Cooper and Nossaman (2013), they identified that of the 359 incidents that were reviewed for this study, "most of the preventable incidents involved human error (82%), with breathing-circuit disconnections, inadvertent changes in gas flow, and drug syringe errors being frequent problems" (Cooper and Nossaman, 2013: 277). The work of Cooper and Nossaman (2013) led to the development of a specific interview technique and coding of the type of incident and identified associated factors. Linkages to this work can still be seen today through mechanisms and systems in place for clinicians to report an incident and also the categories within incident reporting systems.

Sydney Dekker (2014) has been pivotal in terms of the embedding of human factors theory into everyday healthcare practice; Dekker is a Professor of Psychology but also a part time airline pilot. Dekker (2014) described the two ways of looking at 'human error', the 'old way' which was the complex systems within healthcare, for example, would work fine, if it wasn't for the human being erratic behaviours, causing systems to fail and accidents to occur. The 'new way' or Human Factor Theory considers contributory factors that might have led to an incident occurring, for example factors such as was the member of staff overly tired due to working overtime because of staffing shortages. Dekker (2014:8) stated that, "the new view does not claim that people are perfect. But it keeps you from judging and blaming people for not being perfect". Dekker's (2014) definition of human factors encourages learning from incidents and events but identifies the impact that complex environments and organisations can have on the occurrence and likelihood of incidents.

Critiques of Human Factors Theory

Although the introduction and adoption of human factors thinking into the NHS has helped to develop tools and theory that support organisations to effectively investigate and learn from incidents; this theory has also faced criticism. In particular critics of human factors theory and its application in healthcare services is often cited from patient groups in terms of the lack of accountability being placed on a clinician or organisation when a patient safety incident has occurred. Patient groups often cite a sense of cover ups, when improvement relating to incidents reference issues such as, ‘the need to change organisational culture’ or ‘improvement to IT systems’, for example. Actions and references to organisations rather than individuals could be viewed as less tangible than sanctions against individual clinicians. Therefore families may be left with a feeling that the organisation hasn’t learnt from a catastrophic incident.

The theoretical critiques of Human Factors Theory are linked to the long standing debates between Normal Accident Theory (Perrow, 1994) and High Reliability Theory (Human Factors Theory). The main differences between these two theories is that Normal Accident Theory holds that no matter what organisations do, accidents (or incidents) will occur in tightly coupled complex organisations. Perrow (1994) theory was that on rare occasion, and in complex systems, multiple unexpected failures occurs, which could not have been anticipated nor prevented.
Whereas High Reliability Theorists believe that learning from previous incidents can contribute significantly to the preventions or reoccurrence of incidents.

There are many examples in healthcare were the model of high reliability theory or human factors theory has been utilised within incident investigation, and has resulted in learning and improvements being highlighted to reduce or eliminate the likelihood of the incident reoccurring. A highly publicised example of this the death of Wayne Jowett, who died due the incorrect administration of the drug, Vincristine (Campbell, 2001). Vincristine is a drug is routinely in cancer chemotherapy and is safe if injected into a vein, but highly toxic if given intrathecally - into the spine. The learning from this incident resulted in a number of changes to drug packaging and syringes, including that design of Vincristine phials has now been changed so that they can no

longer be fitted to spinal injection kits, eliminating the possibility of particular incident from reoccurring. Although it is positive that the use of concepts of high reliability theory/ human factors theory has enabled points of learning and improvement to be highlighted, there is often a significant time lag in terms of improvement or changes to products being made. Also often improvements occur at the site (or hospital) where the incident happened, rather than across healthcare services.

Models for Incident Investigation

The Swiss Cheese Model

James Reason (2000) is also regularly associated with human factors, specifically as he developed the 'Swiss Cheese' model of incident occurrence. The Swiss Cheese model was based was considered as accident models of risk (Reason, 2000). This model was called the Swiss Cheese model as it is often diagrammatically shown a piece of Swiss cheese, where all the holes (or 'active failures') of the cheese need to line up, in order for an incident to occur. This is a type of barrier model to risk, so this model thinks about the occurrence of incidents in a very linear way, focusing more on the hours and minutes prior to an incident occurring. Criticism of this model include that its linear approach does not allow opportunities to understand the wider complex system for example the organisational or social context of where and why the incident occurred (Dekker, 2014).

Root Cause Analysis

Many NHS trusts have subscribed to using the 'Root Cause Analysis' (RCA) methodology to undertake incident investigations. RCA is a range of tools that first orientated from safety critical industries such as aviation and engineering. RCA fits within the human factors theory narrative. Within the NHS over the last 10-15 years there has been a significant focus and training on RCA in terms of supporting the in-depth investigation of incidents and events. Some of the perceived benefits at the time of the adoption of the RCA methodology, was that this method helped to facilitate, "team-led investigations typically attempting to ascertain the 'what, how and why' of identified patient safety incidents" (Bowie, Skinner, and de Wet, 2013:

51). However due to the inevitable pressures within the NHS there is a lack of evidence in terms of the effectiveness of RCA. For example often once RCA training has been provided to organisations, the intention is for a 'team' of investigators to carry out internal investigations, however due to operational pressures the investigation tends to be left for one person to complete. Also there is an issue in terms of the translation of the RCA methodology into professional practice. This has led to a preoccupation and focus on the 'root' of why an incident has occurred. RCA is actually based on the consideration of the possibility of multiple 'root' causes and secondary 'contributory factors', however in many cases this can lead to organisational incident investigations focusing on individual clinicians or even in some cases patients as the 'root' or the reason why an incident occurred. This focus has resulted in several issues including the establishment of a blame culture within organisations through the focus on seeking out an individual/ service or patient as the 'root cause'.

Secondly if the RCA methodology is used in this narrow, linear way it does not consider any of the broader factors that might have contributed to the incident occurring. Work by Peerally et al. (2017: 417), highlighted that this "promotes a flawed reductionist view" of incident investigation. Take the example of an investigation considering the suspected suicide of a patient. The community mental health services had reported that they had tried to visit/ contact the patient but the investigation found that the patient had 'disengaged' from services and subsequently after several failed contacts they were discharge from the services. Later the patient was found deceased in their own home. Taking a RCA approach through the narrow lens that has been adopted in some organisations may lead to the root cause of this incident was that the patient did not engage with services. However this does not explore the broader organisational and external organisational factors, these could include lack of investment in mental health services at an external organisational level; this could in turn have led to a reduction and rationing in service provision at a more local level.

Criticisms of the RCA model and the increasing maturity and knowledge of human factors theory has led to the move away from the use of both the traditional RCA

model and the Swiss Cheese model (Reason, 2000) to one that recognises the complexity and interdependency of healthcare services.

Systems Engineering Initiative for Patient Safety (SEIPS)

As the human factors theory continues to evolve, so does organisational practice and the models which are utilised to undertake incident investigations. Within some organisations there is now the consideration of the evolution of human factors theory through the use of the Systems Engineering Initiative for Patient Safety (SEIPS) (2006) as a tool to use to better understand why incidents occur. The SEIPS models states that it goes further than the work of Reason (2000). Vincent (2006: 50), outlines this, as it "clearly specifying the system components that can contribute to causes and control of medical errors, incidents and adverse events, showing the nature of the interactions between the components, showing how the design of the components and their interactions can contribute to acceptable or unacceptable processes". For example by using the SEIPS methodology an investigation may highlight that there is a lack of mental health provision in an area, this could then be stratified up to a lack of local funding from Clinical Commissioning Groups and then the lack national funding for mental health services.

The impact of human factors theory is significant to this study as the level to which an organisation adopts this type of thinking and more importantly a culture that focuses on complex systems, rather than the transactional notion of simply blaming individuals. The evidence base demonstrates that organisational culture and leadership behaviours are key to the organisations ability to learn and continuously improve.

Psychological Safety

Throughout this section of the literature review the construct of the term 'psychological safety' has been noted as an important factor and measure of organisational culture, particularly in reference to incident reporting, incident investigation and Human Factors Theory.

Edmundson (1999: 354) defines psychological safety as, “shared belief by team members that the team is safe for interpersonal risk-taking”. In reference to incident reporting and Duty of Candour teams and organisations that have a good psychological safety are often more open and honest when adverse events occur. These teams are therefore more likely to report an incident and importantly learn from an incident or event. Part of the evidence base indicates that organisations that have higher levels of incident reporting also work within an organisational culture that promotes open and honest dialogue, which in turn creates a sense of safety and team cohesion.

Conversely there have also been studies and research that shows that where there is high levels of safety within teams, this can actually lead to teams entering into unethical behaviours. In research by Pearsall and Ellis (2011) they highlight that teams that have high levels of psychological safety may be able to engage in unethical behaviours as they are able to discuss unethical ideas without the fear of consequences. Pearsall and Ellis (2011: 403) state that, “psychological safety, therefore, provides a mechanism through which intent may be transformed into collective, unethical action for highly utilitarian team members”.

Within the NHS the term ‘psychological safety’ has positive connotations in terms of its connectivity with teams that feel safe to raise concerns and challenge when there are issues that relate to patient or staff safety. This is likely to be why any potential negative effects of this phenomenon are largely ignored or else not referenced in terms of the link with psychologically safe teams. However there is an example of this documented in the Kirkup report (2015). This report details the findings into the investigation of the unexpected deaths of babies and mothers at the University of Hospitals of Morecambe Bay. One of the concerns that this report documented was the impact that the strong group mentality had on the denial of the impact of incidents, " many of the reactions of maternity unit staff at this stage were shaped by denial that there was a problem, their rejection of criticism of them that they felt was unjustified (and which, on occasion, turned to hostility) and a strong group mentality amongst midwives characterised as ‘the musketeers’ ” (Kirkup 2015: 8). Evidence within the Kirkup report (2015) clearly demonstrates that this group of midwifes had a strong team psychological safety, but that this had a detrimental impact on the

tolerance level in terms of clinical risk. In organisations where incident reporting is higher it ensures that organisational sub cultures, such as the one described in the Kirkup report (2015) are not able to exist, as there is organisational scrutiny and professional challenge at all levels.

However even with a number of technical tools and aids in place, the rationale for determining the level of harm from an incident is often left to professional judgement or sometimes the view of a clinical team. This is where the element of organisational culture can significantly impact on how the incident is categorised or even whether the incident is reported at all.

In an attempt to measure national variation in reporting cultures the National Reporting Learning System (NRLS) provides publicly available national reports. These reports provide benchmarking information on each NHS Trust in terms of the services that they provide and the number of reported incidents within a given 6 month period.

In March 2016 NHS Improvement launched the Learning from Mistakes League (2015/16), this report uses data from both NRLS and the NHS national staff survey to rank organisations from outstanding (1) to poor (4) reporting culture.
Since the findings from the two seminal reports of 2000, Err is Human (2000) which reflected on the errors in healthcare in the US and also the UK Department of Health report, An Organisation with a Memory (2000) there has been an increased focus on the need to learn and improve following any incident occurring.

Organisational Culture

There is a broader underlying question that relates to this study, which is to consider why from a moral, ethical perspective would a human response to being open and honest when something has gone wrong need to be translated into a statutory requirement? How did we get to a position in healthcare services that they fail to provide the required assurances that this behaviour was embedded into organisational cultures and professional standards?

Organisations with poor reporting cultures have less opportunities to learn and improve as concerns are not reported or escalated within an organisation. The trigger for the Duty of Candour to be enacted is through the reporting of an incident. The reasons why healthcare staff choose to report or not report incidents are multi-faceted but are often centred on organisational culture (Wearing, 2004).

The impact of organisational culture has been documented in a number of key inquires, for example in the Bristol Inquiry (2001), it was highlighted that, "there was an insular 'club' culture [at Bristol], in which it was difficult for anyone to stand out, to press for change, or to raise questions and concerns" Inquiry, B.R.I. and Kennedy, I., (2001: 302). Also within the Francis Report (2013) that highlighted the failings at Mid Staffordshire NHS Trust, it was highlighted that there were significant issues with the organisational culture, ""aspects of a negative culture have emerged at all levels of the NHS system. These include: a lack of consideration of risks to patients, defensiveness, looking inwards not outwards, secrecy, misplaced assumptions of trust, acceptance of poor standards, and, above all, a failure to put the patient first in everything done" Francis (2013: 1357).

Notions of culture are grounded in sociological and anthropological literature. The concept of organisational culture complex construct, which, rarely results in consensual definition. In one review by Brown (1995) it cites 15 different descriptions organisational culture. That being said, a study by Davies, Nutley, and Mannion (2000) highlights there is some agreement around two main broad schools, those who believe that organisational culture is the organisation (i.e., its component parts cannot be separated) and those who believe that component part that impact on organisational culture can be isolated and described. For the purposes of this research the school of thought which focuses on the concept of organisation culture being influenced by its component parts is favoured. The rationale for this is that the research that this thesis focuses upon highlights examples of where components or elements of organisational culture for example leadership and roles does impact on the overall organisational culture, or 'the way we do things round here'.

In an article by Mannion and Davies (2018) they draw together literature from Schein (2010) and their research to develop the concept of the three levels of organisational

culture in healthcare. Mannion and Davies (2018) described these levels as, firstly the visible manifestations (as known as artefacts) of culture, so these could include the different coloured uniforms for different levels of staff for example staff nurses often wear light blue uniforms, whereas a sister would wear dark blue and a matron a red uniform. These visible manifestation can also include the way in which the estate of a hospital is designed with receptionist often being behind a desk and a doctors being in a consulting room. The second level of organisational culture that Mannion and Davies (2018) define is that of shared ways of thinking. This therefore, include areas such as shared vision and values of an organisation and the associated behaviours. For example are the published shared values of an organisation demonstrated through the behaviours of the staff that the organisation employs. The third level, focuses on deeper shared assumptions, which could include how staff feel about their own roles and how this fits within the collective power of healthcare professional within their own organisation and the wider healthcare system.

In a study by Dixon-Woods et al (2014) they consider the impact of organisation culture and behaviour on quality and safety in NHS. Dixon-Woods et al (2014) are not drawn on one particular definition of organisational culture, stating that there are similar core concepts in every definitions of organisational culture, “common emphasis on the shared basic assumptions, norms, and values and repeated behaviours of particular groups into which new members are socialised” Dixon-Woods (2014: 106). This large scale study highlights the impact of behaviours and leadership styles, which often left staff feeling not supported, listen or consulted was seen as endemic issues by some staff in NHS organisations. Dixon-Woods (2014) highlight the direct correlation between these factors on staff retention and patient experience and safety, “In trusts with poor staff health and wellbeing, high injury rates, and a high level of staff intention to quit their jobs, patients reported that they were generally less satisfied, and Care Quality Commission ratings described poorer care and poorer use of resources” Dixon-Woods (2014: 112-113).

Several texts point to the need for a greater understanding of the impact of organisational culture on incident reporting and learning from incidents. Some studies (Archer and Colhoun, 2018) (Barach and Small, 2000) have cited that

doctors appear to be the most reluctant to report an incident or want to be involved in any subsequent improvement actions. Reasons include a fear of blame and liability, including the impact on a doctor's professional registration if an incident is reported and concerns regarding individual practice are raised. Firth-Cozens (2002: 6) state that "physicians view quality improvement programmes as an opportunity to blame them for anything bad that may or may not happen to the patient". Further to this, in a UK study, the sample that was considered, showed that almost 13% of the doctors who responded to the survey (581 doctors included in the survey) stated that a fear of blame was one of the reasons for not reporting an incident (Archer and Colhoun 2018).

It is necessary to not only focus on just one professional group as this could miss possible widespread and underlying barriers to why people feel unable to raise safety concerns. These issues often relate to the organisational culture that they work within. As previously highlighted, there are other safety critical industries, such as aviation, which are seen as far more advanced than healthcare in terms of embedding positive incident reporting and learning cultures. In fact, aviation was one of the first safety critical industries to highlight and embed the concept of Just Culture. Dekker, (2012: 15) defines Just Culture as "all existing definitions of just culture draw a line between acceptable and unacceptable behaviour. A wilful violation is not acceptable. An honest mistake is".

Just Culture

As part of Dekker's work on Human Factors theory, he also developed the term 'Just Culture' (2012). The term Just Culture was developed in order to describe the necessary conditions required to enable a continued focus on patient safety within an organisation. However there has been a recent shift within some healthcare organisations from the use of the term just culture to using 'Patient Safety Culture'. This is due to an emerging evidence base that the term 'Just Culture' in NHS organisations is now associated with fear and blame when linked to reporting patient safety incidents.

The NHS Patient Safety Strategy (2019) has highlighted this issue stating, "'Just Cultures' in the NHS are too often thwarted by fear and blame" (NHS Improvement 2019: 7). There is also a view shared by some healthcare leaders that there is a lack of clarity in terms of what 'Just Culture' actually means and what elements of an organisation would demonstrate that a 'Just Culture' has been successfully adopted. This issue was highlighted in a study conducted by Weiner, Hobgood, and Lewis (2008: 403), where they found that, "although healthcare leaders have expressed keen interest in establishing a just culture in their institutions, the patient safety literature offers little guidance as to what the term 'Just Culture' really means or how one goes about creating a Just Culture".

Therefore the NHS Patient Safety Strategy (2019) has considered both the factors of the negative association with the term 'Just Culture' and this, combined with the issue of lack of clarity of what this term actually means for an organisation and have developed the concept of a 'Patient Safety Culture'. However, in learning from its previous mistakes, the national strategy (2019) has helpfully defined the necessary components and 6 key features that are required within an organisation in order that there is a constant focus on patient safety. The key features are, "staff who feel psychologically safe; valuing and respecting diversity; a compelling vision; good leadership at all levels; a sense of teamwork; openness and support for learning" NHS Improvement (2019: 8). However at an organisational level there is a sense that the introduction and use of the new terminology of 'Patient Safety Culture' is another attempt to try and change culture through marketing rather than addressing the attitudes and behaviours that lead to blame in organisations. Factors that can lead to blame in organisations, include when organisations become preoccupied with the drivers to achieve performance and finance targets at the detriment of patient safety and quality improvement.

It is important that healthcare leaders continually remind themselves of key findings and the evidence base from contemporary inquiries into deep rooted issues with healthcare (Francis, 2013 and Kirkup, 2015), as stated by Berwick (2013: 38) an organisation which is focused on making improvements to patient safety, "require a culture firmly rooted in continual improvement. Rules, standards, regulations and

enforcement have a place in the pursuit of quality, but they pale in comparison to the power of pervasive and constant learning”.

Sociological Theories

Weberian Theory of Rationalisation

Weber’s theory of rationalisation (Ritzer, 1998) is considered as a key and foundational sociological theory. This theory centres on bureaucracy and that in societies that have increasing bureaucracy there are rationalised processes that become irrational. Weber states that there are four types of rationality; practical, theoretical, substantive and formal (Ritzer, 1998).

Weber (1958: 298) stated that through practical rationality people seek, “methodical attainment of a definitely given and practical end by means of an increasingly precise calculation of adequate means”. Weber’s (1958) definition of practical rationality relates to the mundane, day to day tasks (and actions) that we all undertake, in order to fulfil are our own objectives.

Theoretical rationalisation relates to the way in which we try and make sense of the world around us. Whereas practical rationalisation relates to the actions that we take, theoretical rationalisation focuses on the cognitive processes that we undertake.

In Weber’s view (1958) substantive rationalisation relates to the actions that actors take in order to achieve their goals, often linked to economically orientated social goals (Ritzer, 1998).

Formal rationality is the most pertinent of these to consider in regards to the research discussed within this thesis. Formal rationality is linked to the laws and regulation that are enforced within society and often lead to increased bureaucracy; the Duty of Candour can be therefore seen as a type of rationality. Bureaucracy is a modern day construct, which focuses on well-defined hierarchies that convey the rules and regulations that are imposed from those higher up in the hierarchy. In this sense the NHS is very much a bureaucratic organisation as there are specific management structures, which include a number of posts that are stated as statutory

by regulators (i.e., all NHS Trusts must have a Director of Nursing) and these organisations are also required to have specific governance structures in place to manage the business of the organisation. However, NHS organisations do not fully fit within Weber's (1958) classical view of bureaucracy, this is due to impact of the neoliberalist narrative and policies on the NHS which include a focus on market forces, performance and privatisation.

This irrationality of rationalisation can lead to the use of non-human technologies in replace of human judgement; many examples of this are described in the work by Ritzer (2004). Ritzer builds directly on from the work by Weber; Weber and Ritzer's works links through the concept of irrationality of rationalisation, for example, in the strive for efficiencies in the service given by McDonalds, often customers now have to queue to get through to the drive through lanes, to order their food. An example of this irrationality of rationalisation in the NHS, is the development of NHS 111, previously NHS Direct. NHS 111 is a non-emergency helpline that members of the public can call if they are concerned about a health condition, illness or injury. These services tend to be accessed more 'out of hours' therefore in the evenings, weekends and bank holidays when GP practices are closed. This model of provision is based on a call to a call handler who often have no clinical expertise or experience. Call handlers provide advice based on a defined algorithm as to the treatment required i.e., can be managed at home or needs to be seen by an out of hours service. The use of an algorithm is based on the Weberian notion of predictability, in that if a person accurately describes their symptoms then it can be accurately predicted what is wrong with the person and the necessary treatment. Ritzer and Chen (2015: 829) highlighted that McDonaldization, "tends to dehumanise those involved in the process. It tends to turn employees into non-thinking robots". However following the launch of NHS 111 (2014) there have been numerous concerns raised in regards to performance, including the ability for call handlers to answer calls within the defined time period but also safety concerns. These safety concerns include incorrect advice being given by call handlers (both clinical and non-clinical) contributing to the subsequent deaths of two babies (Pope et al., 2017). As highlighted by Ritzer and Chen (2015:828), "seemingly, efficient methods and processes often prove inefficient for customers and sometimes even for organisations and their employees".

McDonaldization of Contemporary Society

McDonaldization is the framework that sociologist, Ritzer (2004) uses to understand the process of the theory of rationalisation developed by Weber. The work by Ritzer (2004) can be seen as an extension of Weber's theory of rationalisation. Ritzer (2004: 828) defines McDonaldization as, "the process by which the principles of the fast food restaurant are coming to dominate more and more sectors of American society as well as the rest of the world".

There are four key principles that are linked to the concept of McDonaldization and that are now central to many industries and organisations, these are efficiency, calculability, predictability and control. Efficiency is key to the operational model in McDonald's, basically how do you get from the starting point to the end point in the least amount of steps. The principle of efficiency can be linked back to the concept of Total Quality Management (TQM) and those who has significant impact on process and concepts linked with TQM, including Deming (1982) and Juran (1974)

Within quality improvement in the NHS, efficiency is linked to the methodology associated with lean working Jones and Mitchell (2006). There are many positive examples where lean methods have been used to make improvements in service delivery, often by making changes that save both time and money. A simple example of this is the management of clinical stock cupboards. In this example, through ensuring that there are processes in place to manage the ordering and organisation of stock within the stock cupboard it can reduce waste as items are not over-ordered and then had to be thrown away as they are out of date. Clinical staff often spend less time looking for a particular item as everything in the cupboard is clearly labelled and managed either by administrative members of staff or electronically.

Calculability in the context of McDonaldized companies relates to the quantitative aspects of services and products like the size and price. Within the NHS this could translate to Accident and Emergency performance measures that measure the

number of people waiting to be seen over a set target time as a measure of organisational and clinical quality. This performance measure does not allow for the consideration of factors within the wider healthcare system, for example a lack of GP appointments may lead to more people attending A&E to access treatment.

The principle of control within McDonaldization relates firstly to the management model adopted by the control, in that all of the 35,000 McDonald restaurants are all managed by the headquarters, which are based in Illinois, USA. Each restaurant has largely the same design and the same operating procedures, therefore ensuring efficiencies, through the reduction of waste. The control of design for each restaurant is an important element as these restaurants are designed to restrict the available actions to customers. Much of the control exerted by McDonalds and other similar chain restaurants relates to the use of non-human technology to control and ensure predictability. For example, consider the McDonald's drive through, there are a set number of steps that the customer must complete to ensure they receive the correct order, these steps are all managed through non-human technologies. This type of thinking and design can be linked within human factors theory. In terms of environment and design within healthcare considers ways that equipment can be designed to reduce the potential for human error to occur, designing out any opportunity for error.

Ritzer (2004) noted several advantages to McDonaldization these include that the availability of goods and services rely less on geography or time, for example you can now access cash from many different sources such as cash back at the supermarket rather than having to go to the bank. Also in the rapidly changing world, the McDonalds model provides uniformed, consistent services. This model also enables that the most popular products can be sourced and spread quickly, through the use of non- human technologies.

However, there are a number of issues with the principles, ethos and impact on McDonaldization. Ritzer (2004) distils these issues as follows, "the downside of McDonaldization will be dealt with most systematically under the heading of the irrationality of rationality; in fact, paradoxically, the irrationality of rationality can be thought of as the fifth dimension of McDonaldization" (Ritzer, 2004: 17).

The NHS should be mindful of concerns that Ritzer (2004) raises, particularly in ensuring the balance between the use of non-human technologies and skilled clinicians. The over or misuse of non-human technologies such as IT systems could lead to increase bureaucracy and the de-skilling of workers.

Neoliberalism and the Impact of Market Forces

Neoliberalism has been the global dominating force since the early 1980s. McCoy and Peddle (2012: 61) state that neoliberalism believes, “in the freedom of the individual, however, the individual is responsible for their own welfare”.

McGregor (2001: 83) highlights that “the term neoliberalism is made up of two notions, neo, meaning new and liberalism, meaning free from governance intervention”. And as Dekker (2020: 125) states, “Neoliberalism promotes privatisation, free markets and deregulation”. Many state that the some of the pervasive narratives that relate to the neoliberalist movement, have resulted in the in the NHS being underfunded, with a culture that focuses on the importance of managerialism and often under increasing pressures from potential privatisation (McCoy and Peddle, 2012).

This persuasive narrative translates within publically available healthcare, like the NHS in two ways. Firstly the impact of the rules and regulation based model on safety, and secondly, through an overwhelming focus on efficiency through the reduction in costs and spend on health care. These ‘efficiencies’ can be felt not only within healthcare but across the welfare system; within social care, benefit, and housing sectors.

Further to this in terms of regulation within healthcare there has been a shift from self to peer regulation to the current era of state and market regulation. In regards to market regulation, this is where the financial forces dictate the direction of travel within healthcare. The CQC was introduced as the regulator to ensure the quality and safety of health care. In the first few years of the development of this regulatory body, performance against financial goals and targets was excluded from the

inspection matrix that the CQC applied when inspecting services. However in March 2018 the CQC published a statement that outlined that there would be an additional domain added to the 5 inspection domains which already existed (safe, effective, caring, responsive and well led), the additional domain is ‘use of resources’.

Since the introduction of the new 6th domain it is unlikely for any NHS Trust to receive higher than ‘requires improvement’ inspection rating, if the Trust is in significant financial deficit. Research by The Kings Fund (2018), showed that in the financial year 2017/18, 44% of all healthcare Trusts in England were in a deficit financial position. This level of detail in terms of inspection ratings is not routinely shared within the general public. NHS Trusts are clearly rated on many different factors however if their financial position is now key to achieving a good or above rating from healthcare regulators then this feeds into the neoliberalism narrative of the need for more competition and options for patients. This narrative enables private providers to demonstrate that they are able to achieve safer, high quality care.

There is much written on the increasing pressures on the NHS due to a number of factors including our aging population, increase of long term conditions (often linked to age) and healthcare illness and diseases related to lifestyle factors such as obesity. This is coupled with the national issue of the shortages of nurses and loss in pay in real terms for nurses employed by the NHS. In 2017 the Health Foundation indicated that the UK national short fall of nurses by 2020 could be between 38,000 and 42,000. This shortage has led most NHS trusts to run international recruitment campaigns, which often focused on recruiting nurses and doctors from within the EU. However following the 2016 referendum, a vote determined that the UK was to leave the European Union. This has meant that the option of working in the UK is much less desirable for often highly skilled European clinicians.

This is a perfect storm in terms of market forces as NHS Trusts have to either use agencies to employ clinicians on temporary contracts at much greater costs than a substantive member of staff, or effectively run unsafe services with insufficient numbers of staff, or reduce or stop the services that NHS trusts are able to provide.

This situation enables the free market via privatisation to become a significant feature in terms of healthcare provision within the UK.

The financial turmoil of the NHS plus the 'scandals' in which NHS services are constantly in the headlines, have supported the neoliberalist view in favour of an increase in the number of private, for profit organisations, winning contracts to provide healthcare services. A report by the NHS Support Federation (2017) stated that in 2016/17 for profit organisations won £3.1 billion of new NHS contracts, this equated to 43% of the total value of awards advertised.

The current shift and focus on the financial aspects of the delivery of healthcare services could have a detrimental impact on patient care, incident reporting and therefore adherence with the Duty of Candour requirements. When, as there currently is, significant economic pressures within healthcare settings to effectively manage and also make savings; more transactional leadership styles can become apparent. Once these methods of leadership are in situ within healthcare settings it is less likely that organisations will actively seek out opportunities to learn and improve. In one study (McLonghlin and Leatherman, 2003) suggests that it is necessary to align and encourages a blended approach to quality and finance in order to meet overarching organisational priorities in terms of safe and effective care.

Conclusions from Literature

Throughout the literature review, a broad underlying theme has emerged which highlights the need for organisational conditions to be such that individuals within these organisations feel psychologically safe enough to raise and report an incident. This is the start of the process of Duty of Candour and importantly, opens up the possibility of supporting learning from incidents and events. There are several inquiries, including Francis (2013) that have highlighted that organisational culture is a barrier to incident reporting. The Francis Report (2013), this report highlighted that in Mid Staffordshire Hospital there was evidence that there was "an institutional culture which ascribed more weight to positive information about the service than to information capable of implying cause for concern" (Francis, 2013: 4).

Throughout this literature review the evidence base has highlighted the need in healthcare organisations for members of staff reporting an incident, to feel safe and supported, in the knowledge that there will be an appropriate and measured approach to an incident emerging. The evidence within this literature review has highlighted the need to ensure an overriding focus on learning and improvement from incidents. Within the organisational context this links to the highlighted literature from Dekker (2012) which focuses on human factors theory.

In a number of the studies reviewed one of the key themes was how patients and families reported a lack of evidence or involvement in opportunities for learning from incidents and events, to reduce the likelihood of recurrence. For example, in the research by Iedema et al. (2011) state that there was "insufficient integration of Open Disclosure with improvement of patient safety" (Iedema et al., 2011: 3). A study conducted by O'Connor et al. (2010) found that patients wanted "assurances that something is being done to prevent similar events occurring in the future" (O'Connor et al., 2010: 373). In professional practice, it is often highlighted by patients and families who have raised a complaint or where an incident has occurred, that they want assurances that similar incidents are not likely to reoccur again in the future. Key to this is the involvement of families in the investigation and learning process. In a report from CQC (2016), highlighted that "when families were involved, they told us that they were not happy with the level of involvement. Only three out of 42 (7%) respondents to our questionnaire said that they had had the right level of involvement" (CQC 2016:18).

The next chapter of this thesis outlines the research methods that have been employed in this study. Also, in the preceding chapters of this thesis the evidence base that has been collated as part of the literature review is reflected upon and triangulated with the research which is the centre of this thesis.

Chapter 3: Research Methods

Introduction

This chapter provides an overview of the research methods used to undertake this study. Within this chapter it explores and clarifies a number of key components that have been considered and implemented for this research, these include: a clear rationale for the use of qualitative, grounded theory approaches; the inclusion and exclusion criteria for the sampling and selection of potential participants.

This chapter also details the recruitment process and any barriers that were found. There is consideration of the fact this research focuses on a sensitive subject; in that discussing factors that relate directly to a patient safety incident could result in causing distress to participants. There is also a reflective approach to the potential researcher – participant impact, with a specific focus on the literature around positionality and how this applies to this research.

The chapter concludes with a step by step approach to outlining the data analysis framework, methods and tools that have been used to support the emergence of key categories.

Overview of the Study

This study is a qualitative study based on the responses and analysis of five in depth semi-structured interviews with members of staff who have 'signed off' a patient safety incident that meets the criteria for the Duty of Candour. All participants were working within roles that have an element of supervisory/ management role and that the participants have the responsibility for ensuring that the Duty of Candour is enacted as required. This cohort was chosen for this research as it ensures that all participants should have had some exposure to the organisational Duty of Candour policy. Due to participant's professional roles, they should be able to reflect on their own experiences of this process and its effectiveness in practice.

Research Site

This research was conducted in an NHS organisation in a largely rural area within the North West of England. The research interviews were conducted from November 2018 to January 2019. At the time of these interviews the organisation provided a number of different types of healthcare services including both inpatient and community mental health services, community based services including district nurses, a range of community children's services for example, health visiting and specialist services, for example community neurology services. During this research the organisation was going through a significant organisational change, due to the transfer of mental health services to other specialist provider and the merging of the existing community based services with a local acute hospital. This organisational change is important to note as it emerged as part of a key category from the interviews that were conducted.

Methodological Approach

A qualitative approach was used for this research, as the researcher was interested in the exploration of potential new theoretical paradigms linked to the Duty of Candour. The discovery of categories and themes linked to the introduction of the Duty of Candour was explored through the qualitative research method of in depth interviews with participants.

Grounded theory was selected for this study as the focus of this research considers the dichotomy of how the social and moral processes impacts on the application of the Duty of Candour within a healthcare environment. Grounded theory was evaluated as the most appropriate research method to support this study, as this research focused on the process of the statutory Duty of Candour being applied when a healthcare incident has occurred. Therefore, grounded theory provided the researcher with clear tools and a framework to use to assess and extract participant's experiences of enacting a process.

The sociological foundations of grounded theory focus on the social environment and process of the phenomenon being studied (Starks and Trinidad, 2017). Grounded theory was therefore chosen due to its ability to enable the researcher to probe

within the interview process for areas that consider how the environment impacts on the social process.

Classical Grounded Theory

The provenance of what is often referred to as the ‘classical grounded theory’ can be traced back to its originators, Barney Glaser and Anselm Strauss (1967) and the development of the seminal text, *The Discovery of Grounded Theory* (1967). The development of grounded theory came as a result and as an alternative to the hypothetico–deductive approaches which were at this time linked to sociology and had a clear focus on the testing of precise hypothesis. The creators of classical grounded theory came from two differing research backgrounds; Glaser was steeped in quantitative research methods whereas Strauss came from a backgrounded linked to research in symbolic interactionism. One of the aims of the classical grounded theory was its ability for it to be applied to qualitative research methods but that it offered, “a foundation for rendering the processes and procedures of qualitative investigations visible, comprehensible and replicable” (Bryant and Charmaz, 2007: 33).

There are a number of key elements which are central to the classical grounded theory approach. These elements include the pillars of the analysis of information through the classical grounded theory, for example categories, constant comparison, and theoretical saturation (Strauss and Corbin, 1967).

Critics of classical grounded theory state that due to Glaser’s roots in quantitative research methods that classical grounded theory focused too heavily on positivist epidemiology at the expense of elements which qualitative researchers find central to the way in which they undertake research. For example there is evidence to suggest that Glaser was an opponent of reflective practice, as Glaser saw reflective practice as a potential variable which could mean that theory would be more likely to be ‘forced’ rather than ‘emerge’. From a review of the work of Glaser and Strauss (1967), it appears that the classical grounded theory approach was very prescriptive and rule based rather than the view that has been taken in this research, that the

methodological approach to any study is simply a framework that supports and enables the emergence of new theory.

Reflexivity, for the qualitative researcher should be a hugely important part of the research process as it acknowledges and allows space for the researcher to consider the potential impact that their own professional and personal life experiences have on their research. This is of particular concern when conducting a Professional Doctorate programme of study, in that the researcher is also a member of staff (often in the same place as the research is being undertaken). The potential impact of the professional role on the interviewees and also the way in which the information received from participants is analysed, should not be underestimated.

Constructivist Grounded Theory

This study will continue to use grounded theory methods however will be more aligned with the work of Charmaz (2014) and the constructivist grounded theory. Throughout the study there is consideration of the classical grounded theory (Glaser and Strauss, 1967) and how the approach proposed by Charmaz (2014) differs and therefore how this methodology has been utilised to support the analysis of the research.

Charmaz (2014) advocates for a much more adaptive and flexible approach to the use of grounded theory. This, therefore differs from the prescriptive, rules based approach which was originally outlined by Glaser and Strauss (1967). At the centre of the constructivist grounded theory approach is the focus on social constructs and the social worlds that both the participants and researchers find themselves within. Charmaz (2014) acknowledges that a researcher cannot ever be fully neutral and the responses that participants give will often be subject to the researchers interpretations. The way in which this research, in line with constructivist grounded theory has tried to reduce the impact of the researcher on the emergence of new theory is through the use of verbatim transcribing to ensure that all words, phrases and expressions are considered in the analysis stage of grounded theory research. The final chapter of this thesis is kept for the exploration of the researchers own

professional practice and the impact that their own social world view has potentially had on this research.

The Research Process and Rigour

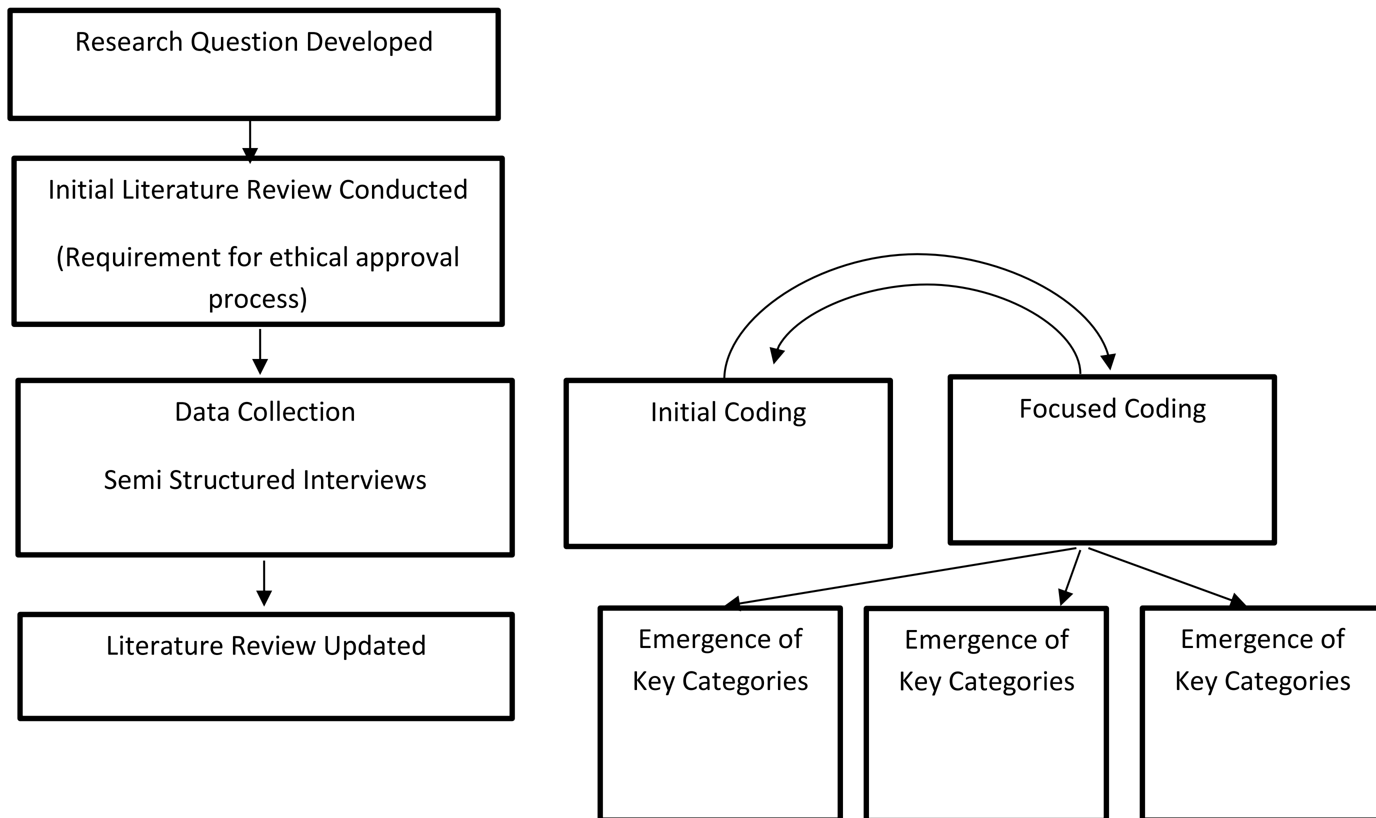
Through the use of a Charmazian focused framework to undertake the research detailed within this thesis, a number of essential steps have been taken. These are shown below in Figure 3.1. This research process was developed and closely followed in order to demonstrate methodological rigour of this research.

For this research the four dimension criteria (credibility, dependability, confirmability and transferability) adapted from the work by Guba and Lincoln (1994) was used to assess and demonstrate rigour. At each stage of the research process elements of the four dimension criteria were considered and strategies put in place in order to determine rigour in this research:

- Creditability (that the perspectives of the participants are accurately reflected, creditable and believable): this was achieved through the interviewing process, whereby an interview guide was developed, that pilot interviews were conducted, that field notes were kept from each of the interviews and that the participants were given a basic overview of the key findings;
- Dependability (to ensure that if these interviews/ research were repeated with the same cohort of participants that the same or similar findings would emerge): developed research process (figure 3.1), tables of evidence collated and analysed through both initial and focused coding methods.
- Confirmability (confidence that other researchers would confirm similar findings): development and use of reflexive journal, to ensure that any individual biases are identified and acknowledged.
- Transferability (confidence that the findings from this research can be transferred to other areas and settings): due to the small sample in this research this is identified as a limitation. However steps have been taken to try and minimise this issue through ensuring that theoretical data saturation was reached prior to the ceasing of any further interviews.

Within quantitative research the terms validity and reliability are often referred to, however these are not terms that are linked within the qualitative paradigm of research, hence the use of the word rigour, in order to demonstrate competency, in the field of qualitative research.

Figure 3.1: Research Process



It is important to acknowledge that the methodology chosen for any research should be an enabling factor rather than an obstruction to the key messages from the research to be highlighted and the emergence of new theory, this is a particularly strong feature of Charmaz (2014) and the constructivist grounded theory approach.

Alternative Research Methods

Early on in the research process other research methods were considered, most notably phenomenology. However, phenomenology was discounted due to the primary focus on the lived experience of participants rather than how the participant

is connected to social processes. A phenomenological approach might have been of value to consider if the focus of the research was to hear patient stories of when incidents had occurred and their lived experiences of these events.

It is also possible that a mixed method approach could have been chosen for this study; through the use of both qualitative and quantitative methods, for example semi structured interviews with participants and figures/ statistics that relate to the level of 'compliance' with the different stages of the statutory Duty of Candour that organisations are required to fulfil. However a mixed methods approach was not chosen, this was firstly because the evidence base indicated that organisations already report and understand their compliance levels with performance measures through regular board reports and CQC inspection reports. Therefore this information is readily available and although it may provide useful context in terms of the organisational culture, it is unlikely to give any further insight or add to the current evidence base.

The number of interviews has always been considered as a guide, interviewing ceased at five interviews as through the latter stages of analysis and coding, the synthesis of information highlighted key categories from a group of relatively homogenous participants.

Sampling

The sample of participants for this research was drawn from a pre-existing database of information that all NHS organisations hold, this relates to incidents that have been reported by a member of staff.

As this research specifically focuses on the process and impact of the experiences of incident reporting and the application of the Duty of Candour, purposive sampling was used for this research. Purposive sampling enables the selection of participants based on the research question being posed, according to Davis et al. (2007:158) purposive sampling is "the deliberative or judgemental element by selecting all

sample elements accordingly to a certain criteria". Purposive sampling has a number of different approaches, the approach that was utilised for this research was theoretical sampling. Theoretical sampling follows the grounded theory methodology, in that the approach taken to the sampling process is to conduct an interview, collect, code and analyse the data and then the next interviewee is selected based on this information (Bryman, 2015). This approach, is ongoing through the research phase, rather than being one distinct or single stage and allows the research to test the possibility of potential significant key categories or new theory. This is linked to the concept of theoretical saturation, which refer to, the point at which a category has been saturation with data and that there is not likely to be any further insights relating to this category, if additional interviews were conducted.

Participants were identified from the Trust's risk management system. This data sheet included those incidents which were reported in the period from 1st April 2017 and 31st March 2018 (inclusive).

The timeframe for this study was incidents that were reported from 1st April 2017 until 31st March 2018. This time period was selected as firstly the regulation came into place for all trusts fromApril2015; therefore it is deemed that a significant period of time had passed for this to have been embedded into practice. Secondly the timeframe needed to be relatively contemporary to ensure that participants were able to recall and describe the events surrounding the reporting and subsequent events associated with the incident. Finally, it was necessary to ensure that enough time had passed between members of staff reporting an incident to any/all subsequent investigations being concluded prior to any interviews taking place for the purpose of this study.

The level of harm from incidents is a key factor in the inclusion criteria for this study. As stated, moderate harm incidents have been selected as the focus for this research.

A decision was made in the early stages of the development of the ethical proposal stage that there would be a focus on moderate harm incidents only, rather than the full range of incidents that meet the Duty of Candour regulation. Incidents that meet

the Duty of Candour regulation range from moderate harm to death. The rationale for focusing on the lower graded incidents (for this study moderate harm incidents), is that this helps to potentially reduce the psychological impact for participants. For example if incidents that resulted in an unexpected death were also included in this study then members of staff would be required to recall memories which related to breaking significantly upsetting news to families and an increase likelihood of discussing incidents which resulted in attendance at coroners court. It was also felt that focusing on these types of incidents (unexpected deaths) may impact on the number of staff (participants) volunteering to be interviewed for this study.

In all five of the interviews conducted the participants discussed specific incidents that had resulted in harm, participants often recalled their (and their team's) upset around the incident that had occurred; however throughout the interviewing process there was no evidence of any of the participants becoming overly distressed or anxious when recalling these events and incidents.

Moderate harm incidents were discussed as part of the interview process with participants; this is detailed in the covering invite letter (Appendix B), and the Participant Information Sheet (PIS) (Appendix C). Even with these safeguards in place, there was still the possibility that participants may have become distressed or upset during the interview process when recalling the events that led to an incident being reported. In terms of ongoing support for participants the PIS also included the details of the Employee Assistance Programme (EAP) that provides a confidential support service to assist employees with personal or work-related problems for any staff within the sponsor organisation.

Therefore, it was beyond the scope of this study to consider incidents where the associated outcome was the death of a patient or service user. This is an identified limitation to this study, as it is easy to conclude that the response and reaction to an incident that has resulted in an unexpected death could be significantly different than one which results in moderate injury or illness. The other identified limitation of this study is that it aims to explore the impact and experiences of staff, rather than the patient's perspective. There are two main reasons for focusing on members of staff as participants rather than patients. Firstly, an incident occurred, whether this incident is graded as serious or less so by the organisation, the grading is, in most

cases irrelevant to the patient, the incident has still occurred. Secondly, the researcher was mindful of the level of upset that might be caused to patients/ families through the recalling of events that occurred prior, during and post incident. Finally, as highlighted in a national pilot study conducted by Iedema et al. (2008) there were issues in securing ethical approval from a number of healthcare organisations, this significantly impacted on the number of participants included in their research.

Interviews

In-depth semi-structured interviews have been used as the data collection method for this study. The main rationale for the use of semi-structured interviews was to ensure that the participant's voice and experiences are heard and are central to the research study, as stated by Sumner (2008, Patient Voices, Online) "unlike statistics, which can usefully reveal the system's experience of the individual, stories reveal the individual's experience of the system". Pepper and Wildy (2009: 18) highlighted that, "semi structured interviews facilitate a less formal conversation where both parties may interact as relative equals".

An interview guide was developed in order to support a semi structured discussion with participants. In terms of the key areas of focus, an interview guide enables the researcher to find out how the participants view their social world. A copy of the final version of the interview guide is provided in Appendix E. The interview guide was developed based on six main areas of focus that were formulated to helped answer the research question, 'understanding the impact of the Duty of Candour regulation on healthcare practice'. Each interview followed a similar structure; firstly introductions were made in terms of the researcher and the participant, with the researcher ensuring that the participant fully understood the focus on the research and had received a copy of the Participant Information Sheet (PIS) (Appendix C). The researcher then discussed the consent form (Appendix D) with the participant, confirmed that the participant was happy to continue with the interview and asked them to sign two copies of the consent form – one for the participant and one for the researcher. The next section of the interview focused on building a rapport with the participants through asking questions that related to their role and work experience,

simple questions including what their job title was, led to an interesting discovery in terms of roles and role conflict. Next section of the interview focused on incident reporting, exploring the organisational reporting culture, this set of questions was included to explore evidence that could help to understand the final aim of this study, which was ‘to seek to understand whether there is any emerging evidence that the statutory requirement is leading to improvements in practice through the learning of lessons from incidents’. These questions were also included to gain a baseline of the knowledge and exposure that participants had, had to the incident reporting system. Moreover this section of the interviews intended to start to explore with participants the organisational culture and appetite for incident reporting, including the responses and any improvements linked to the learning from incidents. Section four of the interview guide was designed to consider the framework of the Duty of Candour and if there was evidence of the statutory requirements being embedded into practice, this section of the interview linked around the study aim of, ‘to understand to what extent do clinicians understand the Duty of Candour process and its application in practice’. Section five aimed to consider the involvement of patients and family members within the Duty of Candour process. This section was developed based on the available literature of Duty of Candour and learning from incidents, which highlighted that the involvement of families within this process, particularly in terms of being involved in the learning from incidents was often very limited (Iedema et al., 2008 and Iedema et al. (2011). The final section of the interview guide aimed to explore with participants whether they had examples of where there had been improvements within services following the introduction of the Duty of Candour. This section gave participants the opportunity to reflect on the implementation of the Duty of Candour and how this had impacted on their professional practice. Questions within this section of the interview guide aimed to go back to addressing the overarching research question, ‘understanding the impact of the Duty of Candour regulation on healthcare practice’.

As part of the preparation for the research interviews pilot interviews were conducted with several members of staff to test the process and questions asked. The improvements from these pilot exercises were included in the draft interview guide. Also following each interview, the interview guide was reviewed and any areas that required further focus prior to the next interview were considered and added to this

guide. This is an important element of using interviews as a method through a grounded theory lens as it enables further exploration of potential categories and the emergence of theory. An example of this from the research conducted for this thesis was that, during the initial interview the first participant highlighted that they felt that the written letters were in fact a barrier to ongoing communication and involvement of patients and families in the Duty of Candour process. Therefore, although there was already a question included in the interview guide linked to written letters, following feedback from the initial interview there was further emphasis on this area in order to explore whether other participants had similar views on this.

As grounded theory was used for this study the number of interviews was not prescribed and remained relatively fluid throughout the interviewing. As and when each interview was completed the memos and transcripts from the interview were analysed to develop initial categories. The development of categories helped to shape the focus of the next interview. This process continued until the point of theoretical saturation has been reached, when it was felt that no further new categories were likely to emerge from the data, the interviews ceased.

Recruitment and Data Collection

For this research participants were selected and eligibility assessed through the NHS organisations' risk management system based on the reporting of a patient safety incident. The researcher made direct email contact with the individuals selected from the extracted data within the risk management system. Prior to potential participants being contacted this method was outlined to the Head of Information Governance within the NHS host organisation. It was confirmed by the Head of Information Governance that direct contact with potential participants could be made by the researcher and that by taking this approach there was no breech of General Data Protection Regulation (GDPR). This method of recruitment was also outlined to the approved ethics panel through both the University of Salford's Ethics Panel and the Health Research Authority (HRA).

In order to make an informed decision, potential participants were contacted via a secure NHS email address and details of this study were sent. Each of the potential participants received a covering letter (Appendix B) and a copy of the PIS (Appendix C). Potential participants were given 2 weeks to respond to the initial invite email at which point, if there had been no response, the researcher then followed up the initial email to confirm whether they wished to be involved or not. As this study is utilising a grounded theory method, the recruitment process was relatively time consuming, as a participant was identified, the interview conducted, and the interview was transcribed and analysed prior to the next interview taking place. The benefit of this method of recruitment was that responses that were provided during the interview were considered prior to the next interview. This provided an opportunity to reflect on the interview and shape any subsequent interviews to focus on an emerging category that needed required exploration.

For this study a risk-based approach to potential issues such as confidentiality was agreed and therefore all participants were required to complete a written consent form (Appendix D) prior to the start of the interview. Based on feedback and improvements made following the review of this documentation through the ethical approval process, additional details were included in the approved version of the consent form. The final version of the approved form included details of how information gained through the interview process would remain confidential and also the process of the anonymising of key information during the transcribing process from audio recording to the written record of the interview. As part of the consent process all participants were informed prior to the interview commencing, that all interviews would be audio recorded, and that participants could opt out of the interview being audio recorded if desired (in which case detailed notes would be made).

All participants were given the choice as to whether they would prefer for the interview to take place over the phone or face to face, this is a similar approach taken to the 100 Stories study by Iedema et al. (2011). All participants were happy to meet for face to face interviews; all of these interviews took place in a private room or office at the participant’s place of work. As face to face interviews were completed the lone worker procedures were followed (as detailed in the Risk Assessment

shown in Appendix A). There was no set time for the duration of interviews, but these interviews typically lasted up to 1 hour. Due to the level of detail contained within the audio recording from these interviews it took between 5 to 6 hours to transcribe by hand each 1 hour interview.

During the interview process, any breaks during the interviews were determined on a case by case basis. Due to the participant's role within the healthcare setting and the fact that all interviews took place at the participant's place of work, in all 5 of the interviews there were natural breaks that were required. During these 'breaks' in the interview, participants were needed to undertake a work related task, often answering a telephone call. The longest break (20 minutes) that was required was during Interview 5, when the participant was required to complete a clinical task.

Clearly the merits of audio recording of interviews need to be considered for each research topic. For this research the benefits of ensuring an accurate record of complex discussions, which focused upon sensitive subjects, outweighed the disadvantages in terms of barriers to openness. Any potential barriers to openness have been reduced through the use of a reflexive methodological journal which documented key points in the research journey, these include behaviours and narrative accounts given by participants both when the audio recorder was recording and when it was switched off, post the formal interview process.

Conducting Research on Sensitive Topics

Sieber and Stanley (1998) stated that when research is socially sensitive in its nature then the ethical issues surrounding the research often become more complex. Sieber and Stanley (1998: 50) defined socially sensitive research as, "studies in which there are potential consequences or implications, either directly for the participants in the research or for the class of individuals represented by the research". Clearly then, the concept of a sensitive topic is applicable to this study, as this research focuses on when patient safety incidents have occurred within healthcare services, this is clearly multi-dimensional in terms of potential social sensitivities. There is a significant amount of research which evidences the level of harm that occurs within healthcare services. Healthcare incidents are often due to

issues within systems and processes rather than any individual human failures (Dekker, 2012).

The incidents that have been extrapolated for the purposes of this study relate to those incidents that have been classified as moderate harm, the classification of the level of harm from these incidents is completed by the person reporting the incident and then agreed by the authorising manager. However, in terms of interviewing participants on topics which are deemed as socially sensitive the level of grading of an incident does not necessarily correlate with the personal impact for them as a healthcare professional.

The study design of this research tried to reduce the potential impact on the participants by only including those incidents which had been graded as moderate harm. It is clear from the previous account of a low/ no harm incident there is still a potential in recalling these events that may cause upset or distress to participants. Participants may well feel that there is a potential for adverse consequences and implications in even being selected to potentially participate in a study which focuses on when something has gone wrong or adverse events in healthcare services. However, these issues noted, it is important and necessary to undertake studies, which do consider sensitive topics as these studies often involve minority or marginalised groups, whose views can be missed or misrepresented in main stream media. As this study is focused on what impact, if any that the statutory requirement of the Duty of Candour has had on organisational culture and ultimately the learning and improvement following an incident occurring. There is currently an identified gap in terms of the evidence to determine what impact this statutory requirement has had in healthcare services and therefore it is deemed necessary to meet with members of staff/ participants to gain insight in to their experiences.

The socially sensitive element of this research was evident through the University's ethical approval process as it was necessary to review, amend, and add additional information on elements such as risk and confidentiality before the School's Ethics Review Panel were satisfied and the study protocol and associated documentation met the required standards for approval. Research by Ceci, Peters, and Plotkin (1985: 994) highlight the extent to which socially sensitive topics can face barriers during the ethical approval process, stating at the time of their research was

conducted that, “socially sensitive proposals were twice as likely to be rejected by human subjects committees”.

The context and institution in which any research is conducted is also an important factor to reflect on in terms of whether the study would be considered as socially sensitive. This potential issue relates to the level of power and autonomy that the participant feels they have. In this study the participants have been selected as those members of staff who have actually implemented the statutory requirements relating to the Duty of Candour, these individuals are highlighted on the extracted data set as ‘DoC lead’. When reviewing the individuals who have assumed this role, they all appear to be of similar professional levels, typically holding clinical professional roles, such as Ward Sister or Ward Manager. These roles are often the most senior nursing roles in small community hospitals or mental health wards.

Positionality

It would be disingenuous not to consider the impact that, I as the researcher can have on the responses given by participants. The consideration of the spatial conditions that I inhabit and the impact that this can have on the responses to questions posed through the interview process is a key element of reflexive practice. From a grounded theory perspective Charmaz (2014: 344) states that this includes, “examining how the researcher’s interest, positions and assumptions influence his or her inquiry”. To consider my impact on the whole research process is a discussion that focuses on positionality. In any research process, but particularly in qualitative research, as the researcher is the data collection tool, through undertaking interviews with participants. It is important for me, as a researcher to be able to demonstrate reflexivity in terms of the identification and acknowledgment of the multiple and often overlapping identities that both the researcher and participants have, reflecting on the impact that these could have on the research process. As Kezar (2002: 96) states “within positionality theory, it is acknowledged that people have multiple overlapping identities. Thus, people make meaning from various aspects of their identity”.

My positionality is that I am in a senior management position in the organisation where the research interviews were conducted. The researcher is not a clinician,

therefore in part, they were undertaking this research to explore staff views of people in managerial roles and the impact that this managerialism may have on organisational cultures.

The impact of my professional role and the way that I may be perceived by participants could clearly had an impact on a number of factors, including the uptake of participants who agreed to be involved in this research. Any issues around low uptake rates could be linked with the participant's reluctance to discuss sensitive information relating to an incident or adverse event with a member of staff who works within a senior management role. This issue was considered at length in order to reduce and mitigate any potential risks which may be perceived as a threat by participants. These mitigating actions include the development of a consent form (Appendix D), this states that all participants are required to sign the consent form prior to taking part in the study. Importantly the consent form includes that throughout the transcribing process that the participant's information would remain confidential and anonymised, unless the participant disclosed something that may cause harm to themselves or someone else, or disclosure of something that may be considered as unlawful.

Even with these safeguards in place it was clear from the interviews conducted that my positionality as a member of staff within the same organisation, may have had an impact in terms of the responses given. During the period when this research was conducted I worked within a department that focuses on the effectiveness of the governance arrangements within the organisation. This team supported front line staff when an external inspector arrives to inspect their services, hence why staff may connect my main role with 'compliance' and ensuring that the statutory requirements are fulfilled. This predetermined view by participants is likely to have an impact on the responses they gave during the interviews. This was particularly evident at the start of the interviews with participants. The answers to these initial questions tended to produce very standard answers that focused on the delivery of the statutory requirements rather than discussions that considered the principles of Being Open and professional practice.

On reflection there was also some nervousness from me as the researcher at the initial stages of the interview process. My positionality, was that I had an expectation

that the participants should understand the basic principles of the Duty of Candour. These factors could have impacted on the responses given by the participants, as highlighted by Hall (1990:18), “There’s no enunciation without positionality. You have to position yourself somewhere in order to say anything at all”.

Also in terms of identity, the participants are likely to have known that I worked in a ‘compliance’ role and therefore they may have had a set of expectations in terms of the answers that I would be expecting to hear. Participants may have therefore adapted their responses accordingly.

The impact of the responses given during the initial stages of the interviews with participants was counterbalanced through the use of follow up and sub questions, these provided more in-depth and insightful responses from participants.

Following completion of the interview process and as part of the analysis stage of this research all participants were emailed to ask to consider and confirm whether they agreed with the key categories highlighted from their individual interviews. This evaluation process enabled the participants to be further involved in the research process as well as confirming the key points that were discussed in the interviews had been recorded and categorised in a way that reflected these discussions. All participants were contacted post interview, by email and confirmed that they agreed with the broad categories which have emerged post interview analysis.

Positionality is much wider than a professional role, or professional identity. It also relates to a person’s background and experiences, their race, class gender and sexuality. Therefore, a methodological journal has also been maintained throughout the Professional Doctorate journey as an aid to reflective practice and to highlight areas where my positionality may have impacted on the responses given by participants.

Methodological Journal

A methdological journal has been maintained throughout this programme of study, to prompt further consideration of methodological views and decisions that impact on this research. Importantly this journal has also helped to ensure a reflexive practice is considered throughout the research journey to reduce the likelihood of the

occurrence of bias and preconceptions arising from the accounts drawn from the research interviews. The journal has also been used to reflect on the researchers own positionality and how this may impact on the research.

Also within this journal, broader reflections on organisational change have been documented. This has been used as a tool to reflect on the impact that organisational change has on incident reporting and more broadly on the organisational culture. When the notes on organisational change were added to the journal it was not known that this topic would later emerge as a key catergory from this study.

This journal has also been used to support the development of memos identified from each of the individual interviews conducted. Memo writing is a key element of the practice of grounded theory analysis, as Charmaz (2014: 162) states, "memo writing is a crucial method in grounded theory because it prompts you to analyse your data and codes early in the research project".

As part of the planning process, time was built into the interview schedule in order that the researcher could document journal entries or memos. These memos documented the researcher's perceptions of the interviews and also recollections of how the participant behaved, including any interesting aspects and use of body language during the interview. Keeping notes during the interview process, in whatever form, is of importance. This is firstly to ensure that all questions or lines of inquiry have been covered during the interview process, secondly to note any key points that the participants make when answering questions and any further sub questions that need to be considered or points for further exploration, and finally to ensure that if there is an issue with the audio recording equipment that the researcher has a record of the discussions.

Data Analysis Methods

Memos

This study, as most qualitative studies are, is inductive in focus and therefore this enables themes to emerge from the participant's narrative accounts rather than information being slotted into pre-defined categories. As a grounded theory approach

was used to analyse the accounts and information gathered from interviews, the analysis process commenced in line with the start of the data collection.

Written memos were also used to support the recording and analysis of responses and are an important tool from a grounded theory approach, “when an analyst actually sits down to write a memo or do a diagram, a certain degree of analysis occurs” (Strauss and Corbin 1990: 118). The concept of memoing is fundamental to the grounded theory approach. In order for this method to conceptualise the data and information from interviews, it is essential that the process of memo writing commences at the earliest opportunity in the ‘research phase’ (during the conducting of interviews). The rationale for this is because this method is used as the link between the data and information collected during the interview process and the emergence of theory, through the development of categories. There is much written (Bryant and Charmaz, 2007 and Charmaz, 2014) regarding the complexity of memo writing. As outlined by Bryant and Charmaz (2007) there are two main issues that inexperienced grounded theory researchers tend to encounter. Firstly, the researcher will produce too few memos and can become increasingly frustrated, as these memos can often seem to not link with any obvious theory. Conversely the researcher produces too many memos which can lead to the researcher becoming overwhelmed with potential categories to code the phenomenon against and a difficulty to link these categories to higher level, more abstract theory. As such an inexperienced researcher may force rather than allow the theory to emerge from the data. Unfortunately for the researcher there are no set ways in which these potential issues can be avoided, other than recognising these concerns and to some extent trying to embrace the uncertainty that a high number of memos developed in the initial stages of coding.

Coding

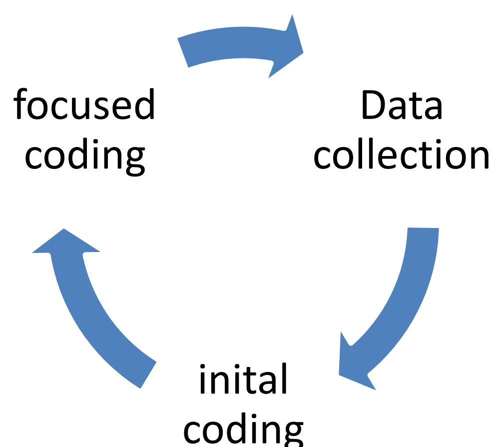
Within grounded theory there is a broad agreement around concepts such as the importance of memo writing and coding. However once this is considered at a deeper level there is much debate and disagreement, this is particularly between what is considered as classical grounded theory developed by Glaser and Strauss (1967), the subsequent work by Glaser (1992), and the work developed by Strauss

and Corbin (1990). In terms of the coding, which is conducted in order for the development of categories and ultimately the emergence of theory, classical grounded theory (1967) proposed theoretical sensitivity. Whereas Strauss and Corbin (1990) proposed a new term, the ‘coding paradigm’. There is a debate as to whether the development of the new terminology by Strauss and Corbin (1990) was simply a way for Strauss to try and distance and differentiate between the work that he had previously led with Glaser (1967) and his more contemporary work with Corbin (1990). However one would hope that other than the complex relationship that Glaser and Strauss clearly had, the seemingly constant iterations of the coding methods is actually an attempt to deal with the issue in terms of enabling the theory to ‘emerge’ from the data, which is a fundamental methodological issue relating specifically to grounded theory.

As this study uses the grounded theory approach outlined by Charmaz (2014), who states that in terms of grounded theory coding and emergence, “coding is the pivotal link between collecting data and developing an emergent theory to explain these data” (2014: 113). Charmaz (2014) conceptualises the coding of data and information through two phases; these are initial and focused coding. During initial coding small pieces of data are reviewed, these are the words and sentences given by participants. Focused coding emphasises on the frequency of codes/ words which have been identified in the initial coding stage. The aim of focused coding is to organise and synthesize large amounts of information, in order to see the emergence of key categories. An example of the initial and focused coding that has been undertaken for this research is shown in Appendix G of this thesis. Charmaz (2014) labels focused codes and coding as the start of the development of categories, “treating focused codes as tentative categories prompts you to develop and scrutinise them” (2014: 189).

Through a grounded theory lens, the data analysis and feedback is seen as an iterative cycle, this is often referred to as ‘constant comparison’. The below chart demonstrates the methods employed during this study:

Figure 3.2: data analysis and feedback cycle



In this study all analysis and coding has been completed by hand, by the researcher. In the initial research proposal and other documents related to this study, it had stated that coding would be completed through the use and with the support of an electronic programme such as NVivo. However, this was re-considered when the analytical process commenced as the researcher wanted to stay as close to the data as possible, this was achieved through coding the data by hand. As a small number of in-depth interviews have been completed for this study, this type of coding was highly appropriate and manageable; however, it is acknowledge that if a larger number of interviews had been conducted then programmes such as NVivo would have been a useful application to utilise.

Categories

From a classical grounded theory approach, Glaser and Strauss (1967) describe categories as “conceptual elements of a theory” (1967: 36). One of the key elements of grounded theory is the need for any categories from the evidence collated to emerge rather than be forced. The ‘forcing’ of information into pre-defined categories is more akin to quantitative research methods. Categories are developed from review of the phenomena which is gathered from interviews for example. Categories gain a higher level of abstraction and conceptualism through constant comparison, which is accomplished through the initial and focused coding stages. Constant

comparison is an iterative process of reviewing information to develop a category based on significant evidence.

The aim of constant comparison is a mechanism to challenge and refine theory and as a potential safeguard to the simplification of positive evidence as confirmatory. From a classical grounded theory approach theoretical saturation has significant prominence and central to data analysis. From Glaser and Strauss's perspective (1967) theoretical saturation is used to describe the end point of analysis, in which there would be no further gains in continuing with the research as the same categories and theory would continue to emerge, "no additional data are being found whereby the analyst can develop properties of the category" (Glaser and Strauss 1967: 61).

However, Glaser (2001) states that theoretical saturation is more than seeing the same events or accounts multiple times, he states, "saturation is not seeing the same pattern over and over. It is the conceptualization of comparisons of these incidents which yield different properties of the pattern until no new patterns emerge" (Glaser, 2001: 191). All researchers who subscribe to undertaking research through a grounded theory lens need to understand the importance of theoretical saturation in terms of the direction given through the seminal work by Glaser and Strauss (1967). Nevertheless, there is still much discussion and disagreement amongst grounded theory methodologists. Charmaz (2014) chooses not to be drawn on a specific view around the necessity of achieving theoretical saturation within grounded theory research. In fact Charmaz (2014) indicates theoretical saturation should be considered on a case-by-case basis.

Due to the grounded theory methods employed to undertake this research and the focus on reaching theoretical rather than data saturation, the impact on the small sample size is somewhat mitigated. Linked to data saturation is the consideration of sample size. The focus for this research is on the sample 'adequacy' (Bowen, 2008) rather than sample size. The adequacy of the sample size has been determined on the basis of the identification of new categories through interviews conducted in the latter stage of the research phase of this project. The more contemporary, open-minded and pragmatic approach outlined by Charmaz (2014) highlights that there is

still much debate and disagreement in terms of what data saturation actually means when applied to qualitative research, particularly in terms of the sample size, this is in part due to the lack of guidelines for determining data saturation. For the majority of research proposals it is necessary to include a sample size; however how would the researcher know at this stage whether more or less interviews are required in order to reach theoretical saturation? This is unknown until the interview process commences. On this matter, Bowen (2008: 140) states that, “the researcher does not seek ‘generalisability’ or ‘representativeness’ and therefore focuses less on the sample size and more on sample adequacy”.

Often in grounded theory studies it is highlighted that, interviews were undertaken until such a time as when theoretical saturation was achieved; however this is a somewhat weak statement. This statement lacks any basis for someone external to the research process to assess whether theoretical saturation has been achieved as no guidance has been provided in terms of the methods and interpretations used to assess data saturation. For the research undertaken, which is described in this thesis, 5 semi- structured in-depth interviews were completed, with this small number of interviews it would be difficult to evidence that theoretical saturation has been achieved. Yet, through the process of transcribing, coding and the development of categories from the data the researcher is confident that no new categories would emerge if further interviews were conducted. This is evidenced through the emergence of the following key categories, which are explored in detail in the Discussion Chapter of this thesis:

- Hybrid professional-managerial roles
- Organisational Culture
- Organisational Practice
- Organisational Change

Confidentiality

As citied in many research journals and texts, confidentiality is the most significant potential ethical issue in qualitative research. This is of particular significance when the research focuses on a sensitive subject, as stated by Ensign (2003: 45), “in

qualitative research, breach of confidentiality and the resultant invasion of privacy are usually the greatest risks of harm”.

Confidentiality in this research has been maintained through the following safeguards:

- All participants received a copy of the PIS (Appendix C) prior to the interviews taking place, this detailed how their information would be used and stored;
- The researcher is up to date with Information Governance Training and GDPR (2018);
- Room bookings for interviews were booked in the researcher’s name or else a generic term used for these booking so no one else is was aware that the interviews were taking place;
- In order to accurately capture all of the information provided during the interviews, an audio recorder was used. All participants were required to complete and signed the written consent form (Appendix D) prior to the interview taking place to state that they were happy to be recorded. All participants agreed to their interviews being audio recorded. During the process of transcribing the information from the interview, the information has remained confidential and anonymous. In order to protect the participant’s identity, pseudonyms have been used for the participant’s name, place of work and other identifying features have been removed from the transcripts and subsequent documents.
- As stated in the PIS (Appendix C) and the written consent form (Appendix D) only a generic overview of findings will be provided to the supporting organisation rather than any specific cases that could identify individuals or place of work. Grounded study analysis will support the maintenance of confidentiality. Grounded theory analysis aims to identify the themes from responses rather than focusing on individual accounts.

Informed Consent

There are a number of agreed ways in which this study is able to evidence that informed consent has been gained from participants prior to any interviews taking place as follows:

- The PIS details the purpose of the study, advantages and disadvantages of being involved in the study and how their responses will be used (Appendix C). The PIS was emailed to all potential participants prior to taking place in any interviews.
- Participants were given a further overview of the research scope and process at the start of the interview.
- All participants signed a written consent form and were given a copy of the signed version of this form (Appendix D).
- At the start of the interview process all participants were reminded that they could withdraw from the study at any time; however that the information provided through the interview would be used in the research unless specifically requested that it was not included, this was up to 1 month after the interviews have been conducted. This is also documented in the written consent form (Appendix D).

Procedure for Selecting Participants

The participants for this study have been selected via an NHS Trust's risk management reporting system. All NHS Trusts are required to report incidents, including patient safety incidents; all Trusts have an electronic reporting system in place for members of staff to report incidents. In the NHS Trust which is the focus for this study, it is regarded as standard practice and is highlighted in the local organisational Duty of Candour policy, that all staff should record incidents which relate to the Duty of Candour in the electronic incident reporting system, "all Duty of Candour investigation reports, copy of letters, notes of discussions etc. must be attached to the incident in Ulysses" (Being Open and Duty of Candour Policy, 2018: 2).

For this study, participants were therefore identified via the risk management system. As agreed as part of the study design a report was requested via the incident reporting team, with the following parameters in place, in order to meet the agreed criteria for this research:

- Reported healthcare incident that has occurred within the healthcare trust, based in North West England;
- The incident was reported within the timeframe of 1st April 2017 and 31st March 2018;
- The incident meets the criteria for a notifiable safety incident;
- The incident graded was as moderate only;
- All/ any associated investigation processes have been completed.

Sample Size

The dataset for this study was extracted from the incident management system on 23rd October 2018. Within this extract there was a total of 91 incidents, which met the criteria for this research. It should be noted that the dataset was extracted on the bases of the application of the Duty of Candour, rather than the member of staff/ potential participant who completed the Duty of Candour requirements; therefore the dataset did include duplicate records in terms of staff names.

Of these a total of 38 incidents were excluded during the initial review of the dataset, this was due to the following reasons:

- 17 incidents/ records were excluded as they related to services that had been transferred to another organisation as of 1st April 2018. Therefore members of staff / potential participants could not be approached as additional ethical approval would be required from their new employing organisation;
- On further review 2 incidents did not meet the criteria for a 'notifiable patient safety incident':
    - 1 incident related to a needle stick injury to a member of staff and therefore as this did not relate to a patient safety incident, the record was excluded;
    - 1 incident related to a safeguarding incident, the description of the incident stated that it was likely that the harm to the child was due to 'non accidental' reasons from a member of the child's family. Therefore, it was deemed inappropriate for the Duty of Candour to be applied to this incident. This incident demonstrates the level of

complexity and understanding required to effectively meet the Duty of Candour regulation. The complexity of incidents and how this relates to the application of the Duty of Candour is explored further within the Discussion Chapter of this thesis.

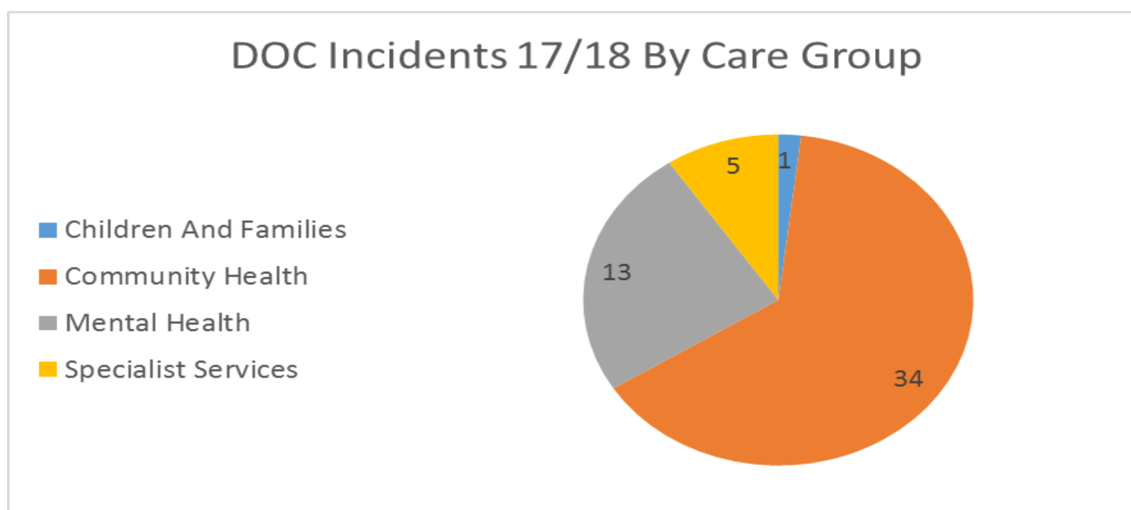
- A further 19 incidents were excluded as although the ‘actual impact’ of the incident was recorded as moderate harm only, the severity of these incidents, included incidents that had a harm levels other than moderate recorded (incidents that had a severity grading of minor, major, catastrophic, or information left blank).

The total sample size once the above exclusions had been taken into account was 53 Duty of Candour incidents. Interviews commenced and continued until such a time as when significant correlation of categories had been identified and therefore theoretical saturation achieved. For this study this related to 5 participants/ interviews.

Sample Characteristics

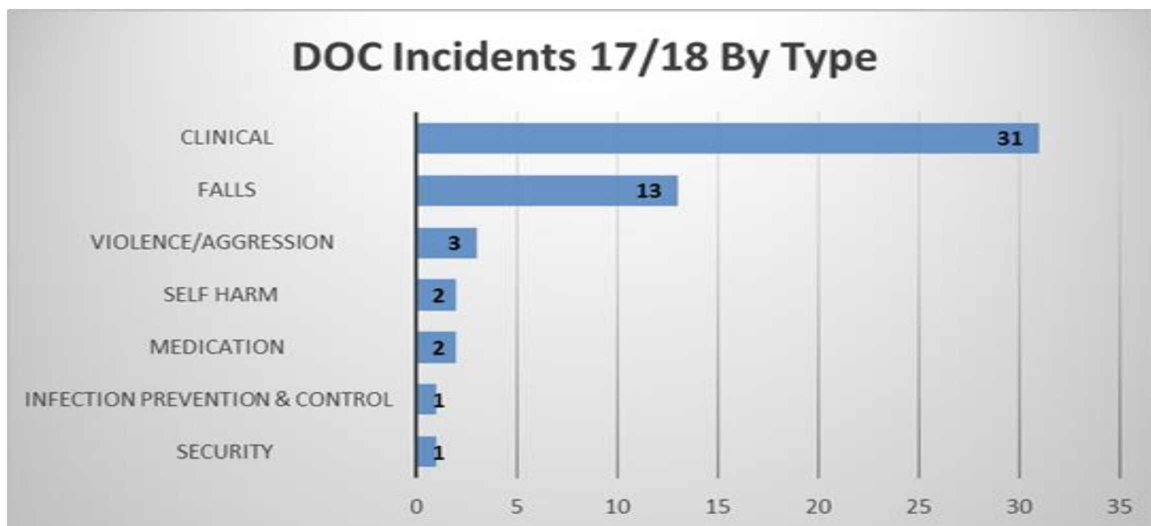
The NHS organisation in which this study focused provides community services for children, young people, and adults. Operationally this organisation was split into 4 care groups: community health, mental health, specialist services, and children and families. In terms of the sample extracted for the purposes of this study community services had the largest proportion of incidents which had evidence of Duty of Candour being reported, followed by mental health care group (as shown below in Figure 3.3). This was a predicted characteristic of this sample, as these are the care groups that contain the highest number of staff and have the highest amount of patient contacts per annum, hence the correlation between the overall higher number of contacts and the increase in the likelihood of an incident occurring and being reported.

Figure 3.3: Duty of Candour incidents by care group for the reporting timeframe of 1st April 2017 and 31st March 2018 (data extracted from risk management system: October 2018)



Within the risk management system, incidents are catergorised by the member of staff who reported the incident. In the data extract used for this study the largest proportion of incidents related to 'clinical' incidents (31 incidents) and also incidents which related to patient falls (13 incidents) (as shown below in Figure 3.4). The majority (85%) of the clinical incidents related to reported incidents of pressure ulcers that had occurred within a community service (ie, district nursing service or community hospitals), both of these services are operationally located within the community health care group. Falls was the next highest catergory within this sample; these incidents occurred across both community health inpatient (community hospitals) and mental health inpatient services. The Duty of Candour is determined at the stage when the manager of the person who has reported the incident, reviews and signs the incident off.

Figure 3.4: Duty of Candour incident by type of reported incident (data extracted from risk management system: October 2018)



As this research was conducted through a grounded theory lens the number of participants included (n=5) was based on the emergence of key catergories and the ability to be able to demonstrate constant comparison and theoretical saturation achieved. The manual transcription was conducted directly after each interview, this process highlighted the emergence of key catergories and also that no new catergories were emerging through subsequent interviews. This indicated that the research was moving towards the point of theoretical saturation and therefore there was confidence in the consistency in the responses given by participants.

If it was felt that additional participants were required for the study then other methods of recruitment would have been employed for increasing the number of responses from community based staff. These additional recruitment efforts could have included visiting the office base at the start and end of shifts and/ or informing potential participants about the research via advertising material such as posters and flyers.

Each potential participant was given a pseudonym, this was added to the dataset spreadsheet and all research correspondence.

The rationale for the participants who declined to be involved in this study was as follows:

- Anne (related to 2 incidents): potential participant stated that they were due to retire in the next few days and therefore did not wish to be involved;
- Jean (related to 2 incidents): potential participant was on maternity leave;

- Katherine (related to 1 incident): potential participant left the organisation;
- Emily (related to 1 incident): no Duty of Candour lead identified;
- The was no response from the other 4 potential participants (Penelope, Harriet, Sarah and Jane) that were identified – all nil responses related to community based staff who had reported a pressure ulcer incident of moderate or above harm.

Conclusion

This chapter has outlined the research methods that have been used to support interviews being conducted and analysed, key to this is the use of grounded theory methods. As noted in this Chapter the use of the guidance and methods highlighted through Charmaz's (2014) body of work has been utilised as a framework for this research.

As the research that is described within this thesis focuses on a sensitive subject, this chapter clearly outlines the safeguards that have been identified and established in order to reduce any harm to participants who have agreed to be interviewed for this research. These safeguards include a focus on moderate harm incidents only. This reduces the likelihood of discussing with participants any patients that have subsequently died following a healthcare safety incident occurring.

The next chapter is the Discussion Chapter, this focuses on the analysis of the narrative accounts shared by participants and the development of key categories and themes from these responses

Chapter 4: Discussion

Introduction

This chapter focuses on the responses gathered through the interviews conducted with participants. At this early stage of this chapter, it is useful to briefly introduce each of the participants in terms of background information that relates to their work setting and professional background. At the time of this research all of the participants were employed by the same employer, however staff were aware that the organisation that they worked for was planning to merge with another local large healthcare organisation. The importance being that at the time when this research was conducted these two organisations were planning to merge and therefore within the responses to interview questions participants did raise some concerns regarding these organisational changes.

Each of the participants was given a pseudonym name, the first interview conducted was with Penny.

Penny

Penny has worked as a ward sister in the same community hospital ward for a number of years and has been qualified as a registered general nurse (RGN) for over 10 years.

The types of patients that are seen within this community hospital include patients that are considered as needed further hospital based care ('step down' care) following an operation for example or people who are normally reside within their own home but require some intensive care following a fall at home, for example ('step up' care). The patients in all of the community hospital settings tended to be older people aged 75 years and above.

The reason why Penny was included in the initial sample for this research was due to the fact she had reported an incident that had trigger the Duty of Candour process. This incident related to a fall, which occurred in the community hospital. The patient who fell was transferred from the community hospital to the local acute

hospital for assessment and treatment. This incident was categorised as moderate harm.

Debra

Debra is an occupational therapist working in both community and hospital roles. Debra primarily works with patients who require rehabilitation and support after suffering from a stroke. When asked more about her role Debra that there was a number of different functions within her role but that she took the ‘clinical’ lead role. Debra has work in her current role for over 5 years and previously worked in a similar role but in different NHS organisation.

Debra had previously reported an incident that met the criteria for the Duty of Candour. This incident related to a fall that had occurred whilst members of her team were supporting a patient have a shower. There were no significant injuries to the patient. This incident was categorised as moderate harm.

Ruth

Ruth works as a registered general nurse (RGN) who works within a community hospital. Ruth has worked primarily in community healthcare settings for over 20 years. Ruth has been in her current role for over 5 years. Ruth undertakes a similar role to Penny, however in a different geographical location.

The incident that Ruth had reported, related to an unwitnessed fall, where a member of staff found a patient on the floor. The patient was transferred to the local acute hospital for assessment and treatment.

Tina

Tina is a registered mental health nurse (RMN) and worked in a mental health inpatient ward. Tina had worked on this particular ward for over 3 years and previously worked in other mental health care inpatient wards. The ward that Tina worked on focuses mainly on patients who are older adults who have a functional mental health illness (i.e., not dementia related).

Tina had reported an incident where a patient had fallen during the night in the bathroom and was found by a member of staff. The patient was taken to the local acute trust for an x ray and further treatment. This incident was categorised as moderate harm.

Gill

Gill works in a community hospital setting and is a registered general nurse (RGN). Gill has worked within her current role for less than 5 years. Gill works in a similar environment to Penny and Ruth however in a different geographical location and in a service that is undergoing significant changes, for examples starting to treat patients as day cases who would have previously been seen within an acute hospital setting.

The incident that Gill reported related to a patient who had fallen whilst in the bathroom. There were concerns from staff that this fall may have resulted in a potential hip fracture and therefore the patient was transferred to the local acute hospital for assessment and treatment. This incident was categorised as moderate harm.

Now that the participants have been introduced to the reader, the main focus of the remainder of this chapter is a discussion of the themes that have emerged from the analysis of the interview. The themes from interviews have emerged through initial and focused grounded theory coding. Throughout the analysis of the interview transcripts and the emergence of themes, quotes and references from participants are highlighted in order to provide evidence of the provenance of claims.

An example of the narrative transcript and associated coding is shown in Appendix G; Venn Diagrams are also shown in Appendix I to demonstrate the logical connectivity between groups and the overlap of categories.

The analysis and coding of the interview transcripts has led to the emergence of four key categories:

- Hybrid professional – managerial role
- Organisational Culture

- Organisational Practice
- Organisational Change

Hybrid Professional - Managerial Roles

From the analysis of the interview transcripts there was an overarching category in terms of professional identity. This was an area of importance that was identified early on in the analysis process as it was highlighted as a potential area for further review from the initial interview which was conducted. Therefore, as per grounded theory method, the interview guide was reviewed to ensure that the area of professional identity, including job title, was discussed at each subsequent interview.

During Penny's interview she highlighted a number of key points, firstly when discussing her professional role and job title, Penny emphasised a point in regards to professional identity, which had not been previously considered. Penny had worked as a ward sister in the same community hospital for a number of years and has been qualified as a registered general nurse (RGN) for over 10 years. When asked what her job title was, Penny stated that all of the leads within the community hospitals had been given a choice as to what their job title should be, either ward sister or ward manager, Penny had chosen ward sister. During the interview Penny reflected that she had chosen this as a job title as, this linked directly with her clinical background and she felt that this was important for patients and families, stating that:

> "Some wards have ward managers and some have ward sisters. But given my experience in the past of being a ward manager one patient said to me 'what's your role' and I said I am ward sister, so the elderly refer to a ward sister has having a nursing background and they feel that a ward manager is a manager" [Penny]

It was evident from a number of the interviews conducted that some participants had a stronger view on the differences between the roles of 'managers' and 'nurse sisters'. Participants who worked within community services all highlighted that they had been given the choice in terms of their job titles, either ward manager or ward sister. All the participants from community services had chosen ward sister as their

job title, with the rationale given for this choice that the patient group that they tended to work with, identified better to job titles which were linked with nurses' professional hierarchy (such as, ward sister, matron).

A further example of this was given by Ruth. Ruth works as a registered general nurse (RGN) who works within a community hospital. Ruth has worked primarily in community healthcare settings for over 20 years. Ruth has been in her current role for over 5 years. Similarly to Penny, Ruth stated that they had been given an option in terms of taking either the job title of 'ward manage' or 'sister', Ruth chose 'sister', stating that:

> "We were told that we could decide for ourselves and I'm old fashioned so I like 'sister' but then people think of me as the manager of the hospital" [Ruth]

In the interviews conducted there appeared to be an underlying negative tone in regards to 'management' or management roles specifically in terms of the needs of nurses to follow a specified professional hierarchical structure, from nurse to sister to matron. This was highlighted in the interview with Gill. Gill works in a community hospital setting and is a registered general nurse (RGN). Gill has worked within her current role for less than 5 years. Gill stated that her job title was a ward sister and the rationale for this was that:

> "I think some people still call themselves team lead, which is technically what we are but in the world of nursing we have specific titles for things, sister, matrons" [Gill]

Gill expanded on the name of the role and professional identity stating that in the world of nursing that there are specific titles for different roles i.e., sister and matron and also highlighting the association with the different roles in terms of colour of uniforms:

> "It's similar to how we wear the different coloured uniforms, so they can see who is in charge, who is a staff nurse" [Gill]

Debra is an occupational therapist working in both community and hospital roles. When asked more about her role, Debra said that she undertook a number of different functions in her role but that she took the ‘clinical’ lead role stating:

“One is more operational but I’m – well I’m clinical – it’s a mix of management and clinical” [Debra]

In research by Sartirana (2019: 634) he stated that where there is a clear requirement for hybrid roles, that the recruitment process must be carefully considered to ensure that the selection of the best post holder to these roles, “it is clear that a careful selection of candidates for hybrid positions is of paramount importance, and whenever possible, it is vital to find management-oriented professionals”.

Interesting, in the interview with Tina, who is a dual training (physical and mental health nurse) and works on an older adults mental health ward, Tina didn’t raise any points regarding her job title, which was ward manager. This could potentially be due to differences in professional hierarchy between mental health and physical health nursing.

The below quote from an interview conducted as part of this research identifies an internal conflict that Penny had in terms of nursing versus her managerial role:

> “Being a nurse with young children all I needed to know was that my children were cared for and if that worry is away from them then they can concentrate on work. I’m not regimented or managerial in any way, I am fair and I am a manager when I need to be but that’s only in the extreme circumstances” [Penny]

This highlighted again, the importance of professional identity and the preference towards a job title that identifies the person as a clinician rather than a manager

The above quote highlights the dynamics and often the internal tension of identity and role. In this case the dual identity of the requirement to be both a nurse and manager. This internal dilemma is linked to role conflict and hybrid roles. The multiple roles that nurses are now require to fulfil link with organisational agency and

its three core concepts of professionalism (O'Reilly and Reed, 2011), which prioritises on professional expertise; managerialism, with a focus on managerial control and leaderism, which prioritises leaders in order that they can inspire others.

This links back to literature and research by Breit, Fossestøl, and Andreassen (2018: 42) who stated that "professional managers are able to use their expertise, legitimacy and social capital to transform established professional practices, values, and identities in ways that non-professionals are incapable of".

Role conflict is when two incompatible roles are projected into one occupant, often this means that either one of the two sets of expectations of the roles cannot be fully met. In incident reporting and the application of the Duty of Candour, this role conflict, could manifest itself through a situation whereby a nurse has a professional duty to report and investigate an incident however as a manager of a ward, by reporting an incident they may be concerned that they will face sanctions or in fact have to discipline a member of staff.

The group of participants that this study focuses on all came from the same homogenous grouping in terms of level of seniority, in that although some participants had differing job titles they were all performing similar, what could be considered as hybrid, clinical and management roles. They were all lead nurses or Allied Health Professionals that were responsible for the clinical care delivered within the ward environment that they worked within. Participants had a management role in terms of the management of staff and budgets. As Penny highlighted:

> "My position on the ward is to oversee patient safety, as well as staff safety, making sure that they are all up to date with their mandatory training, making sure that they are up to date in terms of policies and procedures, all patient risk assessments are completed for the patients regarding falls, Waterlow, MUST tools. Making sure that the records are up to date. Trying to manage the budget and spend (pause) are within my limits, preparing for CQC, making sure the ward is fully staffed and then filling blanks when there is sickness or annual leave" [Penny]

The quote from Penny clearly demonstrates the dual role of a manager and a clinician, undertaking both managerial duties such as managing sickness absence and purely clinical roles including the completion of patient clinical risk assessments.

These findings also link to the evidence base that focuses on identity theory. This theory is often linked to the sociological theory of symbolic interactionism and the work of Mead (1934) "a durable and distinctive sociological perspective that stresses the importance of the meanings people give to their activities" Dennis and Smith (2015: 352). Through an identity theory lens, in terms of incident reporting, nurses are more likely to incident report as their professional identity is tied to social and professional norms and the expected behaviour and morals of a person who fulfils these types of roles. For example within the professional code of conduct for nurses (NMC, 2015), it outlines the requirement and expectation of the professional Duty of Candour to "be open and candid with all service users about all aspects of care and treatment, including when any mistakes or harm have taken place (NMC, 2015:13).

There is also a clear link between how nurses view themselves in terms of their professional identity and the view of the general public, often seeing nurses is honest and caring individuals.

Organisational Culture

In Gill's interview she highlighted concerns in regards to the response when incident and events occur, as when as asked about using the risk management system to report an incident, she stated that:

> "No the system itself I find very easy however it is difficult when I incident report things and I don't get a response" [Gill]

During her interview, Gill went on to describe an example of where she had reported an incident but she continued to receive no response or support from senior managers, therefore she:

> "Yep so what I continued to do was kept putting incident forms in it but I gradually increased the risk rating until I got an appropriate response" [Gill]

Penny described the differences in organisational culture and focused on an example whereby there was a lack of feedback from the local acute trust when an incident had occurred. In the example given a patient had accessed both community and acute services, Penny indicated the different approaches in place for inquests:

> "My statement was 18 pages long so I didn't get called (to inquest) but the sister on the ward (acute trust) where he died, her statement was 2 pages so she got called and she got grilled. So having all of that information helped" [Penny]

In the Department of Health report, An Organisation with a Memory (2000), it stated that in terms of organisational culture and its impact on safety "this is important for two reasons. First, people may come and go, but an effective safety culture must persist. Second, culture is perhaps the only aspect of an organisation that is as widespread as its various defences; as such, it can exert a consistent influence on these barriers and safeguards—for good or ill" (Department of Health, 2000: 35). Also of importance was the warning from the Berwick report, which stated "culture will trump rules, standards and control strategies every single time, and achieving a vastly safer NHS will depend far more on major cultural change than on a new regulatory regime" (2013:11). Berwick (2013) highlighted these concerns in reference to the recommendations that had been agreed through the Francis report (2013). These recommendations included a significant refocusing and restructuring of the healthcare regulator, CQC.

As described within the literature review chapter there is an emerging evidence base (Iedema et al., 2008, and Iedema et al., 2011) in terms of national and international research on the impact that organisational culture has on incident reporting. Although there were no specific questions regarding organisational culture within the initial interview guide, within all of the interviews conducted, the participants focused on various elements that could be considered as organisational culture and it's linked to safety and incident reporting cultures. The concept of culture was used by participants to highlight the differences in terms of conflict of values and priorities between the organisations that were currently employed by and the neighbouring acute hospitals. It was clear from the responses that participants provided that were some concerns and trepidation from the impending merging of the two organisations.

Interestedly, interview with Tina she provided a different response and view in terms of the organisational culture and the impact on patient safety. As Tina worked in mental health services, the services that she worked in was not part of the organisational merger that is described here. In Tina's interview she said described the systems that were in place in order to report, investigate and learn from incidents:

"So we all use Ulysses, electronic system and the staff are aware and use this system. Any untoward incident is recorded on that system, those will come primarily to me - I have got 2 clinical leads who will do them if I'm not here but then they will come to me to review, add any actions and ultimately sign off. Sometimes we send them back to people if we required more information or they are not quite clear about something, we do now, when we can add any debrief or learning lessons so they are all saved and shown on the quality and safety dashboard, so that information is available to us so that we can review that, spot any trends, any specific issues, trends of time, times of day, where in the building so it does allow us to get an overall view of the types of incidents that we are having" [Tina]

International research and literature on human factors thinking (Reason 2000 and Dekker, 2012) highlights the connection between organisational safety cultures and the impact on incident reporting. Dekker (2012) introduced the concept of just culture, Dekker conceptualised this as balancing safety and accountability and focuses heavily on understanding whether a person was culpable of an act or omission which led to a patient safety incident, or in fact were they part of a wider system and or processes in which there were weaknesses. Organisations which adopt the principles of just culture and human factors theory do so in an attempt to move away from transactional leadership styles and cultures, which often focus on the blame or punishment of individuals, at the detriment of truly exposing the underlying reasons of why an incident has occurred.

Prior to human factors thinking being considered within healthcare an assumption could have been made that an incident or error had occurred due to simple human error i.e., the member of staff was to blame and therefore there needed to be some sort of sanction for this member of staff.

An example that has been given through the research process was an incident that had occurred within a community nursing team. This team had significantly less staff than was required to conduct all of their visits so a visit had been completed as an ‘extra’ by the member of staff on their way home from work. The member of staff had visited this patient before and had administered insulin before, so there was a level of familiarity. All checks were not fully completed prior to the administration of the drug. At that time there was nowhere in the patient’s hand held record to file old prescription charts, this led to an old chart being used to administer a drug for which the type of insulin had been recently changed. In this example no harm had been caused to the patient. However, in the example described a human factors approach was used to complete this investigation, and, therefore one of the effective simple, low cost solutions which was utilised to help resolve this issue was the inclusion of a brown envelope in the patient files. All old prescription charts are now held within the brown envelope and then this is sealed; this is an example of where a simple change to process can lead to a significant positive impact on patient safety. If human factors theory had not been applied to this case, the automatic default could have been for the members of staff involved in the incident to have sanctions applied to them in terms of their professional practice.

Within the interviews conducted, a common theme arose in terms of the positive organisational culture of incident reporting within the organisation that the participants worked within. In the interview with Tina, she described some of the work that has taken place and has impacted positively on organisational safety culture. Tina is a registered mental health nurse (RMN) and worked in a mental health inpatient ward. Tina had worked on this particular ward for over 3 years and previously worked in other mental health inpatient wards.

> “I think people are more likely to report now, I don’t really know why that is… there has been a lot of work done to explain that these incident forms are not part of a blame culture, not to pick fault with people but to be used, obviously if there has been something serious amiss then that would have to be addressed but we want to use them primarily as a learning tool” [Tina]

There is evidence to suggest that there is a more widespread culture of learning from incidents in terms of the organisation where these participants were recruited from.

NHS Improvement published the national Learning from Mistakes League (2015) which considered a number of different factors, including the reporting and response to incidents and rated all NHS organisations in one of four categories from outstanding to inadequate. The organisation where the participants were recruited from was rated as 'good' in the Learning from Mistakes League (2015), whereas the acute trust that was referenced earlier was rated as 'inadequate'. One of the key factors that the Learning from Mistakes League (2015) considered was the number of incidents that an organisation reported and whether there was any evidence of underreporting. In the interview with Penny, she highlights the differences between the two organisations in terms of incident reporting, in an incident where a patient is transferred from the acute trust to the community hospital. In this incident the patient has come with an arm band with the incorrect details, which refers to different patient. Penny feels that this should be incident reported, in order that that there can be learning and to reduce the likelihood of this incident reoccurring in the future:

> "I feel like I have done that incident form, I have highlighted that a lady has come with a man's name band, I tried to ring the ward, I tried to ring the matron, and I eventually got in touch with another sister from another ward that went round to speak to the matron. The matron said, I know you had to incident report it but the lady could tell me her date of birth and I was thinking, she can't, she is a dementia patient, she doesn't even know where she is now and it was a student that put the name bands on. That's where it ends with them."

Part of the reason for underreporting of patient safety incidents is linked to the fear of blame and reprisal resulting from reporting of incidents. In one UK study, in the sample that was considered, showed that almost 13% of the medics who responded to the survey (581 medics included in the survey) stated that a fear of blame was one of the reasons for not reporting an incident (Archer and Colhoun, 2018). Other factors linked to underreporting or non-reporting of incidents included that clinicians don't feel that their concerns are listened to or acted upon, so feel that reporting these incidents is meaningless in terms of learning and improvement. In fact, one international study highlighted that the issue of underreporting of incidents in the USA can range from 50% - 96% of incidents not reported annually (Barach and Small, 2000: 759).

The non-reporting of incidents can lead to similar incidents or incidents occurring that lead to greater harm to occur because there has been no opportunity to reflect and learn from a previous incident. For example, without incident reporting of the insulin medication error (that was described earlier), it could reoccur again in the future and lead to significant harm to a patient because other staff weren't aware of the incident occurring. In the interview with Debra, she highlights that a lack of time to incident report had been an issue for her and her team:

> "We don't incident report as much as we should as we do understand that there is a value in recording the near misses, to try and spot the trends, however we are just a bit busy so unfortunately it tends to be the 'something has happened' when it has gotten to that point."

Any missed opportunity to learn within safety critical organisations such as healthcare feeds into the neoliberalism view that there is a need for a free market via privatisation, where consumers (patients) have the option to choose the safest, high quality service available to them. For example some private healthcare providers now advertise that they are able to see patients on the same day for concerns such as investigations relating to cancer symptoms. For the comparable service within the NHS there is a two week rule, meaning that often patients using state services have to wait up to 14 days to be seen.

The main issue that emerged within this category was the potential differences between two organisational cultures and the impact that this could have on incident reporting. There were also some clear communication differences and the impact that these communication issues can have in terms of patient care. In the interview with Penny she describes a situation where a patient was discharged from acute hospital services into the community setting for palliative care:

"What we are reporting through the incident forms is the lack of communication and the poor transfers that are coming and that isn't helping the family or the patient as we didn't have a doctor in on the Saturday which was hard for the family as we had to discuss with the acute trust to get the death certificate. The patient hadn't been seen by our doctor on the ward which is hard for me as on a Monday – Friday we do have a doctor on the ward and under normal circumstances they would have been seen on the ward but having that delay for that family and the upset of them having

to go and collect a death certificate from the acute doesn't contribute to therapeutic end of life care for me" [Penny]

However the testing of the theory of the differences and impact of differing organisational culture is limited as this research project focused on only one of these organisation that was part of the planned merger.

Organisational Practice

Methods of Communication: Written Letters

In 4 of the 5 interviews conducted for this research, participants identified that written letters were a barrier in terms of effective communication with patients and families. Gill described that she was really disappointed that the NHS had got into a position where the formal Duty of Candour was required, highlighting that in her view:

"It should just be our standard to pick up the phone and the openness of that culture" [Gill]

In the interview with Penny, she said that:

> "It gives the patient and the family, my details in black and white, which then put the onus on them if they want to meet with me beforehand. Whereas it would have been the other way around previously." [Penny]

The issue that Penny raises in her interview, terms of the way in which the letter is phrased puts the onus on the patient or family member to contact the services rather than the services actively working to try and support a family when an incident has occurred. The standard letter indicates to the patient or family that an incident has occurred and if they wish to discuss further for them to get in touch with the Nursing Sister or Ward Manager. Whereas the participants in the research felt like the services should be actively engaging with families for them to know more about the incident and how the organisation will learn and improve to reduce a similar incident occurring again in the future.

The findings from the Francis review (2013) highlighted that at the time of the inquiry into the care and treatment of patients seen at Mid Staffordshire Trust that there was a lack of candour in terms of when issues and incidents occurred which related to

patient safety concerns. The findings from this inquiry prompted the statutory Duty of Candour to be developed, the regulatory framework requires organisations to ensure that when incidents are reported that meet the criteria then both verbal and written communication occurs. Through the use of written communication, organisations are more easily able to conduct audits to ensure that a written letter has been sent and also provide evidence of assurance to the Care Quality Commission that the statutory requirements are being met. However, the focus of the Francis review (2013) centred on cultural changes within organisations to ensure that a culture of candour was embedded, to ensure that informing and involving patients and families when an incident has occurred becomes custom and practice rather than being enforced through the healthcare regulator. As Dalton and Williams (2014:2) highlighted, “candour cannot be an ‘add on’ or a matter of compliance; candour will only be effective as part of a wider commitment to safety, learning and improvement”.

When asked, several of the participants highlighted that if something had gone wrong or there had been a patient safety incident prior to the Duty of Candour being a statutory requirement, then they would have still been open and honest to patients and families but that this would have been done through a telephone call or a visit or face to face meeting. As Penny stated:

> “I would have just met with the family face to face and ask them their understanding of what had happened and ask them if they had any questions surrounding what had happened.” [Penny]

To explore the narrative of the element of communication further in terms of the Duty of Candour, it is useful to first consider communication in healthcare more broadly. In terms of the modalities of communication (Vermeir et al, 2015), there is an evidence base which supports the theory that the best method of communication to patients is through face to face meetings. This is particularly in relation to incidents or issues which could be seen as sensitive in their nature, as highlighted by Vermeir et al. (2015: 1258), “face-to-face communication is essential to get the full conversation. In face-to-face communication, all involved parties can not only hear what is being said but also they can see the body language and facial expressions that provide key information so they can better understand the meaning behind the words”.

From the evidence base gathered from conducting this research it is clear that the assurance based focus that one would expect within a regulator has also penetrated the organisational culture where this research is situated. There appears to be a preoccupation from the national regulatory body, CQC and local NHS organisations in terms of the evidence of assurance that the Duty of Candour is met. The easiest, albeit transactional way (compliance focused) for regulators and internal auditors to check this is through a paper trail; hence the focus on the written letter. Both the national legislation (Health and Social Care Act 2008 amended 2014) and local organisational policy state that a letter must be sent out to the patient/ family regardless of the personal circumstances or needs of the individual. Due to the use of the standardised letter template currently being accessed by clinicians and managers within the organisation, this written letter could in fact have a detrimental impact on the continued involvement of patients and families post incident reporting, this is considered in more detail in the sub section below.

Standardised Template Letters

To understand the concerns that have been raised by participants, it is proposed that the issue is not only around the type of communication but the fact that there is a view that standardised and template letters must be used in order to meet the requirements of organisational policy.

Gill raised regarding the use of standardised letters and the barriers that this can cause in terms of ongoing communication with patients and families:

> "The thing that I struggle with in terms of Duty of Candour is the standardised letter and any changes to the letter are so minimal, it's such a formal letter. I would never go about approaching a situation in that way" [Gill]

As part of the interview with Penny the emergence of the key category relating to the barrier that the use of standardised written letters creates, started to emerge:

> "I think that maybe they (patients/ families) just see it as a formality because the letters are pre written, which you can alter and I do try and take a lot of the information out and make it more personal to the patient but it's just a paper exercise" [Penny]

From Ruth's perspective she identified that the use of written letters can often be a barrier in terms of open and honest discussions when something has gone wrong. Ruth highlighted that throughout her clinical career when something had gone wrong/ incident occurred she would contact the patient/ family and inform them verbally. Prior to the Duty of Candour, Ruth's professional practice was that she tended to meet with the patient/ family face to face to inform them that an incident had occurred.

> "I always like to do you verbally first and what I have found is that most patient prefer verbal they don't really like the letters" [Ruth]

From a Weberian view of rationality, the Duty of Candour is a type of formal rationality law/ healthcare rule). The use of standardised letters is an example of the bureaucracy that can lead to irrational responses to what is seen as a rational process (Weber, 1946).

Ruth felt that the statutory requirements as part of the Duty of Candour did not allow for any flexibility or individualised approach to the way in which Duty of Candour was enacted. The irrationality of this approach is that health care organisations may consider that it is more important to follow the statutory requirements rather than an approach that is tailored to the needs and circumstances of the patient/ families involved. Ritzer (1998: 43) states that, "formal rationality often leads to decisions that disregard the needs and values of actors, implying that substantive rationality is unimportant".

From Weber's theory of rationalization this would be an example where human adaptive skills such as empathy are replace with nontechnical skills (completion of standardised letter) due to the bureaucracies that are in place, "bureaucracies control people by replacing human judgement with nonhuman technology" Ritzer (1998: 44).

One example that Ruth gave was of a visit that she had completed to an elderly couple's home for her to apologise on behalf of the organisation as an incident had occurred. Ruth then sent a follow up letter to the wife of this patient to inform them of the findings from the investigation that had been completed, Ruth felt that this had confused the couple stating that the wife had rung her and said,

"What have you sent us this for (letter), we have already had the discussion at the end of the investigation" [Ruth]

To explain the process further Ruth completed a follow up visit to the couple's home. Ruth's view on this was that:

"They were an elderly couple so I think sometimes for elderly people the letter is a bit daunting and they much prefer someone just going in and talking to them" [Ruth]

It could have been presumed that the participants that were interviewed as part of this research had misunderstood the guidance provided in the local policy, in regards to the requirements to personalise the template letter. However there is no evidence of that misunderstanding highlighted through the interview transcripts.

The policy states that both verbal and written communication must be provided to the patient/ family when an incident has occurred. The policy also provides a 'template' letter which it is suggested can be used as the basis of a letter to patients or families. There could be in fact a number of other factors as to why the participants interviewed as part of this research chose to use the template letters. Firstly, it is possible that participants felt that the use of the template letters to patients and families was the safest option. Participants could have presumed that it was necessary to use this template letter to meet both the organisational requirements but also the statutory requirements and reduce the likelihood of any individual reprisal arising from not following the policy as required. For example in the interview with Ruth she highlighted her concerns in terms of the potential ramifications of not correctly following organisational policy:

"I myself worry that if I don't do what the policy states in terms of sending out that second letter – I am going to be reprimanded" [Ruth]

Ruth's comments regarding concerns for the possible impact if organisational policy is not followed links to the Weberian theory of rationalisation. Ritzer (1998) highlights that rationalised system focus on quantity and require employees to undertake a number of set tasks, "incumbents must do those tasks and no others. The tasks must be done in the manner prescribed by the organisation; idiosyncratic performance will get one demoted or even fired" Ritzer (1998: 44). Also Ruth's comments highlight that there is a focus on quantity rather than the quality of the

letter being sent to patients and families. The CQC use the performance measure for Duty of Candour, which is the number of moderate and above incidents v's the number of initial letters sent out and the number of follow up/ second letter sent. This does not consider any points about the quality of the letter and the potential impact (positive or negative) on the recipient of this letter. From the responses given by the participants it indicates that the wrong key performance indicator (KPI) (i.e., letter sent) has been chosen by CQC. This is internalising behaviour that focuses on using a template letter, in order to get a letter sent out as quickly as possible and meet the national KPI. This is not in the spirit of what Sir Robert Francis set out to achieve through the recommendation of the Francis report (2013). The aims of the learning from the Francis report (2013) where to increase candour and honesty in the NHS when something goes wrong, not to focus on sending out a letter, simply to meet a transactional KPI. The potential impact of a standardised letter is that this could cause more harm (psychological) to a patient/ family due to the fact that they feel that they haven't been heard or that they haven't been treated as an individual. In the interview with Gill she highlighted her concerns in terms of sending out an impersonal letter to patients and families:

> "If I was that patient or family receiving that letter, I wouldn't be happy as you can tell it's generic. I would want a phone call or a visit but I would expect on a personal level from that sister or that matron, I just think that maybe we have lost the personal touch." [Gill]

This links to Ritzer's theory of McDonaldization as one of the key dimensions to this theory is that all work can be measured "McDonaldization involves an emphasis on things that can be calculated, counted or quantified" (Ritzer 1998: 49). Also the 'safety' that is felt by some participants through the use of predefined letters, again links to the theory of McDonaldization and the concept of predictability. Through the development of template letters the organisation have an element of control and assurance that each of the letters sent out to patients or families will have very similar content, as highlighted by Ritzer and Chen (2009: 828), "there is safety and comfort of experiencing the same processes and products over and over".

The use of the template letter not only meets the organisational and statutory requirements but also saves the clinician time. This highlights key concepts that are

linked with human factors theory, of ‘work as imagined’ and ‘work as done’. Blandford, Furniss and Vincent (2014) give the example of this in relation to medical devices, for example medical devices (equipment) are always used in the conditions and for the purposes that the manufacturer recommends this is ‘work as imagined’. Whereas ‘work as done’ is how clinicians actually use equipment and the user experience. When this is applied to the Duty of Candour the expectation from the healthcare regulators in terms of the ‘work as imagined’ is that the statutory legislation will be appropriately translated into organisational policy, which is of a similar standard across every NHS Trust in the Country. At a local level the ‘work as imagined’ is that although the local policy includes a template letter that staff understand and importantly have the time to personalise and take an individualised approach to the development of the Duty of Candour letter. The ‘work as done’ is in fact that a template letter is simply amended to include the name and a few other basic details in terms of the incident which has occurred. This is the preferred option for the clinician as they feel it meets the requirements of the Duty of Candour legislation, meets the organisational requirements whilst taking the least amount of time to complete.

Standardised Letters – Using Human Factors Lens

If we consider these issues through the lens of human factors theory, using the Systems Engineering Initiative for Patient Safety (SEIPS) model (Carayon et al., 2006), it helps to understand the rationale in terms of the inclusion of this letter in the Duty of Candour policy:

External Environment:

There is a requirement under Regulation 20 of the Health and Social Care Act (2008 amended 2014) to complete the Duty of Candour for Patient Safety Incidents (PSI) which have been graded as moderate and above. One element of this requirement is to ensure that written communication is provided to the patient/ family.

A fine of up to £10,000 per (PSI) can be issued if there is evidence of the regulation not being followed correctly. There is evidence of the Care Quality Commission discharging this duty through the use of fixed penalty fines for organisations where there is evidence of breaches. Both Bradford Teaching Hospital and Royal Cornwall

Hospital Trust have received fixed penalty notices from the Care Quality Commission for breaches of the statutory requirements. This links back to the concerns raised by Ruth in her interview, Ruth described the need to follow the policy as it is written due to the fear of the consequences if she doesn't:

"Although I myself worry that if I don't do what the policy states in terms of sending out that second letter – I am going to be not reprimanded but I am not following what the actual policy says but I do use my own professional judgement in terms of what that family actually need" [Ruth]

Organisation:

All organisations are required to have a Duty of Candour Policy in place. A template letter has been included in the Duty of Candour Policy.

Tools and Technology:

The template letter can be copied and pasted directly from the policy document into a word document.

Tasks:

To develop a letter to be sent to a patient and/or family when a patient safety incident has occurred. According to Regulation 20 (Health and Social Care Act 2008, amended 2014) it is necessary for this letter to include an apology from the organisation.

Persons:

It is often the Ward Sister/ Matron/ Team Leader who is required to complete the development of this letter as they sign the incident off within the risk management system. This is often a difficult task in terms of using the necessary language to meet the regulatory requirements, i.e. the inclusion of details that relate to the incident and a written apology with the often polarised position of also ensuring that an empathic approach and language. At the time of this research there was no available formal training to support the development of these letters. Therefore, members of staff tend to utilise the template letter as it feels as the safest option. In the interview with

Ruth, there is some inference of concerns of reprisal is the template letter isn't used when contacting a patient or family:

From the use of the SEIPS model (Carayon et al., 2006) it highlights the rationale for the development of the template letter in terms of the support for staff. However, from the interviews conducted for this study the template letter has clearly led to a number of issues including the breakdown and loss of communication and relationships with patients and families due to lack of personalised and empathically worded letters. Gill highlighted the potential impact of written Duty of Candour letters:

"If I was that patient or family receiving that letter, I wouldn't be happy as you can tell it's generic. I would want a phone call or a visit but I would expect on a personal level from that sister or that matron, I just think that maybe we have lost the personal touch." [Gill]

During another interview, Ruth highlighted that for some patients and families it is difficult to explain the circumstances of an incident within a written letter. Ruth provides an example where a patient is prone to falls at home who has subsequently fallen whilst in the community hospital. Duty of Candour has been enacted due to the harm from the fall and the response that the family gave to her was as follows:

"A lot of the time it's a dementia patient who has fallen and the relatives are very aware that risk was there – and a lot of the time they say that. 'You did your best, you couldn't have helped it'. You had everything in place but of course he wandered or whatever. So they don't necessarily attribute any blame to us." [Ruth]

For some participants, the use of this letter has also left them cynical in terms of the Duty of Candour process. Gill felt that it terms of her own practice that the Duty of Candour process was an additional level of bureaucracy. When Gill was asked if she felt that the Duty of Candour has made any improvements to her practice or more broadly healthcare she stated that:

"No, unfortunately I don't. I think it's just a bit of bureaucracy really and although I do like the fact that it holds people to account who normally wouldn't make that contact, I don't find it very helpful." [Gill]

Using a human factors lens there are a number of simple changes that could be made so that template letters can be reviewed but not sent out to patients. Firstly, if we look at a simple electronic solution, the template could still be included in the policy but a watermark added to this document and then changed to a version of the template that cannot be edited. This would allow the member of staff to still be able to view the template (as a supportive measure) however it should allow for the member of staff to pause long enough to consider that a more personalised letter needs to be written, although this solution may in fact create another issue. As discussed earlier in this section the national picture across the NHS and specifically issues around the nursing staffing crisis mean that all staff but particularly clinical, patient focused staff are under an increasing amount of pressure to undertake required duties with more limited time and a smaller available workforce. By providing a template letter which cannot be used or edited for the purposes of the response to Duty of Candour incident may in fact lead to an increase in 'non-compliance' with the statutory requirements, leading to sanctions and fines issued by CQC.

Within any Duty of Candour training there could be sections on how to formulate the written letter, however human factors theory states to be mindful around any solution that includes an element of training. The inclusion of training as a solution focuses on the changes that the individual needs to make rather than the organisation or system and therefore can lead to a re-emphasis on an organisational culture that focuses on blame.

Organisational Change

Healthcare services and in particular those within the NHS are constantly evolving and 'transforming', in sometimes what appears to be continuous cycles of change. The rationale for these changes are often multi-faceted due to a response to demographic and population level changes (including aging population), economic drivers and the changing expectations of people accessing services. Services are also restructured or refocused as a response to incidents and events, for example the issues that have been highlighted through Francis 2013 and Kirkup 2015.

The latest major change for the NHS is the introduction of Integrated Care System (ICS) as a result of the Five Year Forward View (2014). The Five Year Forward View (2014) highlighted that in order to meet the needs of people who use NHS services, coupled with a requirement to reduce costs and increase efficiency, there is a requirement to dissolve the traditional organisational boundaries. The aim was that rather than patients having distinct, unconnected episodes of care in multiple different organisations or services, that these services were seamless, so that patients could interact with them as required and that efficiencies could be made through less duplication of effort.

The core focus of the ICS programme is to radically change how health and care services are managed and delivered in order to meet the societal level changes. One participant in particular, Gill, highlighted that the community service that she worked in has changes significantly in recent times due to the impact of the ICS. She describes these changes as positive due to the fact that the beds that were once only used as a 'step down' from hospital, acute services were now also being used to see and treat day case patients:

> "We were a community hospitals as an inpatient unit and now we moved in to the ICS and so now we are a day unit, so we are open 12 hours every day, including bank holidays and we see patients who only need to be here until 8 in the evening" [Gill]

Gill described a further improvement from the change in provision:

"So with the ICS there are beds and we also have some beds at a residential home which are health funded and we can sign post certain people to there, there is more now available in the community" [Gill]

Publicly the current reorganisation across health and care sectors aims to tackle major public health issues such as obesity, smoking and mental health (to name just a few), through the development of larger multi professional organisations. However, the current organisational change is also due to major economic drivers. This is in terms of the financial control totals that NHS organisations are required to meet. NHS Improvement highlighted that at the end of 2018 that there were 10 English

hospital trusts that accounted for £850 million overspend, including Kings College, London who had reported an over spend of £182 million (NHS Improvement, 2019). Through the implementation of the ICS model it is hoped that savings can be realised through economies of scale. These were also the drivers for other NHS reorganisations and mergers. A study that focused on the structural changes within the NHS in terms of the move to population based Primary Care Trusts in the early 2000s highlighted that, “the most common reasons given for planning to merge were to increase management capacity or to achieve economies of scale in management; these were mentioned by 48% of those planning mergers” (Wilkin, Gillam, and Smith, 2001: 1466).

In this population based approach, NHS England’s ambition of this large scale change to the delivery of service provision is that, “every person who need support from health and care professionals act as one team and work for organisations that behave as one system” (NHS England, 2016: 3)

Clearly this is a very recent change and as the ICS programme only commenced in 2016, a literature search highlighted that no early findings from this change programme and to date no research on whole system changes have been published.

The area that the research that is discussed in this thesis is located in is identified as a national ICS site. Therefore there is a significant amount of focus on the development of Integrated Care Communities (ICC), which have the overarching aim of health and social care services working closely together. There is a view that services which work conterminously, should provide better joined up services across providers. By working on a population focused model (rather than disease or speciality basis), it is hoped that services can be better tailored to the needs of a community.

Debra highlighted through her interview, her experiences of some of the advantages and disadvantages of different service/ staffing models:

“Both the large hospitals in here are quite uni-professional even though you do have an overarching MDT on the unit you are actually organised professionally, I have worked places where you are organised by clinical discipline so there is a surgical team which has a mix of professions in it, but that’s not how they do it here. Being

uni-professional gives some people a greater sense of identity, I personally prefer being organised by your clinical area, as I think you tend to have more in common with the people who you are working with as you may be working with someone who does the same profession as you but does it in a very, very different way" [Debra]

Where this research was geographically situated, as well as the work around the development of ICS, there is also a significant programme of organisational change work ongoing, with the aim to merge the local acute and community services into one new organisation. One of the key reasons for this particular change is due to the potential economies of scale and scope (particularly in terms of shared management and support service functions). However, although there is less written regarding the negative impact of mergers there is evidence to suggest that these change programmes can in fact lead to unintended consequences including problems which relate to "staffing, service integrating, system integration and working practices" Fulop et al., (2002: 246). These issues can lead to difficulties in members of staff being able to deliver 'business as usual' as well as supporting and often being required to lead large scale change programmes. A further issue is the focus on the required changes to structures and processes during the initial period of organisational change, this can lead to a prolonged period where the focus is often on concerns in terms of changes in role, parallel restructure and recruitment processes and re-banding; both pre and post organisational change. One study that focused on the organisational changes within the NHS which took place in the early 2000, with the intention of creating local Primary Care Trusts highlighted that, "In their first year most primary care groups concentrated on establishing an infrastructure, developing their organisation, dealing with the abolition of GP fundholding, and developing a corporate culture of working" (Wilkin, Gillam, and Smith, 2001: 1464).

This type of restructure is linked to the neoliberalist view that healthcare services should be decentralised and managed at local rather than governmental level. This is due to the belief that this model supposedly has the ability to deliver more localised services that can respond better to the local population needs. However through the decentralisation of healthcare provision it also enables central government to be devoid of responsibility when issue such as lack of central funding lead to staff crisis and subsequent patient safety incidents and events.

Within the interviews for this research there was intentionally no specific questions regarding the planned merger with the local acute trust; however, there was evidence that staff were aware of these changes as it was raised within 4 out of the 5 interviews that have been conducted for this research. All 4 of the participants that highlighted this through their interviews were part of the cohort of staff who were merging with the acute trust, the remaining participant was part of the mental health services, which were transferring to a different organisation. In the interview with Penny, she highlights her concerns in terms of the organisational merger:

> "I qualified 10 years ago now, when I applied as a nurse there was no nursing positions and in comparison to now, I find it so bizarre, so it took me 3 years to get a permanent post within the trust, within that time I did do two months with the acute trust and I vowed never to go back and I haven't't" [Penny].

Organisation Change – Impact on Professional Identity

Through an individual lens the consequences of organisational change can have a huge impact on how an individual views their professional identity and in turn their place within the organisation in which they work. As highlighted through the literature review, identity theory is an important theory in regards to how individuals see themselves in terms of their professional role. This theory is also of importance in terms of the link between professional identity and organisational change. Within identity theory when, "organisations change structures and normative expectations; when families move into new neighbourhoods; when divorce, births, and deaths occur, identities shift and the structure of the self is altered" (Piliavin, Grube, and Callero, 2002: 472). Identities can shift when there are changes to the way in which services are structured and managed, for example, this is particularly an issue in mergers and acquisitions when the individual feels that they are not doing the same job as before the organisational change took place. There are studies (Fiol, 2001 and 2002) that highlight that for those professions where there is a significant identity associated with person's professional role (for example nurses and medics) then this is likely to correlate with a higher level of resistance to any organisational change that threatens the employee's identity. Alongside this is a higher resistance to change through a merger from the perceived more dominant organisation. The

employees may identify their organisation as dominant through financial or regulatory performance as well as the differences in organisational culture that has been highlighted by some of the participants in this study.

What is important to consider here is the impact of organisational change (in this case a merger) on incident reporting and in turn the Duty of Candour requirements. There is much written on organisational change in different industries and the impact that these changes can have on organisational cultures and employees. There is, however a limited evidence base on the impact that these changes specifically have on incident reporting. Therefore it has been necessary to re-consider the literature on the barriers to incident reporting and triangulate these with the available evidence base on organisational changes; literature alongside the responses from participants in this study have been used to enable the emergence of potential new theories to fill the current literature void.

The literature on the barriers to incident reporting currently fall within two distinct categories; those which focus on the incident reporting habits of incident reporting in professional groups (Lawton and Parker, 2001) and studies which consider the organisational culture (Wearing, 2004) and how this can impact on incident reporting.

In a study by Lawton and Parker (2001) highlighted how different groups of healthcare staff respond to an incident occurring within healthcare services, noting that nurses and other healthcare professionals are more likely to report an incident as they did not wish to deviate from local policy and practice, which seems to govern nurses more than doctors. Whereas, studies show that doctors are less likely to report an incident because they were more likely to view themselves as an independent practitioner and therefore make decisions as to whether to report an incident on their own professional judgement rather than following policy. In a study by Wearing (2004) he found that doctors were less likely to report, “reporting was discouraged by an anti-bureaucratic sentiment and rejection of excessive administrative duties” (2004: 1927). It is also important to reference back to the context and history of the differences in which, doctors and nurses roles have evolved through the lens of regulation as this is likely to continue to impact on differences in incident reporting. The self-regulation model that doctors have been more accustomed to, rather than any state intervention/ regulation is likely to link to

the view that doctors are able to use their professional judgement as to whether an incident needs to be reported. Whereas nurses are more likely to subscribed to local policy and guidance and also follow the required standards as set through formal state regulation.

Within incident reporting the organisational culture needs to demonstrate to staff that they are working in an organisation which has a balance of accountability and transparency. Without the necessary cultural conditions in place, where staff feel psychologically safe enough to report an incident, under reporting of incidents is likely to exist and therefore any opportunities to learn from incidents and events will be limited and incidents are likely to re-occur (Edmondson, 2004).

For the Trust that is part of this study, no concerns were noted during the period of 1st April 2017 and 31st March 2018 in terms of reporting. The National Reporting and Learning System (NRLS) report during this time period, states that there was ‘no evidence of under reporting’, this report focuses on both the number of incidents reported and also the grading of incidents.

From the interviews conducted for this study Gill described a significant incident which they felt was not appropriately responded to. Gill highlighted that she felt that there was sometimes a delay in response from senior managers when an incident had occurred. Gill gave an example of where she had raised multiple incident reports on the same issue but that the senior manager only responded to this when the incident became more serious and was graded as moderate or above. Gill indicated that if this issue had been responded to earlier then it would not have escalated:

> “I can’t even tell you how many incident report were put in and I gradually increased the risk on the incident forms” [Gill]

Gill continued to say that in this particular incident that she was describing as well as increasing the level of ‘risk’ in the grading of an incident. Following the delays in the response to this incident, Gill also felt that it was necessary to use ‘trigger words’ in order for senior managers to provide any response or actions to incidents:

> “As a team we learnt loads because in terms of reporting an incident we will only get the right response if we get proper trigger words in there, like ‘our patients aren’t safe’ where as if we don’t word it in that way we don’t get the right response” [Gill]

Part of the themes and key categories that have emerged through the research described in this thesis is that a combination of changes and role conflict in professional roles (due to often new and dual professional identities), should be considered and assessed prior to large scale organisational changes. The impact in terms of incident reporting, Duty of Candour and importantly on learning from patient safety incidents could be significant if these nuanced areas are not considered when organisational change programmes, particularly mergers and acquisitions are being planned and undertaken. This new theoretical paradigm can both support the ongoing organisational merger where this study is situated but also be considered for other NHS organisations and beyond.

Additional Theme: Candour with Patients and Families

Throughout the analysis of the interview transcripts there is also evidence of societal level changes that relate to an increase awareness of healthcare organisations responsibilities to be open and honest. However the source of these societal level changes are likely to be much broader and multifaceted than simply being linked to one piece of legislation. Some literature highlights that we are now in a post paternalist age, for example Dalton and Williams (2014: 8) define this era as, “one that is less trusting of authority and of institutions, and which places a greater value on self-determination and choice than was once the case”.

During one interview, Penny gave the following example:

“I met his wife and his daughter a week after the funeral so it was quite early on because they wanted answers. They appreciated that the husband was elderly and he had these other health issues but their view was, what would have happened if this was a healthy 30 year old man. They wanted reassurances that it wasn’t going to happen again” [Penny]

Within the interviews conducted examples of this societal shift are linked to an increased likelihood by patients and families needing assurances that investigations are conducted when an incident has occurred and assurances that similar incidents will not reoccur in the future.

This is a similar finding to one highlighted in the study by Iedema et al. (2011). The participants from this study stated the need to ensure the linkages between Open Disclosure and improvements in patient safety.

In several of the interviews conducted for this research, the participants described examples of what could be considered as demonstrating the changing expectations of healthcare services from patients and families. This could be partly due to the increase in the aging population. This cohort of people who access services are supported to stay well for longer.

An area that was raised through the interviews that were conducted for this research was in regards to patient falls. The expectation from families is often that their family member will be safe in an inpatient setting (hospital ward, community hospital) and therefore is less likely to fall than at home. Issues such as unfamiliar environments and staffing levels mean that it is in fact more likely that someone who is prone to falls will fall during an inpatient stay than at home. This was highlighted in the interview with Tina:

> "Particularly this family that I am thinking about thought that no patient should fall in hospital and that was really difficult as actually sometimes people are at higher risk of falls when they are in hospital because they are unwell, because they are in an unfamiliar environment, that risk can become higher and it was difficult because there was an expectation of, 'well they are in hospital' why have they fallen" [Tina]

In the interviews conducted as part of this research all of the participants described incidents which resulted in a patient falling whilst in a ward setting. Interestingly the participants highlighted in these cases, that the patients that had fallen were all known to be 'at risk of falls'. In these cases there was evidence highlighted to indicate that all falls risk assessments and other precautions for this patient group had been put into place, but the patient had still fallen. In each case where there had been a falls incident that resulted in moderate or above harm, the Duty of Candour policy had been followed and an serious incident investigation conducted to identify whether any further improvements to areas such as clinical care or the hospital environment, to reduce the likelihood of reoccurrence of similar incidents.

Examples from this research highlighted that:

“All her falls paper work had been done, everything had been completed, there was nothing that we could find that hadn’t been completed properly, but as a society I do think we need to be re-educated about the risks of going into hospital, hospital is not the place to be unless you need to be there and even then, it’s quite unsafe” [Gill]

In Gill’s interview when she states that, “there was nothing that we could find that hadn’t been completely properly”, this refers to the findings from the serious incident investigation that has been conducted for this patient who had fell whilst on the ward.

“Well they can fall in here … if that door is shut because we are in a room. Two staff in a room with a patient, that only leaves one other staff member on the ward for ten (patients) and it’s hard for families to comprehend that someone can fall in hospital when they should be safe” [Penny]

These are examples from the research which highlight the difficulty of the concept of a hospital being a ‘place of safety’, when in fact there are often existing factors such as staffing levels or building/ hospital environment which result in potential risks for patients, including falls. In her interview, Tina described the process that related to a patient who had fallen on the ward,

“There was initial contact with the person’s family, if something has happened you want them to be aware of it and not wait for a letter. Incident was reported, 72 hour report was produced and sent to the serious incident inbox and then to decide what level of investigation needed to take place, duty of candour letter sent out, we arranged to meet with the family” [Tina].

Later in her interview Tina was also able to articulate some of the improvements that the ward had made following a number of incidents that resulted in patient falls:

“We have introduced a falls protocol which is a series of standard checks, some of which we would have done anyway but we have got it displayed on the ward and all staff are aware of it. We have done things like …. sometimes really simple things… a patient was in the dining room and fell over and felt herself overbalancing so grabbed onto a piece of furniture that wasn’t secure, so we have removed it. Sometimes it’s about looking at the physical environment for that patient” [Tina].

Additional Theme: Impact of Voice Recording of Interviews

The impact of voice recordings was not a category from the narrative that was gathered through interviews; however, the phenomenon of additional information being shared once the audio recorder had been stopped is still of interest.

Some of the themes from the information captured at the end of the interviews included that:

- The sponsor organisation still had a focus on incidents where harm has occurred rather than focusing on learning from near misses and low harm incidents;
- That incidents often occurred due to poor discharges from acute hospitals into community settings;
- That the written Duty of Candour letter continues to be an issue and that older people are sometimes confused in terms of what the letter means.

Although some additional information was shared post interview (once the audio recorder had been switched off), in considering the additional information given by participants it does not result in any additional categories being identified.

This chapter has explored a number of key categories that have emerged from the research interviews under the headings of: (a) hybrid professional-managerial roles (b) organisational culture, (c) organisation practice and (d) organisational change. The next chapter triangulates the key categories described here with the initial aims of this study in order to develop and outline the main conclusions from this body of work.

Chapter 5: Conclusion

Introduction

This chapter further explores and clarifies the links between the findings that have been highlighted through the Discussion Chapter of this thesis and the literature and evidence base.

Review of Research Aim

To help to focus the discussions in this chapter it is useful to re-consider and revisit the overarching research question/aim as set out in the Introduction Chapter, which was:

To conduct qualitative research that considers the impact of the Duty of Candour legislation within healthcare

The overarching research aim, has therefore been met. As outlined throughout this thesis, 5 in depth interviews have been conducted with members of staff who were involved in the implementation of the Duty of Candour process, following the notification of a patient safety incident occurring. This research used semi structured interviews to discover members of staff's experiences of the implementation of the statutory Duty of Candour regulation.

Prior to this research being undertaken there was very limited evidence of the views of clinicians who are now required to take necessary steps to meet the Duty of Candour requirements. Previously published literature and research from the UK tended to focus on the potential impact of the Duty of Candour regulations on professional practice and registration. However these were mainly journalistic style articles that lacked depth in terms of actual research, describing only the potential

impact of the Duty of Candour on professional registration (General Chiropractic Council et al., (2014), Scammell (2015), and Glasper (2015)).

Prior to this research being conducted there was a very limited evidence base, which considered this topic with staff in an in depth way. There are routine surveys for example the NHS Staff Survey, that asked several questions around incident reporting and whether staff feel psychologically safe enough to raise concerns, however often these surveys tend to lack depth in terms of the responses given by staff. Also although these surveys are anonymised, they are sent out and returned to the employer, which could clearly impact on the responses that staff give.

A wider search of international literature and research further highlighted the gap and lack of evidence in terms of the effectiveness and impact of the Duty of Candour. It was found that there were published international research papers (Iedema et al., 2008 and Iedema et al., 2011) that explored similar topics; both of these papers highlighted research that had been conducted in Australia. The research by Iedema et al., 2008 and Iedema et al., 2011, importantly focused on the patients and families following the occurrence of a patient safety incident, but lacked any focus on a member of staff's involvement or perspective.

As these studies focused on patients/ families rather than staff there was clearly a gap in the previous evidence base in terms of the impact that organisational culture or organisational change has on the outcome for patients and families.

One of the potential reasons for the lack of previous research studies that relates to the area of Duty of Candour and patient safety incidents, is due to the sensitive nature of this type of research. It is a strength and achievement of this research that the researcher was able to recruit participants to this research, who felt willing and psychologically safe enough to describe their experiences and accounts of what happens when a patient safety incident occurs. The participants in this research provide accounts and reasons why they felt that there were still issues when trying to implement the statutory Duty of Candour and also on a wider basis, organisational learning from patient safety incidents and events. As highlighted in the previous

chapter, there were a number of key categories that emerged from the narrative accounts from participants.

Conclusions

It is clear that several of the participants who were involved within this research felt that there was a focus on the transactional, performance measures of the Duty of Candour (i.e., sending out a letter), as highlighted in the interview with Gill:

> "the thing that I struggle with in terms of Duty of Candour is the standardised letter and any changes to the letter are so minimal, it's such a formal letter. I would never go about approaching a situation in that way" [Gill]

This was opposed to working in a culture that valued the ethos of 'being open' and using a person centred approach to the notification and response to an incident or event. In his response to the implementation of the statutory Duty of Candour, Berwick (2013: 34) warned that the NHS should "not subscribe to an automatic 'Duty of Candour where patients are told about every error or near miss, as this will lead to defensive documentation and large bureaucratic overheads that distracts from patient care".

This study has contributed to an emerging evidence base of whether the Duty of Candour is applied in England for those incidents that have been graded as moderate or above harm. This research has also helped to understand, through the exploration of members of staffs' stories and the narrative accounts from participants, how it feels to enact the Duty of Candour requirements.

The key categories that have emerged from this research are as follows:

- Hybrid Professional – Managerial Roles
- Organisational Culture
- Organisational Practice
- Organisational Change

As previously discussed, the Duty of Candour was developed from the recommendations in the Francis Report (2013) and the focus of this recommendation was to provide a legal framework to ensure that all organisations are open and honest when a patient safety incident of moderate or above harm has occurred.

This research has demonstrated that for the participants who were part of this study that they had a good level of working knowledge and understanding of the Duty of Candour process and the steps required to fulfil the statutory requirements. It was evident from participant's responses provided that they were all aware of the learning from the Francis Report (2013). Participants also had knowledge of both the local and statutory policies and guidance.

If measuring against the key performance measures as set out within the requirements of the statutory Duty of Candour there is evidence that incidents are being reported and appropriately graded. Also that those incidents that are considered to be of moderate or above harm are being investigated in more detail. For the responses given by the participants in this research there was evidence that both verbal and written notifications are being provided to the patient and or family.

As stated in an earlier chapter in this thesis the Francis Report (2013) actually highlighted 13 different recommendations in terms of the embedding of the 'being open' principles within healthcare organisations. Out of these 13 recommendations there has been a clear focus on the implementation and monitoring of recommendation 181, *the statutory Duty of Candour*. The reasons for this focus is likely to be due to multiple factors including that for those incidents that are identified as moderate or above harm there is a way in which organisations and individuals can be held to account if they are shown not to be demonstrating candour. It also ensures that any investigation reports completed by the organisation are shared with the patient or family and if these are not offered by the organisation under the statutory requirement the family can request these reports. This is an important factor as there is evidence from previous national cases that information including patient records were not shared or made available to families. It is also likely that the

focus on this element of the recommendations made by Francis (2013) is due to the fact that it is measurable by both healthcare organisations and the healthcare regulator, CQC. This complex area of the management of serious incidents can be quantified into two measures, firstly was verbal contact made with the patient/ family and secondly was written confirmation provided to the patient/ family (through a written letter).

The findings from this research highlight that there has been some training and development of staff in the organisation where this study took place. Through the interviews that were conducted this training was evident from the participant's level of knowledge of the statutory requirements and the process of Duty of Candour. The level and type of training provided varied between basic e-learning training to more focused face to face learning. However this training had not extended to the development of personalised letters and it is likely that the training did not cover this area as this was an 'assumed' skill.

This research has provided evidence that there is an understanding of the requirements which are part of the statutory Duty of Candour and also evidence that the two key performance measures (initial contact with the patient/ family and written letter) are being met and monitored within the organisation where this study was conducted. This is evidenced through the initial data set that was accessed for the identification of participants. However, beyond these points there is very little evidence to demonstrate that the Duty of Candour is in fact supporting the nurturing of organisational culture that focuses on improvement and learning alongside performance. That being said it is a difficult task to try and disaggregate the introduction of the Duty of Candour from other activities that aim to influence the culture, values and behaviours in an organisation, including different leadership styles, policies and training. What is clear, from a national perspective, is that there is still some way to go, even in terms of the somewhat transactional and technical elements of the statutory Duty of Candour. As a recent press release highlighted that the Bradford Teaching Hospitals (CQC, 2019) had received a fine for not enacting these requirements as defined under the Health and Social Care Act (2008) amended (2014).

All participants were able to clearly articulate the process involved for incident reporting, the linkage between incident reporting and Duty of Candour and the necessary actions which are required as part of the statutory legislation for the Duty of Candour. This is likely to be due to the fact that the data set that was accessed for this research highlighted ward sister/ managers who had been identified as approving an incident that met the criteria for the Duty of Candour, therefore there was an assumed level of knowledge. During this research, when asked the majority of participants gave what could be seen as 'text book' answers when questioned about their understanding of incident reporting. There could be a number of reasons for the participants approach to this question, firstly in recent years there has been an increase in the number of inspections that some organisations have received from the healthcare regulator the CQC and subsequently, through these inspections an increased focus on incident reporting. The response to these types of questions from participants, may simply be an indication of members of staffs' knowledge and confidence on the subject but also be evidence of the amount of coaching and inspection preparation that all healthcare organisation now built into 'business as usual' in order to ensure a positive outcome from regulatory inspections. The responses from participants to this question in terms of the focus on the process element could also be due to the lead researcher role within the sponsor organisation, this role includes a leadership role for incident reporting. Therefore, so participants may have responded in a way in which they believe was appropriate for both an organisational response and to meet their perceived expectations of the researcher, in their organisational role.

When asked participants clearly understood the concept of learning from incidents. Participants provided examples of where they had made changes and improvements to the way in which services are provided in order to continuously improve and increase safety and experience of healthcare services. However, there was no direct evidence or examples to suggest that the introduction of the Duty of Candour had led to improvements in practice. The Duty of Candour could have in part led to increased discussions in terms of incident reports and increased the likelihood that these incidents are discussed with patients and families. However, participants were clear that they did not feel there was a direct link between the Duty of Candour and learning from incidents. In fact the majority of participants cited that as well as a lack

of correlation between the Duty of Candour and learning from incidents, the introduction of this requirement has actually increased the bureaucracy around response and learning from incidents. This is due to a dominant focus and culture both from the healthcare regulator, CQC and locally within their own organisation on assurance rather than improvement focus.

The impact of organisational culture and the significant organisational changes on the occurrence and recording of patient safety incidents and the experiences of people accessing these services cannot be under estimated. It is clear from the interviews conducted that participants had concerns in terms of the imminent merger of the two organisations (community and acute healthcare organisations). A review of the current available literature on this particular healthcare system change/ restructure highlighted that as expected and due to the fact that the changes around the development of Integrated Community System (ICS) only commenced in 2016 there is currently a gap in terms of the literature available which considered the impact of such wide scale and whole system changes.

Secondly, this research indicates that it is necessary for both national regulatory organisations and NHS organisations to be more mindful and explicit in terms of their communication of national and statutory requirements. For the Duty of Candour the issue manifested itself in an issue in terms of how patients and families received communication when an incident had occurred. When the statutory legislation was launched there was an emphasis on the need to ensure that there was evidence of written communication i.e., a letter to patients/ families. The focus of the written element is likely to be for a number of reasons; firstly the body of evidence from NHS inquiries (Francis 2013 and Kirkup, 2015) highlighted examples of NHS organisations which had not been open and honest when something had gone wrong. By introducing a statutory requirement that measured effectiveness and assurance by confirming that the number of Duty of Candour letters correlated with the number of applicable incidents, the CQC were able to provide a rhetoric that suggested that healthcare organisations were getting better at notifying patients and families and as such ‘becoming more open and honest’. For Weber (1946), this type of bureaucracy is an example of formal rationality. The use of template and standardised letters is an element of formal rationality that results in irrationality,

through the use of quantifiable means to measure the level of transparency of NHS Trusts when an incident has occurred.

The statutory regulation makes no comment on the style of the written letter, only that a written apology should be included. Therefore, the measurement of success and focus may have become the product of a letter, rather than the quality of the content of the Duty of Candour letter.

It is suggested through this research that this issue perpetuated when it was translated and adopted at a local level. The letter was the focus of the new legislation and therefore there was an unnecessary amount of attention on the development of an organisational policy that centred on formal letters as well as the development of a standardised letter template. The key skills that clinicians have in terms of communication and breaking bad news have started to be eroded as the focus has shifted from one of engagement and improvement to that of assurance.

Strengths of the Research

This research comprised of semi structured interview with members of staff, focusing on a sensitive topic, which was previously under reported and had limited research studies relating to this area. The use of semi structured interviews in this research provided an opportunities to explore individual experiences and the views of the participants. This research therefore adds new knowledge to a limited evidence base, relating to the perception of staff in the implementation of the Duty of Candour. The use of grounded theory methods, including the analysis tools of initial and focus coding have supported the structured emergence of key categories and themes.

Limitations of the Research

This study examines the perceptions and experiences of five NHS members of staff, working in a single organisation. Although this research provides many hours of dialogue from participants, which clearly highlight a number of key themes, it should be acknowledged this study has a relatively small sample of participants. Therefore, it could be considered that this study is somehow less ‘valid’ than other similar research due to its lack of perceived ability for the themes from this study to be ‘generalisable’. However it should be noted that as a qualitative, grounded theory

study, the focus for the sample size was on moving towards a point where, no new themes or potential new categories emerged and therefore theoretical sampling had been achieved. Once this point was reached then the researcher was satisfied that completing any further interviews with this cohort of participants would be futile in terms of the contribution to the emergence of new categories. As Bowen (2008: 140) states that, “the researcher does not seek ‘generalisability’ or ‘representativeness’ and therefore focuses less on the sample size and more on sample adequacy”. It should also be of note that terminology such as ‘valid’ and generalisable are more akin to quantitative methods and therefore these terms have tended to be excluded from the language used to describe this study.

One further possible limitation of this study is the length of time since an incident occurred and the impact that this may have on a participant’s ability to recall the sequence of events. People often change their memories to an idealised state, this is likely to have a bigger impact when discussing sensitive issues such as when an incident as resulted in harm to a patient. Memories tend to change over time and are more difficult to recall the longer it has been since the event/ incident. This links to the seminal work by Festinger (1962) who proposed a narrative that stated that it is a natural human reaction to try and reduce dissonance in terms of when a situation feels uncomfortable, to try and maintain a state of consonance. However, the structure of this research aimed to ‘design out’ this potential limitation by stating that only incidents which had been reported between 1st April 2017 and 31st March 2018 would be considered as part of the sample for this study. Interviews were then conducted in November 2018 to January 2019.

A potential additional limitation in this research is the possible impact from the professional – researcher role within the sponsor organisation. To try and reduce the potential impact of this on the research study, the researcher was very clear to sign off all participant documentation with their university contact details, in an attempt to separate their professional role from that of the researcher for this study. Also, as previously stated a methodological journal was maintained, which as part of the interview process was updated based on the answers that participants gave during interviews.

The final possible limitation in regards to this study is that this research focuses on moderate harm incidents only. There was a clear rationale for this focus, which centred on ensuring the psychological well-being of participants as they recalled sometimes upsetting and sensitive issues surrounding the circumstances and impact of patient safety incidents. By focusing on incidents that were graded as the lowest possible harm but that also met the statutory Duty of Candour requirements, it was an attempt to reduce any possible psychological harm to participants. However, by focusing on this level of incidents and those individuals who completed the Duty of Candour, it is possible that information regarding the learning from incidents has been overlooked as it is likely that more organisational attention would be given for those incidents that may have impacted on a patient death. Therefore for these types of incidents the possibility for greater focus on learning and improvement.

Implications for Healthcare

The impact that this research could have on local NHS organisations is for them to clearly consider national statutory legislation and how this is discussed and introduced within operational services. When the introduction of the Duty of Candour legislation is considered it is clear that one of the main issues is the way in which this was introduced locally. Importantly for NHS organisations to note is how this national requirement has been translated into local policy and practice. In the organisation where this research was situated there was evidence that locally there has been an increased focus on the written element of the Duty of Candour, in some cases at the expense of what would have previously happened (prior to the introduction of the Duty of Candour), which was verbal communication when an incident occurred from the nurse involved or the ward sister.

Currently there is a dominant narrative that focuses on assurance rather than improvement in many healthcare organisations as well as within national regulatory healthcare organisations, such as the CQC. The impact of this on the introduction of the Duty of Candour, is that staff within the sponsor organisation requested a template letter as there were concerns in terms of the language and key messages that needed to be included in the written communication to patients, in order to meet the regulatory requirements.

The inclusion of this template letter within the local policy has led clinicians and managers to feel that it is an organisational requirement to use this letter for all incidents and occasions where the Duty of Candour needs to be enacted and therefore clinicians are simply just ‘filling in the blanks’. Participants highlighted how they have felt disempowered by the perceived requirement to send out standardised letters to patients and families. Also, as part of this research there was evidence shared by participants whereby there have been occasions where patients and families did not understand the rationale for the letter and that this written communication led to more reported upset to patients/ families. As considered in the discussion chapter, the rationale for the use of template letters by clinicians is likely to be due to the pressure within clinical services and therefore the lack of time to consider and develop more individualised letters.

As described earlier in this thesis, the broader impact of the research undertaken is in consideration of the key category that focuses on the relationship between professional identity, incident reporting and organisational change; and the impact this trichotomy has on organisational culture. This research indicates that organisations need to ensure that these factors are taken in to consideration when mergers or acquisitions of health organisations are being completed. As stated previously the impact of changes in roles, the development of dual role and identities (often resulting in conflicting identities), shifts in power balance in terms of who manages and directs services all impact on the resulting organisational culture for any ‘new’ organisation. These factors and how they are represented in a particular organisation need to be identified early on in the organisational change planning process in order for them to be explicitly discussed and factored into job planning and organisational hierarchies. The findings presented through this research is helpful as there is a known evidence gap in terms of research which considers the cultural/ organisational factors that impact on incident reporting.

Recommendations for NHS organisations

There two recommendations highlighted through this study, which if implemented by NHS organisations, could improve communications relating to the Duty of Candour and increase opportunities to learn from incidents:

- Template letters: a basic outline of a Duty of Candour letter can still be provided as guide for staff, but staff should be supported and enabled to develop letters that are personalised in a way in which meets the needs of the patient and families (in terms of style and content), whilst still meeting the statutory requirements. This should be supported through an organisational culture that focuses on learning rather than blame.

- Early on in the planning process in the merger or acquisition of NHS organisation organisations should assessment the risks in terms of opposition organisational culture. Mitigating actions could include a focus on a strong team culture/values for the new organisation, supported by a framework of expected behaviours. This is of significant importance due to the possible impact on incident reports and ultimately learning from significant incidents and events.

Implications for Future Research

This study has focused on the views and experiences of healthcare staff that have enacted the Duty of Candour process, when an incident has occurred. One of the key themes which arises from this study is the fact that participants felt that the formal letters that they understood were required to be sent to all patients/ families who had been involved in an incident were in fact a barrier to ensuring an ongoing positive relationship and dialogue with the patient/ family members.

Future research could consider the particular element of the statutory requirements and the concept of written communication with patients and families both broadly and more specifically i.e., when something has gone wrong in service delivery or experience of healthcare.

Also in terms of further research in this area it would be interesting to use a case study approach to reviewing a small number of specific incidents, reviewing all documentation related to these incidents and conducting interviews with the staff involved and also the patient and or family. This research could help to explore

potential phenomena around the different views of patients and members of staff with a particular focus on psychological theories of cognitive bias and dissonance.

Chapter 6: Impact on Professional Practice

Throughout this research journey, I have been acutely aware of the need to explicitly embed and undertake activities which ensure reflexive practice.

Evidence of this is through the methodological journal that I have maintained, this particular process has in turn helped to support key elements of grounded theory research, which, within the research phase have supported the development of memos.

As part of a reflexive approach to this programme of study, I have considered the space that I occupy in my professional practice. I currently work in an organisation that covers a large geographical, mainly rural location with areas of both extreme wealth and poverty. From a population perspective, elements to note in terms of the impact of this study are that there is a low turnover of staff, with many examples of staff being trained in local universities and colleges and then spending all of their working lives within one organisation.

From a professional practice perspective my interpretation of the spatial place that I inhabit includes of being considered as an ‘outsider’ as I moved to this area a number of years ago but the vast majority of people in the community where I live and the organisation where I work, often live their whole life in the same areas an in the same work place. This intersects with my professional role, as the role that I undertake includes many different elements but focuses on learning and improvement in relation to patient safety. There is an expectation from some that although I am a manager, that it is necessary to be a clinician to undertake my professional role. Not being aligned to a clinical professional group of staff is also an isolating, outsider element, which can impact occasionally on an individual’s view it terms of their opinion of my ability to undertake my professional role.

I see my position within the organisation is to support frontline clinicians to ensure patient safety and continuous improvement however I do acknowledge the ongoing tension between the role of frontline clinicians and managers. From a personal perspective this programme of study and my own professional practice continues to

highlight the tensions between management roles, particularly management roles that operationally manage clinical services. As the resources (both staff and income) within the NHS are becoming increasingly challenging, the tension between operational managers and clinicians continues to become more strained. These issues appear to be as a result of breakdown in communication and relationships due to the differing and often conflicting priorities. Operational managers are often tasked with ensuring that performance targets are met, including financial targets. Whereas, clinicians can often find themselves dealing with the unintended consequences of meeting the financial targets, for example administrator roles being removed to achieve a cost saving, which simply results in an increase workload for clinicians. On reflection, part of my personal rationale for undertaking this programme of study is in part related to the external validation in terms of my own professional practice.

As I have become more embedded into the organisational norms and team cultures the apparent visibility of the occurrence of interpellation reduces and the opportunity to become an established part of a team or community of practice increases. Althusser (1971) states that we, as individuals, *interpellate* with the law based on our own characteristics for example our gender, race or sexuality, “all ideology hails or interpellates concrete individuals as a concrete subject, by the functioning of the category of the subject” (Althusser 1971: 173). This connectivity as a member of a team is essential in terms of the connection with others and developing shared purpose and goals.

It is necessary to have an ‘outsider’ or other as part of an inter-professional group so that the groups’ socialised norms and culture can be challenged as and when required. Often close professional groups who have worked together for a considerable length of time are unable to see the habitual routines that the group conform to, with sometimes detrimental effects on patient care and safety and the over reliance on habitual systems and processes. Wackerhausen (2009) states “habituation promotes phenomenological absence” (Wackerhausen 2009: 462).
The Morecambe Bay Inquiry (2015) which focused on maternal and child deaths stated that “the midwifery staff were already a close-knit group, and it is clear that in response to this perceived external threat they developed a ‘one for all’ approach,

and in fact described themselves as ‘the musketeers’” (Kirkup, 2015: 17). Further research by Wackerhausen (2009) who indicates that there are rules and boundaries within professions which must be adhered to and if these are not and the professional group feels threatened “the immune system of your profession will be activated and you will feel its consequences” (Wackerhausen, 2009: 468).

My own reflections on this research was firstly the willingness for members of staff to choose to take place out of their very busy days to speak to me on this sensitive topic. One of the surprising areas of interest and key category that had arose from the interviews conducted was the use of the template letters. From the participant’s perspective the use of this standardised approach has clearly led to the creation of a number of barriers in terms of ongoing relationships and good communication between the member of staff and the patient/ family. All participants reported that they felt that prior to the statutory Duty of Candour that they did, in fact act with openness and candour but that it is likely that the evidence of this was not documented in a robust way which could be audited and internal assurances given to the organisation. Some participants reflected on the way in which this dialogue with patients and families had previously occurred and felt that a discussion at the earliest opportunity rather than a formal letter was a better method of communicating when an incident had occurred. The statutory Duty of Candour does in fact require individuals and organisations to respond both verbally and in writing however in a top down hierarchical structures that often focus on assurances and performance over quality; the importance of the initial verbal contact with the patient/ family appears to become somewhat unimportant. Some of the focus on only what can be measured within healthcare has been signalled as a requirement through the healthcare regulator, CQC regulatory model and the focus of inspections to healthcare services.

Some of the ways that this programme of study has supported my own professional practice includes the development of technical skills such as the ability to critically appraise and synthesise information from academic sources and the skills to be able to effectively analyse detailed interview transcriptions through a grounded theory frame. Moreover, this programme of study has given me the opportunity to fully immerse myself in the literature that surrounded the field of patient safety, however the discovery of the work of Weber (1946) and Ritzer (1998, 2004) and a better

understanding of the impact of a neoliberalist narrative has been in equal parts a fascinating and worrying revelation.

I feel privileged to have been able to have an outlet through this research process to not only explore areas within the realms of patient safety but also to better understand the role that I inhabit within the NHS. Throughout the past 5 years, whilst I have been on this learning journey there has been significant changes to the landscape of NHS services. The sheer scale and pace of these changes within the NHS has led to increased uncertainty for those delivering these services and to some extent to those who are accessing healthcare services. This research process has provided me with the ability to explore the impact of these changes in a safe and considered way.

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Appendices

Appendix A: Risk Assessment Form (Approved Version)

Risk Assessment Form

<u>ALL projects MUST include a risk assessment.</u> If this summary assessment of the risk proves insignificant, i.e. you answer 'no' to all of the questions, then no further action is necessary. However, if you identify any risks then you must identify the precautions you will put in place to control these.

<u>1. What is the title of the project?</u>

Does the Duty of Candour process impact on improvements in practice: a grounded theory study.

<u>2. Is the project purely literature based?</u> **NO**

If YES, please go to the bottom of the assessment and sign where indicated. If NO, then please complete section 3 and list your proposed controls.

<u>3. Please highlight the risk(s) which applies to your study</u>:

Hazards	**Risks**	**If yes, consider what precautions will be taken to minimise risk and discuss with your Supervisor**
Use of ionising or non-ionising radiation	*Exposure to radiation* ***NO***	*Obtain copy of existing risk assessment from place of research and attach a copy to this risk assessment summary.*
Use of hazardous substances	*Exposure to harmful substances* ***NO***	*Obtain copy of existing risk assessment from place of research and attach a copy to this risk assessment summary.*
Use of face-to-face interviews *Interviewees could be upset by interview and become aggressive or violent toward researcher*	*Interviewing …* *Own classmates=Low risk* ***NO*** *Other University students=Medium risk* ***NO***	***NB:*** *Greater precautions are required for medium & high risk activities* ***Consider:*** • *How contact with participants will be made - i.e. do not give out personal mobile number, home number or home email, etc.* • *Location of interviews – to be held in a safe environment, e.g. University building, workplace.* • *What support will be available, i.e. will anyone else be available to assist if you call for help, etc. e.g. a colleague knows where the interview is to*

	Non-University personnel=High risk ***YES***	*take place and will be contacted when completed and safe – and what action to take after a certain time if not contacted* • *How to deal with aggressive/violent behaviour, what precautions will be taken to prevent this from happening?*
Use of face-to-face interviews *Participants or interviewees could become upset by interview and suffer psychological effects*	***YES***	***Consider:*** • *What initial and subsequent support will be made available for participants or interviewees?* • *What to do if researcher uncovers information regarding an illegal act?* • *What/who will be used to counsel distressed participants/interviewees, and what precautions will be taken to prevent this from happening?*
Sensitive data	*Exposure to data or information which may cause upset or distress to the researcher* ***YES***	***Consider:*** • *What initial and subsequent support will be available to the researcher*
Physical activity	*Exposure to levels of exertion unsuitable for an individual's level of fitness* ***NO***	***Consider:*** • *Health Questionnaire/ Medical declaration form / GP clearance.* • *Trained First Aid personnel/ Equipment.*
Equipment	*Exposure to faulty or unfamiliar equipment.* ***NO***	***Consider****:* • *Equipment is regularly checked and maintained as per manufacturer's instructions.* • *Operators receive adequate training in the use of.* • *Participants receive induction training prior to use.*
Sensitive issues i.e. Gender/Cultural e.g. when observing or dealing with undressed members of the opposite sex	*Exposure to vulnerable situations/ sensitive issues that may cause distress to interviewer or interviewee*	***Consider:*** • *Use of chaperones/translators.* • *What initial and subsequent support will be made available for participants or interviewees?*

	No	
Children	***NO***	• *Adhere to local guidelines and take advice from research supervisor.*
Manual handling activities	*Exposure to an activity that could result in injury* ***NO***	• *Adapt the task to reduce or eliminate risk from manual handling activities. Ensure that participants understand and are capable of the manual handling task beforehand.* • *Perform health questionnaire to determine participant fitness prior to recruitment.*

If you have answered 'YES' to any of the hazards in section 3, then please list the proposed precautions below:

1. ***Use of face-to-face interviews*** *(interviewees could be upset by interview and become aggressive or violent toward researcher)*

Control measures to reduce potential risks:

- Contact with participants will be via work email and/ or work mobile phone.
- Participants are members of staff from the host organisation.
- University of Salford's Lone Working Code of Practice will be followed. Following the guidance highlighted within this Code of Practice, the following local arrangements have been agreed with the host organisation:
    - All interviews will take place in NHS buildings with a manned reception area. This is to ensure that there is always at least one other person on site (other than the researcher and the participant) when the interviews are taking place. Both the researcher and participants will be required to register at reception when arriving for the interview and therefore there will be awareness that we are on site should there be any health and safety issues, including a fire.
    - Where possible interviews will only take place during normal office hours (Monday – Friday, 9 -5), when reception areas are manned. In the case of members of staff who only work evening and late shifts, a 'buddy' arrangement will be agreed. The 'buddy' arrangement will include identifying a key member of staff who I will inform when I arrive to the NHS building, when I am leaving and when I have returned home. Any 'out of hours' interviews will be kept to an absolute minimum however if these are required then they will only be conducted in NHS building which provide 24/7 services i.e., community hospitals and mental health inpatient ward to ensure that there are other members of staff on site during these interviews.
    - No off site visits will be conducted, all interviews will take place in registered Trust buildings and interviews will be limited to be conducted in those building with manned reception areas (of which there are several in each geographical area of the study).
- The study is considering when incidents occur within healthcare services, so it is possible that participants may become upset or distressed during the interview process. However I have tried to minimise any potential risk by only considering incident which resulted in moderate harm rather than those incidents which were deemed as causing or contributing to major harm or deaths. Also the inclusion criteria for this study states that all investigatory processes must have

been completed for any incident (and therefore a potential participant) to be included as part of this study.

- The study is opt in and therefore there is an assumption that those staff who have agreed to be involved in the study are comfortable discussing events surrounding incidents which they have reported in the past.

2. ***Use of face-to-face interviews*** *(participants or interviewees could become upset by interview and suffer psychological effects)*

Control measures to reduce potential risks:

- Support will be available to participants through a free, direct access services will is available to all staff in the host organisation, through the Employee Assistance Programme (EAP). This is a confidential support service to assist employees with personal or work-related problems. Call 0800 XXX XXX8 for direct access to this service.
- One of the inclusion criteria is that all investigation processes must have been completed prior to an incident (and therefore a participant) being included as part of this study. This includes any internal incident or HR investigation or external police/ criminal investigation processes. Also as the incidents included in this study are graded as moderate is unlikely that external investigations were assessed as required. If any illegal activity is uncovered as part of this study, this will be immediately escalated and discussed with supervisor and then escalated within host organisation as required. This escalation process within the host organisation will be to the Deputy Director of Quality and Nursing.
- The EAP provides counselling services. The lower graded incidents have been chosen to reduce to try and reduce the impact of participants become distressed or upset during the interview process.

3. **Sensitive data** *(exposure to data or information which may cause upset or distress to the researcher)*

- Reviewing and considering potential distressing incidents, investigations or accounts of events that have occurred is already part of my day to day professional role and has been for several years. Therefore a support network is already well established through day to day contact with my line manager, Deputy Director of Quality and Nursing. It should be noted that no specific details of the content of the interviews will be discussed with my line manager.
- If further support is required over and above this, then I can access the EAP service.

Signature of student J Barton Date 05/06/2018

Signature of Supervisor ………………………………… Date ………………………

Appendix B: Participant Invitation Letter (Approved Version)

Invitation Letter

Dear XXXX

Exploring the experiences of incident reporting

I am writing to you as you have been identified as someone who may wish to be involved in a study which is exploring the experiences of incident reporting.

The study team are inviting people who have previously reported an incident to tell us their views. I would like to invite you to a one-off interview with me (as lead researcher) to discuss this further.

Before you decide whether or not you would like to take part in this study, please take the time to read the enclosed information sheet carefully.

If you have any questions about the study then please contact me. My phone number is 077X XXXX XXX and I will be happy to discuss any question that you may have.

I will be contacting you by phone/ and or work email within the next 2 weeks to confirm whether you wish to be involved in this study.

Yours Sincerely

Jxxxx Bxxxxx

University of Salford, Professional Doctoral Student

Email: J.BXXXXX3@edu.salford.ac.uk Phone: 07XXX XXX XX

Appendix C: Participant Information Sheet (Approved Version)

Exploring the experiences of reporting incidents

I am writing to you as I would like to invite you to be involved in a research study which is considering incidents that occur within healthcare services.

Before deciding whether you would like to be involved in this research you need to understand why this research is being undertaken, what it will what it would involve from you and how your information would be used. Please read the below information carefully and contact me on the below phone number if anything is not clear or if you have any questions.

What is the purpose of the study?

I want to find out about your experiences of reporting an incident.

This study will seek to understand:

- The experiences that you have had reporting an incident;
- Understanding what the response was following this incident from your peers, team and the wider organisation;
- Whether you had any contact or discussions with patient and families following the reporting of an incident;
- Whether you have been involved in actions or activities which focused on the learning from an incident.

Why have I been selected?

You have been selected as it has been identified as a member of staff who has reported an incident via the Ulysses Risk Management System.

Do I have to take part?

It is up to you to decide whether you wish to be involved in this study. If you do agree to take part, you are free to withdraw at any time, without giving a reason.

What will happen to me if I do take part?

I will be interviewing participants for this study. It is hoped that this can be completed through one interview lasting approximately one hour. There may be a request for a subsequent interview, if any details require further clarification. The interviews will be recorded, using a voice recorder; this is to ensure that the details you provide during these interviews are accurately documented.

The interviews will take place at an office which is local to your place of work or another NHS office venue (if requested). Cxxx Pxxxx Trust is supporting this study and therefore interviews can take part within your normal working hours.

What are the advantages of you taking part in this study?

The responses that you provide may help to shape the response to healthcare incidents in the future. It might support the improvements to practice so that fewer incidents occur.

What are the potential risks or disadvantages of you taking part in this study?

This study is focusing on incidents that occurred within healthcare services. The main risk is therefore the fact that you may find this a sensitive or distressing topic to discuss. This is something that you will need to consider before you agree to be involved in this study.

If you wish to access support or speak to someone following this interview, there is free access to all staff to the Employee Assistance Programme (EAP). This is a confidential support service to assist employees with personal or work-related problems. Call 0800 XXX XXX8 for direct access to this service.

Will my information and responses be kept confidential?

All information which relates to this study will be kept confidential, any incident and investigation report or interview transcripts will have you name removed so that you cannot be identified.

The study will adhere to the good information governance standards as required as per the General Data Protection Regulations (GDPR) (2018).

The information that you share as part of this study will remain confidential, unless during the course of the interview, you reveal something which may cause harm to yourself or to others, or which may be considered as unlawful.

What if I don't want to carry on with the study?

Your participation in this study is entirely voluntary and therefore you are free to withdraw at any time, without giving any reason. If you do wish to withdraw from this study please let me know. The information that you have given up until the point of withdrawal will be used, useless you specifically ask for his information to be excluded from the study.

The timeframe for the request for withdrawal of information is 1 month after the data is collected.

Complaints Procedure

If you have a concern about any aspect of this study, you should ask to speak to the researcher (Jxxxxx Bxxxxx on 07xxx xxx xxx) who will do their best to answer your questions. If you remain unhappy and wish to complain formally you can do this by contacting the Research Supervisor (Gxxxx Cxxxxxxx on 01xx xxx xxx). If the matter is still not resolved, please forward your concerns to Professor Susan McAndrew, Chair of the Health Research Ethical Approval Panel, Room MS1.91, Mary Seacole Building, Frederick Road Campus, University of Salford, Salford, M6 6PU. Tel: 0161 295 2778. E: s.mcandrew@salford.ac.uk'.

Further information and contact details

My contact details are as follows:

JXXXX BXXXX

University of Salford, Professional Doctoral Student

Email: J.BXXXXX3@edu.salford.ac.uk Phone: 07XXX XXX X

Appendix D: Consent Form (Approved Version)

PARTICIPANT CONSENT FORM

Participant Identification Number for this project:

Title of study: Does the Duty of Candour process impact on improvements in practice: a grounded theory study

Name of Researcher: Jemma Barton

Please complete and sign this form after you have read and understood the study information sheet.

Please initial box:

1. I confirm that I have read and understand the information sheet (Version 3, 05/06/2018) for the above study and have had the opportunity to ask questions ☐
2. I understand that my participation is voluntary and that I am free to withdraw from this study at any time, without giving any reason ☐
3. If I do decide to withdraw, I understand that the information I have given, up to the point of withdrawal, will be used in the research, unless I specifically ask for it to be withdrawn. I am aware that the timeframe for withdrawal is 1 month after the data is collected. ☐
4. I agree to the digital voice recording of the interviews. ☐
5. I agree to the digital voice recordings to be transcribed. During the process of transcribing this information, your information will remain confidential and anonymised. In order to protect your identity, pseudonyms will be used for your name, place of work and other identifying features will be removed from the transcripts and subsequent documents. ☐
6. I understand that information I provide will be used anonymously in outputs of the study. ☐
7. I give permission to use quotes and I understand that these will be anonymised. ☐
8. I understand that my anonymised data will be used in the researcher's thesis, NHS and academic publications (including on the internet), and at conferences. ☐
9. I understand that the information I provide will remain confidential, unless I reveal something that may cause harm to myself or someone else, or which may be considered as unlawful. ☐

10. I agree that my data, once anonymised, may be kept and reused by the researcher for further research and as a training dataset. ☐

Name of Participant	Date	Signature
Researcher	Date	Signature

1 for participant; 1 for researcher

Appendix E: Interview Guide (Approved Version)

Interview Guide

Research question: Does the Duty of Candour process impact on improvements in practice

1. Introductory statements

- Introductions
- Length of interview – approximately 45 – 60 minutes
- Confirm that the interview will be recorded (audio only) and that I will be taking notes throughout
- Briefly cover points highlighted in the cover letter/ information leaflet that the participant will have already received
- Clear that involvement in the study is completely voluntary
- Complete consent form (Appendix E)
- Does the participant have any questions at this stage?

2. Background information

- Ask participant to tell me briefly about themselves:
    - What is there current role
    - How long have they been doing this role
    - How long have they worked in this organisation – where did they work previously

3. Incident reporting (reporting culture)

- What is your understanding of incident reporting?
- Have you reported an incident in last 2 years?
- How did you report this incident – what system/ escalation to line manager

4. Duty of Candour

- What does the Duty of Candour process mean? (grading of incident/apology/ letter/ investigation)
- Have you ever reported an incident which you think meets the criteria for the Duty of Candour?
- If you have what where the next step that you took in terms of this process?
- Can you think of any benefits of the Duty of Candour process?
- Any barriers to you following this process?

5. Duty of Candour - patient and family involvement

- As part of the work in regards to the Duty of Candour have you ever met with any patients or family members?
- If you did meet patients and or families how did these meeting go – what did you discuss – how did you feel?

6. Learning lessons from incidents

- In your experience do you think the Duty of Candour support learning from incidents?
- Do you have any examples of where there has been learning following the application of this process?
- How effective do you think the Duty of Candour process is?

Appendix F: Overview of Participants

Pseudonym name given	Description of participant/ key points from interview
Penny	Penny was the first participant that an interview was conducted with for this research. Penny has worked as a ward sister in the same community hospital ward since 2013 and has been qualified as a registered general nurse (RGN) for over 10 years. The types of patients that are seen within this community hospital include patients that are considered as needed further hospital based care ('step down' care) following an operation for example or people who are normally live within their own home but require some intensive care following a fall at home, for example ('step up' care). The patient in all of the community hospital settings tended to be older people aged 75 years and above. The ward where Penny worked was geographically based in a more affluent area and had a close knit community. During Penny's interview she highlighted a number of key points, firstly when discussion her professional role and job title, she rose an interesting point in regards to professional identity, that had not been previously considered. Throughout the interview Penny highlighted concerns that she had which were linked to the organisational merger, in particular the differences in culture from the organisation that she currently worked in, with the organisational that they were due to merge with. In particular Penny felt that there were clear differences in the two organisations in terms of the response and learning from incidents. As part of the interview with Penny the emergence of the key category relating to of the barrier that standardised written letters creates, starts to emerge.

	Penny could identify any key benefits from the implementation of the Duty of Candour other than maybe a letter being sent out to patients/ families indicates to families that the organisation is investigating the occurrence of an incident.
Debra	Debra is an occupational therapist working in both community and hospital roles. When asked more about her role Debra that there was a number of different roles but that she took the 'clinical' lead role stating. This again highlighted the importance of professional identity and the preference towards a role/ job title that identifies the person as a clinician rather than a manager. Debra has work in her current role for over 5 years and previously worked in a similar role but in different NHS organisation. Debra's view of the Duty of Candour was that it hadn't fundamentally changed anything in terms of her practice other than sending out a formal letter to a patient/ families when an incident had occurred.
Ruth	Ruth work is a registered general nurse (RGN) who works within a community hospital. Ruth has worked primarily in community healthcare settings for over 20 years. Ruth has been in her current role for over 5 years. From Ruth perspective she identified that the use of written letters can often be a barrier in terms of open and honest discussions when something has gone wrong. However equally Ruth provided a different example of where the formality of the Duty of Candour process had been beneficial, stating that this family were aware of the Duty of Candour process and therefore she was able to demonstrate and provide assurances to the family that a full investigation into the incident had taken place, Ruth stated that she did use her professional judgement in terms of whether a second letter (following the completion of an investigation) should be sent out however did have concerns in terms of any ramification from the organisation if she didn't fully follow local policy. Ruth overall view on Duty of Candour was that it was beneficial if it helped the NHS to be as open and honest as possible.
Tina	Tina is a registered mental health nurse (RMN) and worked in a mental health inpatient ward. Tina had worked on this particular years for over 3 years and previously worked in other mental health care inpatient wards. Tina had been given the title of ward manager.

	Tina described that she felt that there had been a lot of positive work undertaken within the organisation to encourage staff to report and respond to incidents. Tina highlighted that she preferred the Duty of Candour process as it able the response to an incident to be clearly documented and recorded. However highlighted that the clinical team discuss whether a patient should be given a copy of the Duty of Candour letter and in some cases they choose to give this information their family instead. Tina highlighted that she felt that one of the positive aspects of the introduction of the Duty of Candour was when a meeting is held with a family to discuss an incident.
Gill	Gill works in a community hospital setting and is a registered general nurse (RGN). Gill has worked within her current role for less than 5 years. Gill stated that her job title was a ward sister. Gill expanded on the name of the role and professional identity stating that in the world of nursing there are specific title for different roles i.e., sister and matron and also highlighting the association with the different role in terms of colour of uniforms. As part of the interview Gill gave an example of when a moderate harm incident had occurred and the steps she had taken to follow the Duty of Candour process. In this example Gill described a patient who had fallen whilst in the community hospital and subsequently been transfer to an acute hospital for an operation. Gill highlights the issue that Penny raised in terms of the way in which the written letter put the onus on the patient or family member to contact the services rather than the services actively working to try and support a family when an incident has occurred. Gill described that she was really disappointed that the NHS had got into a position where the formal Duty of Candour was required. Later in the interview Gill raised similar concerns to other participants regarding the use of standardised letters and the barriers that this can cause in terms of ongoing communication with patient and families. Overall the only benefit of the Duty of Candour that Gill identified was the fact that it held people to account that wouldn't normal respond or investigate when an incident occurred. Gill felt that it terms of her own practice that the Duty of Candour process was an additional level of bureaucracy as prior to 2015 she would have completed similar steps as the Duty of Candour process but the focus of the interactions with patient and families would have been more personalised and not as formal as required under the statutory requirements.

Appendix G: Example of initial and focused coding from interviews

Interview 1

13/11/2018

Core categories:

- Professional identity
- Organisation culture
- Organisational change
- Formal letters – impact of standardised letter templates
- Expectations/ changing expectations of families
- Assurance vs improvement focused

Narrative	Initial Coding	Focused Coding
I: Can you just tell me a bit about your role? P: As a ward sister been doing that since 2013, initially started mat cover at X and then move us over to the new build, I went back to my nurses post. Then I was offered a secondment to go to X to be a sister for 12 months, which I participated in, then following on from that the post wasn't advertised but one in X so I went to X for 4 months as a sister that's when the post here was advertised so then I moved over to X as I have always been a nurse a X so it home if you know what I mean. I know exactly what I am doing, I know all of the staff, it was easier. I: So when did you start X in ward sister role? P: Permanently, 2016	Change of role Building move New role Management role Familiarity with surroundings/ community	Role Environment Professional identity Professional identity

I: So can you describe to me what the ward sister role does? My position on the ward is to oversee patient safety and as well as staff safety, making sure that they are all up to date with their mandatory training, making sure that they are up to date in terms of policies and procedures, all the risk assessments for the patients are completed for the patients regarding falls, waterlow, MUST. Making sure that the records are up to date. Trying to manage the budget and spend (pause) are within my limits, preparing for CQC, making sure the ward is fully staffed and then filling blanks when there is sickness or annual leave. I: This role assumes a ward manager role then? P: Some wards have ward managers and some have ward sisters. But given my experience in the past of being a ward manager one patient said to me 'what's your role' and I said I am ward sister, so the elderly refer to a ward sister has having a nursing background and they feel that a ward manager is a manager. So I think so me it's important that the elderly recognise that a sister does have that…. they can reflect back when they were younger and there were sisters and matrons. I: Are they ward sister at the other community hospitals? P: They are all different everybody labels themselves differently and I think as a trust that is something that we have tried to move to but we do differ across the trust I: Have you always worked in X then? P: Yes I have always worked in community hospitals. Qualified 10 years now, when I applied as a nurse there was no nursing positions and in comparison to now, I find so bizarre, so it took me 3 years to get a permanent post within… within that time I did do two months with the acute trust and I vowed never to go back and I haven't. So I have done community hospital work and community nursing before I got my contract. I: In terms of incident reporting, what's your understanding of incident reporting? P: Incident reporting is anything that has happened that needs reported, whether it's a near miss, an injury and it looking at the harms and it data that is fed back to the trust that can analysed, collated,	Management role Clinical leadership role Issues around budget management – 'trying' Regulatory inspections Profession identity – difference between management and nursing leadership roles Nursing title is more easily identifiable by patient group Freedom to act in terms of deciding on job title Difficulty gaining employment Changing needs – as now nursing posts are available Negative view on acute services Improvements from incident reporting 'protects' evidence of legal element of incident and complaints – possibly	Professional identity Professional identity Professional identity Organisational culture Organisational culture Incident reporting Legal view on incidents Estates / building

audited and protects the staff and the patient if any complaints come back later on I: What types of incidents do you get on this ward then? P: Falls, pressure ulcers I: Tell me a bit about the falls then, as this is a unit which is specifically designed, a modern design P: It is, it's one of the more modern designs of the trust in community hospitals. Its x single on suite rooms and the room and the ward are on a curve so that the desk in the middle is supposed to have optimum view for each room, which we can see but then there are blinds and then doors so you can't see what's going on in those rooms if the patients have got the blinds closed I: have you reported an incident in the last two years? Yep (laughs) I: do you know where most of your falls occur? Most of the falls happen in the patients bedrooms I: and do you know what time of day? P: It can vary, it does vary. Patients with a high risk of falls once we have done their assessment we try and socialise then so we can fetch them out in to the dining area so that means that they have got some social stimulation they are less likely to get up and wander and then the high risk are all together so then we can keep an eye on them I: do your staffing levels have an impact on falls…. Do you have any issues with staffing levels P: Staffing levels… it is difficult as we are staffed for the safer staffing which is… my staff work 12.5 hour shifts so it one RGN for the full 12 shift and 2 HCA for full shift supposed to have a 0.5 which don't find beneficial so that extra nurse comes in for early shift which is 7am until 1.15 pm we are always staffed to what we should be but it doesn't impact the falls Now that the trust changed the incident reporting we now have a lot of deaths as well but they are expected deaths and then I think staff trying to get their head around that they have to incident report a death was hard because they were coming to as palliative care patients so they thought why do they have to report them. Because it not an incident or	connected to professional registration Indicates older population group Issues with purpose built facility – estates Issues with visibility could lead to incident occurring Potential estates issue Potential solution to try and reduce likelihood of falls incidents. What is the impact on patient choice Freedom to act/ ability to flex staffing levels accordingly	Estates Estates Organisational culture/ management role Incident reporting

a near miss we are just trying to explain to them it's just a co-morbidity report.		Incident reporting
We had a death a few months back and X and X look into the report and that got fed back to the ward so that was good for the staff to here, as obviously senior managers looked in the notes in terms of the care that patient had received. Obviously observation had stopped but then it was recorded on her notes that she had capacity and she had her obs done so that was the only feedback we got, she was end stage, why would we do an obs, but then when we looked back it was recorded on someone else notes in error so we were doing the right thing but it highlighted that these were put on to someone notes.	Organisational request/ demand Increase of incident reporting Provides example of why deaths must be reported	Organisational change
I: How does that feel when there is a bit more of spotlight on incidents P: So for that situation and that patient, it was fantastic as it was difficult for the staff at the time but from an MDT approach we got to know family really well, as she was with us such a long time and the feedback that we got was that we did go above and beyond so it was good for the staff to see that. My worry is that we are getting a lot of deaths… think we have maybe had 5 deaths in the last 3 weeks, these are transfers from the acute trust and have died within the first 24/48 hours so there isn't that opportunity to build up that case record before the death. I: So are they being transferred for end of life care P: Yep for end of life care but was we are finding and what we are reporting through the incident forms is the lack of communication and the poor transfers that are coming and that isn't helping the family or the patient as didn't have a dr in on the Saturday which was hard for the family as we had to discuss with the acute trust to get the death certificate and the cerm' form as they hadn't been seen by a doctor on the ward which is hard for me as on a Monday – Friday we do have a dr on the ward and under normal circumstances they would have been seen on the ward but having that delay for that family and the upset of them having to go and collect a death certificate from the acute doesn't contribute to therapeutic end of life care for me.	Review highlighted recording error – evidence of the rational for the recording and review of deaths Family involvement Increase in deaths – end of life care – change in service provision Impact of 'flow' issues within acute trust	Organisational change/ culture Organisational change/ culture Family involvement Organisational change/ culture Organisational culture

	Issues in terms of transfer and safe discharges of care from acute Impact on family	Organisation change/ culture
I: Have you have seen any benefits of the joint arrangements with the acute? P: As much as we incident report issues coming over from the acute we are not getting any feedback. I have completed a few incident forms over the last few weeks, one lady came over with a gentleman's name band on and normally if I'm a second nurse on or in a manager role I will ask the nurse to complete the incident form so that I can sign off but because I was the only nurse on duty, I filled the incident form in and I done the next bit of information. I feel like I have done that incident form, I have highlighted that a lady has come with a man's name band, I tried to ring the ward, I tried to ring the matron, I eventually got in touch with another sister from another ward that went round to speak to the matron.	Difference in incident reporting cultures Communication breakdown	Organisational culture Organisational culture
I: do you see a difference in culture between the two organisations? P: Definitely I: and how does that manifest itself in terms of incident reporting? Erm, I don't know…….. we don't get any feedback. Obviously, we do our incident forms, I'll sign them off or I will complete the 72 hour reports and once it's gone to a SIRI, I'll get feedback then because I have had a few inquests. But the ones which are incidents, we don't get much any feedback. I: you mentioned there about inquests, so have you attended an inquest? P: Yes, 2 I: I am interested in when we do an incident report and then a SIRI, it is sometimes difficult to get the SIRI report into a suitable format so that it meets the needs of multiple audiences and agenda – meet the needs	Incident reporting cultures Critiquing the acute trust in terms of organisational culture Different approaches across organisations	Organisational culture/ impact on and from organisation change Professional identity

of the family but also the needs of the coronial process. I just wondered how that feels at inquest… what was your role at inquest? As a manager, management overview. For one of the deaths one of the patients was referred back to us for end of life care and on that incident, I had a really good relationship with the family with we were open and honest with the family from the beginning, I met with the family with Dr X after the first incident and because that then… it was nearly two year before that went to the inquest so it was hard for the family…. Erm that one was ok. The next one was more difficult, again these were both falls on the ward when the patient had died but subsequently it couldn't have been blamed on the fall. So the next one….. So the family had a lot more questioning. Patient was only here for 36 hours. I: Is going to inquest part and parcel of your role? P: For any moderate or severe I would complete a 72 hour report which would then be passed on to senior management to conduct the SIRIs. What I found with the first inquest was that our legal team were so supportive, I remember thinking 'oh what the hell I am doing'. At the first one, bearing in mind that I didn't meet the gentleman, my statement was 18 pages long so I didn't get called. I: Have any of your staff had to attend inquest as well? P: So the first inquest I did go along, the second one, my evidence was read. I didn't have to go to the second one but still went to support all of my staff. Making sure that they have time… protected time to do the statement, protected time to meet the solicitors, even so much as go and see what the inquest room is like because you just picture it as bad as it is on telly, don't you, but once they understand that it's not as intimating and daunting. I: Moving on to Duty of Candour (DoC) then so for those incidents which meet the criteria in terms of moderate and above, what does DoC mean to you? P:DoC to me is acknowledge to patient and family encounter or came across some harm under our care and I think it's got to be phased so that we are not taking blame and	Critiquing lack of response from acute trust Now switched into management role rather than clinical Ongoing communication with the family Impact of the coronial process on families Families just see one 'NHS' Impact of incident on families	Family involvement Service provision Organisational culture - freedom to act Legal view of incidents Communication type – impact of standardised letters Communication type – impact of standardised letters Assurance rather than improvement focused Communication

I think that's hard to put across in a letter because you are putting it in writing and sending it out and that's what I struggle with . I: obviously you have been registered a while and you will remember a time before DoC so do you think there are any benefits to it?	Different approaches to inquests	Impact of formal letters
P: (long pause)… I haven't seen any benefits, no I can't say I have seen any benefits, I think it has taken away the personal approach to response to incidents, as if a moderate harm occurs then staff understand that they apply it themselves and then obviously I do it in writing but I do think it has taken away that personal approach to patient and family because you are putting it in writing, you are sending it to them, I think that maybe they (patients/ families) just see it as a formality because the letters are pre written, which you can alter and I do try and take a lot of the information out and make it more personal to	Giving staff time to development statements – evidence of importance of task	
the patient but is it just a paper exercise? So what you have done before the DoC if something had gone wrong? I would have just have met with the family face to face as them their understanding of what had happened, ask them if they had any questions surrounding what had happened and take if from their I: so does the letter cause a potential barrier? P: I think it does It gives the patient and the family, my details in black and white, which then put the onus on them if they what to meet with me beforehand. Whereas it would have been the other way around previously .	Choice of words – linked with legal/ claims aspect rather than learning Issues in terms of letter	Organisational culture
I: Do you think there are any benefits to the DoC process? P: I don't know to be honest…. I think you would have to ask that question to a patient or family receiving the letter. Possible, yep, yes there is…. the patient and the family are getting something in writing to say that the trust are taking it seriously and investigating the incident surrounding x, y and x	Issues around communication type – formal letters Evidence of Bureaucratic process	
I: so what about incidents where patient and families don't want to be involved P: This is where we have to be sensitive to the patient and families wishes in the investigation process, obviously if families want to heard the crooks and crannies that's fine and you will know right away those patients and families that do want to know the enth degree and other	Previously more personal approach	Learning from incidents

that don’t want and sometimes I think that they just feel like they have to come.	Issue with letter – responsibility has shifted to patient/ family	Incident reporting
I: have you met with patients and families in regards to this (DoC) and are what stage did you meet with them? P: The first inquest, because the first inquest the gentleman had a fall.	Idea for future research	Standardised letters
I had built the relationship up with the family and he died that weekend when I was on duty so I met his wife and his daughter a week after the funeral so it was quiet early on because they wanted answers, they appreciated that the husband was elderly and he had these other health issues but their view was, what would have happened if this was a healthy 30 year old man and they wanted reassurance that it wasn’t gonna happen again and the fact that we met them… they didn’t apportion any blame on us, I think that made it easier to go inquest 2 years later as they were very sincere, they stood and talked to me and so I think if you can establish that relationship early on it does help.	Adaptive approach based on the needs of the family	
I: what about incidents which wouldn’t go that far… something happened on the ward… there was a moderate harm, would you meet with the family		Patient choice
P: Again, I think that’s what the letter takes away as it is putting the ownership on them. Once you have conducted your 72 hour report or your SIRI, you write to them again to say that you have concluded your investigation… would you like to. And going to sister and management meetings each month… you do withhold a lot of information that you tell patients and families because they don’t need to know (pause)… if…. I don’t know.. yep I don’t know but some information they don’t need to know.	Focuses on most serious incident rather than moderate harm incidents Communication across organisations	
I: if an incident happens on the ward do you speak to the patient? P: I do if I can, if they haven’t been transferred I: do they normally get transferred P: Obviously if the care goes beyond what we can give them then they would have to be transferred		Expectations of families
I: so for example #NOK would they go and come back P: If they wanted to because that’s what we found. We had one lady who was nursed in bed and she had capacity and she could see that		Assurance rather than improvement focused

we were busy one day and she tried to go to the toilet herself, fell and #NOK, she had a really large family and they understood that 'mam was a suborn old bugger' as they put it. So they were happy for her to come back and provide her with end of life care as well but we have had some patient that have had harm on the ward and the families have refused for them to come back. It's hard to get over to families that even though they are in hospital and we are a 24/7 service we cannot prevent any falls and hard for they to understand that maybe sometimes the patient is better off in their own home where they are familiar to their own surrounding, they know where everything is at but then they will say, 'well they will fall at home'. Well they can fall in here then… if that door shut because we are in a room. 2 staff in a room with a patient, that only leaves one other staff member on the ward for 10 and it's hard for families to comprehend that someone can fall in hospital when they should be safe. Even when we say we have a falls mat in the patients room… someone with dementia will try and stand over it, taking a bigger step because they think that doesn't belong there. I: Do you think the DoC process helps at all with the learning from incidents? P: Yes You have got the information there,,, I find it hard once you have signed off an incident… it just goes in to an abyss for me. I keep my DoC letters and I can look back and see when I have applied them, what I have applied them for and then we will talk about them in staff meeting in terms of lessons learnt I: do you keep all of your DoC letter on your computer or within Ulysses? P: I attached them to Ulysses but I keep them on my hard drive too. I: does Ulysses cause you any barriers? P: I think it does because the type of incident… when you know you are going to log and incident, you have got it in your head you know exactly what has happened you cannot find a type of incident a sub type and I was going to email the incident team to see if there could be 'clinical'	Key point links with literature i.e., learning from incidents Focus on incident which cause harm Communication issue – in terms of use of formal letter Impact of working in small geographical area – lack of choice	Assurance rather than improvement focused Professional identity

because I think a lot of the staff spend a lot of time sitting try to find the right category I: in terms of incidents more broadly have you got example… you describe when patient state that they 'just don't want this to happen again' of where you have identified learning or improvements PAUSE	Expectation of families in terms of hospitals being a 'safe place'	Organisation culture
P: We have just received a complaint. So at visiting time I am going to go at visiting time room to room introducing myself to all the family members in there as them have they go any questions about care, about discharge process and leave them my details because the main issue from this complaint is lack of communication. So given that I am the senior on the ward if I can identify myself to all the patient and families that should stop something lack this occurring. I: so you have identified in that complaint some issues with communication on the ward – any reflections on leadership on the ward. It was clear that I first came on the ward that it was welcoming and staff liked and respected you	Is this more about the regulators need for assurance rather than patient care/ experience	Organisation culture
For me that's my reflection on having a bad manager. I put myself first, I make sure that the staff have got the off duty up until the new year, they have done for the last fortnight, so of me if the staff have got the off duty and can plan their free time then their happy. Being a nurse with young children all I needed to know was that my children were cared for and if that's worry is away from them then then can concentrate on work. I'm not regimented or managerial in any way, I am fair and I am a manager when I need to be but that's ok in the extreme circumstances.	Contradictory of earlier point where they felt that DoC didn't support learning No example of learning from incident – focus on the assurance process Impact of the 'system'	Patient/ staff choice
I: from your work across sites is there differences in terms of culture and learning? P: I have worked in a number of the hospital sites. On one of the previous wards that I worked on, culture played a huge part on patient care to the point where we were looking to recruit a motivational person to look at culture. That team were so… wouldn't accept change. I: and what do you think that's from? I don't know they always had that reputation P: does the geographical location impact on culture?	Not describing the learning process	

I think that it does. A lot of the sites are all maybe 7-10 miles apart and you have seen the difference here compared to others. The expectation here in X is greater… we do joke that patients in X were just thankful that they had a bed but in X they expect the silver service treatment. I: Do a lot of the staff live in the same area as the community hospital that they work in? P: X… when I first came to X a lot of staff lived and worked in x… staff used to say 'they are a bad family from the estate… you can't turn them away' so I do think it helped if you don't live in the town that you look after. I: Have you got anything else that you want to add in terms of the duty of candour or incidents? P: No… I don't think so VOICE RECORDER STOPPED (P) starts to discuss a recent police case which is due to go to coroner's court next week… they said 'oh should have mentioned this one whilst the recorder was on'. So I indicated that I would take some hand written notes. They said that there had been a lack of senior management support in this case and some confusion about whether the organisation was listed as an Interested Party at this inquest	Interesting quote – consistent with the view of 'managers' Impact of organisational culture on patient care Differences in services provision, service offer, capacity/ organisational culture Phenomena in terms of information when recorder is stopped	

	Impact of working and living in the same community as the patients that you care for Impact of using voice recorder Senior management support	

Appendix H: Venn Diagram

Appendix I: Policy and Practice Literature – timeline