Why do Patients Develop Severe Pressure Ulcers?

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Submitted in accordance with the requirements for the degree of Doctor of Philosophy

The University of Leeds School of Medicine

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Declaration of Originality

I, Lisa May Pinkney, can confirm that the work carried out and written in this thesis was my own work, unless otherwise declared in the document. The contribution of the other authors to this work has been explicitly indicated below. I confirm that appropriate credit has been given within the thesis where reference has been made to the work of others.

The research included in this thesis formed part of the Pressure UlceR Programme Of reSEarch (PURPOSE) (PURPOSERP -PG-0407-10056). This used mixed methods (systematic reviews, prospective cohort, case study, consensus and psychometrics) to identify patient and organisational risk, develop a risk assessment tool and patient-reported outcome Quality of Life and Health Utility measures. The PURPOSE programme was supported by a project team which included Professors Jane Nixon, Andrea Nelson, Justin Keen, and Carol Dealey; Doctors Elizabeth McGinnis and Susanne Coleman, and Mrs Nikki Stubbs and Lyn Wilson, and myself.

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My own contribution and that of members of the project team are articulated below.

Contributions:

Lisa Pinkney: lead role in all aspects including: study design, protocol development, ethical and R&D approvals, centre set-up, data acquisition, and all field work, in depth data analysis, data interpretation and drafting manuscript for the main paper and NIHR monograph chapter section 'retrospective study of the development of severe pressure ulcers'.

Jane Nixon: programme grant lead applicant, conception, and overall lead role in development of Pressure Ulcer Programme of Research (PURPOSE programme) comprising 5 work packages. Role in 'Why do patients develop severe pressure ulcers?' included contribution to protocol development, eligibility assessment, data extraction, quality appraisal, expert witness review of data, interpretation of results and revising and approving the BMJ manuscript/monograph chapter section 'retrospective study of the development of severe pressure ulcers'.

Justin Keen (Professor of Health Politics): programme co-applicant involved in the conception of and work package lead for the severe pressure ulcer work package, including initial work package design at application stage. Role in 'Why do patients develop severe pressure ulcers?' included contribution to protocol development, expert witness review of data, interpretation of results and revising and approving the BMJ manuscript/monograph chapter section 'retrospective study of the development of severe pressure ulcers'

For clarification, the work package comprised three components. As work package lead Justin Keen is listed as lead author on the Programme Grant chapter reflecting his role for the whole work package. However, Lisa Pinkney was the main author and contributor and the lead author on the BMJ paper associated with the work package component 'Why do patients develop severe pressure ulcers? and monograph chapter section 'Retrospective study of the development of severe pressure ulcers'.

Other co-authors: Wilson, L., Coleman, S., McGinnis, E., Stubbs, N., Dealey, C., Nelson, A., and Patterson, M. contributed to the design, protocol development, protocol implementation, expert witness review of data, interpretation of results and revising and approving the BMJ manuscript/monograph chapter section 'Retrospective study of the development of severe pressure ulcers'.

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Pinkney, L. Nixon, J, Keen J and Emmel, N (2018). Exploring the Patient's View in the Development of a Severe Pressure Ulcer. Patient Safety Congress, Manchester (Poster).

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Dedication

For Harvey and Huey. In memory of Gilly Cooke.

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Abstract

This is a retrospective case study about severe pressure ulcers and why healthcare services may contribute to people developing them. Pressure ulcers are caused when skin and tissues are damaged as a result of pressure. They range in severity from non-blanchable erythema (Category 1), superficial skin loss (Category 2) to large wounds involving fat, muscle and bone (Category 3/4). Category 3 and 4 pressure ulcers are also referred to as severe pressure ulcers (EPUAP/NPUAP, 2009, NHS Improvement, 2018). These can contribute to death. Although there is little known about how patients develop severe pressure ulcers, this study offers possible explanations.

As well as the main finding that the health care environment contributes to the development of severe pressure ulcers; four possible explanations are i) patients not being heard, ii) decision making in complex environments, iii) safety culture lacking in mindful awareness and iv) diffusion of responsibility and poor communication between staff, wards and health care services. These also link into a model of intervention. The study's method offers a way of investigating pressure ulcers retrospectively, which differs from current techniques. The main difference is the focus on the patient's or carer's view as the primary source of evidence, in contrast to the current focus on service level investigations. This study offers a 'Safety III' approach which combines empirical (correspondence) approaches of investigation with coherent (rational, explanatory) approaches.

The study recommends including patients and carers in investigating severe pressure ulcers, empowering nurses to make decisions regarding pressure ulcer care and working towards a 'mindful' safety culture.

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Abbreviations
ABX Antibiotics
ADR Adverse Drug Reaction
A&E Accident and Emergency
CIC Community Interest Company
CQC Care Quality Commission
CQUIN Commissioning for Quality and Innovation
DN District Nurse
DS Data Source
EBM Evidence-Based Medicine
ED Emergency Department
EPUAP European Pressure Ulcer Advisory Panel
FY1 Foundation Year Doctor (1st Year)
GP General Practitioner
HCA Health Care Assistant
HDU High Dependency Unit
IBE Inference to the Best Explanation
IV Intra venous
MDT Multi-Disciplinary Team
NASA National Aeronautics and Space Administration
NDM Naturalistic Decision Making
NHS National Health Service
NICE (pre April 2005) National Institute for Clinical Excellence
NICE (2005-2013) National Institute for Healthcare and Clinical Excellence
NICE (post April 2013) National Institute for Health and Care Excellence

NIHR National Institute for Health Research

NPUAP National Pressure Ulcer Advisory Panel

NPSA National Patient Safety Agency

PCT Primary Care Trust

PDSA Plan-Do-Study-Act

PRASE Patient Reporting and Action

Pt Patient

PU Pressure Ulcer

QIPP Quality, Innovation, Productivity and Prevention

RCA Root Cause Analysis

RCN Royal College of Nursing

RCT Randomised Controlled Trial

RGN Registered General Nurse

RN Registered Nurse

SBAR Situation, Background, Assessment and Recommendation

SHA Strategic Health Authority

SPU Severe Pressure Ulcer

SRB Solid Rocket Booster

SRM Solid Rocket Motor

TEC Theory of Explanatory Coherence

TVN Tissue Viability Nurse

UKREC United Kingdom Research Ethics Committee

UKSC United Kingdom Supreme Court

Chapter 1: Introduction

1.1 Introduction summary

Pressure ulcers (PUs), which are also known as bed sores or decubitus ulcers, cause much suffering for patients, and severe pressure ulcers can contribute to death. The introduction to this thesis identifies severe (Category 3 and 4) pressure ulcers as a patient safety issue, and explains why they are a significant problem. It also situates pressure ulcers within current healthcare policy, and thus highlights the personal, economic and organisational costs in the UK and worldwide.

Health services literature indicates that organisational environments may have an influence on severe pressure ulcers (SPUs) and that clinical negligence may also contribute despite little organisational knowledge about how patients develop them (Bennett et al., 2004, Nixon, 2009). These concerns about negligence in healthcare are nevertheless why pressure ulcers are seen as a fundamental patient safety issue.

This thesis was undertaken as part of an NIHR Programme Grant on pressure ulcers (RP-PG-0407-10056). It introduces a retrospective case study method as a way to explore and explain why people develop severe pressure ulcers, focusing on organisational and patient safety issues alongside the patient's view. In doing so, it draws together theories from psychology, sociology, systems theories and organisational studies. The cross disciplinary focus is admittedly an ambitious one and it is not feasible to include all literature from every avenue of thought: however, as patient safety crosses these disciplinary boundaries, it is useful and novel to attempt to synthesise the areas together in one study to understand more about why patients develop severe pressure ulcers in health services.

1.2 Background

1.3 Pressure ulcers-definitions and clinical aspects

Pressure ulcers are caused when an area of skin and the tissues below are damaged as a result of being placed under pressure sufficient to impair its blood supply. They manifest when mechanical load applied to soft tissues causes cell deformation leading to cell membrane rupture and/or impairment of the blood supply and tissue ischaemia,

both resulting in tissue damage. Pressure ulcers are defined by the European Pressure Ulcer Advisory Panel and National Pressure Ulcer Advisory Panel (EPUAP/NPUAP/PP, 2014, EPUAP/NPUAP, 2009) as: "localised damage to the skin and/or underlying tissue, usually over a bony prominence (or related to a medical or other device), resulting from sustained pressure (including pressure associated with shear). The damage can be present as intact skin or an open ulcer and may be painful" (NHS Improvement, 2018). Categories of pressure ulcers are described in EPUAP/NPUAP international guidelines as ranging in size and severity, from skin redness or non-blanchable Erythema (Category 1) and partial thickness skin loss (Category 2) to severe ulcers involving fat, muscle and bone (Category 3, 4, unstageable or suspected deep tissue injury) (NPUAP/EPUAP, 2014; 2009). Typically, they occur in a person who is confined to bed or a chair by an illness and as a result they are sometimes referred to as 'bedsores', or 'pressure sores'. Category 3 and 4 pressure ulcers are also referred to as severe pressure ulcers (EPUAP/NPUAP, 2009). In this thesis I refer to them as severe pressure ulcers (SPUs).

All patients are potentially at risk of developing a pressure ulcer. However, they are more likely to occur in people who are seriously ill, have a neurological condition, impaired mobility, impaired nutrition, poor posture or a deformity (National Institute for Health and Clinical Excellence, 2020, National Institute for Health and Clinical Excellence, 2015). Pressure ulcers are prevalent in healthcare (Smith et al., 2016) and as the elderly population increases, and advances in medical care lead to increased disability and complexity in the management of patients, improving the evidence base for improvements in their prevention should be a focus in healthcare research (Nixon et al., 2015).

The use of equipment, such as seating and beds which are not specifically designed to provide pressure relief, can cause pressure ulcers (Nixon et al., 2019). Pressure ulcers may arise in a number of ways, and interventions for prevention and treatment need to be wide ranging. A priority in clinical practice is prevention of PUs through repositioning (to intermittently completely off-load high risk skin areas) and provision of specialist mattresses/cushions to reduce mechanical load. In relation to specialist mattresses, systematic review evidence supports guideline recommendations that high specification foam (HSF) mattresses are used as a minimum for high risk patients to prevent PUs (Nixon et al., 2019). However, despite these advances in specialist

equipment and knowledge around provision, pressure ulcers may still deteriorate in patients to become severe pressure ulcers (Coleman et al., 2013b).

1.4 Pressure ulcers in a policy context

Pressure ulcers (PUs) represent a major burden and quality of life issue to patients, carers but also healthcare systems (NHS Improvement, 2018) (National Institute for Health and Clinical Excellence, 2015) (Gorecki et al., 2009, Severens et al., 2002, Schuurman et al., 2009a, Bennett et al., 2004, Dealey et al., 2012). As well as the high personal costs incurred by patients there are also high financial costs incurred by healthcare funders and providers in the treatment of PUs due to increased length of hospital stay, hospital admission, community nursing, treatments (reconstruction surgery/ mattresses/ dressings/ technical therapies) and complications (serious infection). The average length of stay in hospital for patients with pressure ulcers is 25 days (NHS Improvement, 2016). Latest figures from the NHS Safety Thermometer suggest that 4.3% of patients in the United Kingdom will develop PUs every year; However, recent prevalence research found that in a typical acute hospital in the UK, the point prevalence of pressure ulceration is more likely to be 7.1% (Smith et al., 2016, Briggs et al., 2013). Pressure ulcers are prevalent in all health-care settings.

Studies around the world have reported large differences in pressure ulcer prevalence rates, varying from 4.7% to 22.9% in hospitals and 7.7% to 83.6% in nursing homes (Whittington et al., 2000, Vanderwee et al., 2007, Vanderwee et al., 2011, Halfens et al., 2013, Smith et al., 2016, Briggs et al., 2013). In the NHS in England, 24,674 patients were reported to have developed a new pressure ulcer between April 2015 and March 2016, and treating pressure damage costs the NHS more than £1.4 million every day (Guest et al., 2018, NHS Improvement, 2018). Finding ways to improve the prevention of pressure damage is therefore a priority for policy-makers, managers and practitioners alike. The total cost of PUs to the National Health Service is £1.4 to £2.1 billion, making up 4% of the annual National Health Service budget (Bennett et al., 2004, Dealey et al., 2012) a number which has remained an area of concern for policy-makers and the UK Department of Health (Department of Health, 2013a). Patients who develop pressure ulcers remain longer in hospital, and often require extensive treatment (Bosch et al., 2011). Severe pressure ulcers can also lead to death (Redelings et al., 2005, Thomas, 2006, Thomas DR et al., 1996)

Crucially (and the focus of this study) pressure ulcers can be preventable with adequate healthcare intervention (Hibbs, 1998, Downie et al., 2014) and because of this they have become an important indicator of quality of that care (Lyder, 2003). Their prevention is included in a number of UK healthcare policy documents, for example, the Department of Health's NHS outcomes framework 2014/15, NHS Improvement, 2016 and the NHS Patient Safety Strategy 2018. Recommendations for prevention include methods for identification and risk assessment and the preventive measures that should be applied. Treatment of pressure ulcers includes recommendations on wound care, adjunctive therapies and support surfaces (NHS Improvement, 2016; (National Institute for Health and Clinical Excellence, 2015, National Institute for Health and Clinical Excellence, 2020).

Pressure ulcers have been highlighted for a number of years now as a quality and patient safety issue in health policy agendas worldwide, but particularly in the USA, Australia and the UK (Institute of Medicine, 2000, Runciman et al., 2002, NHS Institute for Innovation & Improvement, 2010, Department of Health, 1997). Arising from this concern in the developed world, for the past three decades pressure ulcers have also been identified in successive UK Department of Health (DoH) policies as a key quality indicator (Department of Health, 2000); From 'worst' to 'first' in pressure ulcer incidents, (2010, Darzi, 2008a, National Institute for Health and Clinical Excellence, 2015). More recently, reflecting the links between quality, impact and cost, the DoH set out the ambitious aim of eliminating all avoidable pressure ulcers in NHS provided care, (QIPP, 2011), along with developing a Commissioning for Quality and Innovation (CQUIN) payment framework to facilitate this (National Patient Safety Agency, 2008). Although debates on the term 'avoidable' have continued alongside these drivers (NICE, 2018) and have been largely replaced with 'Present on Admission' (NHS Improvement, 2018). Recent changes have also added pressure ulcers into patient safety strategies within Trusts. A review of death and severe harm incidents reported to the National Reporting and Learning System (NRLS) (2011/2012) (National Institute for Health and Clinical Excellence, 2015) found that pressure ulcers were the largest proportion of patient safety incidents, accounting for 19% of all reports. It has also been acknowledged that a significant proportion of pressure ulcers are avoidable (NHS England, 2018). Although since the NRLS review (2012) was done, patient falls have been equal in numbers with pressure ulcer incidence within trusts.

Pressure ulcers also became a 'high impact action' for Nursing and Midwifery (Darzi, 2008a, NHS Institute for Innovation & Improvement, 2010) placing them high on UK health policy agenda, and they were incorporated into a National Operating Framework ((Department of Health, 2012/13). Similarly in the USA, insurance companies implemented a national change to their reimbursement policies to incentivise prevention (hence the research papers focusing on costs in the USA). Healthcare organisations receive a higher baseline allocation of funding to deliver care, but are now liable for treatment costs arising from organisation acquired avoidable pressure ulcers (Department of Health, 2012a, Stevenson et al., 2013).

1.5 What is known about pressure ulcer risks?

One of the main clinical risk factors for developing a pressure ulcer is immobility, whilst other clinical risk factors such as perfusion (including diabetes) and skin/pressure ulcer status have been identified (National Institute for Clinical Excellence, 2001a, EPUAP/NPUAP/PP, 2014, Nixon and McGough, 2001, Nixon, 2009, Coleman et al., 2013b). However, some severe pressure ulcers develop that cannot, however, be explained by the above risk factors alone. A systematic review of epidemiological evidence relating to pressure ulcers identified primary and secondary patient characteristics which increase susceptibility to developing them. This included mobility limitations, skin condition, conditions affecting the circulation (such as vascular disease and diabetes), skin moisture and nutritional deficits (Coleman et al., 2013). However this review also highlighted important research gaps around the complexity of factors surrounding the development of pressure ulcers. It noted limitations in evidence and methodological challenges due to the large number of descriptor variables used to describe risk factors which may affect interpretation and use of the data in metaanalysis, highlighting the need for an internationally agreed minimum data set and further exploration in the area of what other factors lead to patients developing severe pressure ulcers. Study quality was also considered poor in the review. Limitations in underpinning conceptual frameworks and Furthermore, few epidemiological studies include patients who develop severe pressure ulcers (only three to date (see Literature Review below; one of which is this study) and it is not possible to identify from the current evidence base the risk factors associated with development. This highlights an area which needs further exploration.

1.6 What is the significance of Category 3 and 4 pressure ulcers?

Severe pressure ulcers (Category 3 and 4) are seen as a 'serious' clinical event in the NHS, and other health care services internationally, and reported as a patient safety issue when they occur in patients (WHO; Department of Health, IHI). Safety improvement initiatives regarding all categories of pressure ulcers have had varying degrees of success and to date do not offer conclusive evidence around how to address prevention and management of severe pressure ulcers (NHS Improvement, 2018). These Category 3 and 4 pressure ulcers are required to be reported at Board level and to the local Clinical Commissioning Groups (CCG) and investigated within organisations to elicit learning for service improvement (NHS Safety Thermometer, 2017, National Institute for Healthcare and Clinical Excellence, 2005) (Department of Health, 2000). However, despite the interest in learning from Category 3 and 4 pressure ulcers, there still remains little research to date focused on these particular categories. Other than this study, and the other implementation study by Greenwood and McGinnis (2016), which was part of the Programme Grant work stream, there are few known studies which focus specifically on severe pressure ulcers. Various factors at different levels in the healthcare organisation have been examined in an attempt to understand how different categories of pressure ulcer can affect patient outcomes from an organisational perspective (Al-Kandari and Thomas, 2009)((Ausserhofer et al., 2013, Baier et al., 2009, Berlowitz et al., 2001, Blegen et al., 1998). However, Category 3 and 4 skin damage, which may lead to death from an infected ulcer is the focus of this study; and there has been little attention paid to date on this particular sample of patients (Pinkney et al., 2014).

Examples of organisational factors which impact on patients and pressure ulcers include hospital organisation, nurse staffing, workload and factors in direct patient care. A systematic review focusing on this area by Lake and Cheung (2006) found that some studies showed a significant link between nurse staffing and pressure ulcers, but other studies did not show such an association. The review concluded that research to date is equivocal (at times there is a staffing effect and at other times not) appearing to suggest that having more nurses, rather than more of the right ones and in the right environment, does not necessarily achieve better outcomes for patients. The review by Lake and Cheung however suggests instead that skill mix should be a focus for further investigation. Another review by Lang et al. (2004) around nurse staffing ratios found

no support for relationships between basic staffing ratios and pressure ulcers. It is noted in recent research that better models of care may impact on pressure ulcer outcomes (Schubert et al., 2008) which are discussed in detail in the literature review below (Chapter 2). To date, however, it is still largely unclear why some patients develop severe pressure ulcers within the health care system, yet other patients with similar high risk characteristics do not. Costs to the patient and healthcare systems are much greater if a patient's ulcer deteriorates, or they develop a severe pressure ulcer. There has been no attention paid to this area in literature. Category 3 and 4 pressure ulcers and the reasons some patients develop them therefore became the topic for my research questions.

1.7 Rationale

A number of characteristics of severe pressure ulcers substantially influenced my research approach. As it is only possible to identify severe pressure ulcers when patients have already developed one, this meant that the study *had* to be retrospective in nature. Severe pressure ulcers cannot be predicted: we do not know where or when they will occur. Also, severe pressure ulcers are comparatively rare events in terms of the large numbers of other categories of reported pressure ulcers. They are difficult to define and measure using current clinical incident reporting systems. Taking these points into account, it was clear that an experimental study would not be possible and that the study was likely to be observational and involve small numbers of patients.

The study design was influenced by the 'fixed' features of the problem. I realised that the research would require some design choices. Some of these choices flowed naturally from the fixed features, while others involved conscious decisions between plausible alternatives.

The decisions made were that the study had to be an observational, retrospective, indepth study of small numbers of patients (n=8), and that I would collect rich data that would allow me to evaluate any explanation for the development of a severe pressure ulcer, ranging from an isolated event to problems with the organisational context. The rationale for conducting a retrospective case study design is provided in greater detail below and in Chapter 3. Because the findings might be used to inform practical guidance on preventing pressure ulcers particular attention was given to the validity of the findings.

The initial questions that this study seeks to answer are:

Why do patients develop severe pressure ulcers? And more specifically-does the healthcare environment contribute?

Chapter 2: A theory-driven review of severe pressure ulcers and the organisation and delivery of health care

2.1 Chapter summary

This chapter reviews the global literature concerning healthcare and delivery of services for patients with severe pressure ulcers. It focuses on patient safety and organisational perspectives as a basis for understanding how they occur. Little evidence has been available to date about why patients develop severe pressure ulcers and how far healthcare organisation contributes to their development.

Because there is sparse evidence about how severe pressure ulcers develop in healthcare organisations, this review has necessarily drawn on other patient safety theories developed from the literature review, and out of current debates in safety, which includes the recent Safety I and Safety II paradigm shift (discussed below as part of this review). Safety I focuses on why things have 'gone wrong' in healthcare, which was the prominent paradigm until 2015, and Safety II focuses on why routinely things go right which is now widening the thinking around patient safety and generating much debate. Theories developed from this literature review incorporate these wider safety debates. This review considered a broad range of safety-focused literature from psychology, sociology, organisational theory and healthcare when it was initially carried out in 2009 and 2016 (Searches 1, 2 and 3). It has since then been updated to incorporate more recent developments in the field of patient safety (Searches 4 and 5).

This review has thus focused on the care of patients with pressure ulcers, and how this links with patient safety, human error and organisational research. The main research question in this review, which takes us forward to the main study, following theory refining is: How far does the healthcare organisation influence patients developing severe (Category 3 and 4) pressure ulcers?

2.2 Introduction-an iterative and theory driven literature review

The literature review began as a scoping review (in 2009) to search for possible explanations for severe pressure ulcer development in the context of health care environments. It then developed into a theory driven review as the initial fieldwork

progressed and offered insights (2011-16; updated in 2019). I used Ovid MEDLINE, EMBASE, Psychinfo, CINAHL, HMIC, Open Grey, Google, NICE as data search engines alongside snowballing searches. Those above were seen as the most relevant databases regarding health services literature.

Below is a timeline of the iterative process which was used to review literature in the context of this study. The timeline highlights how an initial exploratory review underpinned the first phase of data collection and analysis. At this point I began to formulate tentative explanations as to how patients developed their severe pressure ulcers and to search for these within patient safety literature. The final iteration of the review was to update it following the final write up, incorporating Safety I and Safety II approaches to patient safety, as these emerged as a main debate within this thesis.

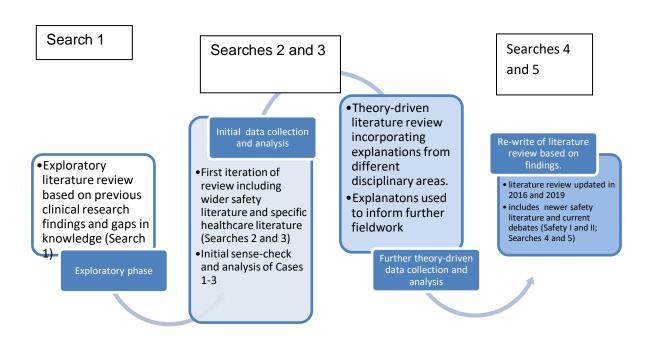


Figure 2.1: A timeline of literature reviewing.

Search 1; Exploratory search for 'Severe pressure ulcer' and 'Category 3 and 4 pressure ulcer' in patient safety and health services literature. 28 papers retrieved; 2 fulfilled the eligibility criteria, which included all primary research which focused on pressure ulcers, organisations/healthcare and safety (detailed below). Also, surveys, qualitative research studies, before and after studies and cohort studies, along with RCTs. I did not include small scale studies, if they were not qualitative. I was not interested in patient level treatment interventions, because they did not offer any

information about the influence of the organisation, I therefore excluded these, along with education programmes for nurses, equipment based studies, and other papers seen as irrelevant to the review questions (see below).

Search 2: Broad snowballing search of patient safety and health policy literature; human error and organisational theories. This did not follow the specific eligibility criteria.

Search 3: Focused search of health services literature 1,185 papers assessed for inclusion and exclusion. 353 assessed as potentially eligible. 74 fulfilled eligibility criteria; 53 relevant studies appraised.

Search 4: Keyword search on Safety I and Safety II (2000 onwards. Revisit of patient safety literature.

Search 5: Grey literature searches: OpenGrey database 171 articles. Google searches.

2.3 A theory driven literature review

I chose to carry out a theory-driven review to define candidate explanations around which to investigate and apply a case study methodology, as research on severe (Category 3 and 4) pressure ulcers is such an under-researched area. Although the approach I took to reviewing the literature followed a scientific realist methodology, it differed in its method of execution from a realist synthesis (Pawson, 2006) (see Chapter 1). In the realist method, the primary ambition is explanation building. 'The purpose is to articulate underlying programme theories and then interrogate the existing evidence to find out whether and where these theories are pertinent and productive.' [p. 74; (Pawson, 2006). A realist synthesis articulates, then tests, revises and refines preliminary theories, which is what I intended to do with my theories or explanations, but I was more interested in multiple causality and explanation building than articulating programme theories. The following section contrasts traditional systematic reviews with theory driven reviews and explains why a theory driven review may be more useful in the context of this particular thesis.

2.3.1 Collating multiple evidence to inform practice in health care

Certain sectors and disciplines have sought to use evidence derived from research in different ways. The idea of closing the gap between evidence and practice (Trinder and Reynolds, 2000) filtered into the healthcare sector, which until recently allowed less transparency in its practices (Davies et al., 2000a). A more questioning outlook has been developed by service users towards doctors and other healthcare professionals,

no doubt fuelled by more accessible information, such as internet resources, the growth of a Ill-informed and educated public, and corresponding improvements in information technology. This has been coupled with a quest for transparency in practices and focus on productivity in service delivery, to match the more managerial and consumer orientated approach in healthcare (Department of Health, 1997), and associated with a subsequent rise in governmental scrutiny and accountability (Davies et al., 2000a, Glasby et al., 2007).

Emphasis on valid knowledge has led to healthcare professionals searching for better ways to defend their professional status. Evidence based practice has appeared in various forms, and one of the ways it has manifested is through accumulating 'rigorous' research evidence in a systematic way to provide a stronger defence for practice. If the emphasis is on a simple outcome-based study, such as a drug trial, then an RCT can be the most 'rigorous' research design to examine effectiveness; however there are many issues with research, that are not relevant to an RCT (Rycroft-Malone, 2006). For example, when there are complexities and service delivery issues involved, the positivist view that evidence must be 'scientific', with its search for a politically neutral 'rational truth' becomes more questionable (Harrison, 1998). Additionally, research is not always interpreted in the same ways, and there remain longstanding disputes about what constitutes best evidence in health care (Forbes and Griffiths, 2002). This suggests that the movement towards evidence based policy is itself contested (Becker and Bryman, 2004). Yet an RCT retains its position as the 'gold standard' in health research and the systematic review method magnifies both its pros and cons, by elevating its status and judging evidence in relation to the research hierarchy as shown in Table 2.1 below:

Table 2.1: The Hierarchy of Evidence (see Becker and Bryman, 2004)

Hierarchy Type:

Type I Systematic reviews and meta-analyses

Type II Randomised controlled trials

Type III Cohort studies

Type IV Case control studies

Type V Cross-sectional surveys

Type VI Case reports

Type VII Expert opinion

Type VIII Anecdotal

Critics of this method of collating evidence include Bastian (Bastian, 2004), who argues that many systematic reviews make "judgement calls" too soon in the process, resulting in incorrect treatment decisions. Systematic reviews are designed to help identify which forms of health care work best by bringing together results from similar randomized trials, assessing them, and combining the best to produce a statistically reliable result that can be more readily applied in other settings. Although the processes of traditional systematic reviews and meta analyses are systematic in the sense that a predefined, transparent methodology is used, they use a linear process, which works well for clinical or drug based trials. However, as Rycroft-Malone et al. (Rycroft - Malone et al., 2004) highlight, in reality, practitioners draw on multiple types of evidence, which are likely to include research, clinicians' experience, patient experience (of themselves as a person and their illness) and local information/data. They state that... 'practitioners need to draw on and integrate multiple types of evidence that have been critically and publicly scrutinised. Furthermore, these processes are not acontextual — the melding of this evidence base occurs within a complex, multi-faceted clinical environment' (2004; p83).

Rycroft-Malone (Rycroft-Malone, 2006) argues that the focus of the traditional evidence synthesis approach to promoting evidence based practice has meant that there has been a neglect of the actual process of implementation and therefore a continuing gap between evidence and practice. People are not 'passive recipients of evidence' but instead 'stakeholders in a problem-solving process called evidence-based practice' and

there needs to be a focus away from individuals to the 'multiple factors that affect implementation success' (2006; p104).

For example, a clinical treatment is not the same as a healthcare programme, which differs from service delivery, and health policy (Pawson, 2006). There have been recent attempts to take into account the complexities involved in implementing evidence into practice using systematic synthesis of evidence. Pawson's model uses theory based evaluation, and instead of focusing on appraising research at the outset, and thus losing credible messages from otherwise poor studies (Pawson, 2006), this theory based method offers a different approach to reviewing evidence, which is more... 'generative rather than successionist' (Pawson, 2006), thus providing a useful contrast to linear reviews. The search and appraisal of evidence is purposive and theoretically driven with the aim of refining theory. Multiple types of information and evidence can be included. Thus, rather than building up the evidence successionally, in an x to y linear fashion, the in between of x to y is examined. The focus becomes less on the outcome of 'what works' and more on... 'what is it about this that works for whom and in what circumstances?' (Pawson, 2006). The approach I have taken follows a realist approach, yet differs from the generative concept of Pawson's causality. Mine sits more with George and Bennett's (2005) idea of multiple causality and theorising, which is developed further as part of my method of analysis (see below).

However, to this end, a theoretically driven review with a realist worldview allowed me to consider multiple types of information and causality when exploring an underresearched area. I searched a range of different types of literature, considering alongside traditional health services databases, grey literature, internet based evidence, 'poorer' quality evidence.

2.4 Search 1: The absence of severe pressure ulcer research

Initially, I searched the literature (see databases) for the terms 'severe pressure ulcer' and 'Category 3 and 4 pressure ulcer'. Pre-2013 when the paper arising from this PhD was first published (Pinkney et al, 2013), there were 0 results obtained. When I ran the search again in 2019, there were 28 papers which had the terms above as a subject heading. Of these 28 papers: 14 were focused on biomechanical aspects of pressure ulcer development (Ruschkewitz and Gefen, 2009, Fang et al., 2018, Kazemikhoo et al., 2015, Portnoy et al., 2011, Ruschkewitz and Gefen, 2011, Sopher et al., 2010, Linder-Ganz and Gefen, 2007, Linder-Ganz et al., 2009, Linder-Ganz et al., 2008, Gefen et al., 2008a, Loerakker et al., 2010a, Loerakker et al., 2010b, Loerakker et al., 2013, Gefen et al., 2008b). 3 were associated specifically with costs of pressure ulcers

(Coomer and Kandilov, 2016, Kandilov et al., 2014, Demarre et al., 2015); 3 were focused on nutrition and how this affected patients with all categories of pressure ulcers (Louw et al., 2016, Banks et al., 2010, Hudgens et al., 2004). 3 were prevalence studies about pressure ulcers (James et al., 2010, Vowden and Vowden, 2009, Vangilder et al., 2008). One study was focused on patients who have spinal cord injury (Goodman et al., 2014); one focused on a case study of a child with spina bifida (Aksu et al., 2013); one was the published paper from this PhD (Pinkney et al., 2014); and one was a study reporting on the outcomes of this work within one local Trust (Greenwood and McGinnis, 2016). This meant that only 2 of the papers fulfilled my eligibility criteria (see below). This initial search highlighted that, although academic research may have focused on clinical risks for patients with pressure ulcers, (Nixon (2009), (Coleman et al., 2013a), there has, to date, been less emphasis on non-clinical risk factors, or underlying organisational processes which may influence the care of patients in both hospital and community settings in regard to severe pressure ulcers.

There have been implications in previous literature that negligence can be a factor in the development of pressure ulcers, particularly in association with deteriorating pressure ulcers, and that better management can prevent them occurring (Bennett et al., 2004, Buckley et al., 2014, Department of Health, 2012a, Downie et al., 2014). These suggestions nevertheless often refer to older papers published several years ago, which suggests a need for updating the research in this area although there have been many papers focusing on the costs of pressure ulcers (Bennett et al., 2004, Bosch et al., 2011, Bredesen et al., 2015a). However, the implication of poor care and the issue of harming patients also suggests links between patient safety issues and pressure ulcers. This link has been highlighted in health policy agendas globally (see Introduction chapter) (in particular the USA; (Richardson et al., 2000, Institute of Medicine, 2000, Institute for Healthcare Improvement, 2004, Agency for Healthcare Research Quality, 2014) Australia; (Healthcare, 2011) and the UK (Department of Health, 2000, Department of Health, 1997, Department of Health, 2013b, Department of Health, 2012a, Secretary of State for Health, 2014); NHSi pressure ulcer definitions, 2018. However, gaps in research evidence in the area of patient safety and pressure ulcers have also been acknowledged within previous literature (Coleman et al, 2013). This review has sought to address these gaps and find possible links between the healthcare organisation and severe pressure ulcers.

2.5 Search 2 (incorporating Search 5): Pressure ulcers as a patient safety issue

I then sought to examine pressure ulcers as a quality of care or patient safety issue and began to search the patient safety literature. These searches informed my epistemological stance and subsequent methodological approach, so will not be discussed in detail here, but I will examine these areas in in Chapter 3.

2.6 Combining disciplinary thoughts (using Searches 1, 2, 4 and 5)

I originally drew together evidence from all of the most prominent approaches to safety. I surmised that underlying theories are different according to each academic discipline, finding that none crosses disciplinary boundaries; therefore none can explain a patient safety problem comprehensively. For example, the Safety I psychological perspective understands an adverse event as a psycho-social, but nevertheless cognitive error, situating it around an individual's reaction to the error or organisational context. This means that explanations are found within this particular of learning. Reason's model (2000) is neat yet is less able to predict organisational factors or 'latent conditions' based on its model, leaving these more to the reader's assumptions. The sociological focus on explaining adverse events in terms of the organisational and institutional culture means that theorists are reluctant to consider an individual or cognitive explanation in examining errors, given their discipline and knowledge. Organisation theorists apply organisational, macro level theory to understanding the topic (more in line with Safety II). This does not encourage them to also assess findings from the individual or small group perspective. Perrow's (1984) account comes near to a combination of disciplines, but doesn't account for cultural overtones, and is criticised for being a rather negative, nihilistic view of safety (Shrivastava et al., 2009). In essence, the theoretical concepts that are adopted for research, like the disciplines that generate them, always frame the locus of attention. We are thus left with ambiguity of meaning, and often with incompatible findings and studies. However, my study's main aim was looking to support or refute the claim that severe pressure ulcers were linked to any aspect of the health care organisation, or the environment surrounding a patient's care. I didn't know where the explanations lay. I needed to somehow consider all of the above areas to explore my research questions. Furthermore, other reviews in patient safety had highlighted the need for cross-disciplinary research in patient safety, (Waring et al., 2010) so it was appropriate to try and combine areas for a possible multi-disciplinary perspective and explanation. Having carried out the broader searches in patient safety to identify research areas to explore, I was now in a position to carry

out a more focused search to explore the areas I had identified above to add subject relative research on pressure ulcers within organisations to my review.

2.7 Search 3: Focused review-Health Services Literature

I thus carried out a systemic search of health services literature to try and link and explore literature in more detail around pressure ulcers, organisational influences and patient safety. I produced a search strategy using key words and MesH terms from key papers found during the scoping search (see Table 2.1 below). The search terms reflect topic areas identified at the beginning of this section.

2.8 Search strategy-search 3

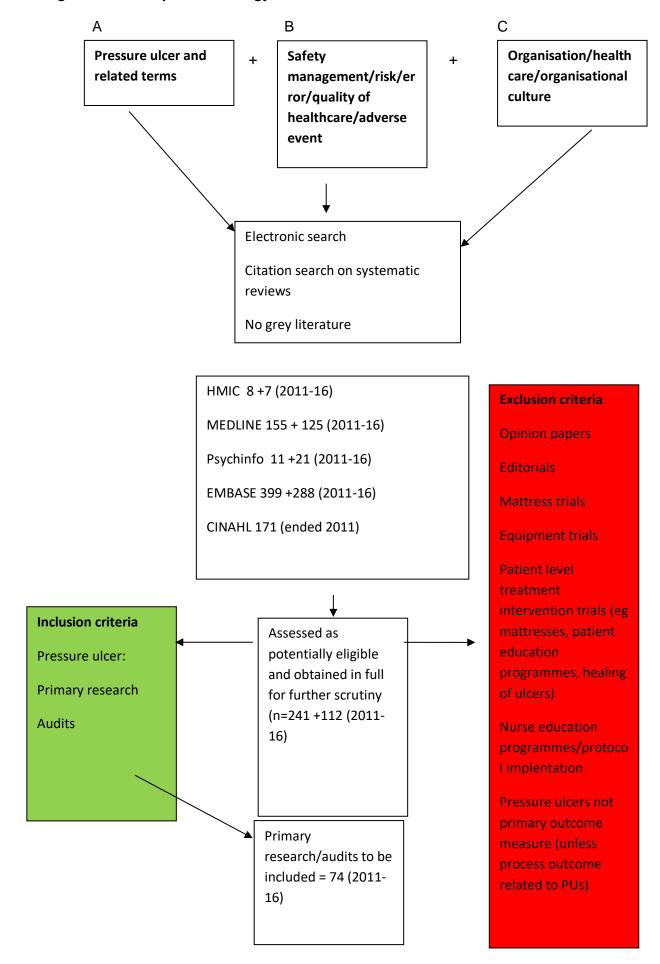
I was able to conduct a focused search based on the refining of my exploratory initial searching. At this point I searched electronic databases from 1996 to 2016 using Ovid search engines. The results are shown below. I searched MEDLINE, EMBASE, Psychinfo, CINAHL, and HMIC. In addition, an auto-alert function was set up within these databases until 2016. I also did a citation search on systematic reviews. I searched grey literature using OpenGrey. I used key papers identified from a theoretical review to identify appropriate search terms, and cross checked these with retrieved papers to make sure I had not missed any further associated terms. The search strategy included all known search terms for PUs, organisations, safety and risk (see Fig 2.2 and Table 2.2 below).

Table 2.2: Search terms

Search terms used:		
 adverse adverse event* bed bed sore* bedsore* clinical clinical incident* damage* decubitus decubitus sore* decubitus ulcer* error* event* incident* 	 models, organizational models, psychological organi#ation* organizational culture organizations patient patient safety pressure pressure sore* pressure ulcer pressure ulcer* 	 quality of health care risk risk assessment risk factors risk management risk* safety safety management skin skin ulcer* sore* ulcer*
medical errors	• prevent*	

Figure 2.2 is a diagram of the initial scope of the search and subsequent strategy:

Fig 2.2 Initial scope and strategy



2.9 Data Extraction and analysis

Data extraction involved reading through each health services study and identifying key findings using a theory focused technique for seeing if the study was relevant to the review questions (7). I also used an appraisal I attached a relevance criteria framework (Fig. 2.3) in order to identify those relevant to our refined literature review question. I included all primary research which focused on pressure ulcers, organisations/healthcare and safety. I included surveys, qualitative research studies, before and after studies and cohort studies, along with RCTs. I did not include small scale studies, if they were not qualitative. As I was not interested in patient level treatment interventions, because they did not offer any information about the influence of the organisation, we excluded these, along with education programmes for nurses, equipment based studies, and other papers seen as irrelevant to the review questions (see exclusion criteria above and Table 2.3 below).

Table 2.3 Inclusion and exclusion criteria

Inclusion criteria

- Primary research
- Pressure ulcers/organisations/safety
- Audits

Exclusion criteria

- · Opinion papers
- Editorials
- Mattress trials
- Equipment trials
- Patient level treatment intervention trials (e.g. mattresses, patient education programmes, healing of ulcers

2.10 Results

1,185 papers were retrieved from the search to be assessed for inclusion and exclusion. 353 were assessed as potentially eligible for inclusion. Of 74 studies initially retrieved, 53 papers were selected and appraised using the CASP tools for research (Critical Appraisal Skills Programme, 2019) (see Table 2.4).

Table 2.4- Included studies

Catego ry numbe r	Categories of research included	Reference	Num ber of paper s	CASP Appraisal
1	Qualitative studies	Dellefield et al, 2008; 2013;	4	Clear aim, appropriate method, clear data and findings. Limited value/scope. No examination of researcher role. Pilot sudy.
		Buss et al. (2004)		Clear aims, method, data, Small scale study, but across sites. Rigorous analysis. Limited scope. Careful analysis of researcher role.
		Johansen et al. (2014)		Clear aims, method, appropriate design, biased sample, limited analysis. Researcher's roles analysed and considered. some useful insights into risk assessment use.
		Latimer et al. (2014)		Analysis and aims not clear, Method not rigorous. Limited scope and little

				researcher role consideration. Interesting findings about the patient's view of pressure ulcers. Locally applicable.
2a	Surveys (perceptions, beliefs, availability of protocols, basic	van Loo et al. (2010)	8	Clear aims, analysis. Poor response rate (45%), good sample, but limited scope as SCI patients only.
	tools guidelines, resources)	Schubert et al. (2008)		Clear aims, good response rate (65%). Large but biased sample, clear method and analysis. interesting insights into rationing nursing care.
		Chaves et al, 2006		Clear aims, method, 48% response rate, limited scope and findings, although large sample used. Some insight into protocols used in agency care.
		Barry et al., 2005		Clear aims, methods, analysis. Excellent response rate (86%). Limited relevance to this research as USA based study and activities. Limited scope, but interesting insights into empowerment of nurse aides.
		Berlowitz et al, 2003,		Unclear aims, but clear method and analysis. Limited scope and sample

				but interesting findings
				about QI and culture.
				about Qi and culture.
		Ausserhofer et al, 2013;		
		Aussemorer et al, 2013,		Clear aims, and rigorous
				methods, and analysis.
				Limited scope and
				application. Good insights
				into patient safety culture.
				I was a second
		Wang et al, 2014		
		Wang et al, 2014		Clear aims, method, limited
				scope.
2b	Prevalence	Paquay et al. (2010)	9	Unclear aims, clear method,
20	(descriptions of	raquay et al. (2010)	9	limited scope. good insights
	compliance)			into clinical judgement.
	compnance)			into cimicai judgement.
				Clear aims, method,
		Gunningberg et al, 2009		analysis, interesting
				findings.
		Dopierela et al, 2007		Unclear aim, methods
		Dopiereia et ai, 2007		unclear, interesting findings
				on prevalence if Pus on neuro wards.
				neuro wards.
		Capon et al, 2008;		
		Cupon of an 2000,		Clear aims, outdated study,
				US based longitudinal
				study, large sample. Useful
				insights.
				Quartiannaira basad study
		Igarashi et al, 2013;		Questionnaire based study, clear aims analysis,
		, ,		-
				Japanese only, useful

				insights. Limited
		VanDenKerkhof 2011		applicability. Census study, clear aims, method, useful insights into prevalence over 15 years
		Halfens et al, 2013;		Clear aims, method, useful findings from prevalence data. Good quality indicators.
		Lahmann et al, 2015;		Clear aims, methods. Useful study Germany based, insights into mobility link with Pus,
		Bredesen et al, 2014;		Clear aims, method, analysis. Useful for insights into ward level interventions.
2c	Before and after studies (implemented organisation	Horn et al 2010 Chaboyer W. et al 2014	19	Clear aims, limited scope Clear aims, limited scope
	change/protocol	McInerney JA. 2008		Clear aims, longitudinal study. Useful insights
		Ballard N. et al. 2008;		Unclear aims, limited scope. One ICU
		McElhinny ML. Hooper C. 2008		

	Classic 1 d 1
	Clear aims, clear method.
	Inadequate data as poor sign
De Locat et al. 2006	up for heel ulcer study.
De Laat et al, 2006	
	Clear aims, method, good
	insights into QI and pressure
Rosen et al. (2006)	ulcer management.
	Clear aims, unclear method.
Hiser et al. (2006)	limited scope and limited
	local applicability.
	Clear aims, clear method,
	but limited scope and
	applicability. Interesting
	insights.
Lepisto et al. (2006)	
	Clear aims and method.
	Poor analysis, and limited
	scope. Useful pilot study.
Eaton (2005)	
Eaton (2003)	
	Clear aims, method, and
	analysis. Limited
	applicability to UK as
	reimbursement to individual
	staff.
Abol et al. (2005)	
Abel et al. (2005)	
	Classiss weeks 1 - 1
	Clear aims, method and
	analysis. Good large scale
	Before and After study.
	Insights into process
	improvement for Pus.
Lyder et al. (2004)	
	Clear aims and method.
	Large scale study (17

		hospitals). Interesting
		insights into pressure ulcer
		improved performance by
		staff.
	Baier et al. (2003)	Clear aims, but unclear
		method and design. Clear
		analysis. Significant results
		of improvement in PUs in
		nursing homes.
	DI (2001)	Unclear aim, method and
	Dlugacz et al. (2001)	·
		analysis. Poor quality study.
	D 11 (2012)	
	Dowding et al. (2012)	Charachara and had and
		Clear aims, method and
		analysis. Insights into electronic health care
		records and PUs.
	Brilli et al. (2013)	Clear aims, unclear method
		and analysis. Useful insights
		but limited scope.
	Burston et al. (2015)	
	, ,	Clear aims, method and
		analysis. Insights into QI
		and Pus.
	N. 1. (2014)	Clear aims, method and
	Miller et al. (2014)	analysis. Large scale study.
		insights into changing
		culture in nursing homes.
		cantare in narsing nomes.
	Hartmann et al. (2016)	Clear aims, method and
		analysis. Large scale and

				longitudinal study. Insights into organisational readiness and sustainability.
2d	Cohort /case control studies (exploring impact of organisational factors on pressure ulcer outcome)	Selected key studies (Bonner et al., 2009)	32 (11 appra ised)	Clear aims, method, rigorous analysis. Useful insights into safety culture, nurses' perception and clinical outcomes (PUs)
		Bosch et al. (2011)		Clear aims, method, and rigorous analysis. Insights into Pu prevalence in relation to safety culture. E.g no relationship with org culture and prevalence.
		Shannon et al. (2012)		Clear aims, method. limited scope as in one organisation. Pressure ulcer prevention package reduced incidence by 67% in both facilities.
		Dubois et al. (2013)		Clear aims, method and analysis. Insights into nurse model of staffing and lower risk of Pu.
		Lee et al. (2014)		Clear aims, methods, analysis. Insights into RN staffing and PU rates. high rates associated with lower Pus.

		Kunaviktikul et al. (2015)		Clear aims, method, analysis. Limited scope due to self reports. insights into nursing extended hours.
		(Bredesen et al., 2015b, Bredesen et al., 2015a)		clear aims and method. unclear analysis. insights into PUs and culture.
		Ma and Park (2015)		Clear aims, but unclear method and analysis. Limited scope and conclusions.
		Dijkstra et al. (2015)		Unclear aim. Method and analysis clear, but limited scope.
		Taylor et al. (2012)		Clear aims, method and analysis. Limited scope due to one US centre. insights into links between nurse and patient injuries.)
		Unruh and Zhang (2012)		Clear aims, unclear method and analysis. not unit level data.
2e	RCTs (implemented organisational change/practice/ protocols/delive ry models)	Van Gaal et al, (2009, 2011)	2	Clear aims, methods and rigorous analysis. Useful study and follow up study for this area.

There were mostly cohort/case control studies (32) and before and after studies (19) eligible for inclusion in the review. Along with 2 RCTs, 9 prevalence studies, 8 survey designs, and 4 qualitative studies.

2.11 Combining literatures to propose theories

I appraised the studies and considered their relevance to my initial review questions. I examined empirical evidence in the light of possible theories from the broader literature, which situated the health services evidence within broader safety literature. During this appraisal, interestingly, and although not surprisingly, I found that there were differing approaches to studying patient safety and pressure ulcers at health services level, which in some ways mirrored the more general patient safety literature. For example, some studies focused on individual or small group level research samples, which led to conclusions and recommendations based within this area, similar to psychological theories (Safety I) set out above. Other studies focused more on safety culture, mirroring a sociological approach to studying pressure ulcer care and management (Safety II). Further papers researched the politics of the healthcare in terms of pressure ulcer care, and focused more organisationally, with political conclusions and recommendations. With these corresponding theoretical stances in mind I then set out some initial theories resulting from the appraisal of evidence:

2.12 Levels of inquiry

Level 1:

Nurses' have individual responsibility for reduction of pressure ulcers

There were several papers covering perceptions and beliefs about pressure ulcer care (9 surveys and 2 qualitative papers). Of these studies, themes emerged around nurses' personal beliefs that pressure ulcer care could be of better quality. Service users felt care could be better quality. Staff self-reported that they were too busy to care as well as they should for patients (Kennedy, 2005). They also believed that they were using outdated techniques of nursing. There was both lack of consistency and varied use of guidelines. They felt that they implicitly rationed patient care, not through choice, but based on resources (Dopierala et al., 2007, Schubert et al., 2009, Chaves et al., 2006, Ausserhofer et al., 2013). Where staff turnover was high, this had a negative effect on patient care (Dellefield and Magnabosco, 2014, Castle, 2001). Models of nursing care

appeared to affect pressure ulcer outcomes, with professional models of nursing care (measured at unit level) having lower rates of safety-related events than functional models (Dubois et al., 2013).

Level 2

Pressure ulcers can be reduced by a strong safety culture

The 19 'before and after' studies offered evidence around Quality Improvement initiatives. These, in the main, reduced pressure ulcer frequency when implemented in sites. For example, these included electronic health records implementation and various other Quality Improvement initiatives such as care bundles and culture change programmes (Dowding et al., 2012, Brilli et al., 2013, Hartmann et al., 2016). Where the organisation welcomed improvement, the culture change towards pressure ulcer prevention was better. This is echoed in more recent Government documents around quality improvement (Care Quality Commission, 2019). Some studies were lower in the quality of the method of approach, and based in one clinical area, or site, limiting the scope of the study findings (Ballard et al., 2008, Lepisto et al., 2006), but others offered longitudinal results, which offered more promising findings of sustainable culture change (Brilli et al., 2013, Burston et al., 2015). With the increasing focus on Quality Improvement at national policy level, these approaches to measuring safety culture have increased massively in recent years, however, remaining at local level. Nevertheless they offer important insights into change at local level, that may be replicated elsewhere, and have continued to appear in health policy with the NHS Patient Safety Strategy (NHS Improvement, 2019b) although the updated literature review has highlighted more mixed results around the impact of safety culture in regard to pressure ulcer care.

One study which examined organisational culture and team climate found that only in pressure ulcer care did institutional management contribute to preventative management at ward level and not in other adverse event areas (Bosch et al., 2011). This was noted to be due, in part, to the 'concerted action' between different caregivers for pressure ulcer care. The evidence from these before and after studies remains misleading, as often when the organisational culture is 'ready' to implement quality improvements, this tends to reduce pressure ulcers (Berlowitz et al., 2003, Ma and Park, 2015) which biases studies towards reporting good outcomes. There is a publication bias issue too, as these studies tend to report good results, but the results

are not celebrated and written up for publication if they are less significant or interesting. There is currently not enough evidence about what factors cause reduction in pressure ulcers, which was highlighted in a recent pilot meta-analysis (Groves, 2014, Miller et al., 2014).

Case control and cohort studies which were appraised in this review offered more evidence around improvements in nursing and care home quality, and these studies (32/11) highlighted that the service environment plays a part in reducing pressure ulcers (Bonner et al., 2009). For example, when residents in two nursing centres were compared (one using a pressure ulcer prevention strategy and the other a control group) the prevention group reduced pressure ulcers by 67% in a 6 month period (Shannon et al., 2012) although this study was limited to one organisation. Another case control study examined unit level nurse work environments in comparison to overall Magnet Hospitals (USA), and found that although Magnet Hospital status and unit level environment were significantly associated with hospital acquired pressure ulcers, (21% lower odds), the unit level appeared to have a more positive (lower odds) effect on pressure ulcer odds (29%) in comparison with non-Magnet hospitals. These findings suggest something around the unit level environment has an effect on pressure ulcers (Ma and Park, 2015).

In countries (for example the USA) where financial incentives have been given to staff for a number of years, this was associated with a lower incidence of pressure ulcer rates (Barry et al., 2005), and ambitious quality measures seem to work (Baier et al., 2009). This appears to have been replicated globally. For example, a Dutch prevalence study, which was conducted between 2001 and 2008 reported declines in pressure ulcers of 8.5% in 2001 to 3.4% in 2008. In the UK, Safety Thermometer data is now published, although few explanations are provided around prevalence rates nationally. Prevalence rates were measured at 5.39% when the Safety Thermometer was introduced alongside the CQUIN framework (financial penalties), and reduced to 4.6% in 2015 when hospitals were no longer required to collect pressure ulcer data for this national policy (Department of Health, 2012a).

A Norwegian study by Bredesen et al. (Bredesen et al., 2015a) found that the average ward patient safety culture was significantly related to the hospital acquired pressure ulcer odds. That is to say the higher the patient safety culture score, the lower the

hospital acquired pressure ulcer odds. This also echoes the supposition that if a ward is 'ready' to improve then safety improvements will occur. However, two other studies carried out previously, which examined links with safety culture and presence of pressure ulcers found no such association (Bosch et al., 2011, Ausserhofer et al., 2013), so further research is necessary to draw more conclusive evidence.

Both RCTs included in the review developed and tested an evidence-based in-patient safety programme, which used bundles and indicators, and a combination of safety guidelines. These studies found that there was a significant positive effect of a tailored educational programme on nurses' knowledge of pressure ulcers. Patients in intervention groups developed 43% and 33% fewer adverse events compared to usual care groups in hospitals and nursing homes respectively (van Gaal et al., 2010, van Gaal et al., 2009). To support this view, with a caveat that the evidence was based on nurses' beliefs, and not a large scale study, a survey of nurses' views of patient safety culture in China found that an improvement in culture was associated with a decrease in adverse events (Wang et al., 2014).

Level 3

Service issues such as delays and service delivery affect pressure ulcers

This level of focus was based on more organisational and political evidence where workload appeared to be a predictor of pressure ulcers, with better qualified nurses achieving lower pressure ulcer rates (Yang, 2003, Unruh and Zhang, 2012). According to Unruh and Zhang (2012) changes in Registered Nurse (RN) full-time equivalents were positively related to changes in RN per adjusted patient day. All patient safety incidents were negatively and significantly related to one or both RN staffing measures; particularly in relation to pressure ulcers, although this was a weak association. Specialist wards appear to help with patient safety incident reductions. For example, in a study by Suwanwela et al. (2007) overall complications in a stroke unit and a shortterm ward were 16.8%, compared to 26% of patients admitted into a general medical ward (Suwanwela et al., 2007). Although this study was based on stroke patients, rather than around pressure ulcers per se. Higher nursing ratios were linked to improved outcomes for residents in nursing homes (Wan et al., 2006, Bredesen et al., 2015a) and lower staff turnover impacted on pressure ulcer rates (Dellefield and Magnabosco, 2014) (Barry et al., 2005). Other studies in acute sites offered arguments for staffing ratios having little impact on quality indicators, yet having an

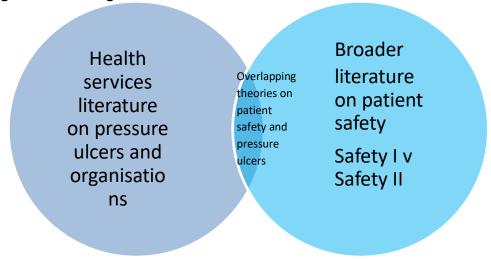
impact on pressure ulcer rates (Lee et al., 2014) although the Lee (2014) study was limited in scope and analysis.

2.13 Discussion

Although the primary research evidence offered interesting insights into areas of pressure ulcer care and the effect of the environment, it has still offered little about the *process* of care and the development of pressure ulcers. Instead, in the main, it has remained concerned with comparing points in time, and how incidence of pressure ulcers may decrease with the implementation of Quality Improvement initiatives. The evidence to date, still offers very little about patients who develop severe pressure ulcers despite quality initiatives, and in this review the studies which focused solely on severe pressure ulcers were either excluded as not being relevant to the organisational focus of the review, because they were concerned with biomechanical aspects, or were the findings from this thesis. The small amount of good quality evidence shows the paucity of research in this area despite nine years of exploratory work.

However, despite the lack of evidence on severe pressure ulcers, the primary research studies did offer three potential levels of interest from which I could refine theories further to underpin a research study. At one level (Level 1) there was a focus on individual staff and responsibility for patients' pressure ulcers, another level (Level 2) focused on service delivery, and the other (Level 3) focused on the organisational culture. In the light of general safety literature these mirrored in some ways general approaches towards patient safety (i.e. psychological, sociological and organisational or political approaches). I thus used the combination of literatures (see Fig 2.4. below) to then apply general theories of safety to pressure ulcer literature, which no one, to my knowledge, has done to date (Nixon, 2009, Waring J et al., 2010, Waring, 2007).

Fig 2.3 Combining literature



Perceiving pressure ulcers as errors or adverse events in a patient safety perspective (Berlowitz et al., 2001, West, 2000) and categorising these adverse events using different disciplinary explanations, helped to address the purpose of the review and organise what sparse evidence there was into testable areas. Following my initial scoping searches I fed back findings of the review to clinicians and verified my tentative theories with them to see if they found them to be applicable to practice (Pawson, 2006). This iterative process helped to construct an investigative, yet inductive approach to explore why patients develop pressure ulcers, despite finding little evidence from primary research literature on severe pressure ulcers.

I combined evidence about pressure ulcers found in primary health services research (Berlowitz et al., 2003, Baier et al., 2008, De Laat et al., 2006, van Gaal et al., 2010, Baier et al., 2009, Berlowitz et al., 2001) to name a few of the studies which offered valid insights, with broader underlying theories on patient safety (Reason, 2000a, Perrow, 1984, Vaughan, 1996, Waring et al., 2007, Waring et al., 2006). I then used this combination of evidence to produce a refined list of possible, testable explanations or refined theories (below) which could be influential in the development of severe pressure ulcers which develop in healthcare organisations. The first theory is a null hypothesis, where a patient may develop a pressure ulcer regardless of the care received (Explanation A). The second theory allows for an interaction with health care services to an extent, but centres around a single error committed by a staff member, team, or service (Explanation B) and remains at an individual interactive level. The third theory (Explanation C) alludes to both Reason's and Perrow's models, which emphasises a causal 'sequence of events', either linear in nature (Reason) or complex

(Perrow). The fourth theory (Explanations D) alludes to Vaughan's model in the main, and would be an explanation if the organisational culture were to be the main cause of the pressure ulcer. The final theory is one which allows for the explanation for a severe pressure ulcer to be a combination of any of the others, or alternatively none of the theories set out (Explanation E). Therefore I set out testable explanations to underpin my study as follows:

2.14 Testable explanations:

Explanation A

A patient will develop a pressure ulcer if good care (current best practice) is provided regardless of the care he or she receives (null hypothesis)

Explanation B

The severe pressure ulcer is caused by a single error

Explanation C

A severe pressure ulcer is caused by a series of errors, or in a complex framework of errors which add together to make a serious incident

Explanation D

The organisational culture makes the severe pressure ulcer more likely

Explanation E

There is an unexplained, or undiscovered theory, or a combination of the above theories

2.15 Conclusions

I initially found out little of how severe pressure ulcers are caused or prevented from the primary research evidence in this particular area. None of the studies I found addressed links specifically between the health care services and organisation and severe pressure ulcers (aside from the work from this thesis). However, despite the lack of findings around severe pressure ulcers in health services literature, by using a theory driven, iterative approach set out above, I was able to broaden the scope and draw on more general theories of patient safety to conceptualise the area of scrutiny. These general theories and my candidate explanations also underpin the primary research literature in this area, and I was able to set out tentative hypotheses to frame my study and investigate patients who develop severe pressure ulcers, to explore whether the environment, if at all, contributes to their development. The paucity of empirical evidence and the theoretical stance I have taken to counteract it, have underpinned the aims of this PhD study.

Chapter 3: A retrospective case study method

3.1 Chapter Summary

This chapter investigates the retrospective case study approach as a method of examining the development of severe pressure ulcers in hospital, defining them as 'adverse events', or 'failures in care'. The method draws on George and Bennett's (2005) case study method, which was derived from the field of political history, and aimed to study historical experience, in order to create analytic explanations. This method examines 'severe pressure ulcers as failures in care' retrospectively, using a process tracing technique and identifies possible causes of them.

Study sites were eight NHS acute and community settings in the north of England between September 2008 and August 2012 and included eight patients who had all developed severe pressure ulcers, who were purposively selected for varied demographic characteristics. The reasons for identifying these particular patients and the choice of case study design are explained below. Although the approach presents some difficulties in practice – notably in demands on time, and the risk of hindsight bias— it has some advantages over current investigative techniques which aim to uncover the causes of severe pressure ulcers based on linear causality. It offers a detailed, coherent view of events and, using analysis of eight cases, develops a style of theorising about the development of pressure ulcers, which highlights the significance of the health care environment.

3.2 Introduction: the importance of quality, safety and case studies

The notion of 'quality' of care has been merged with the notion of 'safety' in the area of patient safety (Darzi, 2008a, Vincent, 2010). Safety is often seen as a dimension of quality, and this notion arose from situations where patients came to harm because of deficiencies in their healthcare, although there is no obvious dividing line between the two areas. Historically, Donabedian, an eminent theorist of healthcare quality, made the distinction in 1968 between the structure, process and outcome of healthcare, and its associations with quality, which gained widespread acceptance (Donabedian, 1968). He suggests that quality is a dimension of elements and interactions within the process of medical care, adding that provider performance (namely the manner and humanity with which care is delivered) needs to be taken into account when judging quality. When Donabedian set forward these ideas provider performance and delivery had not yet been associated with health care, and he drew attention to these in his seminal work. The

Institute of Medicine report "To Err is Human: Building a Safer Health System" in 2000 brought to the forefront links between performance, harm, safety and health care. It established patient safety and the occurrence of adverse events as quality issues, with safety being expressed as the first dimension of quality (Kohn et al., 2000). The World Health Organisation defines quality of care as the proportion of potential health gain actually delivered by a healthcare organisation for its set of patients (World et al., 2006). Quality thus reflects the gap between what can be achieved and what actually happens (Vincent, 2010). Arising from the changing paradigms around quality and safety, there was a theoretical shift from individual blame to system-level and organisational culture as responsible for adverse events, as the technical and social complexity of healthcare was recognised as a contributor to patient harm alongside human error (Department of Health (2000), Reason (2000a), Reason (1997a), (Pidgeon and O'Leary, 2000, Perrow, 1984).

3.3 Safety I: The error-focused psychological approach to patient safety (incorporating findings from Search 2)

Historically, patient safety literature was concerned with the interaction between clinical practice and the work environment at a 'micro' or individual cognitive level (Ballard et al., 2008, Healey et al., 2006, Reason, 2000b). It emphasised patient safety as 'safety science' (Waring J et al., 2010) and still to some extent remains influenced by the field of human factors, cognitive and social psychology (Reason, 2005, Leape et al., 2009, Vincent, 1997, Vincent et al., 2008, Reason, 2000b). This sits under what is termed as Safety I.

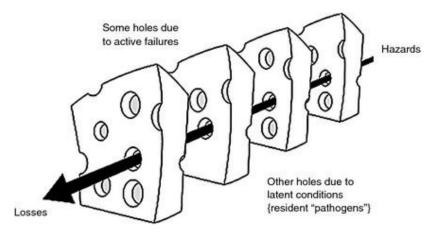
The Safety-I view appeared alongside early patient safety policy publications such as To Err is Human (Institute of Medicine, 2000) when safety in healthcare rose to the top of global health agendas (World et al., 2006, Department of Health, 2000, World Health Assembly, 1997). This approach focused on ensuring that as few things as possible go wrong in healthcare and other complex systems. Given that there were few healthcare systems based tools to look at error in healthcare at this time, these influential reports borrowed from approaches used in technological systems such as aviation and manufacturing. Following this logic, the Safety I approach suggests that things 'go wrong' because of identifiable failures or malfunctions of specific components: technology, procedures, human workers and the organisations in which they are embedded ((Hollnagel et al., 2013, Hollnagel et al., 2015).

Human behaviour in health systems is seen through this positivist orientated lens as logical, measurable and graphical (NHS England, 2018, Campbell and Stanley, 1966). The purpose of investigating adverse events (or things going wrong) through this Safety-I lens is to identify any root causes and contributory factors relating to adverse events, while risk assessments aim to determine their likelihood (Hollnagel et al., 2013, Vincent, 2010). The safety management principle is thus to respond reactively when something happens or is categorised as an unacceptable risk, usually by trying to eliminate causes or improve barriers, or both (Reason, 2000b, Institute of Medicine, 2000).

Graphical linear models, such as Heinrich's (1931) Domino Model, (Heinrich, 1931, Heinrich, 1980) were originally at the heart of Root Cause Analysis, which by its name suggests that it searches for and identifies root causes. This model was prominent in the technological industries throughout the 1980s. This model was later supplemented by more composite linear models such as Reason's Swiss Cheese Model (2000), and these were adopted as the basic safety tools in health care when patient safety became more popular in health policy in the late 1990s (Institute of Medicine, 2000). The graphical view of safety (see Reason's Swiss Cheese Model; 2000) had already became widespread and popular in the safety critical industries (nuclear, aviation, and so on) between the 1960s and 1980s, and is still the most prevalent model used in frontline healthcare safety management today (NHS England, 2015, Reason, 2000b).

However, few people within healthcare noticed that these models were already being challenged by industrial safety outside healthcare as inadequate to newer, more complex working environments (Hollnagel et al., 2015). Also during the 1960s to 1980s, when the Safety I approach was popular in industry, performance demands in healthcare were significantly lower than today (for example, CQUINs (Commissioning for Quality and Innovation). However, well publicised targets such as those in Accident and Emergency departments are now prominent drivers in healthcare (NHS England, 2017) yet complex systems such as the NHS were also less interdependent back then (complex discharges, Choose and Book initiatives etc.). As these systems have become more and more complex and have become more politicised (see Introduction section) it has become more difficult to analyse them in terms of components and graphical representations (Perrow, 1984, Hollnagel et al., 2015).

The Safety I approach, influenced heavily by Reason's early work on error management (1997a) argues that error can be attributed to either active (individual) or latent (organisational) factors which are inherent in the system. This approach provides essentially a cognitive psychological account of human error, focusing on the psychosocial environment, and suggests a 'Swiss Cheese model' (Figure 2.2) as the basis for studying human errors, where holes (errors) line up and multiple holes lead to an 'adverse event'.



Successive layers of defences, barriers and safeguards

Figure 3.1: Swiss Cheese Model: Reason (1997)

This conceptual model suggests that a hazard is always present, but occasionally breaks through if defences are missed, for example a missing defence would be if a health care professional forgot a procedure, the patient did not turn up for treatment, staff did not follow policy properly and so on. If all of these defences fail, then an error occurs. The approach was aimed mainly at Reason's peers, who were cognitive psychologists. Reason updated much of this original work to counteract issues with latent failures and focused more on cultural overtones in his later work (Reason, 2016); however the simplicity of the earlier Swiss Cheese Model had a strong impact in healthcare in its effect on investigative processes (NHS Direct, 2011).

Despite this model being a very simple metaphor, and easily memorised, it has been criticized by organisational theorists. Pidgeon and O'Leary (2000) for example, argue that although the emphasis is on the promotion of active failures by latent conditions, the model lacks an organisational level of analysis to describe 'inter-organisational phenomena' or the interaction between the active and latent precursors. Different layers are explained further in later models, for example, organisational defences, management defences and frontline defences, but the interaction between them is not.

To date, despite further modifications of the model, (Reason, 2004) this influential work has not yet fully developed a 'whole system' of latent errors (Waring, 2007, Wallace et al., 2009). It remains a linear systems approach to error causation, which relies on a sequential pattern and focuses on the 'active failures' to examine error. This school of thought is influenced by work done in other technological industries, and was central to the argument in the USA patient safety report mentioned earlier 'To Err is Human'. (Institute of Medicine, 2000) This approach leads professionals to seek out 'root causes' of errors (Reason, 2000a, Andersen and Fagerhaug, 2006). However, the root causes, or factors, that are associated with this factorial model of error causation, are themselves not developed theoretically or analytically, yet relied upon by health professionals to focus their improvement work (Nicolini et al., 2011). According to this model, these must be tangible and be 'do-able'. A further drawback with translating such ideas, is that health care organisations do not act like technological organisations; they are dealing with humans, not machines, and are more complex and difficult to predict (Waring, 2007, Waring J et al., 2010, Institute of Medicine, 2000). What works for technological systems may not work for more human, decision-focused systems such as the NHS. Neither are 'latent conditions' examined in such a depth of detail, even in Reason's later work (Reason, 2008).

While Reason's model has remained the dominant model in healthcare, an update of this model has been offered by Lawton et al. (2015) in the guise of the Yorkshire Contributory Factors model. This is based on a framework of factors which contribute to incidents in hospital settings. In the centre are the 'active failures' (following the Swiss Cheese model) but around this are a series of circles representing situational factors, local working conditions, and two layers of 'latent' factors, which include the organisation and wider external policies. While this model is both evidence based (following a systematic review (Lawton et al., 2012) and the model is more related to healthcare, which are both improvements in comparison to Reason's model; it is only relevant currently for hospital settings, and is rooted in 'preventing' errors. It does suggest a more complex insight into investigating errors, and is being more incorporated into frontline work across the NHS as a way of investigating errors using the Root Cause Analysis process.

Over the last decade Root Cause Analysis (RCA) and other methods of error investigation have become the main tools for analysing adverse events such as severe

pressure ulcers in health care (NHS Direct, 2011, Ovretveit, 2005). Originally used in high risk industries such as nuclear power and aviation (Carroll JS and Edmondson AC, 2002) RCA was adopted in 2001 by the National Patient Safety Agency, (now NHS Improvement) arising from the Department of Health's report 'An Organisation with a Memory (2000). RCA still remains the most popular method in health care to examine clinical incidents retrospectively, and then to recommend strategies to change practice (Public Administration and Constitutional Affairs Committee, 2017). It is designed to work towards preventing future adverse events based on the learning achieved from incident investigations.

Normally, a root cause analysis is undertaken when an incident is reported; however, this requires correct and accurate reporting of incidents, and not all adverse events are easily reported and measured. Pressure ulcers, for example, often do not have an easily identifiable beginning, and tend to happen on wards gradually, where the staff are sometimes not aware of their development. There have been debates amongst health care researchers and practitioners; whether this technique for analysing incidents works as well as it should (Wallace et al., 2009, Nicolini et al., 2011). Although health care professionals appear to value it as a tool, there are suggestions that an RCA's focus on systems problems is not understood enough by staff trained in its use. Although the tool aims to avoid blaming individual staff members in the event of an error and focuses on the system instead; see Lawton et al. (2012), a large study around its uses conducted in 2009 found that 47.1% of staff who attended a national training programme thought that disciplinary or punitive actions should result from an investigation. Only 49.5% understood the management strategies for how to deal with staff afterwards in a non-blame outcome (Wallace et al 2009). Further UK based recent research in this area has found similar outcomes around the utility and poor implementation of RCA (Peerally et al., 2017). It is often difficult to recruit a wide range of staff members to an investigation, which led to investigations being localised to clinical level. Although most RCA tools are designed to provide a 'helicopter view', in practice health care professionals seem to prefer the tools that allow them reconstruct the event in a temporal linear style, (such as a chronology of events) which follows a narrative rather than argumentative approach (Nicolini et al, 2011). This preference has been shown to lead to narrative rather than argumentative style investigations and conclusions. This also culminates in conclusions based at clinical level rather than staff examining organisational factors such as lack of resources, due to the complex nature of such areas (Nicolini et al., 2011).

Therefore, although staff may understand 'on paper' the human factors approach which underpins the method of RCA, the systems focus is not so well understood when applied to real world cases and outcomes of investigations are therefore not helpful for learning (Peerally et al., 2017). The emphasis on a linear timeline, finding a root cause or causes, and implying a 'reductionist view' of events (Peerally et al., 2017) leads us to over simplify in particular the causes of the pressure ulcer, and implies that solutions can be understood as 'root causes' to fix. This approach however, still remains the most influential school of thought within patient safety in frontline practice, with government health policies still emphasising patient safety as safety science (Waring et al., 2010; Department of Health, 2000; National Audit Office, 2005; National Patient Safety Agency, 2008; Healthcare Commission, 2008). Safety I literature and related concepts therefore offered another area to explore in the study: Did a patient develop a severe pressure ulcer due to a human error, with a root cause?

3.4 Safety II: the organisational resilience/sociology focused approach (incorporating findings from Searches 2 and 4)

Safety II, in contrast to Safety I, focuses its investigations on gaining an understanding of how things usually go right, since that is the basis for explaining how things occasionally go wrong (Hollnagel et al., 2013). Hollnagel and colleagues, who are some of the chief advocates of this movement (which is a relatively recent advance in global healthcare; 2014 to date) remind us that, in contrast to the tried and tested Safety I style tools of investigation, the situation is different for the many more events that go right. Despite their importance, they usually receive less attention in safety management activities such as risk identification, safety assurance and safety promotion. There are no current requirements from authorities and regulators to look at what works well, although things appear to be slowly changing; (Hughes et al., 2019, Lawton et al., 2014), but to date few agencies and departments do that. Possible exceptions are audits and such where good practice is celebrated (NHS Wales, 2010). If we analyse how these approaches differ, a system (for example, a hospital) is said to be unsafe if there are several adverse events; alternatively, a system is said to be safe if such adverse events occur rarely or not at all. This is, by logic, an indirect definition because safety is being defined by its opposite, by what happens when it is absent rather than when it is present (Hollnagel et al., 2015).

Safety II asks that instead of only looking at the few cases where things go wrong, we look at the many cases (90 per cent) where things go right and try to understand instead how that happens (Hollnagel et al., 2013); Lawton, 2014; Hughes et al, 2019). The advocates of the Safety II movement advocate that clinicians are often able (90 per cent of the time) to adjust their work to conditions. Resilience engineering (Hollnagel et al., 2013) also acknowledges this, and argues that the reason why people are able to work more or less effectively is that they continually adjust their work to current conditions. Thus, as health care systems expand, these continual adjustments by staff at the frontline become increasingly vital for safety and therefore present both a challenge and an opportunity for safety management (Weick et al., 2008).

Organisational sociology and anthropology raise the issue of whether culture can be 'measured' using quantitative psychometric methodologies such as questionnaires or surveys. Furthermore, this approach does not support the analysis of safety from an individual or small group perspective (Waring J et al., 2010). This highlights a fundamental knowledge gap between the areas of psychological and sociological research. This approach is Safety II.

Links still remain tentative, to date, in healthcare research between the two areas of Safety I and Safety II, although studies have been done in other industries by sociologists, which have attempted to analyse both areas (Perrow, 1984; Vaughan, 1996). Two such influential studies, focusing on organisational risk, examined failures of large systems in fine detail (Vaughan, 1996, Perrow, 1984). Perrow's 'Normal Accidents' (Perrow, 1984), retrospectively examined accidents in high risk industries. He investigated system failures that contributed to the Three Mile Island nuclear disaster, and situated it alongside other catastrophes in high risk industries, including the Bhopal gas leak disaster and the Challenger disaster. Perrow's conclusions differed substantially from those drawn during prior investigations which concentrated on individual, frontline blame. By focusing on patterns within the system as a whole rather than at an individual level, he found that there was a complex sequence of events within the system which led to the accidents. Instead of a linear approach to understanding the connectivity of tasks, Perrow conceptualised how discrete and apparently unconnected failures can interact in unanticipated ways, leading to accidents which are 'normal' within a system. The more complex and tightly connected a system is, the more there is a high degree of 'interactive complexity'. Similarly, Turner argued in his 'Man Made Disasters' book (1978), that disasters arise from an interaction between the human and organizational arrangements of the socio-technical systems set up to manage complex and ill-structured risk problems. Based upon a

systematic qualitative analysis of 84 British accident inquiry reports spanning a 10-year period, the theory starts from the observation that disasters in large-scale technological systems are neither chance events, nor 'Acts of God'. The man-made disasters model defines a disaster purely in sociological terms, as a 'significant disruption or collapse of the existing cultural beliefs and norms about hazards' (p.72). Turner argues that there is an accumulation over a period of time of a number of events. Within this 'incubation period' a chain of discrepant events, or several chains of discrepant events, develop and accumulate unnoticed, similar to Reason's model, however, the man-made disaster model proposes that latent errors and events are accompanied by a failure of organizational cognition and 'intelligence', as the developing system's vulnerability to failure is concealed by social processes.

Latent failures may cascade to produce catastrophes, as in Reason's and Lawton et al.'s models, but they are not linear, and are unavailable to any humans who are involved within the system. Precautions put in place may even contribute to failures, as they may alter a system that relies on multiple complex connections to function. In contrast to the analysis and uncovering of 'factors', which was associated with the Reason/Lawton models, Perrow's model in particular focuses on producing a 'coherent account' of what went wrong, which takes into account the complex causal interactions within a system within a narrative chronology. His work evaluates both psychological and organisational explanations in one study, and highlights that failures in large scale systems are caused by the 'tight coupling' of connections, where there is little room for error, and where a number of factors can act together to create a high risk situation (Perrow, 1984).

Using a similar approach, Vaughan (Vaughan, 1996), another sociologist, studied the space shuttle Challenger's launch disaster. The technical reason for the disaster is well known; the failure of viton O-ring seals in the solid rocket boosters shortly after the launch, leading to the structural break-up and catastrophic loss of the system and its crew. Vaughan's account demonstrates how this interpretation is lacking in a number of key respects; in particular because it fails to account for why people in the launch team, who had access to all of the information about the O-ring problems, still allowed the launch to take place. She discusses the four-tier launch decision team of NASA, and describes the various communications on the eve of launch that took place between NASA and the engineers and managers of Thiokol, the contractor responsible for

manufacturing the Solid Rocket Motor (SRM). Vaughan, focused instead on the culture at NASA, and similarly to Perrow, contradicted original inquiry reports which found production problems and wrong-doings. These formal inquiries concluded that flaws in decision-making (primarily at middle management level), along with those in the surrounding communication processes, were the primary reasons for the fatal launch decision.

Using an ethnographic chronology of events, Vaughan describes the discussion where Thiokol objects to the launch of the shuttle, due to abnormally low temperatures and fear of malfunction of the O-ring, which is designed to seal the joints between the SRM case segments of the Solid Rocket Booster (SRB). This decision, however, is reversed by replacing engineering judgment based on technical rationale, with management decisions. Vaughan's account shows how the norms through which the risk was judged were negotiated and re-negotiated through the working practices of the teams of engineers. This worked well in resolving many of the safety problems with the Shuttle, but for the O-ring seals, a cycle of decision-making was set in motion where deviances within the system were successively 'normalized' as acceptable through the standard process of risk assessment, which had become institutionalized in the working practices of the organization.

To explain further, Vaughan describes the reasons why small deviances in behaviour amongst workers may slowly become normal, and additional deviances become acceptable in an organisational culture. The formative years of NASA culture were shaped by pure technical culture, where "can do" attitude was a part of the self-image. Slowly, it became structurally more complex and bureaucratic, and later budgetary constraints transformed it into *technical production system*. Vaughan concludes that decision-making was affected when the initial technical culture of NASA became amalgamated with bureaucratic and political accountability, leading to a structural source of the disaster, which she terms 'structural secrecy'. Decisions made by the work group in this culture may look "deviant" and "inappropriate" in hindsight, but to the working group, construction of the risk in the wake of engineering tests, mathematical models and previous flight experience had become normal. To summarise, a series of seemingly harmless decisions were made, which moved the space agency to a disastrous outcome (Vaughan, 1996).

The more sociological examples above highlight institutional problems associated with safety. Barriers to effective organizational learning about safety, which are highlighted by the above case studies, are informational difficulties (for example (Perrow, 1984, Pidgeon and O'Leary, 2000) and organisational politics (Vaughan, 1996). In attempting to foster positive safety cultures, they all recommend that both issues need to be explicitly addressed (not ignored).

3.5 The NHS as a complex organisation

Within the NHS, the ideal of an positive, open culture which encourages admitting error, has still to become widespread (Darzi, 2008b). Instead there are suggestions of 'structural secrecy' similar to Vaughan's concept set out above, and there is diffusion of responsibility within large and complex organisations, which all contribute to adverse events in healthcare settings (West, 2000). In other words, it is easy to pass on the responsibility and ownership of anything that goes wrong day to day within the complexity of tasks, unless these result in catastrophe and are investigated. One of the ways that a large organisation may promote safety is designing a system of "checks and balances" so that important actions are not the sole responsibility of a single individual. For example, powerful drugs are always checked by at least two people before they are administered to the patient. However, such organisational arrangements only work if there are few or no social structural barriers to communication between the parties involved (described above in sociological accounts of disaster). If a junior nurse feels unable to tell her senior colleague that she has just drawn up the wrong dose of medication or is about to remove the wrong drain, then the mechanism for ensuring patient safety will break down. So far, little research attention has been given to examining the NHS in terms of focusing on failures of care using sociological methods such as those described above, which allow for detailed examination of the 'whole' system, including process and social influences.

3.6 Inquiries as analyses

Although recent health policy drives towards 'Never Events' emphasise prevention of adverse events (i.e. accidents, or catastrophes) happening in the first place (Darzi, 2008b); Safety Express (QIPP, 2011), the only source of whole system insights after an adverse event (in this thesis a severe pressure ulcer) has already occurred, are high profile inquiries such as the Francis report (Francis, 2013) and the Bristol Inquiry (Kennedy, 2001). This type of inquiry conducted independently on a large scale, and

with public awareness, may offer useful recommendations for change at executive level, but these are not always easily absorbed into daily practice. The Francis report notes that Mid-Staffordshire NHS Foundation Trust failed to tackle an 'insidious negative culture involving a tolerance of poor standards and a disengagement from managerial and leadership responsibilities' (p.3) This failure was attributed partly to the consequence of allowing a focus on reaching national targets, financial balance and seeking foundation trust status, at the cost of delivering acceptable standards of care. However, Francis himself states that, arising from the inquiry; he 'made a great many recommendations, no single one of which is on its own the solution to the many concerns identified' (p.4). It remains the responsibility of the Trust involved to translate these recommendations into local practice. The Bristol Inquiry (2001), which found high rates of failures among heart operations on babies, found a lax approach to safety amongst doctors and an 'old boys' culture' together with secrecy about failings, and lack of monitoring. This inquiry similarly lists many recommendations arising from its investigation, which were not easily absorbed into daily practice, including:

'To promote a new culture within the NHS: a three-way partnership of respect, honesty and openness between:

- NHS and public;
- professionals and patients; and
- professionals and professionals.'

Although the recommendations, as in the Mid-Staffordshire report, needed to be translated to work in practice, the inquiry marked a turning point in the NHS, with the advent of fresh legislation including the NHS Reform and Health Care Professions Bill introduced in November 2001, which directly addresses the concerns of the Inquiry (Secretary of State, 2001). This focused more health policy attention on safety and culture within the NHS, with a request to make all staff familiar with more psychology based approaches (referred often as human factors) to understanding why errors in healthcare occur. One of these was pressure ulcers, and this thesis aims to address the issue of culture as a possible influence on severe pressure ulcers.

Recent UK government policies emphasise pressure ulcers as one of the main patient safety issues, for example Sign up to Safety (Secretary of State for Health, 2014), Safety Express (QIPP, 2011), Seven Steps to Patient Safety (National Patient Safety Agency, 2004), and the Darzi review (Darzi, 2008a) and are all based around the

concept of best practice sharing to learn about patient safety. Their philosophies originated mostly from safety initiatives in the USA, which used Institute for Healthcare Improvement Breakthrough Series Methodology (Breakthrough Series, 2003), and other best practice sharing methods (Agency for Healthcare Research and Quality, 2016). Similar organisational safety initiatives have gained popularity at pace in the UK with more theoretical insight such as the Model For Improvement (Langley et al., 1994, NHS Improvement, 2016). These have become embedded in new guidance for Quality Improvement in healthcare and are part of the Care Quality Commission's Key Lines of Enquiry (CQC, 2017). This is a welcome development and some excellent initiatives across many healthcare trust have been introduced at local level ((NHS Improvement, 2016). However, these initiatives historically have offered little empirical evidence of how they work in practice to reduce incidence. They are based more on before and after measurement for change rather than research findings. These often rely on Plan Do Study Act (PDSA) cycles (Langley et al., 1994) to trial safety improvements (Institute for Healthcare Improvement, 2004) which are then implemented at local level, then shared through larger networks. The value of these initiatives has been recognised, and must not be denied, but in terms of researching an area, the local level studies do have limitations for adopting in other areas and Trusts.

Guidelines for nursing and pressure ulcer prevention and care (National Institute for Clinical Excellence, 2001a, National Institute for Healthcare and Clinical Excellence, 2005, EPUAP/NPUAP, 2009, NHS Improvement, 2018) are also currently based on consensus and opinion rather than research evidence. These guidelines and practices do show that practitioners are attempting to change practice at local level, and we uncovered best practice initiatives which have since been implemented in the UK with promising effects (1,000 lives, 2008; Sign up to Safety, 2014). So another area of exploration for the study became: Did a patient develop a severe pressure ulcer due to a series of complex errors due to the system, or did the organisational environment influence the severe pressure ulcer?

Although most safety investigation tools are designed to provide a 'helicopter view' of adverse events, in practice, health care professionals tend to prefer investigative tools that allow them reconstruct the events in a temporal linear style, supporting a narrative rather than analytical, holistic approach (Nicolini et al., 2011). For example, Root Cause Analysis (RCA), which was originally used in high risk industries such as nuclear power and aviation (Carroll JS and Edmondson AC, 2002), has become and

remained a popular tool for attempting to analyse adverse events in health care (Ovretveit, 2005). RCA was adopted in 2001 by the National Patient Safety Agency (NPSA), arising from the report, 'An Organisation with a Memory' in 2000 (Department of Health, 2000). This tool, along with other similar investigative tools, is still used to date to examine clinical incidents retrospectively in order to recommend strategies to change practice. It seeks to uncover underlying 'root causes' and aims to prevent future adverse events by applying learning achieved from incident investigations. However, there has been debate within health care, shown elsewhere in this thesis, over whether such tools are sufficiently successful when applied in real world settings (Wallace et al., 2009, Nicolini et al., 2011). Indeed, with the recent advent of Safety II, this debate has been further complicated, with the suggestion that examining 'things that go wrong' may be less helpful than first thought. (see Chapter 1 and Chapter 8). Although health care professionals may value tools such as RCA, there are suggestions that the focus on systems problems, which arises from such tools, may not be fully understood by staff trained in their use (Nicolini et al., 2011). These tools were designed for engineers trained in developing robust solutions in response to assessed risks (Card et al., 2014) and despite improvements in diagnosing system-level problems in health care, the changes to risk control which follow on from the diagnoses have not always been successful (Card et al., 2012, Pham et al., 2010). Workers must generate their own risk plans arising from the investigations, and health care workers are often not trained in safety engineering principles. Indeed there have been recent recommendations that all health are staff are trained in human factors to focus on this issue (National Advisory Group on the Safety of Patients in England, 2013). There is also a current need to improve tools and ways of investigating errors in health care so that in practice they achieve what they are originally designed to do (Card et al., 2014).

A further problem with this current approach to error analysis is that, because an adverse event investigation is undertaken after an incident is reported (National Audit Office, 2005), it not only requires incidents to have been reported correctly and accurately, but the approach is reactive. In practice, systems are not always completely understood and learning is limited to what we can describe and explain about those systems. There has been a recent call for more focus on processes rather than outcomes and less emphasis about what goes wrong. Erik Hollnagel argues that different outcomes ("normal" results vs. "failures") are not distinct binary categories, but judgements of value (Hollnagel et al., 2013). This leads us to look for different ways of examining evidence arising from clinical investigations to find explanations. Recent reviews of patient safety research have also noted the necessity for multi- disciplinary

and mixed method approaches to researching what is such a diverse and complex area (Waring, 2007, Waring J et al., 2010).

Additionally, there have been several high profile inquiries into poor quality care in health care settings, which have similarities with retrospective case study methodology and are case studies in all but name (Keen, 2013). For example, the Francis reports (2010 and 2013) (Francis, 2013), examined failures in health care Trusts in fine detail, providing various sources of evidence, and thus discovered many examples of negligent care and poor communication using one case as a focus. As part of the first inquiry (published in 2010), documentary material was obtained from a wide variety of sources, including the Trust, the primary care trust (PCT) and other NHS bodies, the Care Quality Commission (CQC), the Strategic Health Authority (SHA), Monitor, the local authorities and the four local Members of Parliament. The first inquiry included in its evidence views from 966 individual members of the public and some 82 members of staff from the Trust, past and present, and heard oral evidence from 113 witnesses (Francis, 2013).

One of the many findings of the inquiry was Mid-Staffordshire NHS Foundation Trust's failure to tackle an insidious negative culture involving a tolerance of poor standards and a disengagement from managerial and leadership responsibilities. However, the list of 192 recommendations, which were the outcomes of this first Francis report are referred to as 'high level and will require considerable further detailed work to enable them to be implemented' (p18). This makes the recommendations difficult to translate into daily practice (Francis, 2013). The findings remain wedded to the particular case involved, and do not openly offer analytical explanations drawn from the evidence. However, a retrospective case study methodology using George and Bennett's (2005) complex causality approach could offer a better insight into these cases, in the area of adverse events analysis, or in this case the study of severe pressure ulcers.

This leads us to ask: to improve on existing investigation techniques and understand more about why errors occur, could a retrospective case study method, with its detailed approach of process tracing retrospectively back through evidence, address issues with translating recommendations into practice? Could this gap in health policy be illustrated through investigating the causes of severe pressure ulcers?

3.7 The importance of severe pressure ulcers as an outcome measure

As has been highlighted in earlier chapters of this thesis, pressure ulcers are a major problem for patients, carers and the healthcare system (Bennett et al., 2004, National

Institute for Healthcare and Clinical Excellence, 2005). They affect approximately 1 in 10 hospital and 1 in 20 community patients and can contribute to death. Severe pressure ulcers (Category 3 and 4) have been classified for a number of years now by governing bodies such as the CQC, Department of Health, and National Patient Safety Agency and as serious incidents, or adverse events, and are required to be investigated by hospital Trusts. However, severe pressure ulcers are often difficult to quantify using incident reporting, because often they do not have an easily identifiable beginning, and tend to happen in health care settings gradually (Evans et al., 2006) frequently deteriorating from Category 2 ulcers. These skin ulcers are associated with neglectful care (Bennett et al., 2004), which can lead to under-reporting of incidents (2008) particularly when the pressure ulcers develop gradually. According to NICE guidelines on pressure ulcer prevention, however, they should be reported using incident reporting tools when they develop into a Category 2 (NICE 2005; EPUAP/NPUAP 2009).

Nurses typically have a fairly comprehensive understanding of patient characteristics associated with the risk of initial pressure ulcer development, and pressure ulcer recognition and management generally forms part of their basic mandatory training (National Institute for Healthcare and Clinical Excellence, 2005). Research has shown however, that after these risks are identified, links to care planning are less effective (Johansen et al., 2014, Coleman et al., 2013b). Some patients go on to develop more severe pressure ulcers (Category 3 and 4)and this cannot be fully explained by known patient risk factors (Coleman et al., 2013b). This makes it sometimes difficult for health care professionals to deal with them appropriately and record them accurately as a clinical incident (Evans et al., 2006). Although many investigations have been undertaken to date focusing on the root causes of pressure ulcers, all the previous arguments apply, which have been so far presented in this thesis. This includes lack of knowledge regarding organisational theory on the part of the health professionals conducting the investigations, a focus on service level and frontline changes to practice, as opposed to organisational changes (Waring et al., 2010). The issues with investigating the causes of severe pressure ulcer therefore makes them an interesting, under-developed area to study using a case study methodology.

3.8 Study design

Many studies have focused on the ways in which organisation and culture affect patient safety (McDonald et al., 2006, Waring et al., 2007, Waring et al., 2006). Regarding severe pressure ulcers, however, there is no way of predicting where patients with

these ulcers will appear, or which type of patient will go on to develop severe pressure ulcers. If, for example, I had prospectively identified patients with Category 2 ulcers, in order to evaluate differences between those who developed a Category 3 or 4 ulcer and those who did not, my presence would have drawn attention to the significance of the pressure ulcers. It is likely to have prompted swift action by the local clinical team, and it is possible that this may have halted the progression of Category 2 pressure ulcers to Category 3 or 4. Additionally, this may have biased the observations, possibly substantially, and I could not have been confident that I had observed the whole development process, from the earliest signs and symptoms to the point where action was taken.

It was, though, possible to reconstruct the events that lead to the development of severe pressure ulcers retrospectively. I therefore chose to use a retrospective case study design; specifically a type of process tracing method offered by George and Bennett which focuses on a style of structured focused comparison of cases (George and Bennett, 2005), rather than a traditional ethnographic method, or more qualitative case study method. This method is firmly based within a realist, post positivist philosophy, as opposed to an interpretivist or wholly positivist philosophy. According to George and Bennett (2005) "scholars have formalized case study methods more completely and linked them to underlying arguments in the philosophy of science" (p.6). This demonstrates the utility of case study for researching complex issues, and testing causality that can be applied across varied disciplines; which is what I needed to do. Case study method focuses on identifying complex causal relationships to constitute an explanation of a case. This also, more importantly for health research, offers a more interpreted and less structured method of investigation than current adverse event investigation techniques.

3.8.1 Case study methods: a debated methodology

Although case study methods offer a useful way to allow for all of the explanations set out in the literature review, there are conflicts and confusions within the communities of researchers who use them, (Ragin and Becker, 1992, King et al., 1994, Flyvbjerg, 2006a). Over time, the contributions of researchers from varied disciplines have helped to develop and strengthen case study research, however the variety of disciplinary backgrounds has also added complexity, particularly around how case study research is defined, described, and applied in practice. Despite this variety, one of the common threads is a commitment to uncovering complex 'causal' relationships.

What differs between case study method approaches is mostly how they define causality. Ragin's early concept of case study method as a bridge between quantitative and qualitative research argues that causality is defined by a 'variable' as a causative agent (Ragin and Becker, 1992). Therefore, the early stance of Ragin derives conclusions from analysis of the cross case comparisons focusing on 'associations' between variables.

At the other end of research philosophy, Stake (Stake, 1995), and Guba and Lincoln (Guba, 1978), argue for an inductive, naturalistic case study method, which sits within their interpretivist methodological view, and deliberately avoids the idea of quantifying evidence generated from a case. An interpretative position views reality as multiple and subjective, based on meanings and understanding. The idea here is that causality within a case is instead replaced with interpretation and a reflection of the own researcher's viewpoint. Generalisations would be futile, and causality would be irrelevant. Stake's (1995, 2006) approach has a disciplined approach to the process and acknowledges that case study can use quantitative methods, but the approach is underpinned by a strong motivation for discovering meaning and understanding of experiences in context in line with an interpretivist view. Stake's case study research is "the study of the particularity and complexity of a single case, coming to understand its activity within important circumstances" The role of the researcher in producing this knowledge is also critical, and Stake emphasizes the researcher's interpretive role as essential. Stake (1995) recommends vignettes to illustrate aspects of the case and thick descriptions to convey findings. Knowledge generated is relative only to the time and context of the study and the researcher is interactive and participates in the study. Stake argues that situation shapes activity, experience, and one's interpretation of the case. For Stake (2006), to understand the case "requires experiencing the activity of the case as it occurs in its context and in its particular situation" (p.2).

In principle I agreed with Stake's method (1995) of collecting data sources as part of a case study methodology, however, I was interested less in interpretivist evidence generating because I wanted to accept at face value the evidence I collected as 'real' and true. Yin alternatively (2014) conceptualizes case study research as a form of social science, which is evident in how he defines "case study as a form of empirical inquiry" (p.16). Yin describes his approach to case study as using a "realist perspective" (p.17) and focuses on maintaining objectivity in the methodological processes within the design. Yin's (2014) case study design offers a post positivist approach to research: seeking rival explanations and falsifying hypotheses, the capability for replication with a multiple case study design, the pursuit of

generalisations (if required), minimizing levels of subjectivity, and the use of multiple methods of qualitative and quantitative data collection and analysis. While objectivity is a goal, Yin also recognises the descriptive and interpretive elements of case study. According to Yin, what makes case study research distinct from experimental studies is the case study is investigated in its own context, examined in its "real world setting".

The goal of a post positivist researcher is to use science as a way to apprehend the nature of reality while understanding that all measurement is imperfect. Therefore, emphasis is placed on using multiple methods with triangulation to circumvent errors and understand what is happening in reality as close as possible to the "truth".

Campbell, dismissed case study method in his (Campbell and Stanley, 1966) early work on experimental designs, as having 'no scientific value' as it was thus impossible to generalise from one. Yet, later, in his further work, he changed his stance to advocate the use of case study method (Campbell, 1975). He argued that he had an 'extreme oscillation' away from his earlier disparagement of case studies, and that the 'degrees of freedom' concept that strength of validity is in an increased number of participants or cases, did not need to be applied to this method.

Thus, for my approach there was an acceptance of Campbell's concept of 'validity' as a term within case study method over 'trustworthiness' (associated more with naturalistic case study method) which would satisfy my positivist audience, yet I also wanted to accept the realist approach that allowed for the social context to be taken into account. Therefore, somewhere in the middle of more extreme philosophical viewpoints, I took as a starting point a more pragmatic, realist ontology. I was interested in organisational processes of care as they affect a patient, and wanted to follow each patient's care pathway retrospectively, from the time when he or she had already developed a severe pressure ulcer, to the point where it initially developed, and further back if necessary. I wanted to accept the evidence as 'true' and work with it to analyse causal patterns (Hammersley, 1995; Yin, 2013). My focus was a more bottom up, open exploration of the causes of a patient's severe pressure ulcer, including patient and carer views and elements of the organisational environment. However, I also aimed to find patterns inherent in patients' pathways, or chains of events, which could generalise to other patient experiences. This placed it more alongside Yin's approach. I was also trying to predict why a severe pressure ulcer occurs in terms of these complex causal sequences of events (George and Bennett, 2005). This required adoption of a process-tracing type of approach to look 'behind' the data for complex causes. I chose a theory-based case study method, focusing on theory building (Merton, 1968, Pawson

and Tilley, 1997) and rather than trying to generalise empirically from data, (in a Ragin style) or look for competing hypotheses (Yin's approach) the emphasis was on subtle yet generic features of specific phenomena. I wanted to produce a 'coherent' account for each patient in the study (Hammond, 1996, George and Bennett, 2005) which arrived at the best and most valid explanation (see Table 2.2 and Figure 2.2). I define 'coherent account' as one which makes the best sense of available, yet relevant evidence, similar in nature to the process police use when they build evidence against a suspect (George and Bennett, 2005). I drew specifically on George and Bennett's case study method approach, as they were interested in developing ways of studying historical instances of generic problems, which would permit usable lessons to be drawn. They adapted methods of historical explanation, taken from an historian's approach to evidence, to convert descriptive explanations into analytic explanations, rather than a traditional social scientist's approach. The background of a case study method taken from history and anthropology, rather than say a psychology case study, helped with my approach, as I wanted to examine an historical episode to develop and test explanations, yet keep my explanation coherent in its analysis, similar in the way a historian would approach evidence using a 'best explanation' for what happened.

3.8.2 Explaining the causes of severe pressure ulcers

Often in the social sciences there is an assumption that it is not possible to establish a definitive explanation for any given event or outcome (Hammersley, 1992). However, I took the view that it is important to attempt something practical and pragmatic, and useful for my audience, rather than opt for purely descriptive interpretation offered by such as Stake and Guba and Lincoln, while I still respected their worldviews. If I were to do the study properly, I would need a method which did not make any particular assumptions at the outset about the ways in which severe pressure ulcers develop. I should collect data about each patient with a fairly open mind, and then analyse the data in order to find the best explanation for the facts in front of me; the best coherent explanation for the occurrence of a severe pressure ulcer. This research objective sat well within George and Bennett's concept of an heuristic case study (2005). This is described as a case study which inductively, identifies new variables, hypotheses and causal paths, and which emphasises the usefulness of 'deviant' or outlier cases to offer unexpected outcomes. I was also interested in their theory testing case studies, but felt at the initial stage my theories around the causes of severe pressure ulcers were too tentative to begin to test straight away.

However, the review of the safety literature offered various different 'kinds' of explanations (Reason, 1997b, Perrow, 1984, Vaughan, 1996) (for further explanation of the theories see Chapters 1 and 2). I needed a method which would be open to other possible explanations too. This method needed to consider all possible explanations from each disciplinary perspective, which incorporated breadth, scope, psychological, historical and sociological understanding. The review of safety literature, which was then mirrored to an extent in the health services literature, I had deduced five classes of explanation which would incorporate all disciplines (Pinkney et al., 2013). I needed firstly to specify which these explanations were in the context of severe pressure ulcer development, and then try to find the best explanation, or if necessary find a new explanation, or combination of explanations (see Fig. 2.3). Therefore, for any one patient who develops a severe pressure ulcer, a possible explanation might be as follows in Table 3.1 below:

Table 3.1:

Classes of explanation A-E

- A: The patient was going to get a severe pressure ulcer regardless of the care he or she received;
- B: There was a single isolated error which was responsible for the development of the SPU, or one person made an error which was the reason behind the SPU;
- C. A sequence of apparently minor mistakes was made a risk assessment was not done, a patient was not turned and this sequence produced the severe pressure ulcer. If the particular sequence had not occurred, for example because a nurse made sure that risk assessments Ire done properly that day, then the severe pressure ulcer would have been prevented;
- D: The organisational environment made the SPU likely. For example; a ward that is short staffed, and where assessments are sometimes missed, could be a ward where mistakes are likely;
- E. There was an explanation or combination of explanations not covered by the first four

No single method of approach however, would allow me to identify the best explanation, my strategy therefore was as follows:

• To assess the possibility of explanations A to C, I developed a detailed timeline/sequence of significant events that happened to the patient (see below)

- In order to support or eliminate the fourth explanation (D) based on the wider organisational context, I used a case study method, but a more ethnographic style;
- For the fifth explanation (E) I was looking for either an explanation or combination of the explanations suggested already by the literature, or a new explanation which had not yet been discovered

For the first three types of explanation in this study, a chronological account of key events allowed me to look both at isolated events as they unfolded in 'real' time, and look at events sequentially over time examining the processes involved. The timeline was an interpretation of events from one perspective. This would not drive the data collection; it would only add temporal structure.

3.8.3 Sequence of events

I needed to identify methods that would allow me to evaluate *each* explanation, and its underlying causal assumptions separately. As a timeline is based on an assumption that one cause leads to another, this method allowed me to trace sequences of events that happened, and to uncover complex causal relationships (George and Bennett, 2005). This assumption about causation suggests that if one variable has an effect on another, there is "causation". Studies that measure an isolated event in terms of cause and effect (for example in causing a severe pressure ulcer), and Reason's (1997) sequential assumptions about causation, focus on this relationship. For the first three types of explanation in this study, this approach is helpful for understanding causation. For these explanations a chronological account of key events allowed me to look both at isolated events as they unfolded in 'real' time, and look at events sequentially over time focusing on complex causality.

3.8.4 Institutional explanations

However, I also needed a way of establishing whether or not the wider organisational context might be part of the explanation. A more ethnographic focus, yet remaining within a realist case study method (Geertz, 1973, Hammersley, 1992, Stake, 1995) would offer an alternative class of explanation to the first three above. I chose to focus on social phenomena (Hammersley, 1992); for example 'why is a ward organised in a certain way?' and to understand the environment despite looking causally at this data and remaining within a realist worldview (Hammersley, 1992). Ethnography assumes a different view of causality which looks instead at describing a culture and shared beliefs and would explain how a certain environment may influence (as opposed to cause) the

development of a severe pressure ulcer. The emphasis is less on a linear cause and effect, or a complex causality, but more on a descriptive view.

3.8.5 Alternative explanations

While both the sequence of events or more ethnographic models of explanation were candidates, I also wanted to be open to the possibility of i) a new class of explanation which had not been stated already (E), or ii) a combination of already specified explanations (also E). For example, at the extreme end, it could be that an isolated event happens within a sequence of events, where the environment also makes an event more likely and all three explanations are equally as suitable for explaining why a patient develops a severe pressure ulcer.

3.8.6 Coherent account

However, my overall purpose of the study was to create a coherent account of what happens during the development of a patient's severe pressure ulcer. So, I developed and refined the method according to my findings as I went along. The study took place in 8 different NHS acute and community settings in the north of England between September 2008 and August 2012. It included 8 patients who had all developed severe pressure ulcers, who were sampled sequentially for varied demographic characteristics (see below). Each account took, on an average, 4 months to create, from the initial interview with an individual to the signing off of a detailed account of the development of that individuals' severe pressure ulcer. The reasons for identifying these patients and the choice of case study design are explained below.

3.8.7 Sampling in case study method

There are different types of sampling strategies. Statistics-based research, in the main, seeks to generalise from a sample to the whole population from which it was selected (Bryman, 2004). However, other research strategies do not seek to generalise in this way; they instead focus more on 'theoretical' representation (Morse, 1991, Glaser and Strauss, 1967).

Different case study traditions use different types of sampling. Early Campbell works (cited above), for example, used quasi-experimental methods, and criticised single case studies for their lack of generalisable findings (Campbell and Stanley, 1966). Case studies, in particular, have been criticised for what statistical researchers call 'selection bias' (Geddes, 1990). The idea that cases are selected because they exhibit certain outcomes and contain bias towards verification of the researcher's

preconceived notions, has much been debated over the history of case study research (Campbell, 1975, Flyvbjerg, 2006b). However, often the most appropriate choice is a case that exhibits the given problem. Case studies often use purposive sampling at the outset to select cases with the widest possible range of personal and service characteristics and look for recurring themes, and causal explanation (George and Bennett, 2005, Gobo, 2004, Flyvbjerg, 2006b). Mason speaks of purposive sampling as an inductive and organic practice, which grows and develops throughout the research process, to aid the researcher in what he or she wants to achieve analytically (Mason, 2002). Emmel further refines this sampling strategy from a scientific realist's perspective, and highlights that theory always precedes data collection (Emmel, 2013). Chosen cases allow theorisation of social processes, to test and refine ideas and look for explanations. Then 'casing' is used to further choose cases to challenge or respecify causal processes (Emmel, 2013, George and Bennett, 2005). The tentative theories I developed from the literature review set forward some fragile ideas from which I could begin to sample cases; these could then offer evidence from which to refine further theories.

I used this particular theoretical sampling approach to identify the first of my eight patients, and cases were subsequently chosen to refine theories which emerged from the research (George and Bennett, 2005). However, there were very few patients who had severe pressure ulcers, so there was a pragmatic and demographic element in the choice of cases chosen to help refine theories. In reality, different health care settings where a patient presented with a severe pressure ulcer were chosen, simply to offer a more contrasting process from which to refine the evidence (George and Bennett, 2005). I therefore sampled each patient to cover demographics above any other strategy (see Chapter 4 for further details of my sampling).

3.8.8 Maximising validity?

There is debate about validity in the social research literature; and indeed whether it is a relevant concept (Lincoln and Guba, 1985, Guba and Lincoln, 1981, Hammersley, 1992, Shadish et al., 2002). This debate centres on whether the positivist view, associated with knowledge existing independently of the world, is adequate, or whether it takes for granted the social reality which is precisely the object of study of the social sciences (Schutz, 1964). The backlash against traditional scientific thinking, with which the notion of validity had become associated, led advocates of the constructivist tradition to offer an alternative version of validity. For example, Guba and Lincoln

(Guba and Lincoln, 1981) replace validity with the concept of trustworthiness, which has three main qualities; transferability, dependability and confirmability.

Realists Pawson and Tilley (Pawson and Tilley, 1997) criticise the constructivists' argument on two grounds:

- 1) That evaluation data is "only another construction to be taken into account" and that 'findings cannot be generalised from one context to another' (1989, Guba and Lincoln, 1981) p.45). They argue that while Guba and Lincoln accuse positivists of 'context stripping' they are only able to replace it with what Pawson and Tilley call "context hopping" (p.21). This means that rather than take measurement and outcomes away from the context they are part of; this approach seeks only to move across comparable contexts in a descriptive rather than an evaluative manner.
- 2) Although member checks and negotiations are advocated by Guba and Lincoln to provide credibility to the research process; some of the members within the research may seek to dominate discussions. The negotiated reality may be in itself a threat to the 'rigour' of the research (Morse, 1991). Pawson and Tilley (Pawson and Tilley, 1997) argue that there is a risk that these "hermeneutic dialectic circles go round in circles rather than constituting a linear advance on the truth" (p.21).

The scientific realist view offers a position which "seeks to avoid the epistemological poles of positivism and relativism". Instead it focuses on the "mechanics of explanation" (Pawson and Tilley, 1997)(p.55), whilst also including social context. My concern lay in the mechanics of the explanation and the processes involved in a patient's developing pressure ulcer. I wanted to be aware of the social context, but I also wanted to produce some knowledge which practitioners could work with. Therefore I adopted a type of scientific realist approach, because I was interested in two areas: i) testing a specific research question, ii) explaining the reasons why patients developed severe pressure ulcers. These questions cannot be asked in the context of a purely constructivist study. A constructivist approach would remain focused for example, on examining meanings and thick descriptions, but I wanted to develop mechanisms of explanation, to produce candidate explanations while respecting contextual influences.

Furthermore, as the study was undertaken in the context of an NIHR Programme Grant, there was the expectation that findings would inform clinical practice. The assessment of what Morse (Morse, 1991) refers to as rigour, and the usability of findings, are important aspects for my research audience, which consists mainly of clinicians. Therefore, I decided to use the term 'validity' and its associated sub-

categories to explain rigour, rather than trustworthiness and following a constructivist interpretation. This was because these terms were both familiar to my audience, and this version of 'truth' was more suitable for the realist case study approach I was taking (Pawson and Tilley, 1997).

I took the view that the methods and findings had to 'pass' two tests, which I labelled internal validity (Shadish et al., 2002, Hammersley, 1992, Hammersley, 1991), and construct validity (Shadish et al., 2002). For internal validity, I needed to provide the best possible explanation of the available facts which arose from within the study. Construct validity, here, captures the idea that I needed to be confident that I had generated the best possible explanation of why severe pressure ulcers occur in order to provide a general predictive theory, which could apply to other settings or to other patients. For example, a predictive theory could be that errors are more likely when nurses do not use risk assessment tools properly.

I did not use the concept of external validity (Hammersley, 1991, Shadish et al., 2002), as this refers to generalising across other settings using variable-orientated, cause and effect correlations, and is more relevant to large scale statistical studies in claims to validity. Neither was the constructivist view of generalising using 'transferability' suitable, because of its association with 'context hopping' set out earlier. However, my interest lay in the representativeness of concepts and applicability of theory to other situations; i.e. construct validity (Strauss and Corbin, 1990, George and Bennett, 2005) as I wanted to use findings to help develop and refine my theories. The validity terms I have chosen, while derived from authors associated with a positivist approach, resonate with the thinking of authors from other philosophical realms, although some have reconceptualised the terms. For example, Hammersley (Hammersley, 1991) prefers 'explanatory adequacy' rather than internal validity, and George and Bennett (George and Bennett, 2005) refer to 'conceptual validity' rather than 'construct' validity.

3.8.9 Being Realistic about Reflexivity

The view that we have no way of escaping the social world in order to study it (Hammersley and Atkinson, 1995), has been at the centre of yet further debate between research approaches about the reflexive character of social research (Hanson, 1958). The notion of reflexivity implies that social research cannot be carried out objectively, or insulated from wider society or political framework (Hammersley and Atkinson, 1995).

The positivist view that social research could be carried out using a natural sciences model to produce 'facts', has led to attempts within field research to eliminate the observer-researcher. This view advocated standardised procedures to attempt to replicate the fieldwork by other researchers (Bouchard, 1976). As qualitative research did not meet these positivist criteria, it was subsequently criticised due to lack of rigour (Blumer, 1969). In reaction, the constructivists argued that all findings and data are constructed, leading to doubts whether the research can produce knowledge at all (Guba, 1978, Denzin, 1971). However, to take the view of the constructivists would be to ignore the role that reflexive research can offer in reconstructing "a logic of inquiry that shares much with positivism and naturalism but goes beyond them" (Hammersley and Atkinson, 1995)(p.21). I have chosen to follow Hammersley and Atkinson's (Hammersley and Atkinson, 1995) position in my study. This recognises my reflexive role as researcher, but allows the knowledge that I do gain to be applied to practice, and to be recognised as 'true' within its context; while also appreciating that it can be difficult to interpret (Hammersley, 1992). I developed multiple strategies to work reflexively and transparently in this study.

I reflected my role in building up research evidence, so that I could be aware of where I, and other members of the research, had influenced the collection of data. Part of this reflexive working was the choice of myself as main researcher. I am a non-clinical worker (with a Psychology background) and it was decided, along with the research programme team, that I would be less biased than a person who had a clinical background, and any associated pre-conceived ideas about pressure ulcer care. This clinical area is associated with debated management approaches and associations with quality of care (Dealey et al., 2012, Ausserhofer et al., 2013), so views amongst clinical staff can be conflicting and biased. I also addressed reflexivity and transparency issues within the study by using a stage by stage review process (see Fig. 3.4 and associated sections below) through which I checked data continuously within each patient's account.

3.9 Method, analysis strategy and field method

In this section I describe how I applied the retrospective case study method in practice, with examples from patient cases where an illustration is necessary. I also describe in detail how the analytical strategy was conducted. When carrying out the method I came across a number of technical challenges and I will explain these through a worked example of one patient's account as a field method. I applied the primary data collection techniques introduced above, which are set out in detail below:

3.9.1 Primary Data Collection:

3.9.2 Interviews

Ethical approval for the study was obtained from Leeds West Ethics committee (09/H1307/8), and local research governance approvals for all six study sites were granted. A decision was made to carry out the research field work in Northern England for pragmatic reasons and due to financial constraints. I used a theoretical (purposive) sampling strategy, set out above in Section 4.7, and based on the findings from the theory-driven literature review to find each suitable patient (George and Bennett, 2005, Yin, 2003). As I explained earlier in Chapters 1 and 2, I was looking for patients who would allow me to explore my two research questions, to progress my initial theory about why patients develop severe pressure ulcers, and to explore if there was a link with the environment which affects this. Therefore I looked for patients who had already developed a Category 3 or 4 pressure ulcer, whilst being cared for by health services. These patients could not present initially to services with a Category 3 or 4 pressure ulcer; they needed to have been admitted before their ulcers deteriorated.

I began to collect data for the study by interviewing my first patient with a severe pressure ulcer to capture his or her perspective of how it had developed, mindful that I did not want to bias the data (see Appendix 4 for the Patient Interview Topic Guide). Each patient interview was the initial point at which I began to study each case. I did this before looking at any other evidence so that his or her voice was heard in the research and so that I would not have any preconceived perceptions about what might have caused the patient's pressure ulcer, (detailed in Fig 3.4; Stage 1 below). A tissue viability (i.e. wound care) specialist nurse (TVN) at one of eight identified hospital or community sites identified one person within her local Trust (in practice always her) who presented unexpectedly with a severe pressure ulcer. I identified subsequent patients used a mixture of theoretical and pragmatic sampling to maximise the diversity of individuals and contexts which their pressure ulcers developed (Holloway and Wheeler, 2002, George and Bennett, 2005, Mahoney and Larkin Terrie, 2009). For example, if I identified that one patient was being treated in a community setting, the next patient I chose was one who was instead present in an acute hospital setting. I also sampled for diversity of age, gender, location, and alternative service provision as I continued to collect data. Settings included patients' own homes, acute hospital and surgical wards, a community hospital and a nursing home during respite care. Sampling was also pragmatic, in that members of the local tissue viability nurse teams helped to locate patients who had developed Category 3 or 4 pressure ulcers. It was

not feasible that I would have been able to find patients with Category 3 and 4 pressure ulcers without the aid of the tissue viability teams.

I interviewed each patient while he or she was still on a hospital ward, or under the care of a wound care nurse in the community using my topic guide (Appendix 4). I allowed the patient to speak freely about why he or she felt they developed a pressure ulcer without interruption unless the interview came to a standstill. I then used probes to gain further information if necessary (Denzin and Lincoln, 2000). Interviews were indepth and semi-structured, and contained some unstructured parts where the patient was able to guide the interview without prompting (Denzin and Lincoln, 2000).

I investigated the patient's version of events as soon as possible after the severe pressure ulcer had happened, and following their interview. My aim was to reconstruct a chronological sequence of events, based on all of the evidence offered to me, which offered insight into the development of the patient's severe pressure ulcer (see Table 3.2 below) in order to trace the process retrospectively through his or her pathway to its initial cause (George and Bennett, 2005). The patient interview helped to identify a provisional and unbiased sequence of events, and an idea of the time period involved in the development of his or her pressure ulcer.

Interviews were digitally recorded and transcribed verbatim for accuracy during later analysis (see Fig 3.2). The patient interview normally lasted for an hour and a half. Where relevant a main carer was interviewed alongside the patient. The initial structure to the interview was one opening question, 'Why do you think you developed a severe pressure ulcer?' After this initial question, the patient was allowed to talk freely, of his or her experience of care in terms of the pressure ulcer, and the reasons that led to its development (see Topic Guide, Appendix 4). The patient's perspective and people who they thought were main stakeholders in their case, were the initial framework which I used to explore further (See Appendix 10 for an example of data collection of initial sequence of events for one patient)

3.9.3 Documentary searching

I looked at a range of documentary evidence after interviewing the patient, to make sense of his or her story of events (See Figure 3.2, Box A). This consisted of hand searching through his or her nursing, medical and therapist notes, clinical incident reports and staff rotas, and any other relevant documents which were available on the wards and in patients' homes (see Table 3.5 for details of the range of documents analysed for each case). I searched all available documentation during the period

before and after the pressure ulcer occurred (Roberts, 1996, George and Bennett, 2005). Documents varied in number and quality for each case as each patient had different clinical provisions, and were cared for using varying plans of care. Some care plans, nursing, medical and therapy notes were comprehensive; others were sparser. This made data collection variable for each patient. I made a judgement about the relevant time period for all of the patients based on as far back as I could process trace the cause of the severe pressure ulcer development and how much data there was available within the constraints of research governance and ethical considerations. The end point was when a pressure ulcer had healed enough for a patient to be discharged from hospital. This time period therefore included the sequence of events which led to the development of the pressure ulcer, (as it related to the patient), all decisions made relevant to his or her care, and all ward and community setting movements. For each patient the data collection period took an average of three months between the initial interview, documentary data collection and other interviews with stakeholders who the patient deemed to be relevant to their care, and whose written entries were noted in the patient's notes. Below (Table 3.2) is an example of how I used the sequence of events timeline to record and interpret information (see also Appendix 10 for an example of my data collection during fieldwork).

Table 3.2: Sequence of events timeline

Source of data	Time 1	Time 2	Time 3	Time 4
(below)				
	30 May	2 June	3 June	
Patient/nursing	Significant	Event 2	Event 3	
notes	event 1	'Diabetic foot	'Slept III,	
	Slept III,	clinic R heel	catheter	
	tramadol given	sloughy	normal, asst	
	2am, asst with	wound.	with washing,	
	lolr half,	Dressed with	groins, and	
	cream applied	aquacell	applied	
	to stomach.	Ag.advice	daktarin	
	Started with	continue this	cream, stool	
	loose stool,	dressing and	sample taken.	
	Bristol 7.	refer back if	Bfast in room	

	Unable to obtain stool sample.'	concerns in future. OE appropriate foot lar. Multiple complex wound treatment at acute hosp.'	due to room isolation. Has headache, after bump in taxi on way to clinic.'	
Patient's version of events	I was moved to a side room, and placed on an ordinary mattress			

3.9.4 Other interviews

Following leads from the patient's interview, and supplemented by evidence I collected from patient notes, I then interviewed relevant other people involved in their care (including nurses, health care assistants, ward clerks, ward managers, physiotherapists, and consultants on the ward that the patient was currently admitted on, and if relevant, previous ward staff. In the community this also included home care assistants, district and GP practice nurses, GP practice managers and GPs. I then added data from each interview into my chronological sequence of events timeline (Tables 3.2 and 3.2a). Interviews across all patient accounts totalled 70 (Table 3.3).

Table 3.2a Extension to sequence of events timeline:

Consultant's	'did they	
version of events	realise how	
	high his risk	
	was of	
	developing a	
	pressure ulcer,	
	particularly on	

	his heel or	
	foot? I think it's	
	generally is	
	that people are	
	not aware how	
	much of an	
	effect say,	
	diabetes or	
	cardiac failure	
	has on the	
	viability of the	
	tissue,	
	particularly on	
	the heel.'	
Ward Manager's	Not available	
version of events		
Significant others'	'the ward staff	
version of events,	were	
e.g. TVN, HCA,	requested to	
Informal carer	refer to the	
	foot clinic at	
	ACUTE	
	TRUST and	
	refer him back	
	to the vascular	
	team, and for	
	that period of	
	time just keep	
	dressing the	
	wound dry	
	because I had	
	no- I had no	
	communication	
	Communication	l l
	to what his	

		was at that	
		time'	
Organisational	Patient moved		
information/details	to a side room		

I used broadly the same method as with the patient interview. Each interview began with the opportunity for the interviewee to give their version of what happened, and then on the basis of events and on basis of material that they gave us, I used more direct questions to probe further. I then started to formulate possible hypotheses about the cause of the pressure ulcer which I could take forward to question other informants in further interviews and to code into my temporal sequence of events (Pawson, 2006) (George and Bennett, 2005).

This part of the data collection offered many challenges, as staff members were often reluctant to speak about 'adverse events'. I developed an adapted style of 'cognitive interviewing' to counteract this. The foundation for the creation of the cognitive interview was rooted in several well researched facts about human memory. Research has shown that memory deteriorates over time (Fisher and Geiselman, 1992). This indicates that the more time that passes between initial encoding and subsequent retrieval the less likely accurate recall will be. Often I was not able to interview the key stakeholders in a patient case until some weeks after the patient was developed his or her pressure ulcer. To this end, I introduced some techniques associated with cognitive interviewing. These were Mental Reinstatement of Environmental and Personal Contexts (Fisher and Geiselman, 1992). This technique involves the researcher or investigator attempting to mentally reinstate the environmental and personal context around a 'crime' (in this case the development of the pressure ulcer), while asking about the witness's general feelings and activities at a particular time, in an attempt to trigger recall. In experimental research, this technique has proved successful. It also requires little theoretical background or training (Fisher and Geiselman, 1992). For example, in a study by Geiselman et al (1985) which focused on recall of a violent crime video, the cognitive interview technique led to a significant number of correctly recalled facts, (41.2) in comparison to a standard interview (29.4). My choice of memory aids based on this technique, were medical and nursing notes to help prompt the interviewees' memory. In this instance, following my experiencing that nursing staff members often had poor recollection of all of their patients' pressure ulcers, I ordered

case notes pre-interview and brought them with me to each interview to use as a memory prompt. I asked each interviewee to 'think back' to what I had already coded as 'significant events' and explored these moments in the patient journey with the member of staff to see what they remembered of this event. I followed the cognitive interview style of temporal sequencing, which breaks the interview into beginning, middle and end. I firstly established rapport with the interviewee, by explaining that I was not from any auditing, or quality assurance professional body wishing to 'judge' their answers in any way (see Figure 3.2). I then encouraged them to give an uninterrupted version of their account.

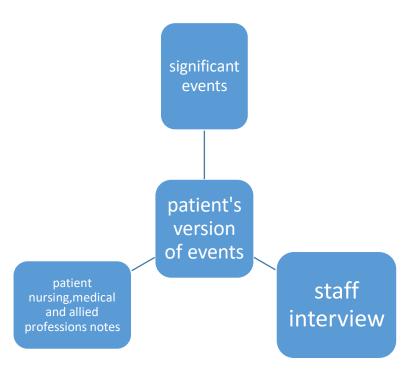


Figure 3.2: Making sense of the data

This was a planning phase to offer a basis for my strategy for probing. This was because this phase often offered little direction from staff, and necessitated the next phase of information gathering. The information gathering stage was where I then guided the interviewee through information rich mental representations of the case, based on the patient's version of events to prompt recall (Figure 3.2). We then discussed the recall of events based on my prompting. Often this offered more insight into the case and allowed for more data collection. I also used Supplementary Techniques, which are similar to the above, but which use more detailed questions and I used these techniques to elicit specific items that the participant witnessed, to jog their memory for details (Tulving and Thomson, 1973). In interviews with staff, these included my asking difficult questions such as, 'In your opinion, did you think everything

was done that could be to prevent the patient's pressure ulcer?' In practice I had to use this technique with certain members of staff, as some were defensive, given the aforementioned proposed links between pressure ulcers and neglectful care (Bennett et al., 2004).

I also used In-depth Reporting; another method taken from cognitive interviewing. I encouraged every detail regardless of whether the interviewee felt it was directly concerning the pressure ulcer. We spoke, for example, about each ward around the time of each patient's admission, what relationships were like between staff members, and how happy the interviewee was with other aspects of their daily work.

I interviewed as many key informants as appeared relevant to the patient's story, according to the initial temporal sequence of events based on the patient's interview, and who were relevant to the documentary evidence. These ranged in number from 3 to 14 per patient depending on the type of care setting and providers, and were carried out to gain as much evidence as possible to help 'make sense' of the data (see Fig.3.2 above). After each interview, I 'de-briefed' with the tissue viability specialist nurse onsite, in order to make sure that I did not follow any 'false leads', (for example, mistakes about who to interview) and to seek local expert advice on whether inferences about possible causes of the severe pressure ulcer arising from interviews were plausible given the context. This process also helped direct me to further relevant people involved in a patient's care, who I may have overlooked.

I conducted more interviews with those seen by the patient, tissue viability nurse, and the expert witnesses as key informants, including informal and other professional carers such as occupational therapists, clinical incident team members, family carers, liaison nurses, and matrons. I gained each informant's perception of the development of the patient's severe pressure ulcer, as they understood it. Each interview also helped to make sense of previous evidence collected from other interviews. The process was iterative and involved looking for further evidence to help make sense of the timeline. 15 interviews in total were carried out relating to the first patient.

Table 3.3 Number of people interviewed by account across all 8 patients:

Viability Nurse Carer Individual Account	Consultant Health/home care assistant Nurse District nurse	Ward clerk Occupational Theranist Physiotherapis Junior doctor	Total Quality assurance Ward Manager Liaison nurses
------------------------------------------	------------------------------------------------------------	----------------------------------------------------------------	---------------------------------------------------------

Alex	1	1	2		2	2	1		1	1	1	1	1		14
Berni e	1		1		2	3	1	1	1		1		1		12
Chris	1		1		2		1		1					1	7
Danni	1	1	1	1	1	1			1						7
Elliott	1	1	2	2	3	1							1	1	12
Frank	1		1		2	1	1						1		7
ie															
Glenn	1	1	1	1	2	2									8
Hilary	1	1	1												3

The average was 10 interviews per patient for the following 7 patients (8 patients in total) resulting in 70 interviews overall. See Table 3.3 above.

3.9.5 Data recording and initial coding

I began to record a 'significant events' timeline from my raw field notes (see Table 3.2 above) in a Microsoft Access database (Microsoft Inc.; 2007) which had discrete sections for significant or key events surrounding a patient, ordered chronologically, with subsections which mapped each relevant person's account of the pressure ulcer development according to the significant event (see also Appendix 10). I inputted all of the evidence I collected from the different sources (patient account, staff interviews, and documents) into one large database. At this point, I realised that I had already begun to code my data according to time and significant events that the patient and I had deemed relevant. Yin (1994) suggests that the early analysis of the data is a critical step in the overall interpretation of the case studies. Miles and Huberman (1994) also outline a number of methods that can be adopted in the early analysis of case studies however no prescriptive practical recommendations are made as to which one to use. I chose to code my initial data around the 'significant events' in each patient's journey relating to his or her pressure ulcer. The significant events varied across different patients, but often centred around nursing and medical entries in notes, and the patient's recollections. The focus was on mapping this developmental process temporally, to trace the process retrospectively, but also to link it constantly to my

research questions (Miles and Huberman, 1994). In effect I was also already examining decisions made by health professionals about the patient at this point, which influenced my analysis and direction of research, rightly or wrongly. I built the rest of my evidence from my field notes around these significant events in a lateral way across my database of evidence using a range of documents numbering approximately 9 types per patient and a range of national documents (see Table 3.4 below). This enabled me to view all events at once, yet to see them ordered by 'significant event' for process tracing purposes. I also made further sense of the context where the pressure ulcer happened, in a broader, more organisational framework by coding organisational issues alongside each significant event, where I deemed them appropriate. For example if a nursing entry stated 'wound care plan documented', I would add an extract alongside from the local policy about when wound care plans should be documented. According to Miles and Huberman (1994) these 'partial ordered displays' allow for the quick identification of the segments relating to the research questions and any potential themes (see Figure 3.3 below). All of these data were inputted into my now very large Access database for examining alongside other sources of evidence, if they were seen as relevant to key events during the patient's timeline.

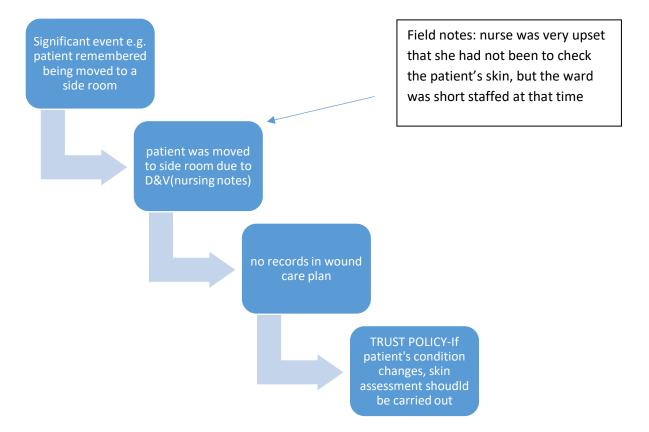


Figure 3.3 Ordering of data

I also collected further descriptive data, which to some degree remained as written field notes (Geertz, 1973), that I had observed and experienced whilst interviewing and visiting different organisations and sites. I referred to these notes to interpret my temporal coding framework in an iterative, back and forth way. If relevant this data was added into the database. I kept extensive notes about my role within the research and how this affected or influenced my data collection. This practice took approximately three months in the field for each patient, and I immersed myself in the rich data, reading and re-reading my field notes and cross-examining the Access database to become familiar with it during this time. I also kept records of access situations (Lofland et al., 2006) including records of when it was difficult to get through 'gatekeepers' to interview certain members of staff. I kept records of my relationship with individual interviewees, and how this dynamic affected how the interview was carried out. I coded this reflective information into my database if it could be linked in any way with significant events and data. For example, if an interviewee found it awkward to discuss what had happened to his or her patient or family member, this was likely to affect the quality of the interview. Or if an interviewee told me about an aspect of their work that he or she felt upset about, relating to the organisation, if it had already appeared in my significant events timeline, this information was coded at this point. All of my written field notes and interview data were then also recorded in a qualitative data analysis software package (QSR, NVivo, 2008) in order to categorise my initial codes further (Richards, 2015) see below for details of categorisation, which happened later in the analysis.

Table 3.4 Range of documents per case (not exhaustive as other documents were retrieved ad hoc if seen as relevant)

Case								
Alex	Nursing and	Tissue	Root	Local Trust	Physioth	Surgi	Local	
	medical	viability	Cause	Tissue	erapy/OT	cal	Trust	
	notes	notes	Analysis	Viability	notes	notes	Patie	
			(RCA)	(TV) policy			nt	
							safet	
			(investigati				у	
			on)				polic	
							у	
Bernie	Nursing and	Tissue	No RCA	Local TV	Physioth	NA	Local	
	medical	viability		policy	erapy/OT		Trust	
	notes	notes			notes		Patie	

Chris	Nursing and medical notes	Tissue viability notes (commun ity and acute)	RCA (by TVN)	Local TV policy	Physioth erapy/OT notes	Surgi cal notes	nt safet y polic y Local Trust Patie nt safet y polic y
Danni	District Nursing and medical notes	Tissue viability notes	No RCA	Local TV policy	Wheelch air Centre/O T notes	NA	NA GP polic y on safet y and referr al criteri a for patie nts
Elliott	Nursing and medical notes	Tissue viability notes	No RCA	Local TV policy	No Physio notes	NA	Local Trust Patie nt safet y polic y
Frankie	Nursing and medical notes	Tissue viability notes	RCA (attended verbal panel and access to written RCA)	Local TV policy	Physioth erapy/OT notes	Surgi cal notes	Local Trust Patie nt safet y

							polic y	
Glenn	District Nursing and medical notes	Tissue viability notes	No RCA	Local TV policy	No Physio notes but notes from respirato ry national centre and respite care home	NA	NA Docu ment s from respit e care home searc hed	
Hilary	Nursing and medical notes (community nursing home)	Tissue viability notes and RCA by TVN	No RCA required as TVN noted PU was present on admission	NA	NA	NA	NA	
Other national or regional document s	A range of historical and current NICE guidance on Tissue Viability and wound care.	Trust measure s/statistic s regarding numbers of pressure ulcers for each Trust in the study.	EPUAP/NP UAP guidance on pressure ulcers	National Patient Safety (NPSA) statistics for pressure ulcers.	Incident investiga tion guidance NHS Improve ment/ NPSA/			

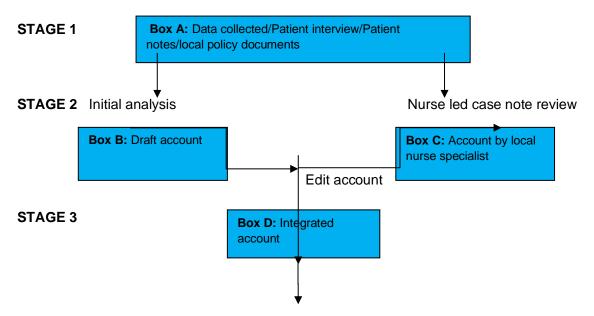
3.9.6 Analytical strategy

I developed my analytical strategy in order to seek balance between both interpretations (from all stakeholders and myself) and explanations about what must have happened. I had identified several threats to the stability of the findings, which were mostly addressed by this strategy. These included different perspectives in

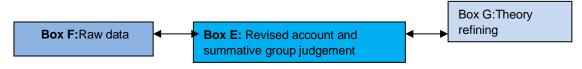
accounts, my non-clinical background, site clinicians' beliefs, research team beliefs and one person collecting the data. I used a continuous reviewing process to address these issues, and in the discussion section below I illustrate, with examples, how I overcame these issues in more detail. The evidence was evaluated against an account of 'good usual care' to further maximise the stability of the findings (see Nurse-led case note review section below).

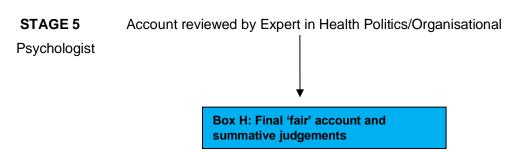
I also dealt with hindsight bias by using the sequence of events timeline, i.e. looking at events as they unfolded in real time (Table 3.2, 3.2a and Table 3.2b) and the 6-stage review process (see Figure 3.4 below). This review process was done on a case by case basis. I used the review process to further strengthen the coherent account and produce the most stable account of what had happened that I could, yet which would remain a 'helicopter view' of events (Perrow, 1984).

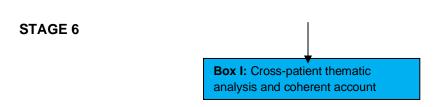
Fig 3.4: Review Process



STAGE 4 Review by expert witnesses group (2 Tissue Viability Nurses (TVNs; not onsite) 1 hospital TVN; I community TVN; 2 academics)







Stage 1: Box A. Data collection, patient interview, patient notes and local policy documents.

Following the patient interview and collecting data from medical notes and nursing notes (Data stage; Box A), I coded the data into my initial significant events timeline, as shown above. I also used *external criteria* at this stage to judge my data; to strengthen it and make it more stable (see Table 3.2b). I looked for evidence from pressure ulcer care guidance and clinical practice outside of the study and my data collected so far to compare with the interpretations of events. I collected a range of local guidance material to cross reference with key events in the development of the severe pressure ulcer. This material was also inputted into my Access database, alongside other previously collected data according to a patient's sequence of events. I also collected material from national and international policies and inputted it into the database for the same reasons. This included NICE guidelines on wound care (National Institute for Clinical Excellence, 2001b, National Institute for Healthcare and Clinical Excellence, 2005), and NPUAP/EPUAP guidance (2009).

Table 3.2b: Sequence of events: external criteria (with patient specific example)

	Event 1	Event 2	Event 3	
	Patient not risk	Patient		
	assessed (no	admitted onto		
	record in notes)	ward and not		
		turned		
Local protocol	Patient should	Turning regime	Ward requires	
guidelines	be Risk	should be	one qualified	
	assessed using	followed as per	staff per patient	
	Waterlow scale,	patient care	at all times	
	Care plan	plan.		
	written up			
NICE guidelines	Patients should			
	receive initial			

	and ongoing		
	PU		
	assessment.		
	Ulcer		
	assessment		
	should include:		
	cause of		
	ulceretc.		
Specific	Older age,		
clinical/co	diabetes		
	diabetes		
morbid risks for			
patient			
Expert witness	Normally		
account of	patients will		
usual care	receive a care		
	plan		
	assessment,		
	and will always		
	undergo a Risk		
	assessment.		
Llighlightod	Patient was not		
Highlighted			
evidence. Does	monitored for		
the event meet	changes in risk		
expected	status		
criteria?			

Stage 2: constructing a coherent account

Although I had already coded my data into a temporal process (Stage 1, and Box B) above) I then used this data to construct a **draft** coherent account of what had happened (George and Bennett, 2005). This **draft account** contained both my sequence of significant events timeline, evidence from interviews with relevant people, documentary sources, policy evidence alongside the patient's own account of what happened in full. This was mostly set out chronologically, with my fieldwork reflections used to interpret my timeline and present it in a coherent account (see Appendix 10).

Local TVNs conducted case note reviews in parallel with my data collection (See Stage 1; Box C), following current guidance for investigating serious incidents in the NHS in England. Sometimes this was a practice that was carried out by them regularly; in other cases I requested them to write a review. This was to add further clinical evidence and insights, which I may not have identified, because I did not have a clinical background. The on-site TVN collected material from clinical case notes, which in her view (all TVNs were female in this study) were relevant to the patient's pressure ulcer and its development. This evidence was put together in a case note review report by the TVN, including departures from local clinical guidelines, which was also written in chronological order.

Stage 3: Integrated account

I then combined the draft account and the nurse's case note review, (Stage 1) to create an 'integrated account' of these data sources (Stage 3; Box D), by interleaving both accounts according to chronology and type of evidence, which would then be reviewed and revised in the stage by stage process (above). My data and timelines were revised in the light of additional facts or insights generated by the TVN's account.

Stage 3b: Changes to the Integrated account

At the beginning of my data collection, for the first four patients, I presented my integrated account to the review team as a possible final account. However, after the first four accounts were reviewed, and following discussion about power balance between stakeholders, the decision was taken by the expert witnesses and myself to include raw data from interviews in the reviewing process from then on to add more emphasis to the patient's version of events. I also added the expert witness' judgements in a discrete section, along with an interpretation of the accounts according to 'classes of explanation' see below.

Table 3.5: Timeline of data collection and initial analysis (Patient 1-4) before changes to integrated account and further analysis

Time in	Month 1	2	3	4	5	6	7	8	9	10	11	12
months												
Patient	Data	Review	LP	Review	Integrated							Expert
	collection	with	account	with	account							witness
	LP	TVN		team								review/
												,

						Revised
						account
Alex						
Bernie						
Chris						
Danni						

Stage 4: Revised account using expert witnesses

Using the improved integrated account as my new source of data, I then incorporated the five possible explanations identified from the safety literature (See Table of Explanations above) to focus each integrated account and produce a more structured 'revised account' of what had happened. This happened one year into data collection and analysis and allowed me and the team to iteratively analyse the accounts based on what had already been collected.

I also incorporated the five classes of explanation into this next stage of analysis (see Stage 4 above) which consisted of a review and progressive focusing of the integrated account by a sub-group of the research team to produce a 'revised account' (Box E). This group included two tissue viability nurse specialists who were not involved with the patient or employed at the NHS site. One was a hospital based TVN and the other was a community based TVN. An academic with expert knowledge in nursing also helped to review the account at this stage. In this stage the tissue viability nurses and academics, who were experienced expert witnesses in legal proceedings, provided an account of 'good usual care' which was a benchmark against which the care of the patients in the study could be judged. I also provided the expert witnesses with raw data so that they could compare the accounts with the original sources of information (Box F). They recorded departures from treatment and care that each individual might *reasonably* have expected to receive. This is similar to how evidence is used within a coroner's inquiry.

The revised account:

1. included information not initially available from the data collection, and further information, arising from the sub-group's reading of individual accounts that I had not yet picked up from interviews with various stakeholders.

- was mapped against chronological events and raw data to look for points of commonality and for events which did not meet the good usual care criteria. This included the expert witnesses recording precise points of departure in the sequence of events from clinical expectations of good usual care. They also recorded where good practice had been carried out, and whether there was any missing information in the accounts
- 4. included whether the expert witnesses felt that the account was a *true and accurate* account of what had happened.
- 5. included a record of the expert witnesses' best class of explanation (see Figs /Table above) for what had happened.

The expert witnesses' views were merged into the revised account, which had discrete sections for the patient account, sequence of events timeline, expert witnesses' reasonable clinical expectations, and the organisational environment. The sections were kept discrete, so that it was clear where interpretations had arisen from (for example, the review team may have had a different perspective to the patient, and I did not want their view to be stronger than the patient's voice in the revised account and ii) so that it was possible to trace back to where the evidence for the explanations came from more transparently.

Table 3.6 Timeline for patients 5-8 and reviewing Patients 1-4

Time in months	1	2	3	4	5	6	7	8	9	10	11	12	Year 3 month	2
Year 2													1	
Patient	Data collecti on LP	Revie w TVN	Account plus TVN Plus Pt data	Review With expert witness es										
Danni														
Elliot							_							
Frankie														

Glen							
Hilary							

Stage 5: Consensus account

Having brought the expert witness' opinions into the account, I was now in a position to bring all these elements together; the existing revised account, what clinicians might reasonably have expected to happen, the patient account, the sequence of events, the environment on the ward at the time, and the expert witnesses' best class of explanation, (see Fig 3.5 below and Stage 4; Box H above).

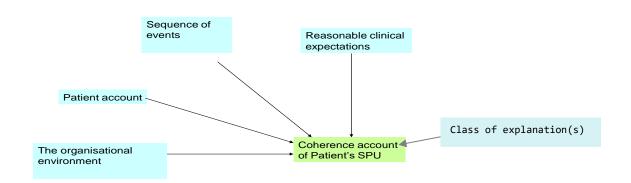


Fig 3.5: Coherent account

An expert in health politics and an independent organisational psychologist then reviewed each revised account carefully. This was in order to check again that it made sense in terms of relevance to local and national policies and the raw data. On the basis of this, the two experts also made a summary judgement about explanations for each patient. It was also the aim at this stage to make a judgement about whether the account offered the best, most plausible explanation of a patient's severe pressure ulcer in the context of current organisational safety research (Box G).

I then identified whether there was a single class of explanation for each patient, competing explanations, or combination of explanations. I then went back to primary data, examining it in two ways:

- If everyone was in agreement, to see whether all of our views were consistent with the primary data, or whether these had drifted away from the actual data. I looked for whether there was a key moment in events, that all team members agreed on.
- 2) If there were competing explanations, I examined the primary data to see if this data was consistent with the findings, and whether there were other points in the evidence that might support or undermine a competing or key argument.

This process followed, at one level, a Yin (2003) and George and Bennett (2005) approach in refuting and supporting hypotheses. Yin's and George and Bennett's approaches offer rival explanations for cross case comparisons and pattern matching. Thus competing explanations were supported or refuted according to strength of agreement with the data.

However, my 'consensus account' did not, in reality, consist of one clear 'answer'; because all those who were interviewed in the study gave us slightly different accounts of events, and it was difficult to 'prove' (demonstrate empirically) who was 'right', but it was the best logical and plausible explanation of what had happened for the patient involved. This follows the principles of Theory of Explanatory Coherence, which arose from the more widely known Inference to the Best Explanation (IBE). IBE was a concept developed originally by Lipton, but my version was based more on the version by Thagard 1989. IBE takes the relationship between theory and evidence to be one of explanation, not logical entailment, and in contrast with a Bayesian and Yin logic approach, it takes theory evaluation to be rather a qualitative exercise that focuses explicitly on explanatory criteria, not a statistical under taking in which we assign probabilities to theories. Thagard suggests that IBE is a mode of inference by which one judges the best of existing competing explanatory hypotheses and theories that have been generated by other abuctive means (Haig, 2009). Thagard captures the idea that a theory is more explanatorily powerful than its rivals if it explains a greater range of facts. Thagard calls this the Theory of Explanatory Coherence (TEC). Explanations are judged more coherent if they are supported by analogy to the theories that scientists (in this case our research team) already find credible.

A major critic, Bas van Fraassen (1989), has maintained that the approach cannot provide a satisfactory basis for believing in a theory, and argued for the conclusion that the best of competing explanatory hypotheses might be "the best of a bad lot," all of which are false. He reasoned that because IBE can select the best hypothesis only from the set of currently available hypotheses. Therefore, he maintained that IBE

provides us with no rational grounds for believing that the hypothesis that is judged best is true.

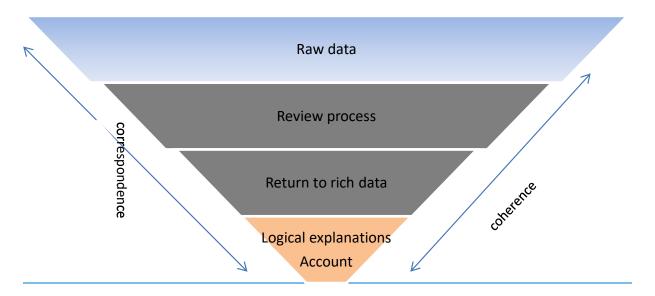
However, proponents of IBE have since argued that scientists appeal to background knowledge (i.e. the expert witnesses views, and primary data collection) in order to select the best of competing theories and that because this knowledge is *approximately* true, their selection of the best theory is generally well grounded theory. Although it should be acknowledged that the best of competing theories might be a poor theory, an explanatory theory with a historical record of successive appraisals like that just mentioned, judged to be better than its rivals, is likely to be the best of a respectable lot, not a bad lot.(Haig, 2009). This also sits with George and Bennett's process tracing case study method in its search for the most plausible explanation from a number of hypotheses (George and Bennett, 2005), yet George and Bennett articulated this in a slightly different way, preferring to keep explanations in terms of typological theories, and contingent and specific generalisations. However despite my conceptual departure from George and Bennett's approach, I was confident with my analysis that each consensus account was the best, most respectable explanation of what happened to the patient (Pawson, 2006).

Stage 6: Cross patient analysis

After each of the eight patients had been subjected to the staged review process on an individual basis (which took approximately four months from the start of data collection to constructing each final coherent account), I then compared across patients in each discrete area of the coherent accounts (see above figure: Stage 6, Box H, and Table 3.7 below). This was to add further strength to, or eliminate the five explanations. I did this by reading all of the accounts closely again, and looking for common explanations across patients which seemed to be emerging from the data, following the principles of TEC set out earlier. This was also similar to the approach set forward by George and Bennett's 'historical explanation' or narrative in their process tracing case study method. At the same time I was aware of the need to provide an evidence based account for the audience I was seeking to provide explanations to. I also used QSR NVivo software at this stage to examine line by line all of my interview evidence and categorise this data using nodes. This process of triangulation offered an interesting new perspective in devising theoretical categories. The temporal process had already offered some insights, but immersing in this rich data using line by line coding helped to establish and strengthen the categories to take forward to the next stage of analysis.

This was actually a very straightforward exercise, in practice, as clear patterns had already emerged from the data, by this point due to the staged reviews. The process was a funnelling of evidence and I was able to eliminate explanations that were not feasible, and keep plausible explanations (George and Bennett ,2005), by checking against the primary data using the line by line coding once again, to find the most suitable, yet coherent explanation. See figure 3.6 below:

Fig 3.6: Funnelling evidence



I then produced one final explanatory coherent discussion of these cross-patient checks. This also incorporated primary data references to provide a transparent audit trail. This helped me to refine theories out of the evidence. These were the best, most stable explanations, given the data collected, that I could come up with.

Table 3.7: Cross patient analysis grid

Patient 1	2	3	4 etc
Sequence of	Seq. of	Seq. of	Etc
Events	Events	Events	
Good usual	Good	Good	Etc
care	Usual	usual	
	Care	Care	
Patient Account	Patient	Patient	Etc
	Acc.	Acc.	
Organisational	Org.	Org. Env.	Etc
Environment	Env.		
Explanations	Explanat	Explanati	Etc
	ions	ons	

3.9.7 Thematic exploration

I then used the accounts to again explore first inductively, then abductively, my categories and themes that were raised in the cross patient analysis, to create causal theories to test (Box I). I was looking at the theoretical explanations generated from the accounts, to elaborate and illustrate these. I returned to immersing myself in possible patterns, theories and themes arising from the data and categorising further, by analysing these in more depth going back to the NVivo categories I had generated from my primary data collection, extracted by line by line coding (Appendix 11). I examined the emerging evidence carefully against raw data, comparing it with current research in the new theoretical areas of focus and then I developed my refined theories from this abductive analysis. I set out a hierarchy of themes and subthemes arising from my account to structure the thematic analysis (see below).

3.10 Methodological issues

3.10.1 Challenges with the method

The method set out above was extremely detailed and raised several technical challenges when applied in practice. Here, I illustrate, by working through one patient account, how I addressed these issues.

3.10.2 Background

Chris was a 75 year old man with multiple health problems. He was staying on an acute vascular surgical ward in a large general hospital when I interviewed him, after having surgery for a pressure ulcer. Previously he had also been on a community hospital rehabilitation ward.

3.10.3 Defensiveness and time constraints of participants

As the study was observational, and was mainly carried out on NHS sites, this was a challenge, as most of the field work took place on busy hospital wards, where staff members had little time to spare to help with my research. Some people were helpful, but a number of informants were defensive, given the issues around severe pressure ulcers and patient safety indicators, so some didn't give enough time, and others did not attend their arranged interviews.

In the case of Chris, the ward manager did not attend her interview despite it being rearranged three times. I finally had an informal interview with her, which was helpful, as it highlighted defensive practices between the ward she managed in the community

setting, and the acute trust. This had led to a communication breakdown between the sites, and had implications for the man's pressure ulcer development.

I used the on-site TVNs as gatekeepers to overcome the defensiveness of staff, and mostly this was useful, however with Chris, some of the issues were amongst TVNs, as sites used different policies and these had caused animosity between acute and community Tissue Viability services. The outsider issue always presents a difficulty as for field researchers and can only be overcome to an extent.

In addition, I was non-clinical and some aspects of the information were not understandable. I overcame these issues with partial knowledge by a parallel clinical review by the TVN (explained earlier). I therefore had an on-site account of what had happened, from the TVN's clinical perspective. For Chris, this included adding aspects of his neurological condition, which contributed to his pressure ulcer.

In addition to defensive informants, there were interruptions and distractions from other staff, and wards were noisy. Interviewees would often avoid talking about the patient's pressure ulcer, and would talk more generally about pressure ulcer care. This was partly because of lack of information about the patient, and partly because of fear of blame if they disclosed information about the pressure ulcer. One nurse became emotional when she reflected on her poor practice with Chris. Because of these issues, I had to use prompts and direct questions to re-focus the interview towards the patient's severe pressure ulcer (see 'cognitive interview section above), and interviews became more conversational. However, every informant could only offer an interpretation of the full story of the severe pressure ulcer; each one individually could not give us the whole explanation of what had happened.

3.10.4 Representing information

I wanted to represent the evidence in the most accurate way to get the most suitable explanation. However, I faced several smaller challenges while trying to do this. I found, while carrying out interviews with each patient that, although he or she was witness to most of what happened there were other people's versions of events which he or she was not witness to, such as decisions made by nurses, Physiotherapists and consultants. Chris knew he had moved on to a side room, and thought it was because the staff wanted him to be nearer to the dining room because he struggled walking too far. However, he had a stomach virus and it appeared, from the case notes, that he had been isolated because of this. The actual entry in the notes is 'Diarrhoea-confined'. Given this sort of partial evidence, I realised early on in the field work that data

collection would have to be substantial and I would have to gather numerous different sources of evidence for each patient to make sense of what had happened.

3.10.5 Timeline issues

The timeline encouraged me to think about evidence chronologically and avoid hindsight bias in the reporting of evidence. See below an excerpt from Chris's chronology: However, I recognised that even a timeline is a judgement, based on someone's perspective, and often based on information that is not easy to interpret.

Excerpt 3.1

(Date supplied)

Nursing notes

Catheter removed at 1.30am. Pt had poor night, anxious re urinating following catheter removal. Used a bottle.

Wound care notes

'L heel has grade ¾ blister. Underlying tissue severely affected. TV referral faxed'. Wound care notes state: 'Diabetic foot ulcer, wound 2-3 days on heel, allevyn, tissue type oedematous. Mattress soft bannow airwaye. Wheelchair.

In each case I chose the patient's story to structure the timeline. The bias towards timelines according to staff members had been part of the issues with current investigative tools. This timeline was different as it offered significant events from the perspective of the patient, rather than the service. I realised that if I wanted to improve current practice I needed to minimise the effect of different perspectives of events. Although I knew each of the accounts was not perfect and couldn't offer the 'right' answers, I began to think that I could still strive for a best explanation of what happened (Lipton, 1991, Haig, 2009). Other issues concerning the use of a timeline were that for several of the patients it was substantially longer than expected, so the data collection took much longer, as shown in Tables 3.5 and 3.6 above. Chris's

pressure ulcer began 4 months before I began to collect data, so I had to process trace back to its initial development, and find case notes, locations and members of staff from four months previously. The staff, understandably, had often forgotten details of the patient by the time I interviewed them, and I used case notes as prompts to aid memory, and cognitive interviewing (Fisher and Geiselman, 1992). I examined the data closely, and looked for emerging patterns across each interpretation in the timeline, looking at events as they appeared in 'real' time. This is how I ascertained that Chris had been confined due to illness, rather than moved for safeguarding purposes. I looked across the data to see at which points that decisions had been made about the patient's pressure ulcer, what actions were taken and who was involved at each point in time. This allowed me to start to make sense of hundreds of discrete events and to interpret this large volume of data. I aimed to produce the sequence of events as it happened in real time, but I knew that I would have to gain other people's perspectives too to help make sense of it. This became my next challenge:

3.10.6 Different perspectives.

I wanted to understand what had happened from each individual person's viewpoint, yet I also needed explanations for the cause of a severe pressure ulcer. Each of the sources of data gave me a slightly different perspective on what had happened, and interviewees (as in Chris's case set out above) had faulty recollections of events. For example, Chris recalled that he had always been on a high risk pressure ulcer mattress on previous wards and was not placed on one on the rehabilitation ward. His pressure ulcer developed when he was on an ordinary bed. However, there was no other reference to this, other than from the patient himself, and in one piece of documentary evidence when they had ordered a mattress for him (i.e. the mattress order form). Nurses did not volunteer this information until asked directly about it. I addressed this issue with carrying out many interviews with different informants, with the timeline above, and with the detailed analytical review process (See Figure 3.4). I needed to be sure that interpretations were stable enough to ensure I had chosen the best possible explanation, whilst retaining an open, helicopter view (Shadish et al., 2002, Guba and Lincoln, 1989, Hammersley, 1991, Lipton, 1991). I used the analytical review process to develop my coherent account for each patient, to counteract different perspectives and to compare the coherent account of what happened with good usual care seen on a ward. The expert witnesses offered their verdict on whether good usual care had been followed and offered a more balanced view of the evidence than if I had simply used my draft account. For Chris, the fact that he had been placed on the wrong mattress was seen as a mistake, but within the context of an organisation which did not recognise him as high risk. He was on a rehabilitation ward but had deteriorated and become high risk due to developing a diarrhoea and vomiting virus. This was not, in the opinion of the expert witnesses, a good enough assessment of his risk status, and this had led to the development of his severe pressure ulcer. However, alternatively regarding Chris, there were also queries over the initial onsite TVN's review, which stated that the cause of his pressure ulcer was poor footwear. The researcher was then instructed to find further information to clarify this. It was decided by the expert witnesses, following a repeated review that this was not the explanation, and that Chris had developed his pressure ulcer following the episode of diarrhoea and vomiting for which he was placed in a hospital side room on a foam mattress.

There were also instances where the expert witnesses disagreed with the researcher and asked for clarification. For example, one discussion included the following disagreements about the researcher's coherent account:

'The researcher has said there were issues at an interpersonal level...I don't think that's the right title, but I think the issue is the right thing, but I don't think that's the right title... It's a cognitive issue.'

These points were duly noted and the account was edited for each patient following the expert witnesses' comments.

Summative judgements for every patient from the expert witnesses were also extracted from the coherent accounts and raw data (namely the sequence of events chronology and interview transcripts) at this stage (see Chapter 4 for results of these).

3.10.7 Power relations

Although I respected the viewpoints of the expert team, I was also aware that they had their own views about clinical practice. At one point they concluded that Chris may have developed his ulcer due to his footwear, and this was not what he had suggested had happened. However, this was discarded after another discussion. However, when his issue arose, to counteract a clinical viewpoint overriding a patient's view completely, I left the patient account intact until the final summative explanatory account. This way I always had the primary version of a patient account to refer to throughout the review process. Although the coherent account was more integrated as it was reviewed, the individual accounts within it also remained discrete; so that it was possible at any point in the review process to see where the primary evidence had come from (see Fig 3.4). The aim was to find a summative explanation which would

cover all disciplinary perspectives and yet offer traceable audit trails back to primary evidence. This was no easy task.

3.10.8 Finding the best explanation

I knew I wanted to be open to all disciplines (see Introduction; Chapter 1) when explaining how a severe pressure ulcer developed. Applying this was more difficult. I used the review process as a forum for applying different cross disciplinary explanations (see Table 3.1 again above), and asked the team to choose which ones, if any, they thought were the most appropriate. I asked them to read each patient's coherent account with the explanations in mind.

I took the most competing explanations from each account and made sure that no other explanations could have fitted. By looking at the primary evidence in tandem with transparent primary evidence, it allowed me to focus the findings into a best explanation within a patient account. For example for Chris, his ulcer did not develop regardless of the care he received, as he developed it because of the conduct of staff (not Explanation A), it was not really due to a sequence of events (not Explanation C), as the *best* explanation was that he was placed on the wrong mattress. However, the organisational culture also made the ulcer more likely to happen because of the staff shortages, poor documentation, laissez-faire management and poor communication between sites (Explanation D).

3.11 Discussion

I came across a number of technical challenges in analysing data as I carried out the study as shown above; namely issues with representing evidence, including partial and faulty recall of events and interpretations, power relationships, and finding an explanation, which I addressed mostly with the lengthy review and analysis process detailed above. I recognise that due to these challenges, this technique of investigating complex adverse events is a time-consuming and multi-method approach (on average taking 3 months at two days per week) and that issues of time constraints and tools of adverse event investigation have already been well documented in research (Waring, 2007, Nicolini et al., 2011). Nevertheless, aside from the drawbacks set out above, I have found that using this approach offered insights unavailable from other methods of error investigation. There has, until now, been no way of discovering the causes of a complex event such as a severe pressure ulcer, which focuses on the patient's view of events rather than an in-house investigation, based on health care professionals' views. This type of thorough investigation has been called for in recent patient safety

literature (Waring, 2007) and is currently gaining support amongst researchers (O'Hara et al., 2018).

Current patient safety studies are still often based around outdated human factors approaches, (Waring J et al., 2010) and thus find a psychological explanation for an adverse event. However, in the context of this research, this would only be able to explain in part what happened to the patients (for example, Chris's wrong mattress). Because my method cuts across disciplines instead, to look for explanations, I was able to explain both in terms of human factors, but include the organisational context.

In parallel, organisational theory emphasises either systems or culture, however, the explanations within this method are able to cover both of these. A sequence of significant events may be responsible (systems) in part for a severe pressure ulcer developing, but these events may take place under a prevailing problem culture, where cultural norms allow pressure ulcers to develop without addressing them, consistent with the normalisation of deviance theory (Vaughan, 1996). This is where deviant or suboptimal work routines become accepted and normal over time, so that staff members fail to recognise risky practices. They conform to the practices, so are not aware that they are doing anything risky or wrong. In hindsight these practices are more easily detectable as deviant but at the time they go unnoticed and not seen as anything out of the ordinary.

This method reveals a means to address the organisational culture and remain close to the primary sources of evidence. The method allows us to formulate an explanatory theory of what happened, which remains grounded in primary evidence (Pawson, 2006). I do not suggest that this time-consuming method of looking at the whole picture should be transferred per se into practice. However, this new way of examining and understanding evidence does suggest ways of incorporating psychological, sociological and organisational research to offer a more holistic, multi-method way of studying patient safety than has ever been practised before (Waring J et al., 2010).

One of the main strengths of the method has been that I don't need to provide *every* bit of evidence, as there is an abundance of rich detail. Instead, I am able to use the evidence that is available to infer that for example, a nurse's account must have been right (or vice versa), because it fits with everything else I know. The logic follows the style of inferred explanatory reasoning that I set out before (Lipton, 1991, Harman, 1965, Haig, 2009), which is where this method departs in its execution from George and Bennett's (George and Bennett, 2005) complex causality approach. This method explains how a cause can be established retrospectively from an outcome, which in

this study is a severe pressure ulcer, by *inferring* the best, most plausible explanation, through eliminating inadequate explanations, and by stabilising the best explanation through reviewing accounts. This way of looking at data balances interpretations and hard evidence in a way that is not recognised currently within healthcare.

The use of evidence gathering and making sense of the data corresponds to a coroner's or large scale inquiry, see Mid-Staffordshire NHS Foundation Trust Inquiry (Francis, 2013, Secretary of State, 2001); Bristol Inquiry; (Kennedy, 2001) and has similarities with the HSIB's approach to investigating several incidents (Health Services Investigation Branch, 2017). However, the difference between this study and recent large scale inquiries is that it does not conclude with a list of recommendations, which can be difficult to put into practice. In contrast, I was able to use the evidence in a coherent way; in the form of an account of events, but also refer back at any point to corresponding evidence in the primary data. This gives a transparent audit trail for my choice of causes and strengthens the evidence, accountability and stability of findings.

3.12 Concluding comments

Although this type of method may offer possible solutions to bridging the gap between theory and practice in health care, it is only a small scale study by nature, and there would be a further exercise in testing resulting explanations out in daily practice. This method offers one approach to uncovering data, and others could be considered, such as a more interpretive approach to elicit different forms of data. Currently, the method has been applied only to pressure ulcer research, and it could be applied to other types of clinical setting to see if it works in the same ways to produce coherent explanations. It could also be tested alongside current adverse event investigation tools to see how it compares in practice, or alternatively, it could also be tested out in areas of good practice to see if it generates similar results.

Chapter 4: Initial analysis-categorising, coding and hypothesising

4.1 Chapter summary

The previous chapter considered the retrospective case study method, and highlighted challenges arising from carrying out the method and analysis with reference to one patient's case. This chapter now describes the results of initial data analysis, stage by stage, through the six stage review process, using examples from raw and coded data. It then introduces brief summaries of each patient's case to describe the tentative candidate explanations which were arrived at for each account following the analysis described in the previous chapter. The final stage of analysis of iterative coding and patterning across cases is then described, which results in four discrete, testable hypotheses which are then expanded and discussed in subsequent chapters.

4.2 Introduction

The evidence that was collected and analysed through Stages 1-6 of the analysis process per individual patient case was checked within each case against the raw data for strength and authenticity by the researcher, the on-site TVN, the expert witnesses and the project team (see Figure 3.4 in Methods chapter, which displays this method of analysis).

This 6-stage analysis made use of both correspondence data and coherence data (referred to in the previous Methods section). To reiterate, this definition refers to accurate and empirical data (correspondence data) coupled with rational or logical data (coherence data); see Methods chapter (Hammond, 1996). This staged analysis was also designed to maximise internal validity (Shadish et al., 2002).

4.3 Table of patients

The eight individuals in the study had differences in their personal characteristics and in their treatment and settings. They were all, however at high risk of developing pressure ulcers, or of existing pressure ulcers deteriorating (see Table 4.1).

Table 4.1: Individuals and settings

Table 4.1:	Individual	Setting
Individuals and		
settings		

Account		
Alex	38 year old woman	Acute hospital,
	with paraplegia	surgical ward
Bernie	65 year old woman	Acute hospital,
	with long-term	medical ward
	chronic neurological	
	condition and	
	undiagnosed	
	infection	
Chris	75 year old man with	Community hospital,
	multiple chronic	rehabilitation ward
	health problems and	
	acute infection	
Danni	37 year old woman	Primary Care
	with long-term	
	degenerative	
	congenital	
	neurological	
	condition	
Elliott	90 year old man with	Acute hospital,
	multiple chronic	surgical wards
	health problems and	
	undiagnosed acute	
	illness	
Frankie	39 year old woman	Acute hospital,
	in hospital for acute	surgical wards
	undiagnosed post-	
	operative surgical	
	complications	
Glenn	65 year old man with	Community Nursing,
	quadriplegia	respite care and
		elective admission in
		tertiary centre
Hilary	89 year old woman	At home
	who fell at home	

4.4 Stage 2: Constructing a draft account

The first stage of focused analysis began at Stage 2 (Stage 1 was the initial data collection; see Figure 3.4 in Method chapter although there were elements of analysis even at the coding of raw data via the timeline). As set out in detail in Chapter 3, this involved the researcher and TVN comparing data collection and field notes per patient. At this early stage, analysis was partial, consisting of a 'draft account' and based largely on the patient's interview and clinical notes (see Figure 4.1).

Figure 4.1 Stage 2



This stage included clinical sense-checking (Hammersley, 1991, Shadish et al., 2002) with the on-site TVN, to make sure that my data collection notes were accurate clinically, and the meaning of clinical terms and abbreviations within each case were clarified. For example, 'Abx' refers to antibiotics within medical notes, and 'FY1' refers to a grade of junior doctor. All relevant data regarding skin status was included, and clarified by the TVN where necessary.

4.5 Stage 3-creating the integrated account

The next stage of analysis involved coding interviews with staff or carers for each patient, who were identified by the patient themselves as being involved in their care, or suggested by carers, or other staff members. A total of 70 recorded and transcribed interviews took place with a range of participants. See Table 4.2 (repeated from Chapter 3) below:

Table 4.2: Number of people interviewed by account across all 8 patients:

Account	Individual	Carer	Viability Nurse	Tissue	District nurse	Nurse	Health/home	Consultant	Junior doctor	Physiotherapis	Occupational	Ward clerk	Liaison nurses	Ward Manager	Quality	Total
Alex	1	1	2			2	2	1		1	1	1	1	1		14

Berni	1		1		2	3	1	1	1	1	1		12
е													
Chris	1		1		2		1		1			1	7
Danni	1	1	1	1	1	1			1				7
Elliott	1	1	2	2	3	1					1	1	12
Frank ie	1		1		2	1	1				1		7
Glenn	1	1	1	1	2	2							8
Hilary	1	1	1										3

After my initial interpretation of the raw data (namely inputting the sequence of events chronology and interview data into the Access Database and examining the data in a cross tabulated way) these data were converted into a written coherent version of what happened (see Methods chapter for how this was conceptualised and structured). Example excerpts from one typical coherent account are shown in the box below:

Excerpt 1

The ward manager stated that the HCAs do most of the hands on cares now, and that the nurses rely heavily on the HCA to come and ask them if there are problems with patients' skin. She felt the HCAs' knowledge was variable. One HCA stated that she wouldn't find a PU with her 'being only a helper'.

Excerpt 2 Discussion

There were further communication delays during Bernie's care, which appear to have significantly contributed to the deterioration of her condition. There were issues with verbal communication on the ward between HCAs and nurses in handing over information about pressure ulcers.

The coherent account was an integration of the researcher's draft account and the notes and clinical knowledge added by the TVN. This was thus called an 'integrated account' (see Figure 4.2). In some instances (for Bernie, Chris, Frankie and Hilary) this included a separate on-site TVN clinical review which was written as part of their clinical role. In some cases this formed their report of the Root Cause Analysis.

Figure 4.2 Stage 3



A typical excerpt from one of the TVN's reports is noted below:

Excerpt 3

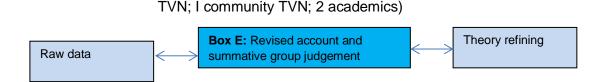
There is no record of skin assessment in A&E or on other ward. A box was ticked 3 days after admission to say skin intact. A full skin assessment is not recorded till 10 days after admission which records grade 1 damage to sacrum, left and right buttocks

4.6 Stage 4- Review of integrated account by expert witnesses.

Stage 4 involved the expert witnesses and project team reviewing each patient's integrated account and all raw data (namely interview transcripts and chronological time line) to produce a revised account and possible judgment (see Figure 4.3). The accounts were considered by the expert witnesses on a case by case basis.

Figure 4.3: Stage 4

STAGE 4 Review by expert witnesses (2 Tissue Viability Nurses (TVNs; not onsite) 1 hospital



As described in the Methods chapter, the team of expert witnesses helped to create a balanced account of what happened, including highlighting the importance of other

issues that the researcher had not considered. Some typical examples of the expert witnesses' review discussions are set out below:

Example 1:

Expert witness A: The fact is they were trying to do it from memory and trying to recall things from memory...

Expert witness B: For Bernie there was no mention at all of physios and OTs – (Agreement from Expert witnesses A and C) – and the physios being involved in repositioning.

Example 2:

Expert witness A So, we're assuming that what we're looking at is the ischial pressure ulcer, rather than anywhere else. But we've nothing definite to say that.

Expert witness B But if he was elevated slightly in the ambulance, given that he's so thin, is there not that potential that although he's not sitting directly on his ischium, that actually, there would be...

Expert Witness C But I don't agree... if you sit like that and you're thin -

Expert Witness A You still miss your ischials

Expert witness B Yes, you still miss your ischials.

Explanations for each patient's ulcer were then inferred by the expert witnesses and myself from each coherent account. These were deduced from the expert witness' judgements following in-depth discussion and the evidence from the data (both raw data in the form of interview transcripts, the sequence of events data and my coherent accounts). Table 4.3 sets out the results of the summative judgements for each patient's account.

Table 4.3: Summative judgments

Patient	A -	B - Single	C -	D -	E - Other
	Unavoidable	error	Sequence of	Environment	explanation
			events	made SPU	(not first four)
				more likely	
1 Alex				Yes	

2 Bernie			Yes	Yes	
3 Chris		Yes		Yes	
4 Danni			Yes	Yes	
5 Elliott				Yes	
6 Frankie			Yes	Yes	
7 Glenn				Yes	
8 Hilary	Yes				

4.7 Stage 5: Final explanations

Following the summative judgments, the eight revised accounts, chronological timelines and raw data were reviewed at one sitting by an expert in health politics and an organisational psychologist (see Fig. 4.4):

Fig 4.4 Stage 5



Box F: Final 'fair' account and summative judgements

Following this final review one overarching explanation from the list of summative judgements A to E (see Table 4.2 above) was identified: **that the organisational environment made a patient's pressure ulcer more likely**. For seven of the eight patients the overall judgement was that the environment, in some way, made the severe pressure ulcer more likely. For three of the seven patients it was the sole explanation. For four others the organisational environment explanation was in combination with other explanations too; in one case a single error was thought to have contributed to the pressure ulcer developing (namely Chris) and for three other cases (Bernie, Danni and Frankie) there was also a sequence of events (see Chapter 3). The expert in health politics and organisational psychologist did not change the overall conclusions and judgements of the previous expert witnesses group at this stage. It

must be noted that the explanations at this stage meant only that these were the areas to be focused on for further analysis and to search for a final theory about why patients develop severe pressure ulcers.

4.8 Brief summaries of explanatory accounts

At this point it is useful to introduce brief explanatory summaries for each patient account to contextualise the analysis further and highlight the judgements arrived at for each case. The use of summarised data for each patient is due to the lack of space within the thesis to reproduce detailed accounts for each individual patient, and for issues around confidentiality.

Patient 1: Alex

Alex was a 38 year old woman with paraplegia, who was admitted to a spinal cord injury unit. She had been on a surgical waiting list for some time, but problems with previous pressure ulcers had led to delays in surgery. When she was interviewed she had undergone surgical repair for closure of her severe pressure ulcer. Her wound broke down post-operatively. The patient's view was that her SPU developed because there had been a failure to turn her every three hours during one night. Alex also felt she was 'blamed' by staff for the deterioration of her post-operative wound. From the expert witnesses' perspective, there was the consideration that this was likely to have been a surgical wound breakdown, which made this case a deviant case in terms of analysis. When the data was collected and the analysis carried out, it appeared that she was not a suitable participant as she did not fully fit the criteria for the study. However, evidence around the care Alex received for her post operative pressure ulcer pointed to a broader set of explanations than the view she offered. This supported other evidence within the study around organisational issues. These were poor adherence with the care plan (including turning her), the ward being under staffed, and poor communications between clinicians. Therefore, this evidence was included as part of the data. The expert witnesses judged this to be that the environment made the wound breakdown more likely (Explanation D).

Patient 2: Bernie

Bernie was a 65 year old woman, who had leg contractures due to a progressive degenerative condition and a previous ankle fracture. She then had a stroke and

collapsed, and on admission to hospital the diagnosis was initially a possible urinary tract infection, which was later changed to pneumonia. There was uncertainty over her diagnosis and a series of failings over a period of days – she was not properly assessed on admission, a full pressure ulcer risk assessment was not conducted until the seventh day. This was attributed, by the expert witness team, to marked weaknesses in nursing practice, and in failures in team working. The nurses did not respond to Bernie's high risk of developing a pressure ulcer. This also sat alongside an escalation of her illness. There was no team work between professionals involved in her care, yet she was a patient with multiple comorbidities. There were frequent ward moves during her time in hospital due to her co-morbidities, alongside queries over her mental capacity, and she was not responsive to instructions by staff. She preferred one position to lie in, although this issue was not considered at length by health care staff. This made the judgement of the case a combination of Explanations B and D.

Patient 3: Chris

Chris was a 75 year old man, who had a pre-existing pressure ulcer, but developed another one (Category 4) while on a community rehabilitation ward. He had multiple health problems including Type 2 diabetes, cancer and congestive heart failure. Chris was moved from a bed in an open bed bay into a side ward, due to a diarrhoea and vomiting virus— and the specialised mattress was not transferred with him. The expert team concluded that although there was a single precipitating event (Explanation B), they took the view that Explanation D was relevant as there were staffing shortages, documentation was poor (risk assessments were lacking) and communication was poor between services.

Patient 4: Danni

Danni was a 37 year old woman with a congenital neurological condition, who lived with her husband, who was her carer. There was a sequence of events over time, beginning with Danni's superficial pressure ulcer, which was not assessed by the practice nurse at her GP's surgery for five months. Neither were her risk factors for developing a pressure ulcer. Danni was instead given repeat prescriptions for wound dressings. This delay in assessment resulted in a deterioration of Danni's skin damage, and she developed a SPU. She was then bed-bound for eighteen months. The expert witnesses observed that the patient was let down by the system as a whole. It appeared that she had not been given proper, detailed advice on managing her own PU risks, or any other basic prevention or management of skin damage. Her husband (carer) had not been properly trained in changing her dressings and treating PUs when

they developed. The practice nurse did not have specialist knowledge of the patient's risks, and there was no early referral to district nurses as the patient was seen to be mobile enough to access the GP' surgery. The patient's GP, as well as the practice nurse, could have referred Danni to a DN much earlier, which may have been a more successful approach to managing her initial wound. There was an overall failure to act quickly enough. Danni was expected to self-manage her wound care without the knowledge to do this successfully. The expert team concluded that there was a combination of a sequence of events and the environment which led to the development of her SPU (Explanations C and D).

Patient 5: Elliott

Elliott was a 90 year old man, and was admitted to hospital with lower abdominal pain and cardio-vascular problems. He was confused, and very ill on admission. He appeared – in retrospect – to have had PUs before his admission, despite his pressure ulcers reported as hospital acquired. But he was not properly assessed, no checks were made on existing wounds and pressure ulcers (nobody looked under dressings), nursing notes recorded pressure ulcers in different places on his body, and a wound care plan was not implemented until 15 days after admission. He was also subjected to frequent ward moves. The expert witnesses felt that Explanation D was the most plausible explanation.

Patient 6: Frankie

Frankie was a 39 year old woman. She was admitted to hospital as an acute admission following previous elective surgery. At the time, there was a major reorganisation of wards and theatres taking place. Nursing staff – on more than one ward – failed to pick up clear signs of PU risk, for example her recent weight loss. There were clear operational problems such as failure to undertake proper risk assessments. Frankie was supine for 24 hours post operatively. The nursing notes on the wards were poor. Basic nursing practices (use of mattress and skin assessments) were not followed throughout her frequent ward moves. Her risks and serious condition were not communicated to the post-op ward staff properly, and a post-op bed on a high dependency unit would have been preferable, but, was not available for her. The expert witnesses judged that a combination of a sequence of events and the environment (Explanation B and Explanation D) were the most plausible explanations.

Patient 7: Glenn

Glenn was a 65 year old man with quadriplegia. He attended a treatment centre some distance away from his home for lung complications bi-annually. His wife was his main carer. He had an episode of acute illness, and around that time areas of redness on his sacrum and hips were identified. Then he travelled by ambulance to a specialist hospital approximately 200 miles away, for treatment related to his respiratory problems, for a night and a day. On his return, he entered his regular respite care facility, at which point a Category 1 PU was identified on his buttock. This continued to develop into an SPU. The expert team noted that DNs in the community, and staff in the 'travel phase' and in respite care all failed to respond to his high risk status. The DNs were task orientated. Nobody took responsibility for this patient's treatment and care. His carer (wife) was the only person with an overview of his condition, but was 'blamed' by services for not accepting a pressure relief mattress, and this contributed to a complex relationship with various services involved in his care. Services surrounding him operated in silos and there were delays in referrals to the TVN. As the patient's condition deteriorated, the services did not recognise this, and permitted the situation to continue unchecked. The expert witnesses felt that Explanation D was the most plausible.

Patient 8: Hilary

Hilary was an 89 year old woman. She was living independently in her own home, though visited regularly by her daughter. She fell as she was getting into bed — resulting in a fractured neck of femur. Her daughter eventually found her, after a period that may have been 48 hours, and called an ambulance. The ambulance staff identified and reported her severe pressure ulcer on admission to the Accident and Emergency department. The expert team took the view that, following this event, the staff involved did everything they should have done. The SPU was identified early, and a care plan was implemented. This was an unavoidable SPU (Explanation A).

4.9 Initial cross case analysis

The overall organisational explanation from the summative judgements by the expert witnesses and review team (see Table 4.2) meant that the area of focus for further analysis was based largely around an organisational explanation, and not around clinical symptoms, individual or clinical errors, or a cognitive psychological explanation (for example an isolated lapse in concentration-see (Hollnagel et al., 2015). This initial process of elimination allowed me to focus more on socio-cultural and organisational

issues when conducting my further analysis, rather than for example, a more clinical one.

4.10 Cross case coding and patterning

The sharpening of analysis involved detailed reading across all of the patient coherent accounts, and cross-checking for patterns and recurring variables (George and Bennett, 2005). Again I checked that the evidence I had developed in the accounts was supported by correspondence evidence from the raw data (interview transcripts and sequence of events timeline) for internal validity (see Figures 3.3 and 3.4 in Chapter 3) (Hammersley, 1991). The coding frame from this cross check is set out in Table 4.4 below. These checks and the coding frame were further checked by the expert witnesses, expert in health politics and the organisational psychologist for internal validity (Shadish et al., 2002). Numbers in Table 5 refer to Patients 1-8, who were involved in the study namely Alex (Patient 1), Bernie (2), Chris (3), Danni (4), Elliott (5), Frankie (6), Glenn (7) and Hilary (8). Data sources were from four different categorical areas which I ordered into Data Source 1; which was the sequence of events chronology; Data Source 2; the expert witness discussions; Data Source 3; the patient's own account and Data Source 4; the other documents relating to local and national guidance and my observational field notes. These are abbreviated to 'DS' from now on in this chapter. The 8 coherent accounts were thus systematically compared (see Chapter 3) using the four sources of data shown in Table 4.4 below and using this framework were cross tabulated with emerging codes which were generated by me, as they appeared repetitively, as I analysed using line by line coding within my NVivo based data.

Table 4.4: Patterns and emerging codes

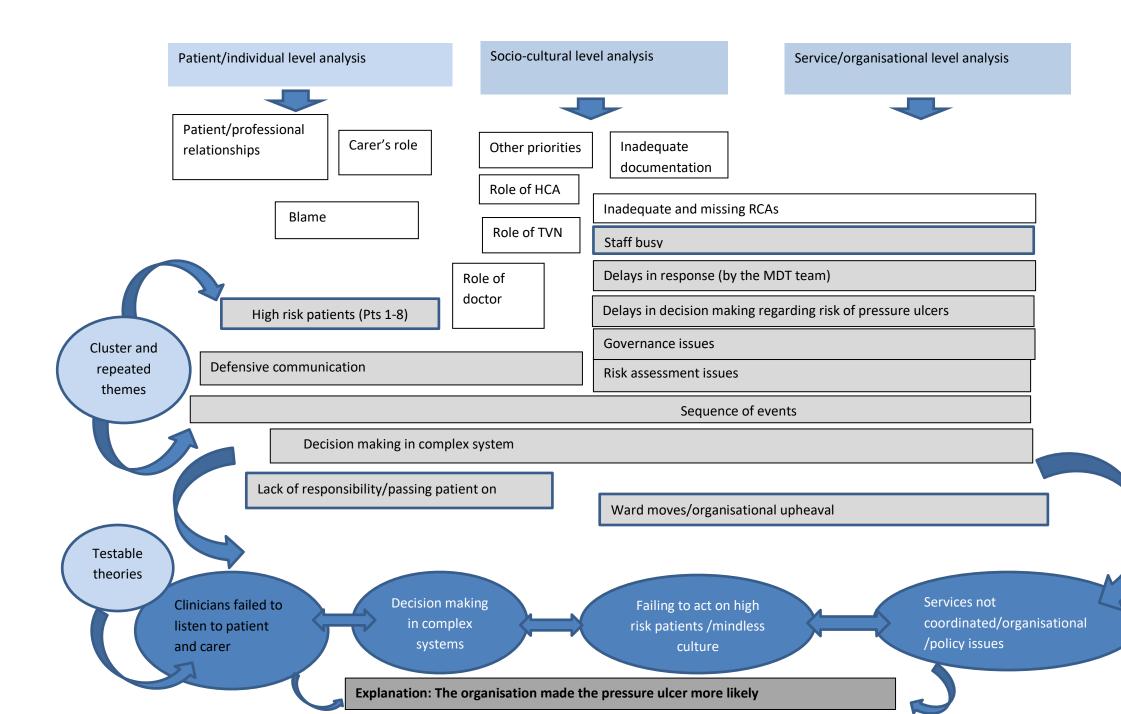
	Data	Data	Data	Data Source 4
Patterns/themes emerging across	Source 1	Source 2	Source 3	
accounts				Organisational
	Sequence	Good usual	Patient	environment
	of events	care/expert	account	
		witness		
High risk patients	Pts 1, 2, 4,	Pts 5, 2, 4,	Pts 4, 5, 6,	Pts 2, 5, 6, 3,
	5, 6, 7, 3,	6, 7,3,	7,	

Lack of	Pts 1. 2. 4.	Pts 5, 1, 2,	Pts 8,	Pts 1, 2, 5, 7,
responsibility/passing	5, 6, 7, 3,	4, 6, 7,	,	3,
patients on	, , , , , ,	1, 0, 1,		
patients on				
Carer's role	Pts 1, 4,7,	Pt 5	Pts 4, 5,	
	8		7,8	
Blame	Pts 1, 2, 5,	Pts 1, 4, 7	Pts	Pts 1, 4
	6		1, 6	
	.		.	
Poor communication		Pts 1, 8, 5,	Pts 1, 6, 7,	Pts 1, 3
with staff	7, 8,	2, 4, 6, 7,3,		
Delayed	Pts 4, 1, 3	Pts 2, 5, 6,	Pts 4, 6,	Pts 4,
decisions/role of				
doctor/delayed				
diagnoses				
Role of TVN	Pts 1, 2,5,	Pts 5, 2, 6,	Pts 7,	Pts 3,
	6, 7,	7,		
Role of HCAs	Pts 1, 2, 6,	Pts 1, 5,		Pts 5,
Staff busy	Pts 1, 2, 4,	Pts 5, 2, 3,	Pts 1, 6, 7,	Pts 1, 2, 3
	5, 6, 3,		8, 3,	
	-, -, -,			
Governance	Pts 1, 2, 5,	Pts 2, 4, 6,		Pts 1, 2, 5,
	6, 3,	7, 3,		
Ward	Pts 1, 2, 5,	Pts 2, 6, 3,	Pts 2, 5, 6,	Pts 2, 5,
moves/organisational	6,7, 8, 3,		7, 8,	
upheaval				
Drievities	Dto C 2	D40 0 4 0		D40 2
Priorities	Pts 6, 3,	Pts 2, 4, 3,		Pts 3,
Relationship with	Pts 1,	Pts 2, 3,	Pts 1, 2, 4,	Pts 2,
staff	2,5,6,		5,6, 7, 8	
Delayed response	Pts 1, 6, 8,	Pts 5, 2, 6,	Pts 2, 6, 7,	
		8, 3,	8, 3,	
DOA:	D(1.5.5	D(= 0 =		D1 0 5
RCAs inadequate	Pts 1, 5, 3,	Pts 5, 2, 3,		Pts 2, 5,

Documentation-poor	Pts 1, 2, 5,	Pts 5, 2, 7,		Pts 1, 2, 5, 6,
	6, 7,	3,		3,
Risk assessment	Pts 1, 2, 4,	Pts 2,	Pts 1, 6, 7,	
issues	5, 6, 8		3,	
Sequence of events	Pts 1, 2, 6,	Pts 2, 4,	Pts 1, 6, 8,	Pts 1,
	8,		3,	
Decision in complex	Pts 1, 4, 5,	Pts 5, 2,	Pts 6, 3,	Pts 1, 3,
system	6, 3,	4,6,3,		
Explanations		Pts 1, 2, 3,		
		4, 5, 6, 7, 8		

The raw data sources (DS 1-4) were therefore analysed inductively using line-by-line open coding at this stage, drawing on the Grounded Theory technique of open coding (Glaser and Strauss, 1967) (see Chapter 3 for further discussion). Open coding produced emerging patterns (see Table 4.3) that were then categorised into new constructs arising from the data (using NVivo 8 software).

The codes that were identified from open coding and cross patterning were then ordered into a graphical and hierarchical representation of causal and variable patterns (see Figure 4.5 below), with prominent and cluster themes (grey boxes) and subthemes (clear boxes) according mainly to the strength and frequency of their occurrence. I then identified causal patterns and relationships according to these (see arrows) which helped me to formulate new tentative hypotheses to explore further. Emmel (a realist) suggests that, causal powers and liabilities can be described and redescribed, as the powers of the sample are better understood (Emmel, 2013), and this is what I began to do at this stage. Although I had returned to the raw data sources for open coding purposes; my analysis and ordering the data in the coding framework above (Table 4.3) allowed me to see that the repetitive codes corresponded in some ways, although not completely, to areas in my literature review, and could be categorised as such. These were that the explanations could be categorised at individual or dyadic, decision based or team and psycho-social level, socio-cultural level and macro or service level. This initial analysis was coupled with the expert witness judgements for each case, which added support for further analysis focusing on organisational influences.



4.11 Brief overview of coding strategy and categorisation

Below I summarise the cluster themes and sub-themes which arose from my data coding and cross-checking. During and after coding, I noted strong and recurrent relationships between emerging constructs and combined these, categorising these into hypotheses to discuss and test, using an iterative coherence check with the data (George and Bennett, 2005, Yin, 2003, Emmel, 2013). Themes are sketched rather than examined in detail in this chapter, for reasons of space within this thesis. However, testable candidate explanations which emerged from the themes are developed in further detail in the next four discussion chapters.

4.12 Patient and micro level analysis

The first area of analysis related to those at micro level, where interactions between individuals impacted on the development of patients' pressure ulcers. Below are the themes which fell into this category.

4.12a. High risk patients

All of the patients in the study were at high risk for developing a pressure ulcer according to risk factor review evidence (Briggs et al., 2013). They were all immobile, and had either had a previous wound breakdown (Alex, Chris, Danni, Elliott, Glenn; Data Sources (DS) 1, 2, 3, 4) or they were very ill, or immobile, and needed a lot of care and service input (Bernie, Chris, Danni, Elliott, Frankie, Glenn; DS 1, 2, 3, 4). Or, for Hilary this was being on the floor at home without help, for a long period of time. This evidence was picked up largely from the clinical notes and patient's history. However, interview data also offered evidence such as 'this was a poorly patient, (TVN, Bernie)' 'she had multiple co-morbidities' (Physio, Bernie), 'he was a very poorly man' (Expert Witness, Elliot). This was the most prominent theme to emerge from the data, and not surprisingly, given the evidence of risk of pressure ulcer development in frail and vulnerable patients (see Table 1 above).

4.12b Carer's role.

Particularly for Elliott and Glenn, the carers were prominent in decision-making and providing continuity of care for their relative (DS 1, 2, 3). This was apparent from their knowledge about pressure ulcer care and comments within their interviews. For example, they used phrases such as 'I felt I was on my own, looking after the pressure ulcer'.

For the community dwelling patients; Danni and Glenn, services often 'relied' on the carer knowing what to do for the patient. They were expected to aid services. For example, typical phrases used by carers were 'I move his legs from one side, into the middle, to the other side, into middle, other side...I alternate them like that.' Glenn's wife also noted that she supplemented the DNs care with her own approach to Glenn's care. For example, she said, 'Next Monday when they come, I'll say, well, we've got to do it this way'

At times the role of the carer had a negative effect for the patients, namely for Danni and Glenn (Data Sources 1, 2, 3) particularly when Danni's husband been asked to do a swab of Danni's wound, but because he hadn't labelled it correctly, so it was discarded, causing delays in Danni's treatment. Glenn's wife refused an air mattress for Glenn, when offered one from the DNs, which may have contributed to his severe pressure ulcer development. Further thematic examples of the carer's role are in Table 4.5 below:

Table 4.5 Carer's role

	T
Carer's role	Typical Evidence
Alex	Carers did not feature
Bernie	Carers did not feature
Chris	Carers did not feature
Danni	'Yeah, he watched them do it and then he did
	it and it was fine, he didn't do any damage to
	it or anything, but they came, you know it was
	them that was coming on.'(Danni)
	'they came in the week, yeah, they came
	through the week, when they knocked the
	weekend off he did it at the weekend' (Danni)
Elliott	I want you to get in touch with CARER
	LP: CARER? Is that your daughter?
	Patient: Yes.(Elliot)

	I just got them from the chemist and some micropores, something. And it was just, really it hadn't broken initially, it was just to stop them rubbing against it. And then it broke down and even then, it wasn't infected at all it was a little bit weepy but it wasn't infected.'(Elliott's carer/daughter)
Frankie	Not relevant
Glenn	'she (Glenn's wife) does an awful lot of his cares along with the carers, she does his catheter and I think she does his bowels when we're not there, you know, if he needs them doing.' (DN) 'And I said to one of the nurses at the surgery, Well, what happens if they don't do it? I said Can I do it? She says, Of course you can' (Carer)
Hilary	(Hilary's carer) 'I asked them (the neighbours) to keep an eye on her, you see I look after them for that reason – and I thought they would have noticed that the bedroom curtains were closed during the day.'

4.12c Poor communication/relationships between patients, carers and staff

Other prominent themes arising from inductive coding were poor communication and relationships between patients, carers and staff. Bernie was seen as non compliant, but her cognition was poor and she couldn't retain information (DS 1). Alex knew her own condition and needs well (from being paraplegic for a long time and accessing services for a number of years), but the staff appeared 'too busy' to accommodate her toileting needs which led to a breakdown in relationships with nursing staff (DS 1, 2, 3). 'Frankie was also seen as 'demanding' but was more ill, dependent, and less mobile

than staff were prepared for on the ward she was on (DS 1; 2). Alternatively, Danni, Elliott and Glenn were patients who had what they considered good relationships with staff. Danni, for example noted that the District nurses were 'like friends' but despite this, her needs were not fully met by services (DS 1, 2; 4). For example, Danni suffered time delays in her referral and treatment that led to her ulcer worsening (DS 1, 2, 3, 4); Elliott was not asked about his pressure ulcer (DS 1, 3) although he was aware he had one, as was his carer, but the ward staff were not.

Time delays in communication with health care staff affected the development of Glenn's ulcer in a similar manner to Danni's (DS 1; 2; 3), which was apparent from his sequence of events chronology. See Table 4.6 below for further examples of poor communication between patients, carers and staff.

Table 4.6: Poor communication

communication/relationships	Typical Evidence
Alex	'I was left in my faeces for several hours.
	'the staff had forgotten to turn me in the
	night because, 'they were too busy' (Alex)
	'I think that's why I felt so mad with the
	Sister that morning when I sat up like I'd
	been told I could do. I think she felt I was
	sat up too much and then I think after a bit
	they stopped me lying on me back as well
	although that initially that's what the doctor
	had advised (Alex)
Bernie	'She'd comply and you'd go away and turn
	your back and she'd be back on it. I mean
	she would comply and turn with it, but she
	wouldn't comply to stop on that side, you
	can't force her (Healthcare Assistant).
	'any time we turn her today, left side, by the
	time we turn she's back to the right side, so
	if she is lying down we all agreed that she
	likes to be on that side'(staff nurse)

Chris	Then they said we'll move you down and whether they didn't think about the bed or not, but they should think shouldn't they really'(Chris) 'he was determined to walk' (staff nurse)
Danni	'they (DNs) came in the week, yeah, they came through the week, when they knocked the weekend off he did it at the weekend'(Danni)
Elliott	'it was the only time I had any kind of communication, really she phoned me back to say (it was the next day) that she agreed with what I said. And they cleaned his mouth and I think she said to me it'd taken six packs to clean his mouth'.(carer)
Frankie	'Apparently I'm [bedbound] and walking about the ward frequently. It's wrongly scored. No, no. They didn't talk to me. They didn't ask me any of the questions.'(Frankie) "That was probably the last moment I felt safe on that ward. I hadn't felt very safe all day, but this was now sort of evening time and I was slipping into, 'I'm in an emergency admission ward at the weekend, at night, and this is one of the worst places to be in the hospital'(Frankie)
Glenn	'I felt like she (Glenn's wife) didn't have a belief or a trusting relationship with them.' (TVN) And there was no communication between anybody the district nurses didn't flag it up

	toeither the TVN or the spinal injuries unit,
	,or anybody. Or the GP.' (Expert witness)
Hilary	Not relevant

4.12d. Blaming each other (despite complex needs)

There was a suggestion of 'blame' on the carer and patient arising from themes within the evidence gathered. This was noticeable for Alex, Bernie, Danni, Elliott, Frankie and Glenn (DS 1, 2, 3, and 4). For each of these patients, the word 'blame' was associated with their, their carer's or health professionals' accounts. Typical phrases involved 'Alex appeared to want individual care' (DS 1, 2, 3), Bernie had a contracture and 'preferred to lie in one position' (DS 1)', Danni was seen as too 'private' for an assessment (DS 1, 2, 3), Elliott's carer 'caused issues' with staff (DS 1, 2, 3), as did Frankie (DS 1, 2, 3) who was described as 'emotional'. Finally, Glenn's carer was blamed for 'refusing' an electronic mattress (DS 2, 3).

The notion of 'blame' was apparent between and within services too. Staff members were often defensive. Regarding Chris, some services blamed the other services involved in his care for 'poorer care' (DS 1, 2). Typical phrases included 'I'm disappointed that they didn't do that' (Consultant) and 'it was the ward that should have done that' (TVN). This was also the case for Bernie, where groups of staff in hospital hierarchies blamed other staff groups for 'poor skin care'. For example the HCAs noted that the qualified staff were not turning patients, as 'regularly as they should have been' (DS 1, 2, 4). Frankie's case was similar, as ward staff blamed other wards for her pressure ulcer. One staff nurse noted that 'she'd been off our ward for over a week then, when it developed' (DS 1, 3). See Table 4.7 below for further examples:

Table 4.7: Blaming each other

Blaming each other	Typical Evidence
Alex	'it sort of got thrown back at me that it was my fault thatwhich annoyed me a bit, I felt I had to fight my corner there.'(Alex)

Bernie	"and everybody (MDT) rallied round and we
	said to her that if she doesn't lie away from
	the place that is going to develop into a big
	sore, and she kept on lying on it' (Staff nurse)
	'We do tell them (Staff nurses) and in one ear and they think they know better'(HCA)
Chris	'I think even though he was seen by us
	(TVNs) as, almost unofficially, but we saw
	him on the ward, they will have been given all
	that advice and support there and then,
	unfortunately you can't please everybody if
	they've not followed advice and
	support'(TVN)
	,, ,
Danni	'I don't know, I can always remember a nurse
	coming in once for this year, not this surgery,
	and saying to me 'You've not been looking
	after yourself', and it was her attitude to me
	that made me think that everybody else
	would think well, you've not been looking
	after yourself you know'(Danni)
EW-11	
Elliott	'I was told by this doctor in A&E that I'd had
	him discharged against medical
	advice.'(Carer)
	'it was as if you were being a nuisance'
	(Carer)
Espalia	(the way do this for man do that for ma'(LICA)
Frankie	'it was-do this for me do that for me'(HCA)
	'you know, you what she maybe doesn't
	appreciate is that that other nurse you
	know, that nurse will have had seven other
	ladies'(Staff nurse)

Glenn	' she (Glenn's wife) didn't want a mattress because she didn't want to pay for the electricity.'(DN)
	'I expected to go and it be an awkward familybut II think she's (Glenn's carer)more questioning why' (TVN)
Hilary	Not applicable

4.13 Socio-cultural level analysis

4.13a. Role of TVN

The escalation of care of a patient often involved bringing in the advice and response of the TVNs. This appeared to happen late in a patient's journey through services (Danni, Elliott, Glenn; DS1, 2, 3, 4). Often the TVNs said that they would have preferred to have been brought in earlier, as they could have helped to alleviate the worsening of the SPU, but there was confusion over the role of the TVNs amongst nursing staff. (This role is discussed in more detail later in this thesis in the sections on Decision-making and Communication; Chapters 6 and 7). Some staff felt that TVNs were too busy to be contacted, so coped with the patient until a PU became a SPU. The TVNs said that they usually were brought in for more complicated SPUs (namely for Alex, Bernie, Chris, Danni, Elliott, Frankie, Glenn, Hilary; DS 1, 2, 3). See Table 4.8.

Table 4.8: Role of TVN

Role of TVN	Typical Evidence
Alex	'We only access the TVN specialists if we are really stuck.' (Staff nurse) 'the TVN is only part-time and it might be a few days before she is accessible, which means asking someone else' (HCA)

Bernie	'Unfortunately we couldn't get tissue viability
	to see her enough because there's not
	enough tissue viability,' 'there's two of them
	and they're really busy'. (Dr)
Chris	"even though they (the ward) referred him to
	us they didn't need to because he was
	already under the diabetes team which is
	standard' (TVN). This was wrong information
	as Chris had a pressure ulcer, not a diabetic
	foot ulcer on his foot.
Danni	the remaining Tissue Viability nurses were
	struggling,' (TVN)
	- V. 199
	'there was no access to Tissue Viability
	because they cover in other localities' (TVN)
Elliott	'he'd been in quite a while before I saw him'
	we say if a patient develops a Grade 2 in
	hospital, we need to have them referred,
	because somebody that comes in with a 2 is
	usually being looked after by somebody at
	home' (TVN)
	'a lot of nurses feel a bit tentative about
	auctioning something' (Staff nurse)
Frankie	'it was just chance that I got a phone call from
	the doctor saying we've got this patient in
	Outpatients now, can you come and see
	them?'(Consultant)
Glenn	the initial referral –was mostly about, the
	mattress.' (TVN)
Hilary	Not relevant

4.13b. Role of HCA

HCAs were often responsible for the initial care of the skin, and were relied on to report any skin status declines (for example, Alex, Bernie, Elliott, Glenn). In some cases,

these staff were not trained adequately enough in patient skin care (especially those working with Bernie, Elliott, Glenn). With the exception of Danni and Alex, HCAs were not comfortable to be left with this responsibility. For those involved with Danni and Alex particularly, the HCAs were confident and well trained in skin care, however for the other patients the HCAs felt inadequately trained to take this skin inspection role on (in particular for Bernie, Elliott, and Frankie; DS 1). Typical phrases included 'it wasn't our job to assess skin' and 'It's down to qualified nurses to do'. There was often a delay however, in communication between HCAs reporting skin damage, and the nurses' response because it relied on a handover of information on an informal basis on shifts (particularly for Alex, Bernie, Chris, Danni, Elliott, Frankie, Glenn; DS 1). Some HCAs felt frustrated and annoyed that they could observe skin breakdown, but the nurses did not act on this, and also they were not allowed to record information about skin, but had to relay it to qualified staff. Typical evidence of this issue included phrases such as 'when you go to a qualified... I'm sorry but I've no time, I'm doing medicine' (HCA). Further examples of the role of the HCA are in Table 4.9 below:

Table 4.9: Role of HCA

Role of HCA	Typical Evidence
Alex	The HCAs 'know what's going on with every
	patient on the ward'.(HCA)
Bernie	'with me only being helper I wouldn't find it
	(SPU) anyway' if somebody says to me,
	right, she's got to be turned every two hours, I
	turn every two hours' (HCA)
	'they rely heavily on the HCAs to come and
	tell them about skin status on this ward'
	(Ward Manager)
	'a break in the skin ?, I always go to the
	nurse to have a look so that it's all
	documented' (HCA)
	'when I'm washing a patient I always go and
	say, right, will you come and have a look'
	(HCA)

Chris	'Well the healthcare assistants get patients
	up so you know' (Staff nurse)
Danni	'we discuss it as a team' (HCA and DN)
	'HCA 1 is really well up on everything' (DN)
	,'I like anything really, bloods, wound care –
	anything. I'll do anything yeah' (HCA)
Elliott	'he was a guy that needed us to do all cares,
	basically' (HCA)
	'we didn't have anything to do with the
	bandages' because that's not my position to
	do that.' (HCA)
Frankie	'healthcare-wise, [during the re-organisation]
	we were generally moving the stuff, so we
	couldn't really look after the patients'
	'(HCA)
	I think we should record in the notes because
	we're the people that are going and wash
	them and see them, rather than the nurses,
	but we see them and then go tell the nurse
	'(HCA)
Glenn	'We have to praise ourselves because
	nobody does' (HCA/Carer)
	we don't actually see the PUBecause it's
	always covered up' (HCA/Carer)
Hilary	Not relevant

4.13c. Role of doctor

Doctors played an interesting role regarding pressure ulcer care, although some seemed to highlight to the researcher that it was not their area of concern, and they used phrases such as 'skin care is seen as a nursing issue' (particularly for Bernie and Frankie; DS 2, 3, 4). However, they often escalated care for patients above the nurses (Alex, Bernie, Danni, Frankie; DS 1, 2, 3). There was something about the decision-making related to this area that was recurrent in several of the cases and needed further analysis and attention. This is examined in further detail in the discussion chapter regarding decision-making. Examples of the doctors' role are in Table 4.10 below:

Table 4.10: Role of doctor

Role of doctor	Typical Evidence
Alex	'in an organisation with such complexity (NHS) it needs someone who has the coordinating ability to actually work the system.' (Dr) 'some consultants, including surgeons, still aren't aware of current NICE guidelines which, state that patients with Grade 3 or 4 ulcers should be put back to bed, and will insist they are 'sat out" (TVN)
Bernie	'it takes such a long time, they lose the bloods, then you've to re-do them' (Dr) 'He (the Dr) said to themwhy hasn't this been done? (HCA) 'I told the Dr over the pressure damage' (HCA) 'to be frank, rightly or wrongly, doctors don't particularly play a part in pressure ulcer care' but(Consultant) 'I'm really interested in sores because my view is they're always preventable' (Dr)

	Medical notes: Refer to Tissue Viability-noted
	last week.(Consultant)
	, , ,
Chris	'we highlighted to Chris that it was quite a
	serious situation and given his medical
	condition, it would take a lot to get it to heal'
	(Consultant)
	'he is a tremendously high risk patient. And
	taking him off a mattress I don't think would
	probably be the right thing for
	him.'(Consultant)
Danni	There is no access to the Tissue Viability
	service unless the patient is actually referred
	into the acute Trust by the GP (TVN)
Elliott	No evidence in this case
Frankie	'if I'd been called sooner then I would have
	said, 'I think we need to do this etc because I
	remembered how difficult the surgery was the
	first time'(Dr)
	'I knew what she was meaning' (Dr)
	'she was actually very sick, I would say' (Dr)
	'They maybe hadn't appreciated the difficulty
	of the initial operation that I had done.' (Dr)
Glenn	No evidence
Hilary	No evidence

4.13d. Other priorities

How staff prioritised their patients was a recurrent theme in the data analysis. Typical phrases around this theme included 'other patients were more poorly', 'nobody realised how high risk she was'. Chris was considered as too 'high risk' by the expert witnesses for the rehabilitation ward he was transferred to (DS 1, 2, 3, 4); Frankie was placed on

a post-operative surgical ward when the preference was transfer to HDU (according to the Consultant; DS 1, and Expert Witnesses; DS 2). Bernie was transferred to a stroke rehabilitation ward, where they were trying to rehabilitative her, but she had pneumonia and was really ill (DS 1; 2). Danni was too immobile to attend the GP's surgery as she could not transfer easily onto the bed at the Practice (DS 1, 3). The lack of prioritising skin care often meant that the patients' needs weren't addressed properly by the staff assigned to them. Their needs appeared too much for staff to cope with. Table 4.11 sets out some examples of competing priorities:

Table 4.11: Other priorities

	1
Other priorities	Typical Evidence
Alex	'I think maybe two or three times they had
	forgotten to turn me in the night because they
	were busy'(Alex)
	'whether they were too busy or forgot, they
	hadn't been back to turn me' (Alex)
Bernie	'it takes such a long time, they lose the
	bloods, then you've to re-do them' (Dr)
	'everything is priority on the list and you
	cannot do it' (Staff nurse)
	"the hospital where I was before was a lot
	better staffed and better organised' (Dr)
	'This ward does not provide a safe
	environment to look after elderly patients
	properly' (Dr)
	'they (staff nurses) have to prioritise medicine'
	(HCA)
Chris	'I think they were trying to safeguard me and
Omio	make it easier for me (when they put Chris in
	a side room).(Chris)
	'I think we were maybe short staffed, and over
	the bank holiday weekend, and we've always

	been one nurse down for a long time' (Staff
	nurse)
	50)
	'the original thinking was that if dependency
	got to a certain level that you'd get extra staff
	-but we didn't' (Staff nurse)
Danni	' In-house, in our job, we don't come across
	large pressure sores. If we do get people then
	they are tiny and they are treatable, or they
	are referred to the district nurses.' (Practice
	Nurse)
EW. W	
Elliott	'He could almost have been invisible because
	he was so unobtrusive.'(Staff nurse)
	'And I think there's a kind of attitude that you
	don't need to turn patients now because
	they're on all these wonderful mattresses
	(Staff Nurse)
	(Stan Nardo)
	(
Frankie	'That's where your key problem is. They
	originally had colorectal post-op patients, but
	then overnight they had to take the urology
	then overnight they had to take the urology major cases as well. These are really poorly
	then overnight they had to take the urology
	then overnight they had to take the urology major cases as well. These are really poorly
	then overnight they had to take the urology major cases as well. These are really poorly andwhat I'm saying is their workload has doubled.'(Ward Manager)
	then overnight they had to take the urology major cases as well. These are really poorly andwhat I'm saying is their workload has doubled.'(Ward Manager) 'I think if she'd gone onto HDU, then the
	then overnight they had to take the urology major cases as well. These are really poorly andwhat I'm saying is their workload has doubled.'(Ward Manager)
	then overnight they had to take the urology major cases as well. These are really poorly andwhat I'm saying is their workload has doubled.'(Ward Manager) 'I think if she'd gone onto HDU, then the
	then overnight they had to take the urology major cases as well. These are really poorly andwhat I'm saying is their workload has doubled.'(Ward Manager) 'I think if she'd gone onto HDU, then the assessments would have been different' (Dr)
	then overnight they had to take the urology major cases as well. These are really poorly andwhat I'm saying is their workload has doubled.'(Ward Manager) 'I think if she'd gone onto HDU, then the assessments would have been different' (Dr) 'They maybe hadn't appreciated the difficulty of the initial operation that I had done.' (Dr)
Glenn	then overnight they had to take the urology major cases as well. These are really poorly andwhat I'm saying is their workload has doubled.'(Ward Manager) 'I think if she'd gone onto HDU, then the assessments would have been different' (Dr) 'They maybe hadn't appreciated the difficulty
Glenn	then overnight they had to take the urology major cases as well. These are really poorly andwhat I'm saying is their workload has doubled.'(Ward Manager) 'I think if she'd gone onto HDU, then the assessments would have been different' (Dr) 'They maybe hadn't appreciated the difficulty of the initial operation that I had done.' (Dr)
Glenn	then overnight they had to take the urology major cases as well. These are really poorly andwhat I'm saying is their workload has doubled.'(Ward Manager) 'I think if she'd gone onto HDU, then the assessments would have been different' (Dr) 'They maybe hadn't appreciated the difficulty of the initial operation that I had done.' (Dr) 'But the District Nurses they just come in, do his bowels, and go.' (Glenn's wife)
Glenn	then overnight they had to take the urology major cases as well. These are really poorly andwhat I'm saying is their workload has doubled.'(Ward Manager) 'I think if she'd gone onto HDU, then the assessments would have been different' (Dr) 'They maybe hadn't appreciated the difficulty of the initial operation that I had done.' (Dr) 'But the District Nurses they just come in,
Glenn	then overnight they had to take the urology major cases as well. These are really poorly andwhat I'm saying is their workload has doubled.'(Ward Manager) 'I think if she'd gone onto HDU, then the assessments would have been different' (Dr) 'They maybe hadn't appreciated the difficulty of the initial operation that I had done.' (Dr) 'But the District Nurses they just come in, do his bowels, and go.' (Glenn's wife)

4.13e. Documentation

One the main observations from the RCA investigations which were carried out for certain patients (Alex, Bernie, Frankie and Hilary), and the clinical notes, was a lack of documentation around patients' skin care, and this seemed to be a causal influence around PUs worsening. Elliott's ulcer was recorded as the wrong body site in the clinical notes, and the lack of documents meant his pressure ulcer looked like a hospital acquired one, which it wasn't, as stated by his daughter and carer (DS 4). Chris's notes were noticeably different in quality from ward to ward (DS 1, 4) with particularly patchy documentation on the rehabilitation ward where he developed his new pressure ulcer. This was in contrast to the vascular surgical ward which he was on previously. Glenn's community nursing notes were very patchy, disordered and confusing, and this was noted by the Expert Witnesses (DS 4). Hilary's notes were noticeably very clear and well set out, but she developed her pressure ulcer outside the hospital. This may suggest that when staff know they are not to 'blame' for a pressure ulcer they are arguably more willing to be very clear in their documentation to note this. The worst documentation for several patients was between wards (DS 1, 4). There is no table of evidence for this, as the omissions in the data showed the issues, rather than written evidence.

4.14 Cluster themes and organisational level analysis

The rest of the themes referred to cluster themes arising from coding of the data (Glaser and Strauss, 1967). I refer to cluster themes as those which have recurring codes in the raw data, but which codes also can be categorised in various codes at once. These cluster themes were relevant to all of the levels of analysis (namely micro, socio-cultural and organisational). However, all of the organisational level themes were also cluster themes.

4.14a. Delayed response

If staff had responded sooner to a patient's early skin damage, then for each person it might have prevented their pressure ulcer from getting worse and developing into a severe pressure ulcer. The community patients (Danni, and Glenn) particularly suffered from the consequences of staff delaying referrals or actions regarding their patients' pressure ulcers while they declined gradually (DS 1, 2, 3, 4). Danni's pressure ulcer deteriorated slowly over the time she first attended her GP's surgery until five months

later when it was examined, and she was assessed properly. Typical examples of delayed response included, 'In hindsight I should have referred her earlier,' which was a comment regarding the practice nurse's lack of action over Danni's pressure ulcer, and 'the pressure ulcer deteriorated more until the Tissue Viability Service was called', which was noted by the TVN who was involved in Glenn's case. Further examples of the delays in response by staff towards their patients' pressure ulcers are highlighted below in Table 4.12. This theme again highlights the issue around role of the TVNs, and how soon they were contacted when a patient developed a lower grade pressure ulcer.

Table 4.12: Delayed response

Delayed response	Typical Evidence
Alex	'they had forgotten to turn me in the night because they were busy'(Alex) 'whether they were too busy or forgot, they hadn't been back to turn me' (Alex)
Bernie	'it takes such a long time, they (pharmacy) lose the bloods, then you've to re-do them' (Dr) "staff look at the skin but don't always act on itto get involved at Grade 2 would have been better' (TVN) Things get lost because they are not recorded' (TVN)
Chris	'the original thinking was that if dependency got to a certain level that you'd get extra staff -but we didn't'(Staff nurse)
Danni	'In hindsight, I would have asked the husband to attend with her and would have checked obviously, what she had said initially was that he had done it before.' (Practice Nurse)

Elliott	'they hadn't taken the bandages down'
	(Clinical coordinator)
	'All the patients were left in gowns all
	day'(Carer)
	The nurses walked past and averted their
	gaze'(carer)
	'nothing gets done about it' (wound care)
	(HCA)
Frankie	'tasks got dropped' (Frankie)
T rainto	taono got aroppoa (rramao)
Glenn	'I suppose they are busy'(Glenn's wife)
	'they referred too late' (TVN)
Hilary	Not relevant

4.14b. Lack of responsibility

Another prominent pattern, according to initial readings, was that individuals or teams did not appear to take responsibility for the decline in a patient's skin status (particularly concerning Alex, Bernie, Chris, Danni, Elliott, Frankie, and Glenn; DS 1, 2, 4). Typical examples around this theme included 'she came to us with it [the pressure ulcer], so it wasn't ours to own' and 'nobody did anything' (Staff nurse). This cluster theme will be examined in depth in the following chapters so will be only described briefly here. However, repeated themes also emerged from the data analysis that nurses did not take responsibility and make decisions about patient care regarding skin status. Often the doctors took responsibility to escalate the level of care (Alex, Bernie, Danni, Frankie; DS 1, 2, 3, 4).

However, a certain 'lack of responsibility' may also appear as a passive style of care towards pressure ulcer developments where the patient was not referred or their skin 'prioritised' (particularly for Bernie, Chris, Danni, Elliott, Frankie, Glenn; DS 1, 2, 4). Glenn and his wife appeared to take the most responsibility for his care. For example, when Glenn's wife explained about equipment that she had located to help keep the

pressure off his sacrum, she stated, 'I got some foam, put two pieces of foam together, one had a hole in it, so that part of his bottom would go in the hole'.

Patients appeared to 'slip between services' in several patient accounts, and no one seemed aware that this had happened until hindsight showed that they had (namely for Bernie, Chris, Danni, Elliott and Frankie; DS 1, 2, 3, 4). Typical phrases around this theme included 'he was under the care of the diabetic foot team' (Ward manager), and 'the District Nurses didn't pass on that information' Staff nurse). Patients, and carers to an extent, appeared to provide the continuity between services (particularly for Chris, Danni, Elliott, Frankie and Glenn; DS 1, 3, 4) but they did not, and were not, able to coordinate services. Typical examples of this included,' they came in the week, ... when they knocked the weekend off he [Danni's husband] did it' and 'she [Glenn's carer] does his bowels when we're not there, you know, if he needs them doing.' (HCA). However, members of the Multi Disciplinary Teams tended not to communicate with each other (namely for Bernie, Chris, Danni, Frankie, Glenn; DS 1, 2, 4), which left further gaps in patient care. For example, the MDT team in Chris's case did not communicate with each other, which was the same for Danni's, and Glenn's (DS 1, 2, 3, 4). Further examples of this theme are included below in Table 4.13.

Table 4.13: Lack of responsibility

Lack of responsibility	Typical Evidence
Alex	this lady had a pressure sore and massive
	surgery to it and if only a little bit opened
	up I don't think that's bad management at
	all.'(Ward Manager)
Bernie	'they have many patients passing through,
	they can't remember people individually'
	(Stroke nurse)
	'why did the staff not use their clinical
	judgment to assess the high level of risk
	involved with Bernie' (TVN)
	I got the feeling that there wasn't really
	anybody taking responsibility' (TVN)
Chris	'we had no communication to what his
	arterial status was so until they could

	establish his arterial status and know what
	plan the vascular team had for him, we
	couldn't do anything pro-active' (TVN)
	Codium t do anything pro-active (1 viv)
Danni	'her issues started way back when she was a
	teenager, really, when she ceased to be her
	mum's responsibility and ceased to be
	health's responsibility ' (Expert witness)
	'they didn't have the 'man power' to check on
	patients and they have to refer themselves. '
	(Occupational Therapist)
Elliott	It's almost like you give up-you think I can't
Linott	do it anyway' (Staff nurse)'
	do it arryway (Stair Hurse)
	'Nobody cared' (Expert witness)
Frankie	there was little verbal communication
	between the medics and the ward. (Dr)
	Services and the marar (21)
	there 'ween't a prepar handaver from
	there 'wasn't a proper handover from
	recovery to the ward' (Dr)
Glenn	"They didn't refer to the TVS or contact the
	spinal cord injurynobody did
	anything.'(Expert witness)
	,
Hilany	Ambulance staff passed on clear information
Hilary	Ambulance staff passed on clear information
	about Hilary's skin status.

4.14c. Staff busy

Health care staff's perception was that understaffing was one issue that led to the patients in this study developing an SPU, and this was definitely a theme which was apparent from the data, particularly for Alex, Bernie, Chris, Elliott, Frankie, and Glenn (DS 1, 2, 3, 4). Chris and Frankie noticed this for themselves on the ward (DS 3), and Glenn's carer noted that District Nurses were 'too busy' to free up time for anything other than bowel care (DS 1, 3). In Bernie's case, most of the staff mentioned 'staffing issues' in their interviews (DS 1), as did Elliott's nursing staff (DS 1).

Often issues with staffing were apparent where there was no contingency plan in place to counteract the understaffing problems. Alex was resident on the ward over a bank holiday weekend (DS 1) and felt the staff were 'too busy' at this point, Bernie's ward was chronically understaffed, which was noted by a number of interviewees, including the doctors, the HCAs, the Ward Manager and Staff nurses (DS 1, 4). For Chris, the staff appeared 'too busy' to be fully aware of his high risk (DS 3), Elliott's staff were preoccupied with a ward relocation upheaval (DS 1, 2, 4), as were Frankie's (DS 1, 2, 3, 4). Glenn's staff had not addressed any other than his bowel care, so they only focused on, and allowed time for this task (DS 3, 4). More examples are shown in Table 4.14 below:

Table 4.14: Staff busy

	T
Staff busy	Typical Evidence
Alan	(4h
Alex	'they were busy' (Alex)
	'whether they were too busy or forgot, they
	hadn't been back to turn me' (Max)
	hadn't been back to turn me' (Alex)
Bernie	'it isn't a failure of ownership it's thatthey're
	incredibly busy,' (Dr)
	increasity busy, (bi)
	'because there's two of them, and they're
	really busy' (Dr regarding TVNs).
	Today budy (Br regarding 1 vivo).
Chris	'the original thinking was that if dependency
	got to a certain level that you'd get extra staff
	but we didn't (eteff nurse)
	-but we didn't' (staff nurse)

Danni	Practice nurse only had ten minute
	appointments (TVN)
Elliott	'the ratio now is 60:40 unqualified to qualified,
	whereas if was the other way round years
	ago' (Carer)
	Staff do not have enough time (to document)
	they are too busy' (Clinical coordinator)
Frankie	' at the time she would have been on a busy
	ward' (Ward Manager)
Olema	(Laurana and Alaurana human (Colonala mifa)
Glenn	'I suppose they are busy'(Glenn's wife)
Hilary	Not relevant

4.14d. Defensive communication and culture

The defensive culture around SPUs was apparent in how the staff reacted to the research study. For several of the eight patients, staff members were not easily available to interview, and made it difficult when they were interviewed. This was evidenced in the response by staff to the researcher when trying to arrange and carry out interviews (which is further discussed in the Methods chapter). This happened particularly regarding interviews with staff who worked with Hilary, Chris, Frankie, and Bernie; DS 3). Often under these circumstances this was indicative of another issue with the ward or service which had made them particularly defensive. For example, for Hilary one of the wards was undergoing an inquiry by the CQC (DS 3). The sister on this ward refused to allow any of her staff to be interviewed. For Chris, the community and acute sites had a poor relationship, as did the staff who worked together caring for Bernie. Fortunately, other evidence from different data sources often made this area of data collection unnecessary. By using reflective field notes and recording issues, stressful and defensive environments could be identified in this way, as it gave a good indication of how the ward 'culture' was (which is discussed below). Further examples of defensive culture are in Table 4.14 below:

Table 4.15: Defensive culture

Defensive culture	Typical Evidence
Alex	'the patient didn't look after herself as well as she could. The breakdown of the wound after surgery was 'just one of those things, (staff nurse) This nurse was reluctant to engage with the interview, and seemed defensive (Field Notes)
Bernie	'there are wards that I know that are very good and wards that I know that are bad' (TVN)
Chris	'he left here (Acute Trust) without a pressure ulcer. And even looking at those photographs, you can tell that had developed within the last few days' (Consultant)
Danni	'Danni did not keep off her sore as much as she should have done,' (Practice nurse)
Elliott	'I would have taken off the bandages, with that doctor there, because I always do.' (Staff nurse) 'it isn't hospital-acquired, his pressure ulcer, though, is it? Because he's come in with it and we've documented it.' (Staff nurse)
Frankie	'I wanted to say that, to me, the initial poor assessments started within the (specialist) ward' (Matron)
Glenn	'he was discharged home on the 27 th And then he doesn't come in until the 22 nd of October.so there's something happened then' (Staff nurse at Respite)

	'Every time he's come his skin looks
	dryAnd I ask, are you using anything at
	home?' (Staff nurse respite)
Hilary	'And the A&E consultant, came and he asked
	me if she had a pressure sore, and I said,
	yes, they've found one and they
	photographed it that day so that they weren't
	liable for any claim.' (Hilary's carer)

4.14e. RCAs inadequate

Investigations into why patients developed their severe pressure ulcers, known as Root Cause Analyses (RCAs) in the NHS (so called because they look for the root causes of a serious harm affecting a patient) were conducted for certain patients (namely Elliott and Frankie). Yet, despite guidance from the National Patient Safety Agency and Department of Health (Department of Health, 1997, NHS Direct, 2011), which suggested all severe pressure ulcers should undergo an investigation into their root causes, Bernie's original RCA investigation was never found, (another was carried out by the onsite TVN), Chris, as a diabetic foot patient, was seen as out of the remit of the ward so the management staff didn't conduct an investigation (DS 1, 2); Danni didn't have an RCA because the investigations were not used in the community at that time (DS 1), and Hilary's SPU was unavoidable, so her situation did not trigger an investigation (DS 1, 2, 3, 4). However, regardless of the investigations being carried out, the RCAs which were conducted for patients did not find the same issues with pressure ulcer causes and care as the study found. Elliott's RCA concluded that 'lack of documentation' was a main issue, and was very vague in its recommendations and scope (DS 1, 4), Frankie's RCA only included the nurses on the wards as informants and for evidence, and didn't include doctors (who, when interviewed had more of an overview of what had happened to complicate her care) (DS 1, 4). Frankie's RCA consisted only of a verbal meeting (I observed this), and a brief discussion, which had no documented learning points or recommendations other than requiring better passing on of documents from surgery to wards (DS 1, 4). This theme was included as RCAs were frequently referred to as a source of learning and service improvement, yet this study found different outcomes from the RCAs (when they did happen) in comparison to those conducted by the healthcare trusts involved. Also, the RCAs which did not

take place *should* have been done as they fitted the criteria for a patient safety investigation into the severe pressure ulcers (Secretary of State, 2014, Wallace et al., 2009). This was particularly relevant for Bernie, Chris, Danni and Glenn.

4.14f. Risk assessment issues

When risk assessments were filled in they did not really help to show any visible decline in patients' skin unless they were filled in regularly. Many of these were not as regularly carried out as they should have been. An exception to this was on the surgical ward where Chris was admitted previously, before he developed his new severe pressure ulcer. Because risk assessments were filled in very regularly, it was easy to see the pattern of decline in his skin status (DS 1, 4). However, in the main, within this study, risk assessments and care plans were patchy and poorly completed, which did not describe the patient's worsening condition (namely for Bernie, Chris, Danni, Elliott, Frankie, Glenn; DS 1, 4). There were no direct interview quotes about this area, as the evidence was picked up from nursing and medical notes, and the evidence was found due to noting omitted data, rather than written evidence. The chronological timelines which recorded these issues are available on request.

4.14g. Sequence of events

The deterioration of SPUs can be shown by a sequence of events which unfolds over time (and was apparent from the data collected as part of this thesis), but staff in the study often had no real sense that the deterioration in skin status was happening because documentation and actions were not monitored or audited. When patients were not tracked from ward to ward their skin often deteriorated without anyone noticing. This issue is examined in detail in the following Discussion chapters. The decline in skin status was most apparent for Bernie, Chris, Danni and Glenn (DS 1) from analysing their clinical notes. It is more obvious in hindsight how each PU got worse, but not always apparent to staff on the frontline in real time, who handover what they see as important, but only what they see at the time (DS 1). The sequences of events data are not available in this thesis as they make patient data too identifiable. The expert witnesses noted in their reviews that sequences of events were of importance in combination with organisational issues for Bernie, Danni and Frankie (DS 2). An example of this concerned Frankie, where one witness noted that "I think there's also a sequence of events – that she wasn't assessed properly at the beginning -By nurses or doctors -And that she wasn't identified as that high risk, so no care plan was in place'. Additionally, the issues leading to the development of Bernie's severe

pressure ulcer were noted by the expert witnesses to be 'cumulative' and she was not assessed until Day 7.

4.14h. Ward moves/organisational upheaval

Moving about from ward to ward was an issue for several patients in the study. Bernie was moved across geographical sites, as well as not being recollected by staff members during the time she was admitted onto the stroke ward. This issue was the same for Chris, Elliott and Frankie; DS 1, 4). One of the ward managers on a ward that Frankie was admitted onto did not know who she was, and refused any interviews because of this (DS 1), and certain staff refused interviews under the same conditions for Elliott (DS 1). The ward and geographical moves meant not only that the patients weren't as well known to nurses as they should have been, but that along their pathway through care, other service level priorities clashed with their needs. Further examples of this theme are shown in Table 4.16.

Table 4.16: Ward moves

Ward moves/upheaval	Typical Evidence
Alex	Not relevant
Bernie	'they should have remembered her, she's
	pretty memorable' Bernie had complex
	problems, it wasn't simply a stroke', (Dr)
Chris	'He was under the care of the diabetic foot
	team, so not us (Ward Manager)
Danni	Not relevant
Elliott	We get quite a lot [of patients from supported
	living'](Staff nurse)
	We get patients referred to us who've been
	in hospital 24 hours and they've still got the
	bandages on from home (TVN)
	The ward do ring the DN but it's not routine
	and not seamless care (Matron)
Frankie	'She came from theatre so we won't have
	known anything about her whatsoever, apart

	from her name and what surgery she's had.
	So we had to just get the basics.' (Staff
	nurse)
Glenn	Glenn moved from home to a national
	treatment centre to a respite unit.(Field
	notes)
Hilary	Not relevant

4.14i. Decisions in a complex system

Staff members appeared to be operating under complex conditions, which seemed stressful for staff involved (namely Alex, Bernie, Chris, Danni, Elliott, Frankie and Glenn; DS 1, 2, 3, 4). Typical phrases regarding the conditions they worked under included, 'it was chaos' (Ward manager) and 'we didn't get chance to sit down as a team and discuss her complex needs' (Physiotherapist-regarding Bernie). There seemed to be no time for staff reflecting on or auditing their work as they carried it out, or for checking their assessments. Typical evidence of this included missing documentation in clinical records. Staff made decisions under the circumstances, with the knowledge that was available to them at that time (DS 1, 2, 4). A typical example of this decision-making under complexity included the decision made by ward staff to move Chris into a side room near the dining room on his ward, partly because he had tested positive for a diarrhoea virus and partly so that he didn't have to walk as far to the dining room. They then overlooked the fact that he was placed on a mattress which was not suitable for a high risk patient. Other examples included the decision to rehabilitate Bernie, although she was very poorly and confused at the time.

The healthcare environment appeared complex in the study and there was no margin for error, or for reflecting if problems did happen (DS 1). Typical examples of this included 'in hindsight I would have referred her earlier' (Practice nurse) and 'she should really have gone to HDU' (Consultant). There was an exception to this regarding the first ward that Chris was on, which used a surgical huddle technique of reflecting weekly as a team when things did go wrong (DS 1, 4). Although staff felt like it was an 'extra task' that they were not keen on carrying out, they still recognised the value of it and said it was 'useful' (DS 1).

Staff appeared in the main to try their best under these complex circumstances, which was evidenced in a range of interviews (DS 3), but which sometimes had adverse consequences. See Table 4.17 below for examples:

Table 4.17: Decisions in complex system

Decisions in a complex system	Typical Evidence
Alex	'the nurse made a judgement based on her
	experience, which I respected' (Dr)
Bernie	'she was complicated. Everyone was
	involved'(Consultant)
	it becomes difficult when people are trying to
	prioritise management and for example you
	work in stroke so they focus on that rather
	then long term management of her
	contractures' (TVN)
Chris	'I think they were trying to safeguard me-it
	was a slip up' (Chris)
Danni	'the holistic assessment potentially goes
	because of the time pressure that they
	(Practice nurses) are under, and they've only
	got what the patient's going to tell them.'
	(TVN)
	'how can they fit that into a ten minute
	appointment where the patient's got to come
	in the door, get on the couch, have a dressing
	done, say goodbye and then the nurse has
	got to start writing all the notes and refer
	them' (TVN)
Elliott	'I didn't have anything to do with [looking
	under] the bandages' because that's not my
	position to do that.' (HCA)
	We often don't change bandages because it's
	five o'clockpharmacy's shut and we can't
	access dressings' (Staff nurse)

Frankie	'we had to apologise to so many patients and say, this is what's happening, we've been told' (Staff nurse) And then they discovered that the mattress that they'd ordered wasn't compatible with my bedframe. So they had to wait for another bed, a different type of bed to become free' (Frankie).
Glenn	'Glenn's wife refused a mattress' (TVN)
Hilary	Not relevant

4.15 Collapsing themes to produce tentative, testable hypotheses

At this stage of analysis I re-formulated testable hypotheses out of the collated thematic evidence. I returned to immersing myself in the patterns, level of analysis and themes arising from the data. I analysed these in more depth going back to the NVivo codes and raw data. I then collapsed the initial codes into four new tentative hypotheses to test against other evidence (which are shown at the bottom of Figure 6).

This process of collapsing codes at this stage seemed to lend itself emergently into individual or dyadic level of analysis, team or psycho social analysis, socio-cultural levels of analysis, and service or organisational level of analysis. It then became easier to examine the relationships between codes, focusing on the data at these different levels of analysis. The collapsing of codes within these areas produced four distinct candidate explanations or hypotheses for further analysis as follows:

4.16 Hypothesis 1: Patients' and carers' voices were not heard (analysis at micro, individual and dyadic level).

This hypothesis combined the codes around high risk patients, the carer's role, blame, the role of HCAs, delayed response, and relationships with staff, and combining these codes enabled me to examine the evidence at a micro and individual or dyadic level. This focused on patients, carers and often the views of individual staff.

There were several recurring constructs referring to the health care staff's response to patients and carers (see figure 4.6 below). Not only was there something in the

analysis emerging around the relationships between them at this micro level, but there were issues around responding to the needs of patients when they interacted with staff. For example Alex, Chris, Danni, Elliott, Frankie, and Glenn all felt that their interactions with certain staff members contributed to the development of their pressure ulcer (DS 3), and felt that their voices were not heard by staff. Alex, Chris, Danni, Elliott, Frankie and Glenn also referred to a delayed response to their needs by staff at this dyadic interactive level (see above Tables for details). On the other hand, staff working with Alex, Bernie, Danni, and Frankie all referred to difficulties in dealing with their patients (DS 1). HCAs were often responsible for patients, with staff nurses trained more fully in pressure ulcer care taking a lesser role (Alex, Bernie, Elliott, Glenn; DS 1, 2, 3, 4).

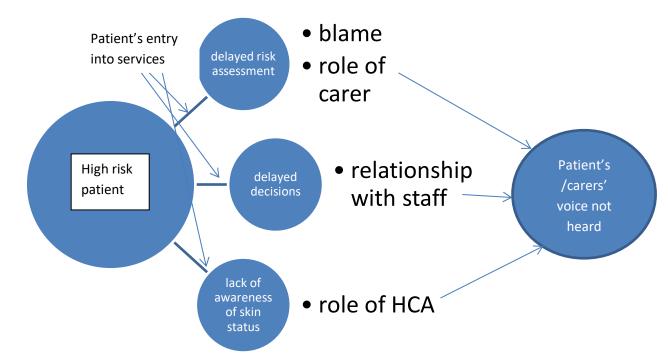


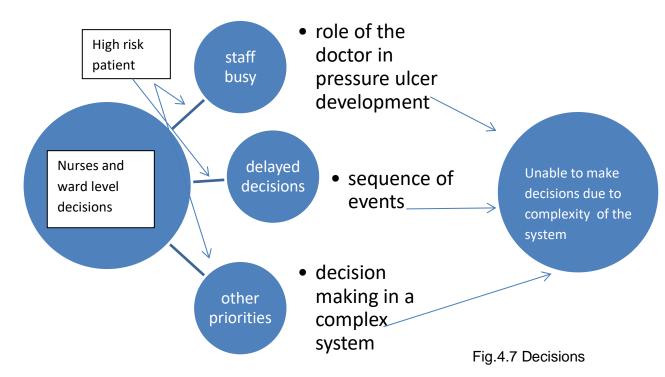
Fig 4.6 Patient voices

4.17 Hypothesis 2: Difficulties in decision-making within a complex system (analysis at psycho-social level)

This candidate explanation combined the thematic codes around delays in decision-making, delays in response, high risk patients, sequence of events, other priorities, and the role of the doctor The focus here was on the psycho-social decision making by individuals, and why these decisions were often difficult for them to make under complex circumstances (see Figure 4.7 below).

Although decision-making also relates to the Safety Culture theory, there were a lot of references in the data to decision-making by certain staff members, and delays in

these decisions around pressure ulcer care, so much so that this area needed to be examined separately from a theory around safety culture. Nurses particularly, were somehow unable or not empowered to make decisions for patients in several cases (DS 1, 2, 3; see Table 18) namely for Bernie, Danni, Frankie, and Glenn. This lack of decision-making seemed to be associated with task-based, rather than judgement oriented nursing (particularly for Alex, Bernie, Chris, Danni, Elliott, Frankie, Glenn; DS 1, 2, 4). This theory will be developed in the chapter on decision-making so will not be developed further here. However, delays in decisions appeared to have an effect on the development of severe pressure ulcers. Although patients' risks were documented (to an extent), they were not prioritised (particularly Bernie, Chris, Danni, Elliott, Frankie and Glenn; DS 1, 2, 3, 4) (see Table above). This meant that referrals and escalations often did not happen when patients contacted services (Bernie, Chris, Danni, Elliott, Frankie, and Glenn; DS 1, 2, 3, 4) and the staff response (particularly from a nursing perspective) was not strong enough to combat patients' high risks in time to prevent ulcers occurring. Patients went on to develop worsening or severe pressure ulcers, under the care of services (namely Bernie, Chris, Danni, Elliott, Glenn; DS 1, 2, 3, 4). Only Hilary's (Patient 8) ulcer was completely outside of the responsibility of services when it developed (DS 1, 2, 3, 4). Again, this issue is discussed further in Chapter 5.



The absence of decision making early in a patient's pathway through services meant that decisions to escalate care were left too late to prevent the ulcer developing into an

SPU (Bernie, Chris, Danni, Frankie, Glenn; DS 1, 4). The doctors were the ones who took leadership and made the necessary changes regarding Alex, Bernie, Danni, and Frankie (DS 1, 2, 3, 4) where doctors stepped in and made decisions, in some cases referring the patients to either a specialist TVN (Bernie) or to a more suitable service (Danni's referral to the DNs). The changes made were often simply to refer to the TVN, or just highlight the worsening ulcer. It seems that until this point the ulcer was being treated as a routine procedure and not considered in detail. The nursing and HCA staff did not seem to fully address the decline in patient skin (Bernie, Chris, Danni, Elliott, Frankie, Glenn).

4.18 Hypothesis 3: Was there a mindless Safety culture? (Socio-cultural level analysis)

This tentative hypothesis combined codes around lack of responsibility, defensive communication, ward moves, delayed response, governance, other priorities, inadequate documentation, risk assessments and ward moves. See Figure 4.8 below:

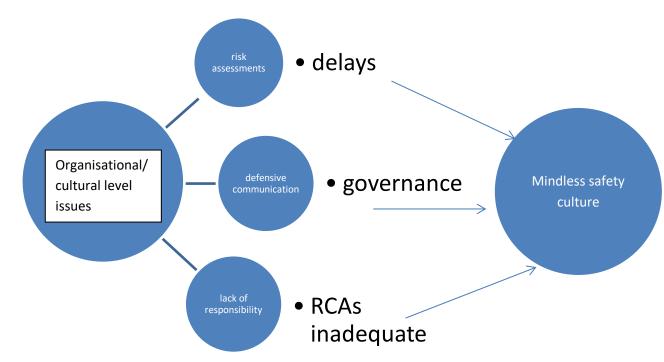


Fig. 4.8 Mindless safety culture

There were many references in the data, which I develop and examine further in the theoretical section 'Safety Culture', around the response to all the high risk patients, which was seen as 'lacking' from services, which was not just at an individual decision-making level. The decisions made in the complex system were part of a culture that

was laissez-faire, or mindless and unresponsive to high risk patients (Weick, 2010). This theory will be developed in the following chapter on Safety Culture so will not be detailed here. However, it appeared that patients' pressure ulcers developed as staff were seemingly powerless as a team to stop the deterioration of them, and the issue here was that they were seemingly unaware of where these ulcers first appeared (Bernie, Chris, Elliott, Frankie, Glenn; DS 1, 2, 3, 4). The culture in health care seemed to 'allow' the pressure ulcers to develop.

4.19 Hypothesis 4: Was there diffusion, poor communication and coordination between health care services, wards and teams? (organisational level analysis)

This theory combines the codes around defensive communication, ward moves, weak and non-existent RCAs, poor relationships, other priorities and sequence of events (see Figure 4.9).

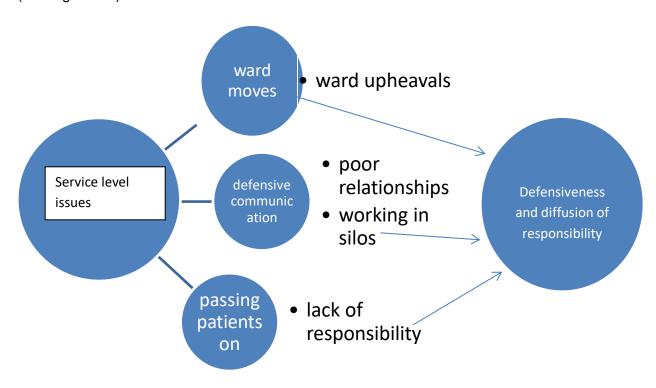


Fig. 4.9 Defensiveness/diffusion of responsibility

Much of the evidence collected referred to service level issues, and gaps between services involved in patients' care. The notion of 'blame' was not readily apparent at service level (this code emerged more between individual staff, patients and carers and vice versa) although for Chris (Patient 3) there was some degree of this. However, the emerging theory was around defensive practices, where services (and wards) did not communicate issues between each other about the patient and worked in silos (particularly for Bernie, Chris, Danni, Elliott, Frankie and Glenn; DS 1, 2, 3, 4). This

presented as a diffusion of responsibility by services (Latané and Darley, 1970) regarding patients (this theory is developed in the chapter of the same name following this section). Services for PUs seemed complex and ill-defined (namely for Bernie, Chris, Danni, Elliott, Frankie, Glenn; DS 1, 2, 3, 4). For example, for Bernie, the Physiotherapist admitted that they did not sit down as a team and discuss her communication needs. Had they done this instead of working in silos then all parties may have followed one plan of action, rather than following the non-communicative approach that led to her ulcer worsening. This happened too for Danni (DS 1, 2, 3, 4). She 'slipped between' services, and the same happened for Glenn, Frankie and Chris (DS 1, 2, 3, 4).

For Chris this was most apparent, as no member of staff working on the rehabilitation ward that he was admitted onto decided whether it was a diabetic foot ulcer or an SPU (DS 1, 2, 3, 4). This meant that he moved between services, yet no one took ownership or responsibility for the SPU. Once again there was no definitive plan of action, so no one was able to make a definitive decision in his care (DS 1, 2, 3, 4). For certain patients risk assessments and documenting decline in PUs seemed to take priority over action and escalation regarding the patient's high risk (particularly for Bernie, Chris, Danni, Frankie, Glenn; DS 1, 2, 3, 4). For other cases the documentation was lacking, omitted or poor quality (Bernie (on the stroke rehabilitation ward), Frankie (on one of the wards) and Elliott.

4.20 Conclusion

Four distinct hypotheses or candidate explanations for future analysis were noted above from inductively examining the raw data and refining the initial analysis; i. patients' and carers' voices were not heard; ii. difficulties in decision-making within a complex system; iii. was there a mindless safety culture? and iv. did diffusion, poor communication and coordination between health care services, wards and teams contribute? These different tentative theories were formulated out of collapsing the codes and moving from descriptive categories to ones which could be subject to further in depth analysis. This section re-examined the codes with the aim of formulating testable hypotheses to develop and revisit. The next section will discuss these hypotheses in much more detail as four discrete chapters then combine them in one final discussion chapter.

Chapter 5: Patients' voices not being heard: If staff had listened more to patients and carers, would they have developed their severe pressure ulcers?

5.1 Summary

This chapter will test the hypothesis that patients felt their voices were not heard, so when clinicians failed to listen to patients and carers, this might have contributed to the development of their severe pressure ulcers. Failing to listen to patients appeared to centre on whether the staff viewed their patients as equal partners, or whether they saw them as 'compliant' with pressure ulcer prevention and treatment. The findings will be reviewed against three areas of literature; the health services and decision making literature, the patient safety literature and the organisational culture literature. This is to provide a systematic and applied approach to testing the hypothesis.

5.2 Background

For patients' voices to be 'heard' by the health care professionals who care for them, we might suggest that a mutual respect and partnership would be the best option for a positive experience. There has been debate over the years in health care over what the best partnership between patient and health professional actually is. A 'compliant' patient is one who follows the care that is given to them, and a non-compliant patient has historically been seen as one who does not. Compliance is defined in the Cambridge English Dictionary as "the act of obeying an order, rule, or request" (Cambridge Dictionary, 2017) so can be translated within healthcare as the extent to which a patient follows a health professionals' advice and treatment. Concordance, on the other hand, is defined more as an agreement reached after negotiation between a patient and a health professional that respects the beliefs and wishes of the patient (Marinker, 1997). NICE recommendations and the Department of Health have been encouraging health professionals to move towards the notion of concordance rather than compliance for a number of years (National Institute for Healthcare and Clinical Excellence, 2009, Department of Health, 2012, Marinker, 1997). Although this is not without its critics, who argue that that concordance can be a poorly defined, idealistic term (Segal, 2007). By the mid-1990s the term 'non-compliance' was perceived as having negative connotations (Marinker, 1997). In contrast, concordance values the patient's perspective and expertise in managing their health, and aims to understand what impact the disease process has on them. The concept of concordance has gathered support in government health policy more recently by the Department of

Health through initiatives such as the Expert Patient Programme (Health, 2012). This particular initiative began in 2002 as a Department of Health research project to find out how to put patients at the centre of their health care. Initially funded by government, the project was devolved, and became a CIC (Community Interest Company). The idea behind the successful programme is that patients self-manage and control their own symptoms and health, by developing more user-led self-management courses to allow people with chronic diseases access to opportunities to develop the confidence, knowledge and skills to manage their conditions better.

However, valuing the patient's choice and treating them as experts in their care are not without their issues, as it may cause a dilemma for a health care professional if the patient chooses to take action that is likely to cause a poor health outcome.

Furthermore, the expertise offered by patients is different from the professional's (McKinnon, 2013). A concordant consultation is meant to be one which includes both these views in the decision-making process regarding management. This is contrasted with a more traditional paternalistic approach underlying compliance where the patient has historically taken a more passive role and been obedient to a health care professional's advice. According to Hobden (2006), paternalism is still a possibility in concordance, provided it reflects the patient's preference for involvement in the decision-making process and that this preference has been actively sought and documented (Hobden, 2006).

If we apply this to the field of patient safety, patients (and carers to an extent) are often first hand witnesses to adverse events, as they are at the centre of their treatment, and are observers of all their care (Unruh and Pratt, 2007). They may not understand the clinical aspects of their care (although with the advent of internet search engines, many are well-informed) but many who have chronic illnesses, become experts over time, and can often offer a valuable and contextual insight into their condition, and can detect unexpected events that occur outside their usual treatment (Unruh and Pratt, 2007). Yet, despite their central role in their treatment, and encouragement through national policies to take on a decision-making role, patients are still often seen, and even choose to be, passive recipients of their care, with a nurse or doctor having responsibility for them (Vincent, 2010, Reed, 2011).

Moreover, patients can be disempowered as a result of this passivity when in a health care setting (Donaldson, 2008) and his or her voice is often lost, but more notably when something goes wrong (Institute of Medicine, 2000). For example, in the Inquiry into wrongly administered vincristine which caused Wayne Jowett's death, future

recommendations were made to include patients and relatives in drug-checking procedures. Both patient and carer could have helped to avoid the fatal mistake, had they been consulted. Instead, doctors new to the ward, who were unsure of procedures, independently carried out routine chemotherapy, wrongly, that led to the teenager's death (Toft, 2001). Some of this vulnerability and disempowerment is due to the patient being too aware that the person caring for them has 'their life in their hands' (Vincent, 2010) p.290. This is where some of the disempowerment lies, and if patients are worried they might be seen as difficult they are less likely to voice concerns (Entwistle et al., 2010).

In addition, sharing of information is not always equal between the patient and health service, and researchers in patient safety have tried to encourage staff to find better ways to engage and empower patients (Unruh and Pratt, 2007, Coulter, 2011). Involvement of patients in the reporting of incidents and safety management has recently been recommended by the Council of Europe and the World Alliance for Patient Safety. The NHS Constitution also sets out the following promise about patient rights: 'to be involved in planning and making decisions about your health and care with your care provider or providers, including your end of life care, and to be given information and support to enable you to do this. Where appropriate this right includes your family and carers. This includes being given the chance to manage your own care and treatment if appropriate.' And 'to an open and transparent relationship with the organization providing your care' (Department of Health, 2013a).

Yet, despite the ideal of giving weight to a patient's view, in practice this is not always the case, and research outcomes have so far rarely uncovered ideal nurse-patient communication (Schubert et al., 2008) or empowered patients (Stevenson et al., 2004). Stockwell's notion of an 'unpopular patient' (Stockwell, 1972), despite being a study conducted years ago, has been shown, even in current healthcare climates to impact on how health care staff react to patients, although others have explored the concept more recently with similar outcomes (Jackson and Kroenke, 1999). Stockwell's (1972) work highlighted that some patients are easier to care for than others, and there are a number of reasons why some patients are more 'difficult to nurse' than others, from simple anti-social behaviour from the patient, to more complex relationships such as 'nurse knows best' and patients who challenge this. A more recent systematic review into concordance also found that professionals do not always explore a patient's preferred role in decision making (Stevenson et al., 2004) and prefer to rely on an asymmetrical relationship which lies more within the paternalistic model of interaction.

However, where patients feel confident in their communication with health care staff, this has been shown to foster a safer environment, and encourages patients to speak up about concerns. In a qualitative study by Entwistle et al, (2010) those participants who felt well informed by staff were encouraged and felt confident to speak up, but likewise, others worried that speaking up might result in staff labelling them as difficult, and less willing to care for them. Although none of the patients had pressure ulcers, and some of the patients had already lodged concerns about their safety, which may have indicated a confidence in 'speaking up', other groups of patients were sampled from a range of settings. In-patients who were dependent on professional help were particularly anxious that speaking up might affect their relationships with staff and make them more vulnerable to neglect or abuse (Entwistle et al., 2010).

This chapter therefore explores the interaction between staff, patients and carers and examines the views of patients in relation to the staff that were caring for them. It tests the hypothesis that if the patients' voices were not heard, or if they had poor relationships with staff that cared for them, then they were more likely to develop a severe pressure ulcer. The evidence is examined against current literature in the areas of health services literature, safety literature and organisational literature for clarity.

5.3 Patients feeling unsafe and vulnerable-Evidence from the data

The findings from this study highlighted many references within the data to patients feeling 'unsafe' and worried about the care they received. For example, although the health care assistant stressed in her interview that they cared for Frankie the same as they would for any other patient, Frankie's perception was to feel vulnerable and frightened regarding her care on the ward. Frankie's account of the reasons why she thought she developed a severe pressure ulcer referred very much to her reaction to the nursing care on the wards she was admitted to. She spoke of people not knowing who she was, 'A bank nurse came to see me after I arrived at the ward (post surgery) and said 'I don't know anything about you, could you tell me your name?' and I was scared, because I'd been entrusted to the care of the ward'.

This was however, later explained by the staff nurse, who wrote in Frankie's notes that she had no notes accompanying her following surgery. She also referred to 'reassuring' Frankie. She noted that she had informed her that she had no proper admission docs hence the questions.

However, this was different than Frankie's perception of the situation. Frankie informed the researcher that she was coming off morphine, and was extremely confused when

she tried to tell the staff that her mattress wasn't inflating properly. Frankie described the incident, when she said, 'I rang the nurse, and they knew that I'd just come off morphine –And I don't think they initially took it very seriously, because what I said to them was that 'my mattress is eating me alive' but I couldn't think ... I hadn't slept properly for days and ... That was as much as I could say'.

However, the TVN explained more fully about the patient's mattress problem when she was interviewed. She stated that there were issues if staff do not inflate mattresses properly: 'The Nimbus mattresses should be inflated fully before the patient's put on it, but sometimes you haven't got time, so you can put the patient directly on the Nimbus mattress, but if it's not inflated fully and then you profile it, it might not inflate properly...The way she described it was just that...'

Frankie's consultant said she knew Frankie better than the staff on the wards she was admitted on, due to having a long term clinical relationship with her, and part of the issue was that Frankie was often not forthcoming in how ill she was she noted that, 'Frankie is very articulate but she tends to play down her ...symptoms. So when she's talking to me, she'll say things, but I suppose because I know her so well, I pick up on things a lot more.'

Frankie may have not communicated her worries well enough. However, for Frankie to feel an equal partner in her care and safe, the staff needed to have heeded her concerns. This suggests a difference in perceptions between Frankie and the health professionals of her situation.

Danni was a woman with a congenital neurological condition, and used a wheelchair to mobilise. She initially developed a Category 2 pressure ulcer which worsened over the course of a year, and became an SPU which resulted in her being bed-bound for 18 months. She had suffered with pressure damage in the same body site (sacrum) around fifteen years before.

Danni mentioned the district nurse in the past 'telling her off' about her pressure ulcer. She noted that she could 'always remember a nurse coming in and saying, 'You've not been looking after yourself'. Danni added that she felt it was the nurses' attitude towards her that made her think that everybody else would think she was not looking after herself.

Danni also spoke of her reticence to access health services, although she attended the GP's surgery as soon as she saw skin damage, which was proactive management of

her skin. However, had she been more confident and assertive in her interactions with health care services, her Category 2 pressure ulcer may have been dealt with quicker, and referred by the Practice Nurse more quickly to specialist services, rather than it deteriorating to a Category 4 ulcer. Danni also claimed to have little knowledge of her pressure ulcer risks. Although this was denied by the staff at the local wheelchair service, who argued that she should have had information leaflets. Instead, although Danni visited the GP's practice, she found it difficult to get herself onto the bed in the practice nurse's office, and for this reason she preferred to ring up and re-order dressings for her pressure ulcer. However, the practice nurse did not ask her to view the pressure ulcer on her sacrum. The expert witnesses voiced this as a reason that Danni's pressure ulcer worsened: They noted that 'There's a kind of sort of misguided ... collusion with the patient, in the sense that she was shy and she didn't like exposing herself, and they knew that, she talked about that herself, so... the practice nurse was colluding with that by letting her not expose herself.

However, Danni did not actually say anything negative about her care, and when interviewed she found it hard to work out why she had developed a severe pressure ulcer. She praised the nursing staff, and did not realise that the practice nurse was not acting in accordance with policy when she did not assess her skin fully.

In another case example, Alex had issues with her voice being heard on the ward she was on. She explained that she ordinarily had a manual bowel evacuation (as she was paraplegic) every night. This action did not happen at the usual time when she was on the ward so she was incontinent during one of the nights she was on the ward. However, she felt the response from the ward sister was upsetting. Although Alex challenged the Sister about having been left in her faeces for a while the night before, the Sister argued with her about it, and in Alex's opinion she blamed her. Alex felt upset and noted that, 'it sort of got thrown back at me that it was my fault that [I was left in my faeces]...which annoyed me a bit, I felt I had to fight my corner.'

5.4 Insights from health services literature

Although Alex's pressure ulcer was seen as a wound breakdown following the research investigation, and limited evidence can be drawn around the causes of severe pressure ulcers as opposed to other categories, Alex's case highlights some issues with the patient voice not being heard and there not being a concordant agreement between patient and staff about his or her care. Equally, Frankie did not feel empowered to speak up, and felt 'unsafe' and Danni felt that she was 'told off'. This echoes the health services literature found in my earlier literature review. For example, patients' abilities

to speak up to ensure their safety are dependent on the settings and cultures of healthcare provision, and particularly on the attitudes that health professionals communicate (Entwistle et al., 2010, Davis et al., 2011, Latimer et al., 2014). As referred to above, the Entwistle et al. study focused on people with recent experience of one of five conditions or interventions associated with different safety problems (childhood asthma, diabetes, breast cancer, elective joint replacement and severe and enduring mental health problems). The study highlights that patients' abilities to speak up to ensure their safety are dependent on the attitudes of health professionals. It also highlights how 'personal factors' such as knowledge and confidence that have been associated with differing levels of patient engagement can be altered by the ways staff behave and relate to patients. When patients are given a voice, however, such as was explored in the Latimer et al. (2013) study, it affected them positively. Latimer et al. (2013) offer evidence directly relating to patients with pressure ulcers in their interpretive study. Although the study was small scale and based in only two Australian hospital sites, the findings highlight that majority of the 20 adults involved in their study, all of whom had suffered pressure injuries, preferred a proactive role in their care. They wanted to be 'heard' and involved in their decision-making to feel safe. These findings mirror the findings in my study.

5.5 Insights from safety literature

Being listened to and encouraged to speak up by health care staff appears to lead to a safer environment, which is supported by several studies in the wider safety literature (Pittet et al., 2011, Department of Health, 2000, Kohn et al., 2000). Yet, the most common complaint among NHS users is that they are neither listened to nor adequately informed about the care they receive (Freshwater and Stickley, 2006, Coulter, 2011). This notion is supported by a systematic review regarding a two way patient and staff communication mentioned earlier in this chapter (Stevenson et al., 2004) where patient participation was associated with positive outcomes. This also mirrors the findings of similar studies which explore the patient voice and his or her view of incidents (ledema et al., 2012). In the ledema et al. qualitative study, patients voiced the challenges they faced when explaining the knowledge of their condition with health care staff. These studies further echo the findings in this thesis, which suggests that how safe patients feel is often interlinked with how confident and involved the patient feels with his or her care.

5.6 Insights from organisational culture literature

Although the possibility that patients may feel unsafe should be at the heart of health care systems there remains an absence of literature in this field which explores the links between the patient's view of safety and the system. More recently, O'Hara et al. have been looking at the patient and family's voice in the context of resilient health care (see Chapter 10 for a discussion of resilience), and the findings are relevant to those within my thesis. O'Hara et al. note that the aim of their study (O'Hara et al., 2019) has been to demonstrate how, without the patient and carer perspectives, our understanding of resilient patient safety may be limited, and does not account for variability introduced by these key actors within a system, that both supports, and compromises, the resilience of the health care system. Without this understanding of the perspectives of these key participants, we risk misunderstanding the resilience of our healthcare systems. O'Hara notes that in the main, to date, the evidence for resilient health care has almost exclusively been undertaken from the perspective of staff and does not include the patient's perspective. The suggestive findings in this thesis around the patient's view of what they see as safe or unsafe care regarding their pressure ulcers, offer some support in attempting to understand and heed the patient's perspective.

5.7 Patients recognise the value of staff caring for them-evidence from the data

Patients feeling 'unheard' is not supported as much by one of the patients particularly in the study, who was happy that his voice was heard. Chris developed a pressure ulcer after being placed in a side room. Although he knew he was provided with a pressure relieving mattress that he had become accustomed to using over the long time he was in hospital, he felt that the nurses were only doing the best they could for him, and that it was an unfortunate mistake that they forgot to turn him when they placed him on an ordinary mattress. Following this he developed his heel pressure ulcer in a rehabilitation hospital. Chris noted that, 'They thought I would be better to be a bit nearer, [to the dining room] and they wanted me to have exercise but it was quite longit was the full length of the hospital more or less you know to walk. I think they was [sic] trying to safeguard me and make it easier for me.' Chris recognised the care that the staff were showing towards him, and felt the mistake was just 'unfortunate'. Likewise, Danni was very complimentary about the nursing staff who came to visit her and they became 'like friends' as they visited her daily at one point. She spoke positively about her relationship with the nursing staff.

5.8 Insights from health services literature

Reiterating from comments earlier in this chapter, it is probable that Chris had a more 'concordant' and partnership style relationship with the staff on the wards. There appeared to be more mutual respect and less frustration towards the health services staff. Recent literature in this area has noted that concordance is centred around 'having a consultation that allows mutual respect for the patient's and professional's beliefs, and allows negotiation to take place about the best course of action for the patient.' (Hobden, 2006). It appears from Chris' perception that this mutual respect was apparent in his case. Although the consultant in wound care noted later that the change to an ordinary mattress shouldn't have happened, at least Chris felt that the staff had considered him in the decision to move him. This changed his view of his care. Hobden (2006) argues as part of that staff need to build 'genuine, patient-centred relationships with patients.' Again, it appeared that there was more of a patient-centred relationship with Chris than with other patients within this study. Other literature which has explored the partnership within pressure ulcer care includes again the study by Latimer et al. (2014) which found that for concordance and partnerships with patients to work, processes should be reorganised to make explicit the patient's involvement, and to use the views of patients to inform prevention strategies. Although caution must be taken in generalising from a small scale study.

5.9 Insights from the safety literature

Again, when considering the patient's respect for staff looking after them, in terms of the broader patient safety literature, there are a number of studies reflecting the mutual respect between patient and health care professional. For example, in a survey study of 80 medical and surgical patients by Davis et al. (2011) doctors' and nurses' encouragement appeared to increase patient-reported willingness to ask challenging questions; however no other consistent findings were observed. There was little uniformity in patient involvement in their care. The study concludes, in spite of its conflicting findings, that efforts are needed to encourage patients to participate challenging safety orientated behaviours as these are behaviours where patients appear less inclined to take on an active role. To some extent the patients in my study had varied views on their personal safety, if at all, and this makes it harder to extract confident claims about them. However, others were very vocal in their perceptions of feeling unsafe.

Research has often been carried out relating to medicines management and how patients will take medications if they feel empowered in their relationship with their GP. This tends to be focused on 'adherence' to drug regimes, and is easier to measure than

'adherence' or compliance with pressure ulcer management. Again, though, reflecting my earlier findings set out above, a major reason for non-adherence within medicines management is higher patient-physician discordance leading to decreased patient satisfaction (Weingarten et al., 1995). In the study by Weingarten et al. (1995) they found a significant association between patient satisfaction and the performance of some but not all preventive care services (median satisfaction score 4.2 on a 1-5 scale where 5 was most satisfied). However, the authors do not state whether there was a relationship between patient satisfaction and quality of patient care. Also the study is limited in its location, and number of physicians involved (48).

5.10 Insights from organisational culture literature

Patients recognising and appreciating staff caring for them, is often hard to measure from an organisational cultural perspective, as the results are compounded with other variables. This issue was discussed earlier in Chapter 2. Nevertheless, guidance from professional bodies is to use tools such as Patient Reported Outcomes and Friends and Family Tests, to inform health care provision at a service level (Care Quality Commission, 2019; NHS Improvement 2019). A study by Tzeng et al, (2002) found that the strength of organisational culture predicted job satisfaction amongst nurses positively; job satisfaction predicted inpatient satisfaction significantly and positively; and inpatient satisfaction predicted general inpatient satisfaction well and positively. The direct effects and the calculated indirect effects (based upon standardized coefficients from regression analyses) demonstrated that nurses' variables, strength of culture and job satisfaction, interestingly, had a cause-effect relationship with a path coefficient of 0.297 (strength of culture on general inpatient satisfaction with nursing care) or higher on inpatient satisfaction variables (Tzeng et al., 2002). Also, a Before and After study by Wick et al (2015) developed a trust-based accountability model to address all elements of preventable harm in colorectal surgery patients. This initiative resulted in a rapid improvement in patient outcomes, patient experience, and cost. 90% of patients said they would recommend the hospital to their friends and family after the pathway implementation, as compared with 79% before. Although it was not clear if specific behaviour changes had made a difference or not. Other similar work has been done by Rebecca Lawton and colleagues on Patient Reported Outcomes and safety culture (2015), which discovered that the Friends and Family test was associated with patients' perceptions of safety, but was not associated with safety outcomes. Staff responses to a specific patient safety culture survey were not significantly correlated with patient responses to the patient measure of safety, however, both independently

predicted safety outcomes. Lawton et al, (2015) concluded that feedback from patients about the safety of the care that they receive can be used, in addition to data from staff to drive safety improvements in healthcare, and further work should be undertaken to consolidate these findings. For patients such as Chris, in my study, his respect for the staff involved in his care highlights the value of positive feedback from patients in contrast to the more negative experience of Bernie and Frankie. However, this alternative finding casts more doubt over whether the patient's voice impacts on the development of a severe pressure ulcer.

5.11 Non-compliant patients-evidence from the data

Overall, issues regarding the apparent concordance and compliance of patients as separate entities were apparent from the evidence collected as part of this thesis. As far as the notions of concordance and compliance are understood and accepted as a real construct, by both the author and the participants. Staff beliefs often centred on their patients' 'compliance' or 'non-compliance' with treatment, rather than their aiming for a shared partnership with the patient during their care, and some referred to patients as 'difficult'.

Frankie's case, for example, highlights this issue. She was a confident, assertive person (evidenced in her interview), however the staff did not seem keen on her when interviewed. A HCA noted that she felt she was difficult to nurse, giving an example about what she thought Frankie was likely to say: 'Do this for me, do that for me'...'You're not doing it like this, we do it like -- 'Do you know what I mean? She's a bit --She was a little ... She was a little bit, [difficult]'.

Bernie was a 65 year old woman, and had mobility problems. She had a contracted leg from a previous stroke, and was admitted into hospital after collapsing. Three days following her admission to hospital, she was referred to the stroke team and transferred onto a stroke ward where she stayed for six days. Bernie had cognitive impairment following the stroke, which led to her not following instructions for turning herself when she moved onto the stroke rehabilitation ward. The physiotherapist was reflective about the MDT's communication with Bernie, and felt that they had not appreciated the cognitive difficulties that she had. The physiotherapist summarised the issues as follows,' ... looking back, I think we should all have just sat down and been clear about what we were going to accept in her interests and not, because by the time she was discharged, and not going to walk, and with long term soft tissue management issues, she still believed she could get up and walk, and that was the level of cognition deficit

we were dealing with, so I don't think I appreciated her ability to consent properly' (Physiotherapist).

Bernie was seen as not 'complying' and following instructions as she did not turn when she was asked moving back into the position she had been lying in before. This was seen as a factor in the development of her severe pressure ulcer as she did not follow her pressure ulcer care plan properly, which can be common in stroke patients (Dehghan Nayeri et al., 2014). Despite the issues with her memory, due to the stroke, Bernie was viewed as 'non-compliant' by ward-based staff, who argued that this was the main reason that she didn't follow her pressure care plan. A HCA noted that "She'd comply and you'd go away and turn your back and she'd be back on it...she would comply and turn with it, but she wouldn't comply to stop on that side, you can't force her.'

However, as stated earlier, the physiotherapist explained that Bernie's 'non-compliance was due to cognitive impairment, 'She wasn't really very compliant with the positions that people were trying to put her in because she couldn't retain the information as to why they were doing that... I remember having to tell a lot of people that Bernie lacks insight into her problems, (Physiotherapist).

The expert witnesses also noted that Bernie's case indicated mistaken assumptions from staff members about her cognition:

Expert Witness 1 stated: 'I thought there was a big thing around assumptions – assuming that the patient knew, and then said that she was non-compliant. So, they didn't actually go through explaining to her that this is what you've got, and recognising that she's been quite ill and she's got some cognitive impairment. They just assume that you've told her once and that's it.'

5.12 Insights from health services literature

Bernie's cognitive abilities made it difficult for her to follow the instructions to turn in bed, set out by staff to avoid a pressure ulcer. Yet, even mild cognitive deficits can contribute to lack of adherence to treatment plans, with the patient and health professional's relationship being a factor in compliance (Okuno et al., 2001). If Bernie had been assessed correctly rather than been dealt with as non-compliant, she may have been treated more carefully regarding her skin and rehabilitation. A small observational study by Calhoun et al (2017) used the Braden risk assessment scale to assess a patient's risk of developing a pressure ulcer. Patients who presented to a

busy 21-bed emergency department over a six-month period with a Braden Scale score ≤18 and who were expected to be admitted to the hospital were placed on a two-hourly turning protocol. These patients had wearable wireless sensors placed to monitor patient turning. These reminded patients when they needed to be turned. Turn activity data was compared for those continuously monitored patients for the duration of their ED and entire hospital stay. Descriptive analyses and tests of difference were performed to obtain percent compliance and change in compliance scores by patient, group, and Hospital-Acquired Pressure Ulcer (HAPU) incidence. During the study period, the initiation of patient turning protocols in the ED contributed to an overall 38% reduction of hospital acquired pressure ulcers. This type of intervention may have worked better with a patient such as Bernie. However, staff who cared for her seemed to assume that they knew what she required without actually asking her or helping her in the ways she needed (Morse, 1991, Stockwell, 1972). Although there was no evidence that any parties were behaving neglectfully, there appeared to be a lack of consideration around the patient's needs, as she could not remember to turn herself.

5.13 Insights from safety literature

More general literature into non-complaint patients offers insights into patients who do not, for many reasons, comply with their health care professional's advice. However other studies in this area have found that staff are still not willing to relinquish their 'control' and felt they know best in relation to their patients (Henderson, 2003). In a qualitative study, referred to earlier, which examined patients' abilities to speak up about safety concerns (Entwistle et al., 2010), patients were found to be worried that speaking up might result in staff labelling them as 'difficult' and being less willing to care for them in future. Frankie was in fact labelled as 'difficult' which supports this idea. In-patients who were dependent on professional help (as were most of the complex patients in this study) were anxious that speaking up might affect their relationships with staff and make them more vulnerable to neglect or abuse. There were similarities in the findings around patients in my study and the study by Entwistle et al (2010).

5.14 Insights from organisational culture literature

The notions of 'non-compliance' or the 'difficult patient' are recognised in national policy and the NHS constitution (2015), which asks staff to acknowledge things going wrong, by offering apologies, (Sign up to Safety, 2014) and engaging patients in their care more. The data for my study was collected just before the guidance around 'Being

Open' and honest was offered by national health care bodies, however, the tentative findings around the lack of partnership and mutual respect between patients and health care staff in terms or pressure ulcer care, highlight the many complaints within the NHS around 'whose fault is it'. The NHS Constitution (2015) asks that patients should follow the health care professional's advice, but, particularly in Bernie's case, and for other patients in this study, her condition made it difficult for her to follow advice. It is my suspicion that, if Bernie's case become a complaint, the settlement would have been in her favour. There is now, thankfully, much more policy interest around shared care and the patient voice (Elwyn et al., 2016, Department of Health, 2013b, Department of Health, 2012).

5.15 Staff not responding to patient issues-evidence from the data

Elliott was admitted from a supported living home into a district hospital with cellulitis (swelling of his legs). He had existing pressure ulcers, but there was some confusion about where these were during his admission, although there was a plan in both the nursing and medical notes to check under the 'bandages' on his legs. It was found, through the research investigation, that Elliott had already developed a pressure ulcer pre-admission, but as the staff did not document the Category of the pressure ulcer on admission, and appeared not to have checked under his bandages for five days, it was recorded by the TVN on review as a hospital acquired Category 3 pressure ulcer. Elliott said that he didn't feel 'right' about the care he received care at the hospital and urged the researcher to talk to his daughter about it:

Patient: I didn't feel right and proper... you could get in touch with CARER...

LP: CARER? Is that your daughter?

Patient: Yes. Because...she was crying when...if you have a chat with... CARER. Because when CARER cried she was genuine.'

Elliot's carer spoke of her issues with the ward sister on the ward, and the lack of responsiveness from the ward staff to her father's condition. She told the researcher that, 'All of the time that he was in, on all of the wards, I was never once approached by a nurse to tell me about my father. It was always me that had to ask to see someone. And I think there was only once that I ever spoke to a sister...and they didn't know which ward he was going to and she said she'd ring me to let me know which ward he was going to. She didn't ring me. It took me God knows how many phone calls -- to find out which ward my father had gone to.' Elliot's carer added that she had concerns

about her father's dry mouth on one occasion, and her sister had raised concerns about this, but felt that the response was lacking from ward staff.

5.16 Insights from health services literature

Some of the evidence I collected around the response of health care staff is reflected in the health services literature. For example, in a cross sectional survey study by Schubert et al. (2008) nurses self-reported implicitly rationing nursing care. Higher levels of rationing were associated with better outcomes for their patients, and a reduction in adverse events.(Schubert et al., 2008). In another qualitative study in this area, (Dellefield and Magnabosco, 2014) where nurses saw pressure ulcer prevention as their mission, and had positive responses to their patients, the outcomes were better for both staff and patients. However, this was a small scale study with a convenience sample, so the findings must be interpreted with caution. Nevertheless, these similarities point to an area of interest and possible further investigation.

5.17 Insights from safety literature

The concerns about staff responding to their patients' concerns reflect those found in several patient safety studies which have examined the active role of the patient in safe care (Giles et al., 2013, Scott et al., 2016, Lawton et al., 2017)). Lawton's more recent work on Patient Reporting and Action (PRASE) (Lawton et al., 2017) argues that although patients (and carers) are willing and able to provide feedback, the engagement of staff is crucial to act on the feedback and absorb it into their practice otherwise the intervention will not be successful. This, and other studies around patient feedback in patient safety ((Lawton et al., 2011, Scott et al., 2016) have encouraged patients to record and feed back to staff their concerns around safety using written tools which are then analysed by staff, with the aim of feeding back into practice. However, for the patients, such as Bernie, in my study, it did not seem overall, as if patients were encouraged to speak up about their concerns; they may have been actively discouraged, if anything.

5.18 Insights from organisational culture literature

From an organisational culture perspective, the explanation that staff do not respond to patients' needs is very much reflected in the Bristol Inquiry (2000). According to findings from this high profile Inquiry, the 'club' culture prevailed and there was "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" (p2357). As mentioned earlier in this thesis, the sad deaths of so many babies during the Bristol scandal, and the Inquiry that followed, have impacted hugely on subsequent health policy since the Inquiry's publication. This suggests that the importance of the collective staff response at an organisational or cultural level can have a massive impact, and just how serious the consequences of a lack of consideration of patient needs can be.

5.19 Discussion

Given that this study has focused on the development of severe pressure ulcers in health care, it is understandable that there is little evidence of fully satisfied patients. These complex wounds cause much suffering for patients making them feel vulnerable, and by nature affect those more vulnerable (Gorecki et al., 2009). Therefore it is not surprising that their relationships with health professionals can be fraught, and we must take care not to assume this is indicative of every person's experience in health care settings.

However, research experts agree that the patient's voice can have a strong impact on nursing care and safety (Donaldson, 2008, Leape et al., 2009, Coulter, 2011). This drive for patient involvement has been reflected repeatedly in government policy to see the patient as expert rather than passive recipient of care (Vincent and Coulter, 2002). The patient is being viewed increasingly as a partner in health care as health policies move towards more patient choice. Initiatives such as *No decision about me, without me* (Health, 2010), and other patient directives, champion more patient involvement, for example, Patients for Patient Safety (World Health Organization, 2013). The Duty of Candour also aims to include patients in all investigations (Sign up to Safety, 2014) aiming to foster trust between patients, carers and services, and thus minimise complaints and lawsuits. Other recent government policy drives, such as the formation of Health Services Investigation Branch (Health Services Investigation Branch, 2017) aim also to foster patient involvement in investigations, and be more active participants.

The above evidence from this study appears in some ways to support the idea that patients can help with their safety concerns, and some become very knowledgeable about their care (namely Chris and Frankie). However other patients were too ill to be active partners (Elliot and Bernie) and caution must be taken in suggesting that patients must always take an active role. The findings did not always say that patients were unhappy (Chris and Danni). However, the evidence also shows that 'concordance' was lacking in several of the cases in this study. This resonates with issues that Elwyn et al. have highlighted around challenging staff views around 'non-

compliance' (Elwyn et al., 2016) and supported by the Entwistle et al study (2010). Elwyn et al (2016) drawing on their MAGIC study of concordance and shared decision-making, put forward a strong argument that the main aim of concordance is not the giving of information, or information exchange, but the achievement of overall understanding by the patient. It is likely that such understanding occurs when decision making is seen more as a process rather than an instant outcome. This process was recognised by Chris, when he valued the nurses' input despite the mistake they made at once point in his care. However Frankie spoke passionately about not understanding why the staff who were caring for her behaved as they did.

Patient led safety initiatives where the patient is more involved and powerful in his or her care management have been encouraged in recent years, despite a lack of robust research evidence to prove that these initiatives actually change practice (Lawton et al., 2017, Lawton et al., 2011, Wales, 2010). This lack of evidence may however, be more around the staff's reaction to the initiatives, rather than failed interventions per se (Lawton et al, 2016).

Both Doherty's (2012) systematic review and Lawton's recent work call for more exploration of clinicians' attitudes towards patients' engagement in safety to aid understanding on how to effect more profound cultural change (Doherty and Stavropoulou, 2012, Lawton et al., 2017). If attitudes do not foster learning and acting on patient concerns, involving patients appears to be less effective (Lawton et al., 2017). Despite evidence shown of more involvement of patients through incident reporting of such as severe drug reactions (ADRs), and reporting hand hygiene issues on NHS sites (NPSA) these initiatives have also shown limited success in encouraging patients to challenge health care professionals (Stone et al, 2007). The patients in my study did not seem to feel confident enough to speak up about their safety concerns, particularly Danni and Elliott.

So what can be done to improve relationships and encourage the patient to feel confident and empowered? In pressure ulcer care particularly, patients still remain largely uninvolved in the process, aside from being given a verbal and written apology (Sign up to Safety, 2014). This is partly due to the nature of their vulnerabilities and situation, as was also found in the Doherty et al. review on barriers to speak up about safety (Doherty and Stavropoulou, 2012). In the review, the authors found that incidents were reported and dealt with at a professional level, rather than genuinely engaging patients and carers. Pressure ulcers are more complex to report in local trust incident reporting systems than, for example, falls (Runciman et al., 2002). Patients

who are traditionally more unwell are those who will develop severe pressure ulcers and very unwell patients are less likely to have the energy to speak up assertively (Doherty and Stavropoulou, 2012). Elliott's interview was indicative of this problem, as was Bernie's. Therefore, if a patient is too ill to have an active voice in their relationship with staff, this issue will remain a problem for pressure ulcer care unless there is a way to encourage and allow time for a more balanced relationship, with recognition of the frailty of patients, particularly at the time of treatment. Elliott managed to tell the researcher about his problems during his interview, yet there appeared to be no evidence of his worries being communicated to health care staff. The encouragement of patients to speak up in health care appears to be an ambitious target. However, this would be a theory to test in future work in this area.

5.20 Conclusion

The hypothesis set out at the beginning of this chapter was whether or not patients' voices not being heard led to the development of their severe pressure ulcer. To some extent this has been supported by the evidence and consolidated by research evidence already published. Indeed there is value in a positive patient experience whatever treatment they are undergoing. Although this study is exploratory, there is enough support for this possible theory to warrant further investigation. A practical, more applied way to test this could be a detailed, shared treatment plan around pressure care in high risk patients (see (Elwyn et al., 2016), which could be a way of engaging the patient and carer more fully in their treatment, to monitor deterioration of pressure ulcers and to aim to prevent the pressure ulcer deterioration earlier. Some NHS trusts have already moved towards shared care agreements, although there has been no research published regarding pressure ulcer care to date. However, a shared agreement could be measured or audited to see how this affects a patient's pressure ulcer. This idea is discussed further later in this thesis (Chapter 10). The tentative findings of this chapter advocate that patients assessed at risk of pressure ulcers should be given comprehensive information, and communicated with as soon as skin damage appears, so that they can make informed decisions about their treatment. This would disregard the concept of the 'non-compliant' patient and move towards a more concordant approach.

Chapter 6. Decision-making in a complex environment.

6.1 Chapter summary

In this section I discuss the hypothesis that the decision-making by staff in response to high risk patients impacted on the development of their severe pressure ulcers. I also discuss issues around decision-making in a complex environment, including risk assessing and using clinical judgment for 'high risk' patients. When staff are faced with a situation where they recognise a safety issue, they have to respond with a decision or action(s), but often the patients within this study developed pressure ulcers slowly and nebulously, and staff were not equipped at the time to make informed decisions to prevent them deteriorating. The reasons for this are discussed below.

6.2 Background

There are numerous similar terms to describe decision making in health care. Clinical decision making is the most commonly used (Ford, 1979) (Field, 1987, Luker and Kenrick, 1992). Other terms include clinical judgement (Benner et al., 2009); clinical inference (Hammond et al., 1964) (Hammond, 1996), clinical reasoning (Grobe et al., 1991), and diagnostic reasoning (Carnevali and Thomas, 1993, Radwin, 1990). Although these terms are used interchangeably, they relate to slightly different perspectives of what is now thought of as a continuum of decision-making which is discussed in detail below. Fundamentally the terms above describe the choice of a discrete option from a range available to a clinician. Three examples of possible choices might involve selecting interventions, making a diagnosis, or the communication of future prognostic possibilities: clinical decisions inevitably involve these choices (Thompson and Dowding, 2002). However, there is still debate and lack of understanding around how people make clinical decisions within health care (Thompson and Dowding, 2002). This debate will be considered alongside the evidence in this chapter.

For clarity, I define clinical judgement as one made at *individua*l level within health care setting. *Decision-making* incorporates the contextual or environmental and patient influence when an individual makes a decision (Thompson et al., 2011). Decision-making is often defined by intellectual leaders in the field as making an informed choice about what action to take from a range of alternatives (Cheyne et al., 2006) (Lamb et al., 2011).

6.3 Pressure ulcer management

The process of pressure ulcer risk assessment and management is associated with a process of both decision-making and clinical judgment (Samuriwo and Dowding, 2014). The authors of this systematic review define *judgement* as the assimilation of different types of information about a situation to arrive at an overarching assessment of it, while decisions entail making a choice about what action to take from a range of alternatives. This is also supported by other authors in the field of decision-making (namely (Cheyne et al., 2006, Lamb et al., 2011, Dowie and Elstein, 1988). The Samuriwo and Dowding (2014) review highlights a lack of robust research evidence exploring how nurses make judgements and decisions related to pressure ulcer risk assessment, how they categorise pressure ulcers and how they plan care to prevent or manage pressure ulcers. These review findings sit within the lengthy debate around variations in assessment of category which are offered by current pressure ulcer risk assessment tools such as the Waterlow, Braden and Norton scales (Nixon and McGough, 2001). Variation of assessment would ordinarily lead to variation in action planning or prevention measures. If the evidence suggests that the subjectivity of interpretation is not mitigated by the use of a prescriptive tool, then that is a risk factor for decisionmaking in itself. There is currently little understanding of how, and if, pressure ulcer risk assessments and grading judgements affect the decisions that are taken by nurses regarding pressure ulcer prevention or management (Samuriwo and Dowding, 2014).

However, although judgement and decision making are concepts which share many links, according to other authors they require different cognitive processes which are explained below (Thompson and Dowding, 2002, Gillespie and Peterson, 2009) and the impact of variations in either the judgement or decision process may have different effects on the care patients receive.

6.4 Different approaches to decision-making

There are debates within the clinical decision making field about how to differentiate between models of decision-making. There is not room within this thesis to enter into this debate fully. However, a general guide is offered by prominent authors in the field who suggest the categories of decision making are: normative (where the decision-maker is rational and logical in an ideal word) descriptive (where the description of how individuals reach a decision is focused on), and prescriptive (aiming to improve the decisions of individuals) (Thompson and Dowding, 2002).

However, other authors have aimed to categorise the approaches slightly differently, and this is a useful overarching model. Banning (2008) argues that there are three main over-arching approaches to decision making, which are: information processing, an intuitive-humanist approach and a cognitive continuum (Banning, 2008). What makes this a useful conceptual position is that Banning demonstrates that these theories originate from different academic disciplines historically. Clinical decision-making initially arose from an information processing model, alternatively called the hypothetico-deductive model, or scientific process model, which has its roots in medical decision-making (Joseph and Patel, 1990). This is usually represented by a four stage hypethetico-deductive process:

- the clinician takes part in a patient encounter and gathers preliminary clinical information about the patient (also called **the cue acquisition stage**)
- following this, the clinician generates initial and **tentative hypotheses** (usually around 4-6 in number). These are related to already gathered data and short term memory-based cues
- the third stage involves the clinician **interpreting the cues** gathered and classifying them as confirmatory, negative, or non-contributory hypotheses
- in the final stage the clinician weighs up the pros and cons of each decision alternative and chooses the one most favoured by the evidence, or **evaluates the hypothesis** ((Thompson and Dowding, 2002).

This model was initially adopted in nursing, for example using decision trees to analyse how the information was processed in a logical manner (Thompson and Dowding, 2002); however, other authors in the field of decision-making, such as Hammond (1996) highlighted the difficulties with using this approach, as it made professionals more cautious when trying to make decisions under uncertainty. Hammond argued instead that uncertainty is 'irreducible' and we must acknowledge that we, as human beings, will always have an impact on decisions. Hammond's (1996) comprehensive review of the debates within decision-making also argues that decision-making is an ongoing rivalry between intuition and analysis, accuracy and rationality.

Arising from this debate, an alternative explanation for how decisions are made, and sitting at the opposite end of a deductive theory, is the idea of intuitive-humanist approach. This approach asserts instead that the motivational force for a decision is not the decision 'task', but instead is dependent on the individual undertaking it, and

their expertise and experience (Benner, 1984, Benner and Tanner, 1987, Benner et al., 2009). Definitions include:

- 'understanding without a rationale' (Benner et al., 2009)
- 'a perception of possibilities, meanings and relationships by way of insight' (Gerrity, 1987).

This theoretical approach has been popular in nursing as it distinguishes the expert from the novice and nursing often appears intuitive to the outside observer, involving an almost unconscious level of cognition (Hamers et al., 1994, King and Clark, 2002).

Recent developments in decision-making have however, focused more on the concept of a cognitive continuum (Hannond et al., 1987), which asserts that decisions vary in the degree to which they rely on intuitive and analytical processes. Conditions such as amount of information and time available determine where decisions fall on this continuum and whether people rely more on patterns or on functional relationships. At the far end of this continuum and a development of the intuitive-humanist approach, is an instinct based model, namely the naturalistic decision making (NDM) paradigm. This theory originated in fieldwork, rather than tested a pre-defined model of decisionmaking. It suggests that decisions are made under uncertainty, under time pressure, with ill-defined goals, and are based on expertise, pattern matching or recognition of a given situation, and are thus nonlinear, non-analytical and not necessarily logical, rational or based on risk/benefit considerations (Klein, 2008). In a further study focusing on this area, only 45% of decisions were found to be planned in a study in emergency departments, and were opportunistic, and not always being made about one patient's care, but incorporating a whole department's views in considering a decision (Franklin et al., 2011). The important point to note about this work is that in this NDM model there is a tension between safety and efficiency. It is not only about the individual making the decision, but about the system within which they are a functioning part. This, of course includes achieving concordance with the patient, as Chapter 5 discussed.

Part of the reason for the focus on decision making theories within this study, is that an evidence-based culture of decision-making has long been advocated by UK health policy (DoH: 1989, 1993, 1994, 1996), and with this has come an increasing need for transparency and accountability in how health care staff make decisions. For nursing particularly, the increasing focus on autonomous decision-making has sat side by side with the desire for nursing to elevate its status professionally, and with this has come

decision making based on evidence, using intuition when necessary as well. The Advanced Clinical Practitioner (ACP) or Advanced Nursing Practitioner (ANP) roles are recent developmental roles which allow elevated status for nurses (this also includes physiotherapists, pharmacists and occupational therapists). Both roles focus on leadership, expert knowledge and decision making skills. A mixed-method, case study by Begley et al. (2013) examined the role of the ACP. This consisted of field observations (92 hours) and included a service user survey. The study's result was to define the ACP role as one requiring a registered practitioner to have acquired an expert knowledge base, complex decision-making skills and clinical competences for expanded practice, shaped by the context in which the individual practices" (Begley et al., 2013). In contrast to the ACP role, the Samuriwo and Dowding review (2014) found that most nursing decisions focussed instead on discrete areas such as: dressings, pressure ulcer monitoring, monitoring observations, referrals to colleague/ senior nurse/ doctors/ clinical nurse specialists/ therapists/ pharmacist, referral to relatives/involvement of relatives, interpreting results mainly of blood tests/exercise tolerance tests, and staff development/ supervision/ training.

Nurses however, do seem to vary within their profession and with doctors in their decisions, particularly in wound care. Vermeulen et al. (2007) examined the agreement, assessed by a questionnaire, between a sample of doctors and nurses who chose between gauze or occlusive dressings for a selection of wounds. The study was based on one hospital and the response rates were better for doctors than nurses, which may have biased the sample. However, an interesting finding was that for wounds that warranted gauze dressings, the mean level of agreement among nurses was poor (kappa [I] 0.23, 95% confidence interval [CI] 0.15-0.31). Agreement was even worse for occlusive dressings (I 0.12, 95% CI 0.07-0.16). Experience with more wounds did not lead to a greater consensus about what to do; the lack of agreement did not diminish in line with nurses' increasing clinical experience (Vermeulen et al., 2007).

To expand the above argument, regarding pressure ulcer care, decision-making focuses on the assessment of risk of skin breakdown and choosing which actions to take to maintain skin integrity. This is an integration of judgement processes (judging the risk of the patient) and 'deciding' what to do to minimise the risk. Therefore, it appears to be more focused on assessment, monitoring and prevention, (Samuriwo and Dowding, 2014) and not currently on making decisions regarding patients when they deteriorate, as this concerns the doctor, or specialist nurse, which is apparent in the evidence in this study (see below). This chapter however, also suggests that

clinical judgements and decisions were made in *uncertain* circumstances for the patients involved in the study and this may have impacted on the choice of decision made. For example, severe pressure ulcers ordinarily appear in patients alongside other comorbidities, and in patients, judgements, whether by nurse, or doctor, or specialist nurse, may contribute positively or negatively to the pressure ulcer management of patients.

6.5 Delays in decision making: Evidence from the data

The previous analysis chapter (Chapter 4) highlighted that delayed referrals and decision making were readily apparent in this study. For example, the practice nurse assessing Danni noted that she 'should have referred earlier to the DNs, as they knew more about complex wounds'. There was also an issue around decisions not being made at all concerning Danni, and delayed decisions, but this will be covered further in the following chapter on safety culture.

Bernie's TVN also stated that they should have 'referred to her earlier'. This was echoed by the doctor involved with Bernie, who wrote in the medical notes 'Refer to TVN requested last week'. The TVN involved with Glenn also stated that she wished the staff had referred him earlier to her. She added that for some nurses 'they might be able to deal with [a pressure ulcer], but some of the nurses they might not, so it tends to go on their professional judgement'. Glenn and his carer also noted that they felt the DNs 'should have referred earlier'. However, in contrast, some decisions based around Chris' care were made in a more timely manner, including the decision, rightly or wrongly, to situate him in a side room. Staff also referred him to the rehabilitation unit in an arguably hasty decision, as he had wanted to 'get home'. However, there is some value in discussing the issues around delayed decision-making, as when this happened there were some similarities which are worth further exploration.

6.6 Delays in decision making: Insights from the health services literature

The specialist TVN nurse is usually not on-site when initial management and decision making around a pressure ulcer are needed (Flanagan, 1996), which is evidenced in the analysis within this thesis (see Data Analysis chapter, and the following chapter, for further details. They tend to provide a consultative service, which supports frontline staff (Flanagan, 1996). However, a systematic review in this area reports that there are numerous delays in decision-making and referrals to the TVNs by nurses, (supported by evidence in this study) which then has implications for analysis of care, and is not consistent with best practice (Samuriwo and Dowding, 2014). The systematic review by

Samuriwo and Dowding (2014a) also suggests that most nurses do not appear to assess their patients' risk of developing a pressure ulcer on admission to acute services. Instead this is often deferred to the day after admission or even later in the patient's stay (Samuriwo and Dowding, 2014, Unbeck et al., 2013, Fossum et al., 2011, Funkesson et al., 2007) (Gould et al., 2004). The review highlighted that it can take up to three weeks for nurses to consider the efficacy of the measures that they may or may not have implemented to protect a patient's skin (Fossum et al., 2011, Funkesson et al., 2007, Gould et al., 2004). For the patient, this three week delay may have profound implications for the quality of skin care that they receive, as often patients do not stay for a lengthy period of time in one care setting especially in the acute phase of their illness when they are at the highest risk for skin breakdown (Goulding, 2011, Czaplinski and Diers, 1998). This was the case for Bernie, Frankie and Chris in this study. Although recent recommendations by NHS Improvement have brought in a six hour admission window of assessment (NHSi, 2018).

6.7 Insights from wider safety literature

Staff often have to make decisions about complex patients within time constraints, and in these cases they may refer to what they know, (ad hoc, intuitive reasoning and rules of thumb) rather than following analytical, step by step decisions (Catchpole, 2013). This point is explored further in the discussion below. However, as was shown in the introduction to this chapter, the decision-making literature ((Thompson et al., 2004, Hannond et al., 1987) has shown that the more complex the information cues that a decision-maker is faced with, the more likely it is that he or she will opt for intuitive reasoning and not use a hypothetico-deductive approach. It has also been shown more recently in psychological studies on decision-making, that intuitive decisions are very rarely optimum and we are actually poor intuitive decision-makers (Catchpole, 2013). This may in turn jeopardize patient safety and the quality of care (Brindley, 2010, Wong et al., 2012).

6.8 Complex patients: the uncertainty around co-morbidities and which are prioritised

As people live longer, there are countless patients who present to health services with numerous needs, which could be considered 'complex'. Recent surveys of primary care practices found that 25% of patients were considered complex by doctors. Although healthcare decision making usually follows medical literature, including domain specific evidence-based medicine (EBM), guidelines, checklists, and protocols, these are frequently insufficient for responding to complexity. In Lundgren-Laine et al.'s

study (2013) *ad hoc* decisions related to organizational issues such as placement of the patient, the availability and capability of the nurse, the timing of the treatment and ensuring the continuum of care from shift to shift. Uncertainty or *ad hoc* decisions, may lead to inconsistency and vagueness, distorting the decision-making process towards intuitiveness, which has been shown to incorporate bias (Lundgren-Laine et al., 2013). The complexity of needs of the patients in this study meant it may have been harder for health care professionals to make an initial judgement in a timely and effective manner. This variability in need is what would define a complex patient, and as well as their high risks which may have been missed on admission by staff, the complexity, arguably, would need more regular assessment. Whether this affected the decisions given the patients' complexity in this study is discussed below.

6.9 Evidence from the data

Four of the eight patients in the study were of an older age (over 65) namely Bernie, Chris, Elliott and Hilary, and three others had chronic illness, (i.e. Alex, Danni, and Glenn). All would be considered complex or frail patients, and all but Hilary were high risk for pressure ulcers as they were immobile at the time their pressure ulcer developed. Hilary became immobile after she lay supine on the floor of her house. These issues relate to the complex decision making process introduced above in the Introduction section, as all the patients had comorbidities which impacted on the management of the care they received.

To illustrate the decisions made in this study for complex patients, on admission Bernie was queried for a diagnosis of stroke, a UTI, shortness of breath, malnourishment, and dehydration. She already had problems with mobility due to a previous foot injury. She remained unwell with a low grade temperature following on from her admission and it was found she had pneumonia, but this was not diagnosed until 18 days later following a chest x-ray. Therefore, she remained a very ill patient; at high risk for pressure ulcers during the time that staff were trying to make decisions about how best to treat her. For example, a staff nurse on the stroke rehabilitation ward noted that Bernie, 'was very, very ill, she had pneumonia, and wasn't eating. Despite this concern, a positioning care plan was not put in place until 6 weeks after her admission when she already had a degree of skin damage

Staff members' lack of knowledge of pressure ulcer care also contributed to Bernie's pressure ulcer's development, as they had difficulty accurately describing body site and grade of wound (noted in the TVN report). As noted in the systematic review in the introduction to this chapter, accurate categorisation and accurate anatomical recording

is pivotal in prevention of pressure ulcer deterioration (Samuriwo and Dowding, 2014), and with this in mind one can further appreciate the nurses' lack of knowledge as a contributing factor. Bernie arrived at the Emergency Department unable to communicate any reason for her being there, and did not remember anything about her initial stay for at least a week. This was noted in her initial admission documents which state that was 'confused and disorientated'. Yet staff were under pressure to make decisions about her diagnosis and plan from the outset (Johnson et al., 2017). Staff members made referrals and decisions based on what they could uncover about her in the absence of other knowledge. For example, the medical notes state a list of possible diagnoses 'inflammation, urinary retention, and predicted Urinary Tract Infection, Chronic Obstructive Pulmonary Disease, Ultra Sound abdomen. Will need urology review re retention'. Although many patients who are admitted through Emergency Departments are equally as unwell as Bernie and are accurately diagnosed and assessed as high risk of pressure ulcers, the complexity of Bernie's condition appeared to impact on staff missing documenting her skin status, which was recorded as medium risk at the time. The TVN noted that this was inaccurate.

Danni was also a complex patient based on the criteria set out above. She had a congenital neurological condition, and was wheelchair bound. She had developed a pressure ulcer previously, which made her aware of what one was, so on developing one, many years later, she acted promptly to access health care and deal with it. In her case, the nurse at the GP's practice examined the pressure ulcer briefly, but left Danni and her carer [husband] to care for it, 'assuming' that they both were competent in pressure care. This judgement to allow Danni to care for her self and not monitor the wound, and not to escalate the case to more specialist care, meant that the pressure ulcer worsened into a severe ulcer before anything was done to monitor it more carefully. Danni visited the practice nurse, but it was noted by the nurse that appointments are only ten minutes long, and there was not enough time to look at her wound in the time available, or offer any advice around the pressure ulcer to prevent it worsening. The Practice Nurse noted that she only got 'ten minutes' to advise and treat Danni. This is assuming that a booking for a double appointment for Danni was not considered. There was no evidence of this from analysis of the GP's patient notes. When asked by the researcher whether the message about skin care could be passed on to a patient in that time, the nurse replied, 'Not if you are doing a dressing... it's hard to do it in that time.'

Also, in part, the practice nurse dealing with Danni, was under pressure by her GP's practice not to refer out to specialists, as part of her local policy remit. She explained to

the researcher that she 'tried to deal with the pressure ulcer in-house' although she was not familiar with 'complex pressure ulcers', and thus the Danni was not referred as quickly as she should have been to more specialist care, given her circumstances.

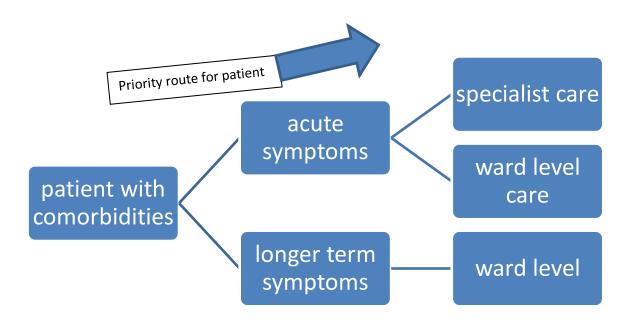
Chris had multiple comorbidities too. He had been a cardiac patient, was diabetic, had cancer and already had a healing pressure ulcer. He then developed C-Difficile on the community hospital ward. As the consultant said about him 'he was a very unwell man...and he didn't need another pressure ulcer'. However, the staff made a decision to place him in a side room on a foam mattress, rather than thel high risk air mattress that he had previously been on.

In certain cases, contextual influences prevailed over decisions made by an individual. This was apparent in Frankie's case, where her consultant would have preferably placed her on a high dependency unit (HDU). However, because the consultant had moved over to another site, he was aware that he did not know the staff well, and there was no room on the HDU at that time. He did not exercise his power to push for sending her to the ward regardless, as he was not as familiar with the culture there. This meant that Frankie was placed on a ward which did not respond to her needs enough. This was noted by both her specialist consultant and the ward sister. This, more cultural decision-making issue however is described in further detail in the chapter on Safety Culture, so is not explored further here.

6.10 Insights from the health services literature

The evidence above around high risk patients resonates with current health services literature on decision-making which was referred to in the introduction to this chapter (Thompson and Dowding, 2002, Samuriwo and Dowding, 2014). The more complex the patient, the more difficult the decision will be. Thus, the health services staff may have been in an uncertain position, not knowing which choice to make for the best for the patients who presented with several comorbidities. Several models to help decision making at initial admission offer insights into this area, for example the work around recognising sepsis in patients (Johnson et al., 2017, Syyed et al., 2015). However, acutely presenting symptoms, such as sepsis, are bound to be prioritised over skin status, and less obvious symptoms (like skin damage) are rarely focussed on at this stage. This is especially true regarding pressure ulcers which sit behind a more acute diagnosis needing urgent attention (Evans, Evans et al., 2006). Then gradually, pressure ulcers which deteriorate may become the worst symptom and in turn lead to acutely presenting and life threatening symptoms. The priority route for patients is set out in a process diagram below (Figure 6.1).

Figure 6.1: Priority route for patients



Thompson and Dowding (2002) discuss the idea of super-strong rules when making decisions, similar to the priority route I have set out in Figure 5.1 above. They use an analogy of horse racing to illustrate. There is never a certainty in racing that one horse will win, but some rules outweigh others, e.g. form and previous race history. The same is true of decision making for patients, particularly if they are complex. Although health care staff cannot guarantee an outcome, due to previous knowledge of patients and probabilities, some decisions can be made based on stronger options (for example dealing with an obviously septic patient) and possible outcomes. Pressure ulcers however, fall into the category of smaller rules which sit alongside stronger diagnoses, until they take over as a more serious issue, as with the patients within this study.

6.11 Insights from organisational culture literature

According to (DiCenso et al., 1998) evidence-based decision making generally involves combining clinical expertise, patient preferences, and research evidence within the context of available resources. This echoes March and Simon's work on *Bounded Rationality*, which proposes that when individuals make decisions, their rationality is limited by the information they have, the cognitive limitations of their minds, and the time available to make the decision. Decision-makers can only ever seek *a satisfactory*

solution, lacking the ability and resources to arrive at the optimal one (March and Simon, 1958, Simon, 1955). However, I would argue that this area of decision-making is more aligned with a 'social rationality' where decisions are made within a complex system and are based within social as well as cognitive systems. This concept will be developed in the Final Discussion chapter of this thesis, referring to all of the theoretical chapters, however, it also leads on to the next area of decision-making regarding this study, which is around how decisions are made collectively and alongside colleagues.

6.12 Who makes the decisions? Evidence from the data

In several cases, (namely Bernie, Chris, Elliott, Frankie and Glenn), nursing staff did not make a definite decision, until much later, to refer to Tissue Viability, which is consistent with findings from elsewhere, (Samurio and Dowding, 2014). In some cases the doctors involved in the patients' care tended to make a more definitive decision what to do next (particularly for Alex, Bernie and Danni). For example, Bernie was on a stroke rehabilitation ward. The doctor asked the nursing staff to refer her to the Tissue Viability Specialist, and noted this n the patient's notes. Yet this conflicts with the idea that pressure ulcer care is in the remit of nursing staff. The doctor was surprised that he had to get involved as he always saw pressure ulcer care 'as a nursing thing'. This belief was stated in his interview. Alex's consultant was the main decision-maker over her care, which was picked up in several interviews with nursing and HCA staff, despite the private disagreement of the nursing staff on the ward. Alex also followed her surgeon's advice against the advice of the nurses (which differed) and this caused a degree of tension between her and the nursing staff. The consultant's view was noted by the ward sister to be 'out of date', yet the consultant appeared to override the nursing staff's decisions. There is little reference to decisions made for Chris and Glenn by doctors regarding their care, so this was less of an issue in their cases.

6.13 Insights from the health services literature

This issue of delaying and deferring decisions is referred to in some of the decision-making literature, for example, Thompson et al (2009) suggest, rather sweepingly, that nurses need more confidence in making autonomous decisions, rather than referring on to specialist services. (Thompson and Dowding, 2009). However, this seemed to be supported for some nursing decisions around pressure ulcer care for the patients in this study, in that referrals and escalations were not made in a timely manner, as shown above, and they were overridden by medical decisions. Following recent policy changes, both nurses and doctors are now both supposed to make autonomous clinical

decisions about patients. However, it has been shown in health care and political literature that medical dominance and the medical profession has limited the full realization of nursing's historical rise in status to autonomous decision makers (Chua and Clegg, 1990) (Schutzenhofer, 1987). In a qualitative study of English nurses and decision making processes carried out by Traynor et al (2010) nurses often described themselves as 'overruled' in hierarchical decision-making processes, where they had to comply with decisions made by other, higher ranking nurses or by other professional groups, notably medical doctors (Traynor et al., 2010). The study was small scale and only involved qualified nurses attending post-qualifying courses at a London university, however, it offered some insights into the 'experience' of nurses and 'situational decision-making'. Participants were asked to talk about influences on their decisionmaking, and the responses were that staff used 'situated decision making' and managed their decision-making in a very complex way. This highlights that, despite a professional rhetoric which strongly emphasises its autonomy and separateness from medicine (Salvage, 1988) nursing's close proximity to the medical profession raises the question around how far it exercises control over its own practices (Walby and Greenwell, 1994).

According to a study focusing on 120 nurses' use of research in decision making, (Thompson and Dowding, 2009), many of the decisions they faced were made in *conjunction* with colleagues or specialised sources of advice such as clinical nurse specialists, pharmacists or doctors. Although this should highlight the essence of a multi-disciplinary team. Often, however, these sources constituted 'information' sought as a response to uncertainty. At other times the other individuals were 'stakeholders' in a decision and their views had to be accommodated in the decisions made by the nurse – for example, doctors' role in prioritisation of cases for discharge. Almost all the decisions nurses made which involved stepping outside the realm of personal experience and internalised knowledge, involved these other sources.

This issue relates again to the literature on the autonomy of nurses (Thompson et al., 2004), where their role is currently being elevated as decision makers in UK Health Policy (Begley et al., 2013). This role is often in conflict with medical staff regarding their historical position as primary decision makers (Chua and Clegg, 1990, McDonald et al., 2005).

6.14 Insights from wider safety and organisational literature

Who makes decisions and how, links again to the work of Hammond (1996) on human judgement, where medics, for example, are expected to make decisions as part of their medical training, and the focus of this is often on a 'coherent' approach to decision-making. This was referred to earlier in Chapter 3. This coherent or rational approach is in spite of the move in the 1990s towards the more evidence based model for decision-making. In the 1990s, the correspondence approach gained momentum with the evidence-based medicine (EBM) movement, defined as "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. (Sackett et al., 2007, Sackett et al., 1996)(p.71). Nursing has been associated more with evidence based and structured decision making, (Thompson et al., 2004). This dichotomy in how staff make decisions for patients with pressure ulcers is discussed in further detail in the Discussion below.

6.15 The role of risk assessments

Risk assessments in wound care do not currently contain elements of decision making for pressure ulcer care, as they tend to be 'static', and offer a one off picture of a patient's risk at a point in time. Validated tools such as the Waterlow risk assessment and the Braden scale (most commonly used) are not currently linked to a workable care plan (Samuriwo and Dowding, 2014). These tools tend to offer a recommendations list based on the scores, but the list is general and does not help staff to make informed choices. Evidence from a systematic review in this area found that nurses did not seem to use a pressure ulcer risk assessment score (PURAS) as the basis for their judgement of pressure ulcer risk on a routine basis. A PURAS was used by only 32% of the nurses in one study (Acaroglu and Sendir, 2005) and only 27% of the nurses in another study (Tolmie and Smith, 2002). Some nurses (between 11% and 23%) also reported having more confidence in their clinical judgement than in PURAS, (Gould et al., 2004; Tolmie and Smith, 2002).

6.16 Risk assessments: Evidence from the data

For patients involved in this study, the risk assessments were not used adequately in most cases to make any decisions about patient care. For Frankie, for instance the Ward Manager noted that she scored 'at risk, according to the Braden scale'. However, Frankie was 'high risk' as she had lost a large amount of weight and was post lengthy surgery, and immobile. The Matron concerned with Frankie also noted that 'the

minimum expectation would be then that the Braden [risk assessment] would be done, you would have a daily skin assessment and a weekly Braden...But that wasn't done'.

For Bernie, the TVN review noted that her skin assessment and risk assessments were not completed adequately. She stated 'There is no record of risk assessment in A&E or on the acute assessment ward. A Braden score is recorded 6 days after admission on the stroke ward. The score assesses a low level of risk but is probably inaccurate.'

For Chris, however, on the first vascular surgical ward he was on, the risk assessments were fully completed and done regularly, so there was a clear picture of how his skin status changed from week to week. This corresponded with his own view of noting how things were 'better' on that ward than the community rehabilitation ward.

6.17 Insights from the health services literature

Although risk assessments are noted to play a pivotal role in pressure ulcer prevention according to authors in the field of nursing care (Arblaster, 1998) (Bolton et al., 2007), this study, and others have pointed to repeatedly unwell scored risk assessments. For example, a large scale Swedish cross sectional survey of retrospective audits identified that there were a number of inadequacies in pressure ulcer related nursing documentation of 413 hospitalised patients (Gunningberg et al., 2008, Gunningberg et al., 2004). These shortcomings included the omission of a recognised pressure ulcer grading scale, poor pressure ulcer risk assessment and no clear statements about the measures taken to protect the patients' skin (Gunningberg et al., 2008, Gunningberg et al., 2004).

Pancorbo-Hidalgo et al., in a study on risk assessment sensitivity reported on sensitivity and specificity estimates for validated pressure ulcer risk instruments, and concluded that the Braden scale showed optimal validation and had the best balance between sensitivity (57.1%) and specificity (67.5%) as compared to the Norton and Waterlow scales (Pancorbo - Hidalgo et al., 2006). However, the low values in general suggest that Braden scale scores poorly predict who will develop a PU and who will not. A comprehensive risk assessment framework, based on patient risk factors has recently been field tested (Briggs et al., 2013). An important feature of this risk assessment framework (named PURPOSE-T) is the inclusion of skin status which was identified as a key predictor of PU development. It is hoped (early findings are indicative of good inter-rater agreement rates) that this latest development in risk assessment tools may shed light on how to incorporate a more useful and predictive

pathway for high risk and immobile patients, which guides staff better in decision making.

6.18 Insights from safety literature

Risk assessments are intrinsic to safety literature in general. The National Patient Safety Agency (2004) highlighted the importance of risk assessment when it published its Seven Steps to Patient Safety. These steps included the need to integrate risk-management activity, involve patients and implement solutions to prevent harm. Risk management is an essential part of the NHS focus on patient safety as it allows staff to minimise both the risk and the consequences of an adverse event. It can also provide an early-warning system and maximise the probability of a positive outcome. Therefore, it is important that staff prioritise risk assessment in their practices. However, for some of the patients within this study, this importance was not recognised.

6.19 Insights from organisational culture literature

If an organisation is focused on safety there should be recognition of both risk analysis and assessment. In Vaughan's study of the Challenger launch, risks were taken by the staff, in launching under unsafe conditions, which were indicative of a risk-taking culture where financial priorities overshadowed the safety concerns and the risks pointed out by engineers were overridden.

6.20 Discussion

However, where does this evidence lead us in terms of assessing the utility of decisions and judgements made by health care staff about the patients with pressure ulcers in this study? It appears from the above evidence that decisions about wound care in particular, are often delayed, deferred, and made under time constraints without full knowledge of patients, who are complex. This would support the idea to some extent that this impacted on the patients' severe pressure ulcer. We also know that delays in decision making and its impact on patients is also supported by other studies in this area (Samuriwo and Dowding, 2014, Catchpole, 2013).

However, the data in this study also suggests that a naturalistic decision making paradigm is a prominent feature of how health care professionals make decisions regarding preventing pressure ulcers, incorporating uncertainty, time constraints, with ill-defined goals and decisions that are non-linear. Staff members seemed, within this study, to make intuitive decisions and judgements, rather than processual or scientific

logical decisions, despite given certain tools, such as risk assessments to aid clinical judgement. Although it would be fair to recognise the limitations of these risk assessments and the clinical variation and uncertainty, which make them an 'adjunct' to clinical judgement. This nevertheless supports the idea, raised in the introduction to the chapter, of experienced nurses using their expertise intuitively, rather than reliance on processual decision aids. This makes the case also for training in pressure ulcer prevention and management for novice staff to increase their knowledge and understanding in making decisions, rather than reliance on snapshot tools. The use of risk assessment tools was varied from the evidence in this study. The validity of these tools as decision aids has also been brought into question by other experts in decision-making (Samuriwo and Dowding, 2014). This issue also relates back to 'mindless' or automatic processing practices, which are discussed in more detail in Chapter 7 (Mindless safety culture). There was little evidence in the documentary analysis and interviews carried out as part of this study that staff were adhering rigidly to risk assessments and protocols for several of the patients.

It seems also apparent from the data analysed that the complexity, or high risk, of the patients is an important factor leading to the way they are dealt with. What was highlighted from the evidence above is that patient complexity, high risk of pressure ulcers and the uncertainty around decision-making must somehow be accounted for better within a large system of health care if severe pressure ulcers are to be prevented. Rather than ignoring this uncertainty, which seems largely the case for the patients involved, who get lost within a decision-laden system, there must be a more effective way to make intuitive decision making more transparent in the earlier stages of a patient's pathway. For some staff (where they used a decision tree in other studies regarding pressure ulcers) it appeared to be a useful aid (Samuriwo and Dowding, 2014).

If we also consider social judgement theory regarding the decisions made, the idea that an individual makes a decision based on a number of factors, and there are few possible outcomes based on these factors, then it becomes easier to understand. This incorporates the social rationality principle mentioned briefly earlier in this chapter, developed by Brunswik (1952) and further explained by Hammond (1996). For example, Brunswik's lens model (1952) (on which social judgement theory is based) is a good way of modelling this idea simply. Clinicians use 'cues' to make a judgement. For example for high risk patients this could be noting the frailty of the patient, the age, the presentation of their illness. However a judgement can be weighted in different ways according to how the cues are used. Two different clinicians (judges) may arrive

at different conclusions based on what weighting they give to each cue. One, with expertise in respiratory medicine may focus on the wheezing of the patient, another who has recently seen a Category 4 pressure ulcer develop in a patient may focus on the skin status. Therefore, crucially even before 'decision cues' are used there are also 'environmental' influences on the judge. These can include not only the expertise of the person judging, but time constraints to actually make a decision, lack of knowledge, changes to ward environment affecting the type of judgement cues and so on. Thus, rather than focusing on autonomous decision made by an individual nurse, who refers after an assessment of a wound for example, it may be more helpful, yet more complicated, to work out how decisions are made within an environmental context. Decision analysis may be useful if it focuses more on clarifying which other social influences are also at work, but there is not space to discuss this here. Alternatively, the next chapter on Mindless Safety Culture uncovers some of these influences. This finding also echoes the earlier references to decisions made in a naturalistic system where other influences prevail (NDM).

6.21 Normal accidents waiting to happen

This study is retrospective in nature, which meant staff were able to reflect later and report on decisions they made after the event. Often we are not aware of the wrong or right decision in real time (Perrow, 1984). It is easy to say this should have happened or that, but the staff do not always have the resources available at the time that we do when we look at what should have happened for a particular scenario. This is one of the benefits (and faults) of Root Cause Analysis and other such investigative techniques. The practice nurse involved with Danni suggested that in hindsight she would have reacted differently to her pressure ulcer. However, hindsight can also offer biases towards us knowing more when we piece all of the facts together after an event. In other words, the person looking retrospectively, attempts to make sense, or a coherent whole, out of all that he knows about the event. Fischkoff (1975, 2003) advises that "In situations where information is limited and indeterminate, occasional surprises—and resulting failures—are inevitable. It is both unfair and self-defeating to castigate decision makers who have erred in fallible systems, without admitting to that fallibility, and doing something to improve the system." (p.311).

At the time, particularly in the cases of Bernie, Danni and Frankie, staff members dealing with the patients made the decisions that they felt were appropriate at that time, not fully aware of the alternative consequences if anything else affected the decision.

In a huge system such as the UK National Health Service, with so many interchangeable parts, things must inevitably go wrong, as this uncertainty is irreducible (Hammond, 1996) noted earlier in this chapter. 'Medicine used to be simple, ineffective and relatively safe; now it is complex, effective and potentially dangerous" (Perrow, 1984). This is where Perrow's concept of 'Normal Accidents' becomes so integral to this study. Although doctors in particular, are trained to be autonomous in their decisions, this is not always helpful in such a large system with so many influences. There is something about the dialogue between doctors and nurses, and taking in to account their social environment, which we need to tease out regarding their the decision making to make it more equal for all professions, and more open to scrutiny, so we can learn how to make the best choices in uncertain circumstances.

6.22 Conclusion

The evidence gathered in this area would suggest that issues with delays and the ability to make decisions in an uncertain environment did impact on the severe pressure ulcers which developed in patients in this study. They certainly appeared to have some degree of involvement. Although these claims remain at an exploratory and qualitative level of analysis. This conclusion however, leads us to think about the systems of care in pressure ulcer prevention, rather than individuals simply being accountable for decisions they made at the time. The theoretical debates raised within this section also suggest that staff use intuition to make decisions in a complex environment regarding prevention and treatment of pressure ulcers, rather than relying on validated tools such as risk assessments. These debates highlight gaps in frontline practice and there may be further value in clarifying the actual decisions made using decision analysis within a social environment, rather than focusing on an individual's actual decision. It is also possible that expectations are not high enough of prevention and management of pressure ulcers at initial presentation of complex patients. Future consideration could be given to awareness-raising at frontline level and a more prominent research and service improvement focus on the decisions made regarding pressure ulcer prevention and management.

Chapter 7: Mindless or mindful safety culture: The impact on pressure ulcer development.

7.1 Chapter summary

This section focuses on evidence which was gathered to formulate the question whether or not a 'mindless' style safety culture contributed to the development of severe pressure ulcers. This chapter first defines safety culture and situates it within a complex adaptive system. It then explores some of the reasons why professionals within this study failed to respond to patients in a timely manner. The healthcare environment is then further examined for evidence which supports or contradicts the 'mindless' hypothesis. Finally, the chapter discusses the reasons for supposing that mindful awareness will result in a safer culture.

7.2 Introduction

Safety culture is an ill-defined concept (Vincent, 2010). As patient safety has evolved as a discipline, there have been more detailed developments in defining what it really means. It originates from the concept of 'organisational culture', which grew in popularity in the 1980s. In brief, and given that the history and debates around organisational theories would be the basis for another thesis, it suffices for the purpose of this chapter to highlight that organisational theorists moved the focus away from structures and management practices (see Weber's Bureaucracy Theory, and Taylor's Scientific Management Approach) (Weber et al., 1947, Taylor, 1913) towards an emphasis on the 'culture' and 'values' of organisations in order to interpret and understand them (Schein, 2010).

7.3 Definition of culture

'Culture' within an organisation is typically thought of as the sum of a group of specific characteristics. These may be behaviours, day-to-day rituals, ceremonies, practices, unwritten rules and relationships (Kroeber & Kluckhohn, 1952 (In (Bidney, 1954). Alongside 164 definitions that they collect around culture, Kroeber and Kluckhohn note, 'the psychologist tends to focus on the individual, the sociologist on social structure, the anthropologist on culture' (p.200). This thesis attempts to combine all three of the above approaches to understand why severe pressure ulcers develop within the healthcare environment, incorporating the individual, the social structure and the culture (see Method and Literature Review).

Psychologically-oriented cultural theorists see organisations as influenced by underlying beliefs, norms, values, attitudes, and systems of knowledge, which are consistent and enduring. For them, culture is a composite but static 'social fact' and dependent on individual cognition (Hofstede, 2001). For others, culture is better construed as being dynamic and emergent rather than static (Chia, 1996, Davies et al., 2000b). Essentially, culture can either be defined in terms of shared meanings held and exhibited through behaviours, or instead defined in terms of people's practices. The central debate over the definition of culture is around whether culture is either what an organisation 'has' or 'is' (Vincent, 2010, Hollnagel et al., 2013).

In a synthesising view of the different meanings of culture, Schein offered a composite model (1985). At the surface level Schein positioned visible artefacts, such as structures, dress and ceremonies. He explained the median level of the model as beliefs and values that appear outwardly as assertions, strategies and goals, and the third, underlying level consisted of unconscious assumptions, taken-for granted expectations, thoughts and feelings (Schein, 1992). Schein articulated this further in his 'Organisational Culture and Leadership' work (Schein, 2010), where he speaks of culture as 'the foundation of the social order we live in and the rules we abide by'. Schein refers to anthropological models of culture when he asks us to think of ways in which we share experiences, such as group norms, observed behavioural regularities, values, habits of thinking and shared meanings. However, he adds 'structural stability, depth, breadth and patterning or integration. Above all, he argues that culture is about shared assumptions that are learned by a group. These assumptions can be taught to new members as the correct way to perceive think and feel.

In applying this theory to healthcare, the priority of patient care is the overriding *value*. Underlying this there are differences between professionals and different providers, in terms of their *attitudes*, *formalities* and *power* to overrule each other. Vincent summarises this further in his description that culture in healthcare can be seen as 'the way we do things around here' (Vincent, 2010).

7.4 Safety culture within health care

Safety culture is one aspect of an overall 'organisational culture'. The UK Health and Safety Commission (1993) offered the following definition of safety culture as 'the values, attitudes and behaviour that determine the commitment to an organisation's health and safety programmes.'. The culture of safety in health care is often seen as an evolving concept, and focuses on preventing medical errors and maintaining patient safety. It emphasizes mindfulness to danger, communication and taking an active

approach to risk (Weick and Sutcliffe, 2001). Promoting a culture of safety has become one of the pillars of the patient safety movement (Francis, 2013, Department of Health, 1997, Department of Health, 2013b). This is despite recurrent debates about the definition of culture (Vincent, 2010). In recent years there has also been increasing understanding within healthcare that various factors such as the emphasis on efficiency and cost, and professional norms among healthcare providers combine to create a culture contradictory to the requirements of a safe culture (Vincent, 2010). Consequently, despite efforts towards a so-called 'mindful' safety culture, the culture of the healthcare industry is regarded as a potential risk factor threatening the patients for whom it provides care. At frontline level, Weick and Sutcliffe (2001) and Hollnagel (Hollnagel et al., 2013) encourage an organisation to have a 'mindful' safety culture in contrast to a 'blame' or 'mindless' culture and to express expectations by praising what is approved and making clear what is disapproved. This is in contrast to a 'culture of low expectations' or 'laissez-faire' approach.

7.5 Safety in a complex adaptive system

On the other hand, to refer to safety simply as 'culture' has been described as 'conceptual shorthand' by other writers in the patient safety field (Hollnagel et al., 2013). Being safe can mean different things to different groups of people (see previous chapter on the patient role for a debate around this dichotomy) and can be described in a number of ways. Other experts in the area of patient safety have preferred to conceptualise health care instead as a 'complex adaptive system', which allows for a different, more structural lens to examine safety. A system is defined by a collection of components that cohere in a pattern to produce an outcome (Braithwaite; In Hollnagel, 2015). Complex systems refer to multi-scaled, diverse, interactive hierarchical and heterarchical systems, where behaviours cannot be predicted easily. The most common definition of a complex adaptive system, based on the work of John Holland, is a dynamic network of agents acting in parallel, constantly reacting to what the other agents are doing, which in turn influences behaviour and the network as a whole (Holland, 2006). Control tends to be dispersed and decentralised and the overall behaviour of the system is the result of many decisions made constantly by individual agents. A complex adaptive system emerges and changes, and can self-organise, adapt and learn from the 'bottom up' but this means behaviour within it is difficult to predict (Hollnagel et al., 2013).

Perrow conceptualised safety within a complex adaptive system in his work 'Normal Accidents' (Perrow, 1984). He suggests that accidents are inherent within a system. In

terms of specific accidents, he argues that we cannot predict them or know where they will appear, hence the term 'normal'. This debate has been covered more fully in Chapter 2 (Literature Review) in this thesis. However, Perrow's complex systems view (Perrow, 1984) sits alongside Vaughan's more socio-cultural view of what causes disasters (Vaughan, 1996) with both viewing safety and risk through slightly different lens'. To recap, Vaughan focused more on the social processes regarding the *Challenger* space shuttle disaster. She found, rather than an inherent systems failure, that poor judgement was behind the disaster within a culture which normalised risky or deviant behaviour and decisions.

The results of the data collection in this thesis, linked to the initial review of the literature, have suggested, in general, that the environment contributed to the development of patients' severe pressure ulcers, (Explanation D; and aligned with Vaughan's theory on culture) but this could also be understood in terms of 'sequences of events' for certain patients (Explanation C; aligned more with Perrow's theory on complex-adaptive systems).

Braithwaite (2013) suggests that, as agents within a system interact, they produce emergent behaviours and attitudes which then become the 'culture' and have distinctive, localised 'patterning'. These cultures within health care affect and react to each other, and can be grouped as wards or departments, or more localised small cliques of groupings, and in-group and out groups. Braithwaite thus argues, as does this thesis, that there is a place for both of these lens' within healthcare (Hollnagel et al., 2013). Healthcare can be understood as a complex adaptive system which has sub-cultures within it, one of which is a safety culture, and both elements of which contribute to the development of severe pressure ulcers.

The main question I am posing within this chapter is how far do the complex adaptive system or the safety culture (whether mindful or 'laissez faire') contribute to patients developing pressure ulcers? Also, can the two be juxtaposed successfully to study the development of severe pressure ulcers more usefully than current investigative techniques which are used within the NHS today (for example, Root Cause Analysis)? I have drawn together evidence from various data sources to examine these questions.

7.6 The systems perspective-lack of response

The sequence of events chronology and associated documentary sources (for example, local policies, clinical notes) were useful aids regarding the above questions, particularly in terms of a systems approach. I was able to examine the evidence

already set out in patterns as it unfolded over time. I was also able to delve into responses, actions and escalations within the health care environment as they happened during a patient's pathway, whilst exploring whether these were adequate, or contributed to the development of the severe pressure ulcers. This was poignant for those patients where the judgement by the expert team was that a sequence of events contributed alongside the environment (namely, Bernie, Elliott and Frankie).

7.7 Lapses in response-evidence from the data

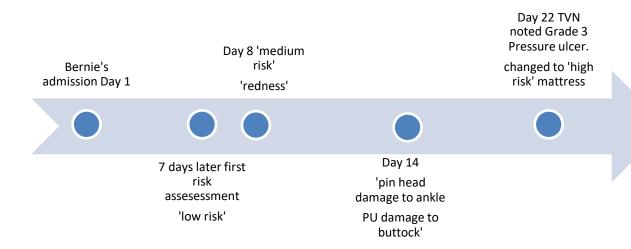
For some patients in the study, the sequence of events was a complex build up of lapses in care, which escalated, almost unnoticed by staff, into a severe pressure ulcer (see Reason 1997 and Perrow, 1984). Bernie, for example, already had leg contractures from a previous stroke (making her high risk for a pressure ulcer before she was admitted). She was brought in to A&E after collapsing. There was no record of skin assessment at point of entry into services. Seven days following admission, Bernie received a diagnosis of a simple lobar haemorrhage (stroke). She was confused. Her Braden pressure ulcer risk assessment score was 16, which scored her at low risk of a pressure ulcer, although she was immobile, and dehydrated so this was underscored. This was the first documented pressure ulcer risk assessment in her notes. Staff continued to miss her high risk of pressure damage during her admission. For example, on Day 8, a red area the size of 10 pence was noted on Bernie's thigh, and the following day she was transferred to a stroke ward, yet she was now only recorded as medium risk for pressure ulcers. The rationale for this was given as decreased mobility, incontinent, stroke, and elderly. The Ward Manager on the ward felt that 'patient care took priority over documentation'.

Bernie remained on the stroke ward for six days, and was confused throughout her stay. She was then transferred to a stroke rehabilitation ward (on Day 14) where 'pin head' pressure damage to her ankle was noted at transfer, and she was noted to have Pneumonia. At this point Bernie also was noted to have pressure damage (2cmx 2cm size) on her right buttock. Bernie's mattress was changed to a 'high risk' mattress, but 'no nimbus was available'. (A nimbus mattress is an alternating air mattress and recommended for patients at high risk of pressure damage). This was nine days after the first record of any skin damage (Day 16). She kept returning to sleeping on her right side while she slept. She received a nimbus air mattress ten days after skin damage was first described. The medical consultant advised to refer Bernie to Tissue Viability, although this action was not carried out until five days later (Day 22), following another prompt by the consultant. The TVN in Bernie's case noted a lack of adherence to

policies when she said, 'Bernie clearly would come up as high risk on the scales'. However she added: 'more focus is generally placed on clinical judgement at the [local] trust site than on risk assessments, but why did the staff not use their clinical judgment to assess the high level of risk involved with Bernie?.'

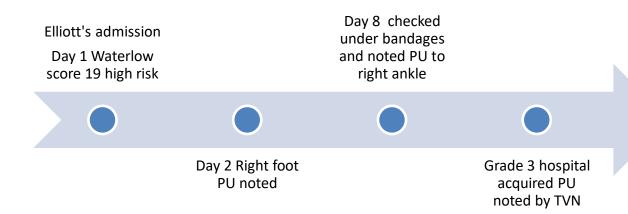
By the time she saw the wound, the TVN noted that the ulcer was a Grade 3 (3cm x 2.5cm). She noted that Bernie was mobile in bed, but recorded in the nursing notes that she couldn't tolerate her left side (the side opposite to the side which developed a pressure ulcer) when sleeping. The TVN also documented that the wound should be reassessed weekly, and following this intervention it began to heal.

Figure 7.1 Bernie's pathway



Elliott had a similar experience in terms of missed documentation and assessments. He did not receive a timely risk assessment when he was admitted to hospital. He was nearly ninety at the time of the study, and was admitted into a district hospital, primarily with cellulitis.

Figure 7.2 Elliott's pathway



Elliott had a contracted leg (as did Bernie). He also had existing pressure ulcers, but there was some confusion about where these were during his admission, although there was a plan in both the nursing and medical notes to check under his bandages on his legs. It was found through the research investigation that Elliott had already developed a pressure ulcer pre-admission, but as the staff did not document the Grade of the pressure ulcer on admission, and appeared not to have checked under his bandages for five days, it was recorded by the TVN on review as a *hospital acquired* Grade 3 pressure ulcer (see timeline B above). A staff nurse felt that the reasons why staff did not check under bandages was that staff were 'afraid' and 'worried' about how a wound may have been dressed by a district nurse. Also, there was a concern from staff members that the pharmacy shut outside office hours, 'because it's five o'clock…pharmacy's shut….we do have an emergency cupboard but that's not to say that everything would be in it.'

The clinical risk coordinator added that there was no evidence to show that staff had checked under the bandages to check for a pressure ulcer. She noted that nursing staff 'hadn't taken the bandages down...'she added that 'we know that from the information. There's no documentary evidence....until Tissue Viability took them down: And if we can't prove it was there on admission, we've got to own it.' Although Elliott came in with a pressure ulcer 'under his bandages' the TVN had no option but to record the previous pressure ulcer as hospital acquired because there was not documented proof that anyone had checked or assessed his skin before. His daughter (carer) however told the researcher that he had had the pressure ulcer for around six months:

A: 'So I would say he had it for about six months here [home].

Q: On his right ankle?

A: His right...it was weepy but it wasn't infected. And then it gradually got bigger, and we got the community nurses in ... maybe two or three times a week, and if it came off or needed changing, I would do it...When he went into SUPPORTED LIVING... I would say it was only about that big... 50p size.'

The district nurse also noted that Elliott's pressure ulcer was a Grade 2 before his admission to hospital. She stated' It was probably *a 2* when I first saw it. It wasn't a Grade 3 when I last saw it'.

There is no real way of knowing whether this is correct however, as another district nurse who was interviewed felt that it was a Grade 3 when she had last seen it. Despite the difference in judgement, the pressure ulcer had developed before the admission to hospital.

7.8 Insights from health services literature

Both of the sequences of events above (see Method) highlighted delays and lapses in response to pressure ulcer skin damage by healthcare staff involved. Bernie was not assessed (there was no evidence of documented assessments) for pressure ulcers until seven days after her admission despite her being a seriously unwell, immobile, high risk patient. Firstly, this highlights a lack of adherence to the local trust policy around pressure ulcer assessment and skin damage, which states that all patients identified by the screening process should have a 'documented formal risk assessment commenced within 2 hours and completed within 24 hours of admission or transfer'. Secondly, national NICE guidance states that patients should be assessed for pressure ulcer risk when they are admitted into an NHS service (Elliott's was not) and RCN guidance (2001) recommends that: 'The timing of risk assessment should be based on each individual case. However, it should take place in under six hours of the start of admission to the episode of care.'

A key issue in management of pressure ulcers is identifying individuals who may be at risk of developing ulcers, so that prevention strategies can be introduced (Samuriwo and Dowding, 2014). However, this relies on the ability of nurses to accurately identify in a *timely* manner whether or not a patient may be at risk of developing an ulcer. However, Samuriwo et al's review also suggests that nurses rarely use a risk assessment to help them to identify their patients' risk and that this impacts on the speed that care planning is commenced. There is also research evidence that

numerical risk assessments (e.g. Waterlow and Braden scales) have little effect on nursing judgement and offer little predictive value (Webster et al., 2011) Haigh and Pinkney (in press), so this may be one of the reasons why nurses in all of the examples above did not respect the local and national policies around timely assessment (Samuriwo and Dowding, 2014); (Johansen et al., 2014). This is despite the recommendations. More recent research in this area has developed evidenced based risk assessments, which aim to support care plans rather than produce a numerical score, but this work is in its infancy (Briggs et al., 2013).

For the patients above, who were assessed using numerical risk assessments, there was a similarity in the lapses in timely response by staff. This echoes research evidence which highlights that nurses often do not 'prioritise' pressure ulcer prevention. Athlin et al (2010) for example, found that nurses place a low value on pressure ulcer prevention, which reflects the same as the result from Moore and Price's (2004) Irish survey study, despite in the latter study the majority of participants expressing a positive attitude towards pressure ulcer prevention. This was not however, reflected in practice. Similarly, Samuriwo (2010) found that the despite the high value that nurses appear to place on pressure ulcer prevention, the day to day work is often delegated to HCAs. In this study this was the case for Bernie; the first documented pressure care entry is by a HCA. Samuwiro (2010) concludes that pressure ulcer prevention may be 'perceived' by nurses to be important, but 'less urgent' than other aspects of nursing and therefore easier to delegate. The time element is important, as it highlights that pressure ulcer prevention does not get urgently prioritised, and patients do not receive a 'timely response'. However, Samuriwo and Dowding's (2014) review also highlights that a combination of delays in a formal pressure ulcer risk assessment and the manner in which they are used can increase the risk of pressure ulcer formation and is not currently indicative of best practice. Yet guidelines for best practice are explicit in local trust and national guidelines. However, best practice guidelines did not seem to be followed in either of the cases above, which may well have impacted on the development of the patients' pressure ulcers.

7.9 Insights from safety literature

Much work has been done in the field of patient safety and lapses in response. The impact of Reason's modelling on the NHS was originally based around cognitive lapses at individual level, and thus began the movement towards the uptake of Root Cause Analysis (RCA) in patient safety and the NHS as a whole. Identifying lapses in care (as opposed to response) are very much at the forefront of patient safety frontline practices

currently. Indeed the author of this thesis herself, often finds herself debating with colleagues about 'lapses in care'. Although this highlights an issue around what a 'lapse in care' actually means, as it is not an easily identifiable construct, and whether 'lapse in response is a more helpful term, if it is at all.

7.10 Referral delays-evidence from the data

Referrals to specialist tissue viability services and decisions around care planning were not prioritised and were poorly understood, and even forgotten about, in some cases within the study. The expert witnesses stated this in their judgement that a referral was not made quickly enough for Bernie. They referred to a 'delayed referral.' The referral process to tissue viability was not followed through promptly in response to Bernie's Grade 2 pressure ulcer, after the expert witnesses also commented that 'they [the staff] didn't up the care at all...until she developed a Grade 2 pressure ulcer.' This was evidenced by a reminder written in the nursing notes by the consultant which states 'refer to tissue viability, suggested last week'. However, one of the junior doctors argued that the staff on the ward 'couldn't get tissue viability to see her enough'. This he added was 'because there's not tissue viability...there's only two of them and they are really busy'. This suggests that referrals to the TVNs may not be an easy task for ward staff, which would impact on how quickly staff referred.

In the community, a similar picture of delayed referral appeared around Danni's case, where delays in both assessment and referral by a practice nurse allowed her pressure ulcer to deteriorate unnoticed. The nurse did not refer Danni to more specialist services.

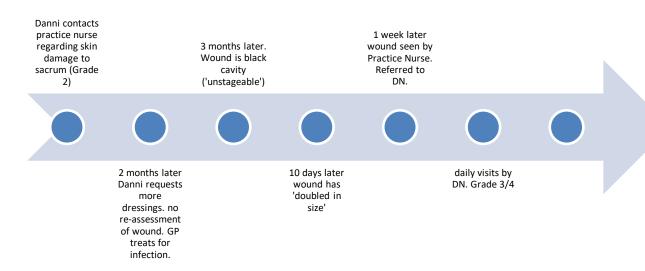
Danni visited the practice nurse at her GP's surgery, yet was never assessed comprehensively until two months after initially reporting skin damage. Danni first noted her pressure ulcer when she got out of the bath and she noticed a blood stain on her towel. Two days after this she made a visit to the practice nurse at her GP's as, in her words, 'she didn't have to see the doctor'. The practice nurse noted that there was a small broken area the size of a penny on her left buttock (she saw Bernie's wound at this point). The wound was irrigated and Danni was given a dressing, and left to dress the wound by herself, with her partner's help. The practice nurse noted to the researcher, 'we irrigated it...And Danni said then that she would look after it herself at that point.'

The expert witnesses highlighted this lack of referral by the practice nurse in their judgement of Danni's care, when they noted that, 'when Danni did find something, she

went to her GP and then they didn't look at her, assess her, and treat her from there, and if they couldn't assess her because she was in a wheelchair and it was too difficult to get her onto a bed, they didn't then refer her over to the district nurses to go and do that assessment at home.'

It was noted, in nursing notes, by the practice nurse initially that 'no action would be taken, unless the wound inflamed', however the wound did develop some inflammation, but no action followed from this and it was never measured properly. Two months after discovery of the pressure ulcer, Danni returned to the practice nurse for more dressings. The practice nurse did not examine the wound at this appointment. The wound had started to be smelly and sloughy at this point. Danni was seen by the GP and was prescribed Metronidazole. Danni said that the nurse had a word with the doctor at this point (Pt Interview). She was able to request more dressings simply by phoning the GP's surgery.

Figure 7.3 Danni's pathway



Three months later, Danni then saw the practice nurse again. The wound was now noted to be a 'black cavity', which was then irrigated, de-sloughed, a dressing was applied, and a further appointment was made for three days later. The nurse said in her interview that this was the first time she had seen the wound. She noted that it was larger than a 50 pence piece, but again did not measure it with a ruler, or take a photo of it.

Ten days later Danni returned to the surgery, and the wound had doubled in size and was smelly (nursing notes). She was noted by the practice nurse to be anxious and embarrassed by the wound odour. She was advised to keep off it as much as possible (medical notes). One week later, Danni was seen again by the practice nurse, after having been in bed all week to keep pressure off the wound. Her husband had been dressing the wound every day and applying gel. As Danni had to be bed bound now, a referral was now made to the district nursing team for home visits. The practice nurse did not record the size again at this point. She spoke of her mistakes in her reflections about this when she said, 'In hindsight, I ought to have probably referred her more quickly to the district nurses, rather than me dealing with it in-house.'

The nurse also noted that, 'It prolonged.' And explained that 'It started to do very well, but it wasn't healing up as quickly as perhaps it should have been, because she should have been off her bottom completely... when she came back it was getting a lot worse then I had to do something. But I ought to have done it earlier' (Practice Nurse).

A district nurse (DN) then came to see Danni and it was decided that she would receive daily visits. The DN did a Waterlow pressure ulcer risk assessment and Danni scored a 17, (high risk). It was noted that the wound was 4x3cms. The DN remembered that the wound was a Grade 3 to 4 (SPU). By the next month, following daily input, it was noted that Danni's wound was shallower. The HCA and staff nurse felt that the wound got better all the time. The wound continued to improve (nursing notes). Danni's pressure ulcer improved gradually and by the next year it had fully healed. Nursing input was stopped at this point.

However, as can be seen from the sequence of events above, Danni first went to the GP's practice nearly two years prior to the pressure ulcer healing fully. The practice nurse did not (from the evidence from interview and the chronological sequence of events) act as promptly as she could have done, which resonates with the above issues raised in Bernie's case around delays in response. The pressure ulcer was not assessed in the first few months (this is evidenced from the Practice Nurse's own interview), which compares with the issues with Bernie's admission, and Danni was not given any advice or knowledge about her sore, when it developed initially. Danni was left mainly to manage the wound herself, with her husband's help, until the referral five months later to the district nursing team. A lack of recognition by health professionals involved of Danni's high risk status seemed to be a contributing factor for the development of the SPU, coupled with the lack of referral to a TVN, or someone more experienced at wound care.

Additionally, Glenn's pressure ulcer was dealt with by district nurses for a long time before he was referred to Tissue Viability services. Glenn was 65 years old at the time of the study, and had suffered a spinal injury 34 years ago when he broke his neck.. His wife was his main carer, and he had district nursing input twice weekly to manually evacuate his bowels. Glenn stayed in bed most of the time on a pressure relieving foam mattress.

There were several district nurses involved in Glenn's care. The Tissue viability Nurse pointed out that Glenn's wife dealt directly with her directly eventually because of this issue. She said, it's funny how I've always spoken to her [Glenn's wife/carer] about the progress as well....because, at the moment with district nursing, it'd take me days to get the information I wanted. Because of how the teams have been formed, you'd never get the same person going in which can't be helped so I've always phoned her. Because I've found that I've got information that's good and worthy, I know that I can trust if she said 'I'm worried', it's something that I need to be worried about as well.'

This issue around delays in referral to the tissue viability team was also echoed by the expert witnesses when they noted that, 'the district nurses were task-orientated, the Category 1 development didn't raise any alarm bells with anybody, apart from the patient himself, who was worried...and there was no communication between anybody ... the district nurses didn't flag it up to the TVN or the spinal injuries unit, or anybody. Or the GP.'

The expert witnesses judged that, 'The organisational failures are really around the district nurses not picking up the cues, either the physical cues from the examination of him, or the messages from the patient and his wife, and acting appropriately on those messages, isn't it? Why aren't they?'

7.11 Insights from health services literature

When patients (particularly Bernie, Chris, Danni, Elliott, Frankie and Glenn) presented with initial symptoms of skin damage, the staff seemed to respond with a lack of urgency around escalating care regarding skin integrity. This was evident by analysing the sequence of events chronology. Also, when less obvious issues around lack of escalation were noticed in the sequence of chronological events, it became apparent that each delay can contribute to a worse outcome than initially imagined. However, aside from putting preventative strategies in and anticipating problems ahead (discussed above), there was a lack of prompt escalation of care and referral. Bernie's, Danni's and Elliot's pressure ulcers seemed to deteriorate under these circumstances.

As well as echoing the literature findings around lapses in care at the risk assessment stage, set out above (Athlin et al., 2010, Moore and Cowman, 2008, Samuriwo and Dowding, 2014), this issue resonates with literature around the tissue viability specialist nursing role, which remains poorly defined, and access to their advice and input can be variable (Flanagan, 1996). Staff seem unsure when to refer or how to use their input. Samuriwo (2011) found, in his doctoral study around nursing perceptions of pressure ulcers, that nursing staff felt the TVNs were too preoccupied with reviewing patients themselves and did not provide nurses with sufficient training to empower them to make appropriate decisions about pressure ulcer prevention and management. Although this work is based around the opinions of nursing staff, there still appears to be confusion around the role of the tissue viability specialist nurse and variability in how nursing staff are able to access their expertise (Catania et al., 2007, Samuriwo and Dowding, 2014, Flanagan, 1996). This may be one of the reasons why nursing staff above did not refer as promptly as they should have to tissue viability services. There is little high quality research around the role of the tissue viability nurse in clinical settings, and how nurses refer to them, so further research to examine the escalation pathway to tissue viability would be a useful exercise.

7.12 Insights from safety literature

The errors (mainly in documentation) and time lapses in assessment and escalation, despite not following local and national policies, may have not seemed an issue in real time to frontline staff working with Bernie, yet when the lapses in care were examined together over time, they highlighted a lack of overall response to Bernie's risk of pressure damage. The evidence from the above cases points to each pressure ulcer being caused by a complex sequence of events (Perrow, 1984) within a complex system which made it difficult for staff to recognise that their actions were contributing and interacting within that system to cause the severe pressure ulcers. Here was a combination of a lack of follow up and knowledge by professionals at the first point of entry to services, and a delay in treating a pressure ulcer effectively when it was in its early stages, but only seen clearly by patterning the events over time. This is also the style of investigating incidents which Root Cause Analysis (RCA) employs, with varying success, following Reason's Swiss Cheese theory (Hollnagel et al., 2015).

The technique of Root Cause Analysis (and other tools which examine evidence chronologically) is not without its critics, particularly in recent years. Dekker et al., and other prominent human error researchers, have been critical of the safety movement's reliance on procedural, reductionist solutions (Dekker et al., 2011). They have

highlighted how hindsight bias can thwart efforts to understand causality in serious incidents. Hindsight bias occurs when people investigating a situation already know the outcome, and they view the 'error' from a post error, rather than real time perspective. This issue was discussed in the Methods section of this thesis, so will not be discussed again here.

7.13 Insights from organisational literature

The danger however, with the enlightened position above, according to theorists such as Perrow, Vaughan and Hollnagel, is that we may simplify complex accident trajectories into simple, linear processes and identify decisions that may have been ambiguous in real time as 'wrong'. We may attribute blame when the actions of individuals are not blameworthy, but actually the 'whole' system is at fault (Dekker et al., 2011, Perrow, 1984, Hollnagel et al., 2013). This argument will be discussed more fully in the Final Discussion section of the thesis as it forms a recommendation for changing and improving current investigative practices in line with new directions in patient safety research.

However, aside from methodological weaknesses and debates around whether sequences of events are linear or complex, these sequences of events were noted by the review team to contribute *alongside* environmental or socio-cultural causes to the development of patients' severe pressure ulcer. Environmental and cultural influences are now discussed below.

7.14 Environmental contributions to severe pressure ulcer development

The environment was judged by the expert witnesses to impact *most* on the development of patients' pressure ulcers. For several of the patients within the study this was the case. Alex, Chris, Elliott, Frankie and Glenn were patients identified by the research team as those whom the environment was solely responsible for their severe pressure ulcers. Bernie's and Danni's cases also involved a sequence of events. One of the examples drawn from the data was that Frankie's pressure ulcer developed within a trust which was under organisational upheaval, and the environment around her played a significant part in the development of her pressure ulcer. This is described below.

7.15 Misplaced patients within organisational disruption-evidence from the data

Frankie was admitted to hospital following complications with an abdominal operation.

After a 4 day delay in diagnosis, Frankie had prolonged and complex surgery involving

two (specialist and general) surgeons and was transferred to a new post-operative surgical ward. According to the nursing notes, she came from theatre with no 'easy care' information. The nurse informed her that he/she had 'no proper admission documents'. The staff nurse told the researcher during her interview about the issues around having to ask the patient questions again, and highlighted some of the weaknesses in the current system, noting that 'She came from theatre so we won't have known anything about her whatsoever, apart from her name and what surgery she's had. So we had to just get the basics. So...you're going to pick somebody up from theatre that you've never met before...'

The specialist surgeon noted that Frankie would be transferring to the new ward from theatre. It was written that the doctor would 'ensure the weekend team were aware.' At this point, the doctor also noted that Frankie's sacrum 'appeared hot'. Aquafoam (a foam dressing to alleviate soreness) was applied. An air mattress (to alleviate pressure) was ordered and Frankie was advised to change position in bed. The following day Frankie was noted to be *at risk* of pressure damage. The plan was to assess and reposition her every four hrs. Frankie scored at *low* risk on the pressure ulcer risk assessment (Braden scale 18). Frankie was sitting out in a chair (no pressure relieving cushion was supplied (Nurse Interview). Her left bottom 'appeared red'. Skin was intact.

One ward manager in the trust told the researcher of the issues they faced overnight with other patients coming onto the ward with different needs, when she stated, 'That's where your key problem is. They originally had colorectal post-op patients, but then overnight they had to take the urology major cases as well. These are really poorly and...what I'm saying is their workload has doubled.'

One specialist surgeon noted that Frankie was part of organisational upheaval and this impacted on her movement between wards. She stated that, 'Frankie's (general) surgeon, would have liked her to go onto HDU (High Dependency Unit). But, you know, it was his first day at the other site; and I think he felt he didn't really have much sway ... you know, I think if he'd been here in his own territory, he would have got on the phone and said, look guys, this is not negotiable, she's going wherever. And I think if she'd gone onto HDU, then the assessments would have been different.' The specialist surgeon also reported that the general surgeon did not feel empowered by the organisational upheaval at that point to make a definitive decision about where Frankie went to, which meant that she was admitted onto a general post-operative surgical ward. The ward manager on the post-operative ward also added that the ward

moved to another site while Frankie was admitted, and that this had played a part in her pressure ulcer development. She stated, 'For us, it was a pain moving. You had boxes everywhere and it was higgledy-piggledy. So at the time she would have been on a busy ward...'We moved on the Saturday morning and it took us from 8 o'clock till half-one before all the patients were in the bays and the side rooms. And then we still had ... other things to do – you've still got your boxes to unpack, the drugs to put away, CDs to take from one cupboard to another, so it was quite labour-intensive.'

Frankie's description around the discovery of her pressure ulcers highlighted that she felt there was a lack of awareness of 'tasks' when she said, 'I think that when they first discovered the bruising there was a massive reaction but it wasn't followed through in any depth or detail.' She added that,' there didn't seem to be the resource or the level of awareness of the task to follow it through. So the fact that I'd been turned once didn't mean that I got turned again. The task got dropped.' One of the expert witnesses judged Frankie's treatment on the ward above as chaotic, and stated, 'The staff on the ward were all over the shop without adequate resources.'

The expert witnesses felt that one of the main issues with Frankie's stay were that staff did not realise or were not aware how ill she was on the several wards that she was on. One of them stated, 'I think the other issue that runs through all of this is that nobody appreciated how ill she was. So on the specialist ward there were delays, then on the post-operative ward there was a lack of recognition that she was so ill'.

Frankie was discharged 13 days after admission. The outpatient report stated that the pressure ulcer was then improving. Frankie's severe pressure ulcer thus appeared to develop in a particularly unstable organisational environment. The expert team concluded from the evidence that the organisational environment *caused* the sequence of events leading to the development of Frankie's severe pressure ulcer (D caused B in the explanations). Frankie was in the midst of an upheaval of the organisation i.e. surgical services moving hospital site.

Another example of where the patient was misplaced according to his or her needs, and the prevailing culture on the ward was not helpful, was regarding Chris, who was 'keen to go home' and was 'allowed' [in his words] to be sent to a rehabilitation hospital when he was still an unwell patient, thus still at high risk of a pressure ulcer. Chris had been in hospital for a long time leading up to the development of a new pressure ulcer. He had multiple chronic medical problems. He was already being treated for other skin damage which had developed at home. From the interviews with staff and from Chris's own account it appeared that the ward staff saw their unit as a rehabilitation ward, and

that this activity appeared to take priority over other patient care. The fact that Chris had to be assessed to see whether he was 'suitable' showed that there was a difference between this and acute hospital care.

Therefore, the staff, who were focused on rehabilitation, on this ward may have had different priorities than the staff on the acute wards that Chris had been on previously, which is similar to the different priorities on the specialist surgical ward that Frankie was on. The diabetic foot consultant involved in Chris' care also suggested that the rehabilitation ward may have had other priorities, She stated, 'If they are thinking his priority is getting him mobilised and they then are not fully aware of all his medical conditions that put him at such a high risk, then they may have miscalculated his risk. This means that they have probably made that decision not based on anything apart from what they want to be.'

7.16 Insights from the health services literature

Studies have found that if patients are 'wrongly' placed on a ward, otherwise known as 'outliers' this places them at more risk of injury (Czaplinski and Diers, 1998). The Czaplinksi and Diers (1998) longitudinal study included five years of patient data for approximately 11,000 patients who had been inpatients in one USA speciality hospital. Although the one site location casts doubt on generalising from the study, it found that outlying patients (Frankie fell into this category as she was both a specialist and general surgical patient) received a lower standard of care than on units where specialist nursing care was offered. According to the study it also affected length of stay. This result is also supported by a prospective cohort study by Schuurman et al, 2009, which found that length of stay was significantly increased in intensive care for patients with pressure damage, although this result wasn't significant for patients on cardiothoracic wards (Schuurman et al., 2009b).

7.17 Insights from wider patient safety literature

Patients who are outliers on wards may compromise input from knowledgeable staff, may provide an unsuitable ward environment, and can be inappropriate for individual patients' needs (Goulding, 2011). Goulding also argues in her mixed methods study on medical outliers, that the placement of patients on clinically inappropriate wards is a specific patient safety concern and constitutes a latent condition which may expose patients to a number of contributory factors that underlie adverse events. This resonates with the issues raised across this thesis around factors which are not readily observable to staff caring for patients (see Chapters 2, and 9).

As can be seen from the evidence above, the organisational picture is needed alongside the sequence of events, to understand what happened more fully. However, the issue with outlying patients is also coupled with other more socio-cultural organisational factors, which are outlined below.

7.18 Socio-cultural issues-evidence from the data

There was an amount of social and professional tension between staff groups on the rehabilitation ward that Bernie was on (Consultant; HCA 2) and unrest on the ward between different 'sub-cultures', which included longevity groups, different racial groups and hierarchical groups (HCA1; HCA 2; Consultant; Matron). This was due to two wards becoming one rehabilitation ward, as part of two hospital sites merging services. Although this appears superficially to be unrelated to Bernie's severe pressure ulcer development, there were, in this case, definite communication barriers amongst sub-cultures (new staff) and longer serving staff members. The lack of information exchange between competing groups meant that information was not passed on as it should have been. This resonates with safety literature around hierarchies and different cultures on wards (West, 2000), where different professional groups view information differently due to their backgrounds and skills, and communication is limited. This also relates negatively to literature on 'positive safety culture' which suggests that staff members need 'open communication and trust to foster a strong patient safety culture.

Ward staff ratios were not the recommended ones for stroke rehabilitation, 43% RN:57% HCA instead of 65% RN:35% HCA, these ratios included a slant towards more HCAs rather than qualified staff nurses who were trained more comprehensively in pressure ulcer care. The HCAs were the dominant professional group numerically on the ward due the larger ratios, and there was talk of new nurses who started working on the ward being 'one of us' [in contrast to the rest of the qualified nurses who were members of staff before a merger between two sites]. A HCA explained there was a problem with HCAs and nurses on the ward, 'it's difficult when it's on a ward like this where you've got staffing levels at which are just not right at all, you've got one qualified staff like I say to two healthcare, you've got your qualified saying...well, I'm sorry but I can't do this, I haven't got time... because, well they're so nasty aren't they?'

The social group issues were echoed by both the matron and ward clerk who highlighted that the amalgamation of wards two years ago had produced a 'difficult' culture on the ward. One other HCAs noted that she struggled to communicate with the registered nurses over pressure ulcer and personal care of patients when she stated,

'I'm saying to the qualified – I need help. She then added that the 'qualified' response was. 'I'm sorry but I can't, I'm doing medicine'. The HCA concluded that, this is when I'm in tears and I think to myself she needs cleaning up...What do you do, and then I'm going out of here not feeling appreciated'

7.19 Insights from the safety and organisational literature

Socio-cultural groupings in the NHS and how these impact on safety issues have been explored elsewhere and echo the evidence above. For example, Edmundson suggests that teams and staff members must feel safe with each other if they are to communicate issues and learn well together (Edmondson, 1999). McDonald also speaks of the differences between professional groups in her ethnographic work comparing doctors and nurses within operating theatres and how they follow different cultural rules, which mean they have barriers to communication (McDonald et al., 2005).

7.20 Discussion

When we look at the sequences of events and delays in response alongside the organisational environment, we can compare staff members' actions and responses within organisational contexts which led them to be less aware of pressure ulcer risks, for various reasons. Samuriwo (2010) usefully highlights that pressure ulcer care is not as high on nurses' priorities as it should be, which was clear from Danni's, Bernie's and Frankie's cases, for three different reasons. Danni's nursing input was hindered by the policies which meant a woman who was immobile in terms of accessing services had to attend a GP's surgery for a brief appointment. Bernie was caught up in cultural tension between staff groups, who did not pass information to each other. Frankie was admitted when the wards were in upheaval.

However, above all, the responses and decisions made for all of the patients above appeared to suggest a mindless (Weick et al., 2008) as opposed to a mindful awareness of skin care. Why was it that the staff just didn't respond with more awareness and recognition to patients who were all high risk of skin damage given that this area has neglectful and patient safety connotations?

'Mindlessness' within organisational research roughly translates as behaviour in an organization which has a reliance on often outdated routines, a dysfunctional awareness of a changing external environment, and the inner state of the people working in the organization. Some argue that mindlessness may be necessary for

repetitive work, but mindlessness closes us off to possibility, freezes our responses, and prevents needed change (Filo, 2013). Mindlessness, despite its detrimental general meaning is possibly a useful starting point, as it suggests the opposite of mindful awareness. Weick and colleagues (Weick et al., 2008) noted that within organisations when fewer cognitive processes are activated less often, then an actor goes into a 'mindless state' and acts in an 'auto-pilot' mode. This automatic processing is in response to repetitive and non-dangerous tasks which would elicit a prompt reaction, and is thus a mindless, automatic response. Others have argued that this is a 'failure to rescue' (Hollnagel et al., 2013) which is discussed in more detail in Chapters 2 and 9.

Alternatively, the concept of mindfulness, which originated in psychological literature by authors such as Langer (1989; 1997) refers to openness to novelty; alertness to distinction; orientation in the present, sensitivity to different contexts; and most importantly implicit, if not explicit, awareness of multiple perspectives; (Langer, 2016). According to Weick and Sutcliffe's systematic review (2001) mindful organizations spend more time examining failure as a lens from which to view the health of the system, more time preventing the simplification of tasks, more time observing operations and their effects, more time developing resilience to manage unexpected events, and more time locating local expertise and creating a climate of deference to those experts. These capabilities of an organisation are labelled mindful organizing (Weick and Sutcliffe 2001). Research on mindful organizing offers three definitions (Vogus & Sutcliffe, 2007a; Weick & Sutcliffe, 2007): (1) it results from bottom-up processes; (2) it enacts the context for thinking and action on the front line; and (3) it is relatively fragile and needs to be continuously re-accomplished. This contrasts very subtly, and must not be confused with Ray and colleagues' version of what they term 'organizational mindfulness' (2011). These authors claim that organizational mindfulness is evident when leaders create cultures that encourage rich thinking and a capacity for action. It is a more top down approach. There is not room in this thesis to debate these differing concepts further. Instead, a more recent approach I would like to elaborate on is Hollnagel et al. 's (2013) version of mindfulness, which offers a more elaborate view of this concept as 'rescuing, recognising and managing' emerging complications, and suggest that organisations which are mindful, are more able to rescue before failure occurs. This leads, they claim, to a more resilient organisation.

The concepts above, aside from being heavily debated amongst organisational safety experts (Levinthal and Rerup, 2006) resonate with the issues around the mindless responses that the patients faced in this study. So how can we change practice

concerning pressure ulcer care from mindless to mindful awareness? Or alternatively, away from 'failure to rescue' towards 'rescuing'? Levintal and Harrop ask us to think of organisational mindfulness as both a sustained high level of sensitivity to errors, unexpected events, and to subtle cues suggested by the organisation's environment or its own processes; and the capacity to engage in a flexible range of behaviour in response. They suggest that mindfulness involves thinking in real time, and is simultaneous with an action. In contrast less mindful behaviour is seen as routine and given less attentional focus (which has similarities to pressure ulcer management for some of the patients within this study). Mindfulness should be necessary both because ongoing organisational activity often deviates from plans and expectations (as with complex patients), and because ongoing activity may reveal not previously recognised issues (in this study newly developing pressure damage). In order to prevent unexpected events like pressure ulcers, mindful organisations should be preoccupied with resilience ((Hollnagel et al., 2013) which is the ability to contain and manage realtime unexpected events in an adaptive, flexible fashion (Levinthal and Rerup, 2006, Hollnagel et al., 2013). This means reinforcing automatic processes (such as conducting pressure ulcer risk assessments and responding to pressure ulcers) and raising them to a consistent level of awareness so that they do not slip into mindless practices. This, however, did not appear to be the case for several of the patients who developed severe pressure ulcers in the study.

To an extent this idea of mindful awareness has been addressed recently in the advent of 'safety huddles' or 'safety briefs' in healthcare, during which common patient safety issues (for example, patient falls, and pressure ulcers) are discussed regularly (once a day at least) on a ward setting as a multi-disciplinary team. These daily huddles aim to keep such safety issues at the forefront of staff's minds and thus increase situational awareness (Venkataraman et al., 2017). Safety huddles now form part of NHS Improvement's suggestions for patient safety best practice. A recent evaluation of safety huddles (the HUSH project; Huddling up for Safer Healthcare) found that 6,051 falls were prevented through the use of them. Based on cost estimates from NHS Improvement, this equates to £15.7 million in avoided healthcare costs (Improvement, 2019). However, research studies in this area are in their infancy, and work is mainly found through Plan Do Study Act Quality Improvement initiatives. Safety huddles have been found by some small scale studies however, to facilitate better information sharing and communication within and across departments and increase shared understanding of the cultural assumptions of safety, risk and threats (MacDonald, 2014). These have also been found to offer better quality of information sharing and

increased accountability, which enables a culture of collaboration, resulting in an increased quality of collective awareness of safety issues (Goldenhar et al., 2013). These interventions, which aim to increase mindful awareness of pressure ulcers and other patient safety issues in such a complex environment, and where other priorities compete for staff attention, would be a further area of systematic research.

7.21 Conclusion

Examination of the data in terms of sequences of events has highlighted the delays in response by staff members towards pressure ulcer risks in patients. In these cases specific events played a role: however these occurred in organisational environments which fostered a 'mindless awareness', and hindered the staff in doing their work to their best ability. This analysis of the evidence thus supports the question set out at the start of this chapter around whether mindless awareness contributed to patients developing severe pressure ulcers. Furthermore, if we examine the evidence using both a sequence of events and the organisational culture surrounding patients simultaneously, we can achieve a more comprehensive understanding of what might contribute to the development of severe pressure ulcers. This understanding is only partial, given the exploratory nature of this study and its tentative findings. However, these insights into pressure ulcer and the contextual influences surrounding them could offer research or quality improvement opportunities, to enhance the benefits of interventions such as safety huddles, and keep pressure ulcer care at the forefront of healthcare practice.

Chapter 8: Diffusion, poor communication and coordination between health care services.

8.1 Summary

In this chapter I examine the hypothesis that a lack of coordination and communication between professionals, sites, wards and settings contributed to the development of severe pressure ulcers in the patients in the study. This theory is explored using the psycho-social concept of 'diffusion of responsibility'.

8.2 Background

The Mid-Staffordshire NHS Foundation Trust Inquiry (2011) referred to the concept of diffused responsibility as a causal factor in the events where a number of patients died. Donald Berwick's (2013) government review, following the Inquiry, noted this issue as a general problem in the NHS. It stated that, 'Responsibility for oversight and remedy for quality and safety concerns was, and is still to some extent, diffused in the NHS in England, with that responsibility divided among many agencies, and with unclear or at times non-existent lines of coordination, communication, pattern-recognition and follow-up for action. When so many are in charge; no one is.' (Berwick, 2013). This divided responsibility was a key area identified within the review, and one of the many issues at the Trust around system and communication failings, which led to serious patient harm.

Social psychologists theorise that people tend to act differently in a large group than they would alone. Often when many other people are present, we feel less personally obligated to help. Known as the 'bystander effect, the phenomenon was tested in a number of classic social psychology studies by Latané and Darley (Latané and Darley, 1970), prompted by the stabbing and of a young woman Kitty Genovese, where no one intervened after hearing the woman screaming. She then died of her injuries. Latané and Darley used students as participants in one particular experiment, who were placed in a room—either alone, with two strangers or with three strangers to complete a questionnaire while they waited for the experimenter to return. While they were completing the questionnaire, smoke was pumped into the room through a wall vent to simulate an emergency. When students were working alone they noticed the smoke almost immediately (within 5 seconds). However, students that were working in groups took longer (up to 20 seconds) to notice the smoke. Latané and Darley claimed this phenomenon could be explained by the social norm of what is considered polite

etiquette in public, and that one feels less responsible to act in a large group. This has been known since the 1960s among psychologists as 'diffusion of responsibility'. Although the theory has been contested by other psychologists as being pre-women's rights, and lacking in socio-cultural analysis (Manning et al., 2007, Cherry, 1995) it remains an accepted and influential theory to date.

In a large system of health care, such as the NHS, there are many people working together for patients, and as well as the multiple interactions which characterise a large organisation, there is often a diffusion of responsibility and 'many hands' approach. The increased specialisation amongst the 'many hands' brings problems of coordination, communication, and cooperation, i.e. it is no longer possible for one person to hold all the specialist knowledge needed to treat patients. Members of a health care delivery team are mostly educated and trained separately. They have little informal communication aside from work (McDonald et al., 2005, Vincent, 2010). Thus they may have only limited understanding of each other's role (West, 2000). This is not just because of the increasing scientific and technical sophistication of medical care, but also because of increasing specialisation of the occupations and professions involved in health care. The nursing profession, for example, has become increasingly specialised over time (Samuriwo and Dowding, 2014).

Given some of the background theories on how people function in large groups, it is no surprise that communication failures remain one of the leading causes of adverse events in the NHS (Kitch et al., 2008, Leape, 2009, Kohn et al., 2000). Analysis of a patient's full care pathway is critical as communication failures are not discrete events and information loss in one phase of care can potentially compromise safety in a subsequent phase (Greenberg, 2007).

However, despite the awareness of the contribution of communication failures in current research, issues with communication and coordination between wards, professionals, sites, and agencies on the ground are still hard to prevent (Halverson et al., 2011, Kitch et al., 2008).

One of the themes to emerge from this study was a lack of coordination and communication between services wards, community and multi-agencies. Below, I explore this area to see whether or not the evidence within this thesis supports the hypothesis that these areas were a causal factor in the development of the patients' pressure ulcers. Also, I explore whether or not the evidence supports a theory of diffusion of responsibility. I have used the sequence of events alongside other data sources (e.g. interviews) to examine the area in question.

8.3 Communication issues at MDT level: evidence from data

Within this study, arising from my initial coding, there were recurrent themes which identified issues with communication and coordination at ward level between members of different professional groups within the multi-disciplinary teams. This had an impact on how shifts were planned and whether things were forgotten. For example, on the stroke rehabilitation ward where Bernie was admitted, the staff spoke of their frustrations around working with other professions. There was unease between nurses and health care assistants on this ward, which was partly to do with the merging of two wards from different sites. This had led to some resentment among healthcare assistants who were previously working on the site towards new staff. They spoke of working together as a team and how they felt left out, when they said during a collective interview, 'we're nursing assistants, healthcare assistants, we're meant to be assisting the nurse, not working on our own...and I think that's what's forgotten to be honest.' (HCA, Site 2). There were also issues with verbal communication on the ward between HCAs and nurses in handing over information between each other about pressure ulcers (HCA 2). Another HCA from the same ward stated about communication with nurses that, 'They don't give you feedback...they don't come to you and say to you...and I'm thinking to myself, well, I passed it on what's getting done about it, I want to know what's getting done.' The same HCA added further details about her frustrations with Bernie's skin care, 'She was incontinent, every time she was incontinent with faeces that made it worse, because of the dressings were getting in touch with the faeces. Now when you go to a qualified, and you say to the qualified... this dressing is all full of faeces, it needs changing -I'm sorry but I've no time, I'm doing medicine.'

One of the staff nurses, in contrast, when interviewed, felt that everyone helped equally to care for Bernie. She stated that, 'the physios did their bit, the night nurses did their bit, the day nurses and so on...' although she did not mention the HCAs' role.

Alternatively, the junior doctor on the rehabilitation ward noted that they found it difficult to contact the Tissue Viability Nurses. He said, 'I mean, away from medical, she had this pressure sore and unfortunately we couldn't get tissue viability to see her enough because there's not tissue viability... because there's two of them and they're really busy... I don't think they've got many people.' One of the staff nurses noted the same thing, when she said, 'the business of referring patients, isn't very good... if I want to refer somebody to Tissue Viability then I've to ring up and ask if I can refer this patient. Most of the time you don't get a person, you just get an answer machine, so I leave the

name of the patient, and often they do come, but sometimes people have said they've rung up and there's nobody there and they haven't left a message, or they've left a message, and people don't come. It could do with something...a form to fill in-a referral form.'

The TVN, in contrast, felt she hadn't been called early enough. She argued, 'when they first realised that Bernie was having this problem with not re-positioning...if they'd called us in then as a preventative measure then maybe we wouldn't have ended up with the pressure sore that we did have.'

However, (as shown in the earlier chapter around delayed response) the consultant had left a note in the nursing notes which showed a week's delay in contacting the TVN. He wrote 'refer to tissue viability, requested last week'. This evidence suggests that the staff on the ward did not act as promptly as they might have done in communicating over Bernie's pressure damage to other specialist areas.

The ward was very short staffed by nurses (noted in the consultant geriatrician interview, ward manager interview, and HCA interviews) and nurses seemed unable to deal with information straight away (evidenced in delays in nursing documentation), but also there appeared to be tensions between groups which led to a lack of communication between them (see previous chapter). For example, the consultant geriatrician on the ward noted there were issues between staff groups. He said, 'I know the HCAs very well...there have been issues between the HCAs and the nurses, about a number of things. I've witnessed it as an observer on the ward.' He argued that the HCAs, 'didn't feel listened to...and what else can you do except talk to someone else, outside the nursing system.' This issue may have been in part because many of the HCAs had been on the ward longer than newer registered nurses, which collectively they highlighted in their interviews with me.

Interestingly, the ward leader offered her view on why Bernie's pressure ulcer deteriorated, which she felt was around communication. She stated, 'there are times when you are missing some of the things and screening tools are not done promptly, they are not done as patients' conditions deteriorate or change or even get better.' She added that, 'I still think you would get your instance of pressure sores, things will still happen...but it [the severe pressure ulcer] developed.'

The physiotherapists rehabilitating Bernie also spoke of their frustration with working alongside other professions, and regretted that they 'hadn't just sat down as a multidisciplinary team and discussed her needs'. One physiotherapist felt that this lack

of team working on the ward had impacted on how Bernie was treated by all members of staff concerned, and contributed to the development of her severe pressure ulcer. This evidence was supported by other staff members working on the ward, such as the consultant geriatrician, staff nurses, and the visiting junior doctor. All expressed concern about communication patterns between ward staff. The expert witnesses also judged that this impacted on Bernie's severe pressure ulcer. They noted that, 'the lack of knowledge on the ward of the TVN role and how to contact them and how to do that referral, and they seem to put a lot of responsibility on the link nurse, but they didn't know who the link nurse was. They couldn't identify her, she'd left...it comes down to management, leadership and team-working.'

The expert witnesses judged that Bernie was passed on with a lack of responsibility between teams. They stated, 'There was lack of clarity about whose role it was to manage her risk. And it seemed like the nurses passed it to the physios and the OTs, and the OTs passed it back and thought it was a nursing role, the nurses seem to take what the consultant says or the doctors on the ward.' They concluded that, 'It was just a complete shambles, in terms of who was responsible.'

Similarly, for Glenn, in a community setting, the issue of communication between professionals was also apparent. No one except his wife appeared to take responsibility for coordinating his care. Each service carried out their own specific tasks and left without communicating or collaborating with other teams. The HCAs communicated well with the patient and his carer however, (evidenced from Glenn and his carer's interview). Glenn's carer noted the differences between the District Nurses and the carers when she said 'the district nurses... they're in and out. The carers are a completely different kettle of fish...they always bring it to my attention if there's any marks on his body whatsoever...Any red areas at all.' Whether or not the HCAs communicated with the DNs is not evidenced in this case.

Glenn and his carer felt alternatively, that poor communication between members of the DN team led to his pressure ulcer deteriorating. Glenn noted' 'They should have known which way the pressure ulcer was headed. But with different nurses coming in...Nobody knew...they kept saying... I haven't seen it for three weeks, or I haven't seen it for a while ... it was just getting left'.

The expert witnesses also felt that for Glenn, communication was an issue. They stated that, "...the failures are really around the district nurses not picking up the cues, either the physical cues from the examination of him, or the messages from the patient and

his wife, and acting appropriately on those messages'. They added, 'They didn't refer to the TVS. They didn't contact the spinal cord injury ...nobody did anything.'

However, for other patients in this study, on the wards particularly, there seemed to be more cohesion, at least between staff nurses and HCAs. An example where staff at ward level communicated well between professional groups was regarding Elliott's care. The healthcare assistant spoke of good communication between them and staff nurses, when she said, 'we tried to have a nurse and a healthcare doing things together so the nurse could see any changes or anything to the patient. I would say generally we tried to do the best that we could and because we were all friends and we knew each other it wasn't hard'.

For Alex's care the HCAs also appeared to have a good communicative relationship with the staff nurses. One stated that, 'the majority of time they (nurses and HCAs) all work together...and know what's going on with every patient on the ward'. She added that, 'if Alex's sore broke down they would all work together trying treatments, and if not they would try others, communicating through handovers.'

For Danni, the DNs and community HCAs also spoke well of each other and seemed to work closely as a team. When they were interviewed collectively, a HCA stated that, 'We discuss it as a team, don't we?'

Staff Nurse: As a team. And then you think oh well we'll try that next time we go, don't we?

HCA: Every day.'

Danni's pressure ulcer healed under the DN and HCAs who worked together closely, were aware of each other's roles and met frequently. The pressure ulcer however, had already deteriorated earlier, under the care of the practice nurse and GP. The communication between professionals was different, and not as effective at this point in Danni's care pathway. The practice nurse noted that she 'should have referred to the DNs earlier'. This issue will be discussed further below under the heading 'lack of communication between services.'

The expert witnesses judged that for Danni's case the practice nurse should have communicated Danni's needs earlier and referred her on to another, more specialised service earlier. They stated, 'in another GP's surgery the practice nurse may well make the referral much quicker, recognise that it's not within her skill set. So, you know, it's that bit, the referral on, that's the missing bit, wasn't it?'

8.4 Insights from health services literature

The findings from this thesis appear to support the theory that when communication is poor between the MDT this affects the development of patients' pressure ulcers. This was not only suggested by ward staff, but by the judgements of the expert witnesses for a number of the patient cases. Poor communication within MDT teams has been highlighted as an issue in health services literature. In a qualitative study by Sutcliffe et al. (2004), which focused on errors or 'mishaps', out of 70 of the identified mishaps, practitioner's knowledge (30) and communication (28) were cited most frequently as the most important factors that contributed to each mishap. The study only focused on one teaching hospital and only elicited the patient's view, therefore only offers one perspective of an error. However, the data showed that in some relational contexts too little information is communicated and is not timely. The authors of the study argue that communication failures arise from vertical hierarchical differences, concerns with upward influence, role conflict and ambiguity, and struggles with interpersonal power and conflict. Although these are grand claims, and not necessarily explored in depth, these findings echo some of the inter-relational conflict which is found in my study. This suggests an avenue for further exploration.

Improving communication has been a key area of focus in improvement work in latter years, bringing such interventions as 'teamwork training', to healthcare settings (Blegen et al., 2010, Dellefield and Magnabosco, 2014). Recent research studies describe promising results in general medical units, in operating theatres, and intensive care units where teamwork training sessions have been introduced as a means of improving teamwork and collaboration (Blegen et al., 2010).

Nevertheless, caution has to be applied to interpreting Blegen et al. study's results as there were a number of interventions implemented concurrently. This was the case for much of the research on improvement methods, which were studied as part of the literature review for this thesis (see (Al-Kandari and Thomas, 2009, Ausserhofer et al., 2013, Bosch et al., 2011). The Blegen et al. study raises issues with measuring safety climate as an indicator of improvement. This also resonates with the previous chapter in this thesis on safety culture, where definitions of safety climate and culture are themselves cause for debate.

8.5 Insights from safety literature

Nonetheless, effective teamwork has long since been agreed within patient safety to be an indicator of safer care, with initiatives such as structured communication between professions advocated as a good tool (Institute for Healthcare Improvement, 2004). For example, an experimental study in handover methods by Bhabra et al in 2007 found that there can be up to five handovers on wards over a typical weekend, and only 2.5% of information from the first handover is retained at the final handover if there is no written record. If notes are taken, 85.5% of information is retained. If a standardised proforma is used, this rises to 99% (Bhabra et al., 2007). For a number of years in the history of patient safety, studies have confirmed that communication breakdowns are involved in the great majority of adverse patient outcomes (Leonard et al., 2004, Wheelan et al., 2003).

These findings have also been the foundation for recent work on standardised proformas such as the SBAR, which originated in the Royal Navy as a method of improving communication. It stands for Situation, Background, Assessment and Recommendation. This way of communicating aims to capture as much information in a handover possible to facilitate communication.

One RCT study which examined the SBAR method of communication found that warfarin management in patients in an intervention group which used the SBAR was improved. The intervention was associated with a statistically significant and clinically meaningful higher percent of time in the therapeutic range, indicating better warfarin management (Field et al., 2011). There appeared however, to be no such structured communication within my study regarding pressure ulcer prevention or care at the time of data collection. Mostly, communication in pressure ulcer care appeared to be passed on intermittently, with no structured approach.

8.6 Insights from organisational culture literature

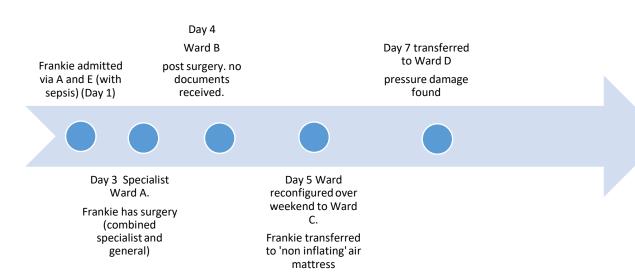
Since the time of data collection there have also been other culture focused interventions such as the safety huddle (Goldenhar et al., 2013), which was discussed in previous chapters. This initiative, although not tested widely to date, appears to foster better daily communication, teamwork and collaboration within teams (Venkataraman et al., 2017). Work in this area continues to gather support in health policy fields with the advent of the NHS Improvement guidance for spoken communication (NHS Improvement, 2019a) highlighting its important in patient safety. The evidence from my study also appears to support the view that less effective teamwork at MDT level may contribute in some way to the development of certain patients' severe pressure ulcers.

8.7 Lack of communication between wards: evidence from the data

Not only were there issues around communication at MDT level within the same site, according to the study's findings, but also between wards at particular sites. A number of patients in the study were subjected to ward moves, with associated communication failures. This included Bernie, Chris, Elliott and Frankie.

This issue was highlighted during Frankie's experience of being in hospital. She was moved from ward to ward (twice), and one of these wards was reconfigured during the time she was admitted (see Fig. 8.1). No formal written information went with her, leaving staff on the admitting wards not knowing what her needs were. When Frankie transferred wards, she said that it made her 'feel frightened' that new staff dealing with her did not know what was wrong with her. The timeline of events, drawn mainly from written documentation, showed that the absence of communication between wards meant that ward staff did not have full information on Frankie's risks for developing a severe pressure ulcer (see previous chapter for more details) and Frankie was too ill before and following surgery to communicate her needs clearly. For example, to explain that her mattress was uncomfortable and faulty, Frankie told ward staff 'it's eating me alive' rather than a straightforward complaint about the faulty mattress. She was still on morphine at that point which, in her words, had affected her cognition.

Fig 8.1 Frankie's pathway



Staff on Ward B were not really aware of Frankie's poor communication and high risk of skin damage at the time as surgical notes were not passed on for her. The nursing notes stated, 'She came from theatre with no easy care' [surgical notes]. Secondly there

was little verbal communication between the doctors and the ward. That was related to the ward reconfiguration as the general surgeon felt it was not his 'patch' because he'd just moved across to another site. Frankie's specialist consultant, who knew her well, (as she had treated her as an outpatient for a number of years), noted, 'I was quite cross that the first that I knew my patient had come back was in theatre, so I was called to theatre to see her'. She argued that the trust's policy was that when 'a patient's readmitted, the original operating surgeon should be informed' but she noted that this 'didn't happen'. She added, 'And there 'wasn't a proper handover from recovery to the ward.'

The consultant also highlighted the communication issues around the general consultant and the bed managers/ward staff when she said, 'Her [general] surgeon, would have liked her to go onto HDU. But, it was his first day at Site 2 (Ward C), and I think he felt he didn't really have much sway ...if he'd been here in their own territory, my impression was he would have got on the phone and said, look guys, this is not negotiable, she's going wherever.'

The ward manager's view also supported the evidence that there was little information for the ward when patients arrived from theatre. She stated 'you're going to pick somebody up from theatre that you've never met before, you don't know if she can walk normally, you know, whether she's normally incontinent.'

The expert witnesses judged that Frankie was admitted while the environment was in 'chaos'. One noted, 'I think that even if they'd done everything right, she was never going to get the right care – she was in the wrong place, she was admitted into chaos and I know the ward said that they'd got more staff in and they'd got senior support, but that...was to move, not to care '.

The same issue of little information passed on through handovers between wards arose for Bernie, who was moved through wards because of her co-morbidities and while she was being diagnosed, although this is not uncommon in hospital stays where patients are diagnosed with stroke (see evidence from the literature below). On the acute stroke ward, the staff there could remember very little about her, although Bernie was with them for nine days. One staff member stated, 'as they have many patients passing through, they can't remember people individually.' The consultant geriatrician pointed out that recalling patients is often difficult for staff, when he said, 'it's not that they can't recall her, it isn't a failure of ownership it's that…they're incredibly busy, and if you mentioned a female patient with a stroke on a stroke ward it doesn't help much. They see hundreds and hundreds and hundreds of people a year with strokes.'

Bernie was a complex patient, whom the consultant later stated he found 'hard to forget', as Bernie was 'medically unusual', but the focus of the care on the acute stroke ward was around treatment for the patient with stroke symptoms and Bernie did not quite fit the category due to her other comorbidities. This is, however also typical of stroke care (see literature below).

When Chris was transferred to the community rehabilitation hospital, his high risk of developing a pressure ulcer was not communicated fully to the new team there, partly because he had been in hospital so long, (he also had multiple comorbidities) and he had asked the staff if he could go home via the rehabilitation unit. However, the staff on the rehabilitation unit were aiming to rehabilitate him. He was noted to be a diabetic foot patient, but he developed a pressure ulcer due to other reasons related to his comorbidities and his being placed on an ordinary mattress. However the staff did not change their view that it was a diabetic foot ulcer, even when challenged by the researcher.

Chris's pressure ulcer developed when he was placed on an ordinary mattress in a side room, when he developed a diarrhoea and vomiting virus, and was unwell and dehydrated. The staff however, prioritised the quarantining of him over his high pressure ulcer risk. He then developed a pressure ulcer, but he was still treated as if it were a diabetic foot ulcer, so there was no learning from this situation, (and no subsequent investigation undertaken) despite nurses dealing with him in an appropriate manner, and putting in preventative measures when they discovered the pressure damage. This was evidenced in interviews with the staff nurse who discovered the pressure ulcer, the Ward Manager, and Chris.

Elliott, in his interview, noted that moving wards had distressed him, and although he had a Category 2 ulcer before he went in to hospital, the lack of communication between him, his carer and the ward staff, meant that he (or his carer) did not get chance to disclose this ulcer to the staff, and it deteriorated, and was then recorded as a hospital acquired ulcer. There was a lack of communication about what his skin damage was on the ward. No one on the admitting ward found out why his leg was bandaged during his stay, or at least no one recorded this.

The initial skin damage had happened before he was moved around wards, but it is unclear how far the damage was when he was admitted. His carer (and Elliott himself) noted that the moves impacted on her father's health, when she said, "he had about four or five different moves, which I don't think helped his mental state. Because this

ward, I think he was on about three times, and then another ward, and then he was on another ward, which is orthopaedic, and he was there for about a week'.

8.8 Insights from health services literature

The patients above moved around several wards. These patients' skin care needs seemed to have little attention drawn to them as they moved. Athlin et al. (2010) carried out a small scale qualitative study, which found that patients who had been assessed as non-risk patients yet developed PUs had been moved between wards and this appeared to be a factor in their development. Although the findings of the study by Athlin et al must be interpreted with caution given its small scale, as does this study's findings, the results show similarities.

8.9 Insights from safety literature

It appeared that no one was aware of the patients' movements and the lack of skin inspection until the benefit of hindsight (Bernie, Chris, Danni, Frankie and Glenn). This shows the value of detailed retrospective investigative work to examine patient safety (discussed in the final chapter of this thesis). For example, a member of staff on a new ward may ask questions that are in line with current ward policy, (for example, query and document a patient's skin status) but there may be dynamic changes in a patient that are not picked up when a patient transfers wards, like a Chinese whispers effect (Bhabra et al, 2007). It is often seen as the admitting ward's fault that they do not pick up on cues about high risk patients, unless these are communicated well in the first place. This is particularly true of pressure ulcers, where the origins are not as easily traced to a single point in time (Runciman et al., 2002).

This study used a retrospective chronology of events based around each patient rather than from a health service perspective (see Chapter 3), and this made it possible to see, albeit in hindsight, the 'latent' communicative failings that staff dealing face to face with patients are often not able to pick up (Reason, 1997b, Perrow, 1984, Lawton et al., 2012). However, this issue aligns more with Perrow's Normal Accident theory, and Lawton's Yorkshire Contributory Factors model than Reason's, in that the errors are inherent within the complex system of health care, and it is difficult, if not impossible to see these from a frontline perspective until after the event (Perrow, 1984). This argument will be returned to in the Final Discussion (Chapter 10); and there is little published literature related solely to this area, but it was apparent that there is an issue related to pressure ulcer development between ward moves, which needs to be explored further.

8.10 Poor communication between community and acute trusts-evidence from the data

Not only was communication between wards, and the MDT factors which impacted on patients developing severe pressure ulcers in this study, but communication problems between acute trusts and community services were also evident, particularly for Chris, Elliott and Frankie.

Elliott was admitted with district nursing care in place but his existing pressure ulcer was not communicated to staff on the admitting wards, nor were the reasons that he had bandages on. The ward staff did not follow up why he had these with the district nursing team (who had dressed his wound), but neither did they take responsibility for checking his wounds, and it was assumed from trust staff, that his ulcer deteriorated in acute hospital (it was noted to be a Category 2 before his admission and the TVN reported it as a Cat 3 in her assessment). However, none of the health care professionals on the ward examined him in a timely manner to assess why he had bandages on, or at least if they did they did not document it. There was a query about whether this had happened in one of the nurses' interviews, but it is not definite. She stated, 'I would have taken off the bandages, with that doctor there, because I always do.', but there was no action, or escalation following this, if it did happen.

Chris 'slipped between' professional services i.e. the diabetic foot clinic and the acute rehabilitation team on the ward. As he already had a diabetic foot ulcer on his right foot, he was under supervision by the diabetic team. The TVN on the rehabilitation ward described some of the communication issues around Chris when she said, 'the ward staff were requested to refer to the foot clinic at the acute site and refer him back to the vascular team...and for that period of time we had no communication to what his arterial status was... so until they'd established that, until they could establish his arterial status and know what plan the vascular team had for him, then we couldn't do anything pro-active other than to relieve pressure and dress it, with simple dressings'. She also noted that, 'we were told that if he had a diabetic foot it comes under the care of the diabetic service and not under the tissue viability service, so really even though they referred him to us they didn't need to because he was already under the diabetes which is standard.' However the TVN was not aware that when Chris went for his monthly appointment with the diabetic foot clinic, he had developed a pressure ulcer alongside the diabetic foot ulcer. When she visited him on the ward, she was not aware that he had a pressure ulcer as well.

The diabetic foot clinic wound care specialist noted that she was 'disappointed' in the health provision when Chris developed pressure damage alongside his other comorbidities. This suggests a communication issue between the service provision for patients with both a diabetic ulcer and a pressure ulcer.

The expert witnesses noted for Chris that, "it was partly to do with services not communicating his needs to one another, and partly that he's slipped through a net of services, none of which would take responsibility for him to be beneficial and work preventatively."

Danni's needs also slipped between the GP practice and district nursing team, as she did not fit the criterion for treatment by the district nursing team due to her independent mobility. She was seen as mobile as she could physically attend the practice, yet she was not fully immobile (she used a wheelchair and could not transfer easily on to the bed at the GP's). However, she did not qualify for a district nurse visit her at home, where it would have been easier to assess her, until she had developed a severe pressure ulcer.

However, in contrast to the above evidence, communication at the initial admission for Bernie, by her GP, was much clearer, and she was admitted quickly, with the podiatrist and GP working closely together to admit her. The admission notes state that, 'Bernie was found by her podiatrist at home on her sofa, unable to mobilise and feeling dizzy. She was brought in to A&E'

The handover for Hilary by the ambulance service was also very clear and structured, with written evidence, and had allowed the staff at the acute site to identify her skin damage quickly and put a care plan in place as soon as she arrived at hospital. Hilary's daughter told the researcher that she found her mother on the floor of her bedroom and called an ambulance straight away, and she was admitted to the local A&E ward. The ambulance crew noticed that Hilary had a pressure ulcer. They did not state what grade it was at this point. They also took a photograph while Hilary waited in A and E, according to Hilary's daughter the reason they gave for this was 'so that they weren't liable for any claim.' Aside from the slightly defensive views associated with this comment, the communication between services was clear.

8.11 Insights from health services literature

The importance of off-loading pressure for diabetic foot ulcers has been explored and stressed in recent literature (Bus, 2016). For example, Bus (2016) found that with good

off-loading foot ulcers heal much more quickly. In terms of responsibility, it appears that the care (for someone as high risk for skin damage as Chris) should have been the same regardless of which service he was cared for under. However, the issue of whether the services were coordinated actually has no bearing on whether he developed a pressure ulcer, because he was placed on an ordinary mattress, which contributed to his severe pressure ulcer. The expert witnesses noted this in their judgement. Chris did not have an RCA investigation conducted, as it was felt by the Ward Manager that his pressure ulcer was a diabetic foot ulcer. However, the different services' lack of joint working compounds the issue in staff recognition and awareness of the cause of the skin damage. This has been pointed out elsewhere in studies relating to pressure ulcer trajectories (Athlin et al., 2010). Athlin et al.'s qualitative study found that too many healthcare personnel were considered (by nurses interviewed) to be involved in the care of the individual patient. This meant that nobody knew who was responsible for what, which often led to neglect and failure in the trajectory of care. As this was a small scale study it has limitations in its generalisability to other settings, but supports the findings in this thesis between communication issues in pressure ulcer development.

8.12 Insights from safety literature

Communication is a key component in the area of patient safety (Francis, 2013, NHS Improvement, 2019a, Bhabra et al., 2007). Communication tasks vary across the whole of the healthcare system and the communication boundary between primary care givers in the community and hospital based health services, for example, often use different task styles and organisational structures, which make communication more difficult. This is a recognisable issue from the evidence gathered in this study, regarding the patients and the communication issues they were faced with. However, as Lawton et al (2012) point out in their systematic review of contributory factors to patient safety incidents, communication problems are often not noticed by staff at organisational level, but only at local or ward level (Lawton et al., 2012) and these are then not translated to organisation-wide actions. In contrast Perrow (1984) highlights that this issue can also be reversed, and systemic errors are not necessarily noticed at the frontline. This complicates the issue of communication and responsibility further. Therefore staff are often unable to identify issues between sites and to see them as systemic errors, as has been suggested in this study.

8.13 Discussion: Diffusion of responsibility

The findings above suggest that there were several issues around communication between teams, wards and settings which may have contributed to patients developing severe pressure ulcers. The problem with communication is that it is multi-faceted and offers a range of possible reasons for being inadequate. The full range of possibilities cannot be explored fully here. However, the poor communication in this study did appear to be associated positively with a diffused (or lack of) responsibility for patients' skin care, despite some discreet areas of good practice (Latané and Darley, 1970). This does support the hypothesis, as much as it can given the evidence collected, that poor coordination and communication do contribute to patients developing a pressure ulcer. No individual member of staff appeared to have taken responsibility for the decline in Bernie, Chris, Danni, Elliott, Frankie and Glenn's pressure ulcers because of the diffusion of their responsibility within the NHS's complex system. Some of this may relate to decision-making capabilities within a complex environment, where nurses often do not have hierarchical authority to make decisions about escalating patient care above ward level (Samuriwo and Dowding, 2014). In a few cases, doctors escalated the level of care for the high risk patients in this study. In some ways this is indicative of their professional training and autonomy but has been discussed elsewhere in this work (decision-making chapter), so will not be explored further here.

There was a diffused responsibility relating to ward level communication and decisions (regarding Bernie, Frankie and Elliott). No one took active responsibility for decisions and communication around patients' high risk of developing skin damage. The ward leaders in several cases had little knowledge of the pressure ulcer problems for specific patients (namely for Chris, Elliott and Frankie). When staff wanted to refer patients, they had difficulties trying to contact the tissue viability service (regarding Bernie, Chris, and Glenn). The issue around the role of the TVN highlights again (it is also discussed elsewhere in this thesis) the problem of when to refer patients, how much involvement the TVNs should have on a ward, and how this can cause confusion (Flanagan, 1996). This would be an area to explore further in research, as current studies do not offer much evidence of the reliance on TVNs.

Similarly, other patients in this study were treated by multiple services (namely Chris, Danni and Glenn) but no one appeared to take full responsibility for their overall risks and needs. They also seemed to 'slip somewhere between' the responsibilities of services while their pressure ulcers deteriorated. This is typical of the issues raised in

all of the public Inquiries into patient safety (National Advisory Group on the Safety of Patients in England, 2013, Francis, 2013, Kennedy, 2001).

It also seems there was little responsibility or accountability. Nursing staff did not appear to take responsibility for the *deterioration* of ulcers when patients were admitted into their care, and instead focused more on specific task-based care, and often delegated skin inspection tasks to HCAs. This is one of the main issues associated with pressure ulcer care (Samuriwo and Dowding, 2014). Clinical judgements also appeared to take a back seat behind focusing on risk assessments, which is also apparent in other literature in this area (Dowding et al., 2012). Doctors took responsibility for the change in patient skin care in certain cases (for example regarding Bernie and Danni) despite the view from their interviews that skin care was seen as the 'nurses' responsibility'.

The lack of responsibility, however, at a systemic level, relates again to a 'mindless' cultural attitude to pressure ulcer development, which links to the previous chapter on safety culture. Ultimately the above issues with patients highlight confusion over who is responsible for pressure ulcer prevention and care. Who does have responsibility for which aspect of skin care and how does this manifest itself? The doctors felt the responsibility for skin care and assessment belonged with the nurses; the ward leaders spoke passively of patients with pressure ulcers on their wards; and the TVNs were absent from real time concerns and decisions over patients.

When patients frequently move around wards, it is easy to be dissolved of responsibility as the patients do not stay in one place long enough to become anything more than an anonymous stroke patient, for example. This fits well with the psychological theory that the more people involved the less responsibility one has to take. However, pressure ulcers, by their nature, also afflict patients who already have co-morbidities, and their risks of skin damage sit alongside other competing health priorities (Samuriwo and Dowding, 2014). For patients who are not well known by staff and treated for their other illnesses in the first instance, the idea that their skin care will take priority is a huge ask.

Work has been done in the field of teamwork research to create a safer, more collaborative environment for patients. Lingard et al. (2004) found communications addressed to the wrong person and with unclear purposes, led to a quarter of all communications being seen as failures, in similar findings to Bhabra et al (2007). The success of checklists in surgery have partly been attributed to the focus on teams working together at the same level, and everyone having a say in decisions, but with

clearly defined team goals (Nagpal et al., 2010). However, this style of team work was also not apparent, or relevant in this study. Team communication, rather than individuals, can impact massively on safety, positively or negatively (Ballard et al., 2008, Edmondson, 1999). When working well they can provide an effective barrier to unsafe practices (Venkataraman et al., 2017). Wound care passports have been used recently to try and link communications better between services, which aim to remain with the patient once they develop any skin damage, and offer information about how they are being treated, but there have not been any research studies into their effectiveness to date. And, as long as IT systems and processes between health care services do not comply with each other, this is also a difficult tool to make a success of (Hua et al., 2012).

The role of carer and patient as key to the coordination of care is an interesting finding from this study (see Chapter 5) and is relevant again here. This is a key area which may offer a solution to the problem of communication between parties. No one has more interest in their well being than the patient themselves (Coulter, 2011, Vincent, 2010, Vincent and Coulter, 2002). The only caveat is that the patient must be able to communicate well enough, or be cognitively able, to monitor and understand their skin status and risks (2008, Bazin et al., 2016). Patients and carers, however, may provide continuity and counteract the diffusion of responsibility between services (Berger et al., 2014). They may offer insights into where care is lacking, or highlight issues with communication. Lawton et al have researched the patient's role in this area in a large study on the patient's role in patient safety (Lawton et al., 2017, Lawton et al., 2011) as has Scott (Scott et al., 2016). This is also gathering support in health care policy with the advent of Improving Safety Critical Spoken Communication (NHS Improvement, 2019a), and Liberating the NHS: No Decision about me without me. (Department of Health, 2012b) The patient's communication with health care professionals would be an area for further research specifically relating to pressure ulcer care. However, in this study, the evidence was that patients were not utilised for their knowledge for helping to coordinate and communicate between services (except for Glenn's and Danni's carers, who took the role on voluntarily). Instead, different areas of MDT, wards and services operated in silos and did not communicate well between each other.

8.14 The role of error in the complex system

Additionally, for the patients involved in this study, information loss often occurred over time, what was lost was not fully apparent to staff at each handover, consistent with the normal accidents idea that errors become normal within a large system. To reiterate,

'Normal' accidents, or system accidents, are so-called by Perrow (Perrow, 1984) because such accidents are seen as inevitable in extremely complex systems. Perrow argues that operator error is a problem, but big accidents almost always have very small beginnings. Such events appear trivial to begin with to those at the frontline before cascading unpredictably through a system to create a large event with severe consequences. With the slow onset of decline in skin integrity, starting from small beginnings, namely Category 1 or 2 skin damage, this can have consequences if staff are not aware constantly of changes to skin status. This fits well with Perrow's theory (Perrow, 1984). Using timelines to track patients' decline in skin status is helpful, but they are only used retrospectively for pressure ulcers as part of incident investigations, and wound care risk assessments and wound care plans are rarely used dynamically by staff to assess skin (Angood, 2008, Briggs et al., 2013). A linear timeline is also only part of the casual factors, which include environmental perspectives. In hindsight we can see how a patient's skin has declined due to subtle changes in circumstance and risk status but this is not always obvious to staff in real time. Coleman et al. have since developed a more dynamic approach to risk assessment (Briggs et al., 2013) notably the PURPOSE T tool, arising in part from this study's findings. This tool monitors risk using a pathway approach, which leads to the implementation of a care plan. However, results from this work are still in their infancy and it is not known whether this will address the issue of dynamic skin status. The SBAR and safety huddles (Goldenhar et al., 2013, Field et al., 2011), mentioned above, also aim to improve issues with handing over patients, and keeping pressure ulcers at the forefront of health care staff's minds, but again, time and further research will tell whether these are able to prevent severe pressure ulcers developing or deteriorating.

8.15 Conclusion

This chapter has highlighted that problems of poor communication on hospital wards, between wards and between multi-disciplinary professional groups may lead to patients developing severe pressure ulcers. However, the findings are exploratory and simply offer opportunity for further research into this area. The chapter has also highlighted how, if no one takes responsibility within a large complex system, and passes patients on from ward to ward for example, this may reduce the care of a patient in terms of pressure ulcer management, which is more likely lead to the development of a severe pressure ulcer. This links to the theory of diffusion of responsibility. Key areas for safety and prevention of pressure ulcers appear to be good coordination and communication, including the patient's and carer's view too if possible to provide information, and in this study, good practice in all of these areas appeared to be

missing. This study's findings have offered some grounding for further exploration, and although more current safety work is heading towards focussing on the area of team work and communication, more research needs to be done to expand and tease out the subtleties of interventions.

Chapter 9: Reflections on a very long PhD journey.

"Reflexiveness is the essential condition, within the social process, for the development of mind." (Mead, 1934)

9.1 Introduction: A passion for pressure ulcers.

I set out on my PhD journey fresh from a jump from forensic psychology. I had always loved psychology ever since I found my mum's old encyclopaedias in our loft and I passionately presented a study to my eleven year old class mates about why we yawn and why yawning is such a social phenomenon. They yawned- I hope because of the social phenomenon and not my delivery technique.

However, after a number of years studying forensic patients, and being genuinely being frightened by the people I encountered, I felt that scoring people out of 30 for their psychopathy traits and making legal decisions based on this score was ethically wrong (I refer of course to The Hare Psychopathy Checklist-Revised). I needed a new direction for my love of psychology; I was fast becoming disillusioned. However, I was then lucky enough to gain a 'permanent' (it was back in 2007) position as a researcher in the Leeds Institute of Health Sciences.

Here, I met the most qualitatively focused research team that you can imagine. Instead of scoring people with binary numbers and inputting data into SPSS, they pontificated in our shared office about ontological positions and how 'science' is simply a construct. We all wondered what a search for knowledge really entailed. I could go on.

At the same time, I felt out of my depth. Most of my colleagues had backgrounds in sociology and I felt a bit lost in their musings. When one of the professors (Justin Keen) asked me to join him as a researcher on a project with one of his colleagues from the Clinical Trials Unit (Professor Jane Nixon) who was an empiricist, I felt strangely safe again. Jane had asked Justin Keen to be part of her huge programme grant investigating pressure ulcers because of his health policy and systems knowledge, and his leanings towards qualitative research. I preferred this research ground, where we measure but allow for some musings and social contexts. This seemed to fit my research persona. It also amused me that I was seen as a qualitative researcher at our meetings in the Clinical Trials Unit.

My PhD was born. Jane and Justin had written three paragraphs tagged on the end of the large programme grant about pressure ulcers (their words; not mine). The original idea for a small qualitative study was based on a hunch from Jane and her team that the healthcare system somehow contributed to patients developing pressure ulcers, but they did not know how. Some patients got better, and others deteriorated despite having similar risks and presentations, and as caring nurses by background, this still bothered them. Justin, who remains an eminent Professor in Health Politics, was asked to help to devise a study around this.

Justin and Jane then asked me to write a proposal about how to study why patients develop pressure ulcers. I did not know what a pressure ulcer was at this point. I had certainly never seen one, although have of course now. Justin instructed me to go and read Normal Accidents by Charles Perrow (1984). I read it, and was as enthused by this book as much as my mum's encyclopaedias! How had Justin connected nuclear accidents to bed sores/pressure ulcers? My passion for pressure ulcers was ignited in this connection. I read (nearly) every book on safety in our university library, fascinated by the psychological orientation of safety. However, what I had not realised in my exuberance was how long and hard this research journey to connect pressure ulcers and safety would be, and how many academic disciplines I would need to study.

There are many times since I started studying pressure ulcers that I have wished I could go back to coding binary numbers in SPSS. Many psychology colleagues have passed their PhD Vivas during my research journey, and I've read their studies, which are often based on careful re-analysis of current theories.

However, I have met some wonderful people in the course of my research. Some of whom aren't now with us. It is for them that I have kept plodding on this arduous journey to get their voices heard. This isn't sycophantic or tokenistic. I met people who gave me their time when they were in their last days of life (#Thelast1000days by Professor Brian Dolan) illustrates this beautifully). For this I will be eternally grateful, and when I have wanted to give up on this thesis, I think of these brave people and get back to writing.

The problem with cross disciplinary PhDs are that they cannot possibly cover everything about what the thesis needs to cover. Where to draw the line is so subjective that I came unstuck many times. Was it a study on severe pressure ulcers? Was it a study on organisational systems from a psychological perspective? Was it a study on safety of complex systems? Was it a study on patient experience?

My biggest reflection then, is a PhD of such cross disciplinary focus worth completing? Yes. After I registered this as a PhD under Jane's instruction in 2009, ten years later still no one has connected severe pressure ulcers and patient safety, to try to understand

how the organisation has contributed to why patients develop Category 3 and 4 or severe pressure ulcers.

9.2 What is reflection?

So what is reflexivity? Simply, it is the process of self-critique by the researcher to examine how his or her own experiences might or might not have influenced the researcher process (Dowling, 2006). There are many definitions of reflexivity as a concept, and there is not space in this thesis to debate the differing approaches. Rather than attempt a review of the variety of ways in which the concept of reflexivity has been defined and employed (Berger, 2015, Finlay, 2012, Fook, 2002, Forbes, 2008, Finlay and Gough, 2003) instead here I discuss reflexivity and highlight some of the ways in which it has been applied to research methodology, and to my research in particular.

In contrast to quantitative methods' claim to objectivity (see Chapter 3 on debates about quantitative data and qualitative data), qualitative research has often been criticised for being influenced by researcher's bias (Buckner, 2005). The subjective nature of the data construction associated with qualitative research (Guba and Lincoln, 1989) and the focus on the researcher rather than the process of research are criticisms that have led to a closer examination of researcher's reflexivity and its role in analysis. Thus, reflexivity can be seen as a continuous awareness, assessment, and reassessment by the researcher of the researcher's own contribution or shaping of the research and consequent findings (Dowling, 2006).

Reflexivity acknowledges the role of the researcher as a participant in the process of knowledge construction, and goes beyond a process of introspection or self awareness to celebrate the role of the researcher in data construction. In addition, technical research skills used in qualitative research such as interviewing (Hsiung, 2008) demand that the researcher engage in the study of self both as subject and as object.

9.3 Methodological Reflexivity

For my study, the concept of 'methodological reflexivity' or reflexivity from a critical standpoint was relevant. This concept acknowledges the relationality of the researcher with the research, but also strives to ensure that standardised procedures have, nevertheless, been followed throughout the research process. Regular monitoring and testing of assumptions and approaches, ensures that the researcher can establish the 'reality' of the research (Rogers et al., 2016). Dowling (2006) calls this the "politics of

location". Methodological reflexivity thus identifies and examines ethical, social and political considerations that affect the field of enquiry.

Examining the institutional context and strengthening research rigour are methodological goals which can be achieved through this reflexive process. My choice to 'hear' all the voices of stakeholders, (my voice, the patients, nurses, HCAs, doctors, and expert witnesses) in the research study supported this stance. The coherent account for each patient was designed to reflect these voices. I was looking for the 'truth' or 'reality' in the process, through constant monitoring and testing of the coherent account using my staged review process (see Chapters 3 and 4).

The notion of a staged review process did not arise from my researching the concept of reflexivity though. It emerged from reflective discussions with my supervisor, Justin. I remember returning from fieldwork with my completed 'coherent account' and the TVN's account of what happened. However, the patient's version of events (elicited from my interview with them) was vastly different from the TVN's version. "What can I do to empower the patient?" I asked Justin. "It seems unfair that the patient's view is overthrown by everyone else's professional opinion." This has happened for Chris, Frankie and Danni (see Chapters 4, 5 6, 7 and 8). So we decided that I should keep the patient's account in full until the end of the analysis to give it 'strength' of political and social location throughout the six stages of scrutiny. My 'politics of location' then was deliberately skewed in favour of the patient, and I still, to this day make no apologies for this. This decision led to my analysis that professional decisions are not always in line with a patient's view (see Chapter 7). This, for me, is one of the main strengths of this thesis, and is discussed in more detail in Chapters 3, 4 and 7.

I was also trying to find a middle ground and 'reality' throughout my interviews with staff. Staff members who I interviewed were nervous, worried and knew that pressure ulcers were associated with quality of care and patient safety. Extracting rich data from sometimes stilted interviews was not an easy task (which again I explore further in Chapters 3 and 9). However, a reflective relational position here also helped me to navigate through the 'lack' of material and find ways to use my judgment about what happened. I also used the opinions of the other members of the research review teams (that is the TVNs, the expert witnesses, the psychologist and the health politics expert) to establish the reflexive 'reality', search for the 'best explanation' and validate the findings. This was both a strength and a weakness of the study, and is discussed as such in Chapter 10.

9.4 Prospective and retrospective reflexivity

According to Attia and Edge (2017) reflexivity can also be divided into two other types: prospective and retrospective. They argue carefully, from an educational viewpoint, that reflexivity should be seen as a developmental learning approach, and extend the idea that reflexivity is bi-directional and context-dependent (see Cole and Masny (2012) and Mann (2016). Attia and Edge (2017) propose that it is useful to characterise reflexivity as comprising two interacting elements: prospective and retrospective reflexivity (Edge, 2011). Prospective reflexivity, according to their view, refers to the effects of the researcher on the study, whereas retrospective reflexivity refers to the effects of the study on the researcher. Reflexivity, for them involves a process of ongoing mutual shaping between researcher and research. Development thus involves an increase in awareness of processes of interaction between researcher and context. Rather than see development only as a welcome side-effect of reflexive research, Attia and Edge (2016) see the development of the researcher as central, with reflexivity in an instrumental relationship to the process.

Attia and Edge's (2016) conceptual understanding of reflexivity fitted my approach and development as an early career researcher. In a study, such as mine, which took ten years to research and write up, and caused me much personal stress over the years, both types of reflexivity, as described above have been central to my development as a researcher and for my research. Below I discuss how the two different concepts impacted on my study, and on my life as a researcher.

9.5 Prospective reflexivity

When I was asked to be part of a research team which studied 'bed sores', I could not see the reason why I was asked. After conversations with Jane Nixon, who clearly must have had vision beyond mine, I realised that the team of mostly nursing background academics wanted a researcher who was not a nurse.

As experts in their field, they knew the pre-conceived ideas that most of their professional colleagues had about pressure ulcers. Jane, instead, wanted a 'blank slate', and a researcher who had the technical skills but no content knowledge of pressure ulcers at all. This was not to skew the data with any professional opinion. Therefore I already was employing prospective reflexivity before I had collected any data! I was affecting the study with my lack of knowledge. However, I did realise, soon after drowning in a mass of medical jargon, and worrying that I might miss vital information, that I would need a professional view as well, to aid my data collection. This is where the TVN's account was useful in collecting information that I might have overlooked. Therefore, I set out on my research study of severe pressure ulcers as a researcher who had some degree of

expertise in psychology, and although I have since gained much detailed knowledge of healthcare, and the politics of health care systems, I have mostly remained committed to a psychologically focused stance during the ten years.

9.6 An outsider's perspective

My psychological interest meant that I interpreted much of the data from an outsider perspective. I was interested in the people behind the interviews, and the cognitive decisions that were made by participants. In some ways my perspective enriched the study with psychological insight, and encouraged an exploration of the psychological responses of participants. However, in other ways the focus on the psychological was at the expense of exploring content knowledge around the clinical presentations of patients. Several times I was asked by the wider research team to return to the field to gain further data because there was not enough clinical evidence to find a best explanation for the cause of a patient's pressure ulcer. In some instances the lapse in time made it difficult to collect further data.

9.7 A developing appreciation of sociological insights and organisational theory

Whilst I remained wedded to a psychological perspective at first, I realised over time that a wider reflective stance was necessary to understand the concepts of patient safety and severe pressure ulcers. The psychologists who had attempted to understand and conceptualise the area of patient safety and human error found themselves moving towards organisational theory ((Reason, 2016) and sociological theory (Hammond, 1996) to understand and explain human error. I too found that it was necessary to look wider at more sociological theories such as March and Simon's 'Bounded Rationality' and Perrow's explanation of errors in complex systems (March and Simon, 1958). As I referred to earlier in this thesis (Chapter 2) Reason did not manage to explain error fully in terms of psychology. My dilemma was also therefore in part because I realised the decisions taken by staff in a complex environment such as the NHS, were both socially dependent and organisationally driven. The challenges for my study were how far to steer the focus towards these areas, and how far to remain committed to social psychological explanations. I still believe that patient safety theorists are still grappling with this issue (Hollnagel et al., 2015, Reason, 2016, Nicolini et al., 2011, Waring J et al., 2010, Lawton et al., 2014), and it will be some time before we are comfortable with the most useful theoretical position.

9.7 Differing perspectives enrich the data

However, in the same way a coroner has to make a best explanation judgement around why a patient has died, and what the conclusions must be, the choice of using expert witnesses was key to finding the 'reality' within my study. The reason for revisiting their role, is that this was another area where my prospective reflexivity led to a research design decision, and became a strength of the study. The role of the expert witnesses helped to triangulate and enrich the data with other perspectives which led to a more developed understanding of the data. The role of the expert witnesses has been discussed elsewhere in the thesis (Chapters 3, 4 and 10) however I explain below how I came to my decision to have expert witnesses, and why this choice was an example of prospective reflexivity.

While I was writing the proposal for Jane and Justin, one of the TVNs working on another study within the Programme Grant, told me about a passionate coroner who was an expert in pressure ulcers. His name was Nigel Chapman, and he was based in Nottingham. I contacted him by email to ask for his advice, and he invited me to meet him. He remains one of the most important people I have ever met, and has had considerable influence on my career ever since. When I met him, he asked if I wanted to attend his coroners' inquiry about a patient who had died due to complications of a severe pressure ulcer. I was really keen to gain insight into what led to the patient developing the pressure ulcer, so I took him up on his kind offer. This was life changing for me; the charming gentleman I had met initially, donned a gown and wig and became someone I did not recognise. He was an intimidating figure, who interrogated every participant at the coroner's inquiry (apart from the deceased patient's family, whom he treated with gentle respect). I watched with trepidation, as ward managers, Tissue Viability Nurses and other staff nurses were questioned on their practice, and as Nigel Chapman repeatedly asked why they felt their patient had developed a pressure ulcer. The high levels of emotion involved from all participants during this inquiry was something I will always remember. After all staff had been interrogated thoroughly, the coroner called up the 'expert witness'. Immediately I could tell that this person was a voice of reason in the inquiry. While being repeatedly asked about how the patient's pressure ulcer developed, the response from the expert witness was often, "I would have expected that this should have happened at this point". It appeared to me that this was not an idealised expectation but simply an expectation of normal care. The expert witness repeatedly used the word 'normally'. I realised that this person was key to working out what was 'normal' care on a usual day, if there is such a thing in health care. After the inquiry was over, I asked Nigel Chapman about how he concluded the case, based on all the evidence presented to him,

and how he decided who, if anyone was to blame. He answered that he made a personal judgment based on all of the evidence.

My PhD research design was conceived. I told Justin Keen what I had witnessed and learnt, and he loved the idea of drawing together evidence as a coroner would. It also had similarities to the design set forward in a (George and Bennett, 2005) book called Case Studies and Theory Development, that Ray Pawson had asked us both to read. The next ten years of my life I then spent trying to turn this initial concept into a workable study design, which highlights prospective reflexivity as a central part of my research study.

9.8 Retrospective Reflexivity.

This section has been more difficult to write, as this PhD has affected me in many subtle ways that are hard to articulate. Firstly, and probably most importantly, it has changed the course of my career from an academic one and taken me to a role in an NHS environment.

I was a different person when I started out on this journey ten years ago. I was enthusiastic about research and approached the prospect of studying for a PhD with excitement. Now, I tell anyone who expresses a desire to study for one, that it is the hardest thing I have ever done.

The main aspect of retrospective reflexivity however; which I discuss here, is about the people I interviewed as part of my research study. I refer mainly to the eight patients, who were interviewed and gave me their time and energy, when they were suffering from severe pressure ulcers, which must have been painful and debilitating on top of their other conditions. The fact that they each had a severe pressure ulcer meant that they were frail, had complex needs or were ill (see Chapters 3, 4, 5, 6, 7 and 8). In my darkest moments when I did not think I could finish this PhD, I thought of their suffering and about the time they gave to me, and this reflection gave me the drive to get this done; for their voices to be heard, at least. In this way too, the detailed investigations about every patient, and the reasons they developed their pressure ulcers, also impacted on my decisions as a researcher, and then as a Patient Safety Manager. I am now very much oriented towards the perspective of the patient, knowing that their version of what happened to them is often different from the professional's.

9.9 The power of the patient-centred perspective

Although there have since been research studies and policy drives within patient safety which are now centred around the patient's view (O'Hara et al., 2018) (Liberating the NHS; No decision about me without me, Department of Health). This study has evidence supporting this view, and more importantly for me, has steered my perspective towards a particular patient-centred, or user-centred view point. This is the most important message of this PhD, in my view, as it offers a 'situated position' for patient safety centred on the patient, while linking the patient's view to wound care. This links to the 'politics of location' mentioned above, but develops this in order to examine the 'power' dynamic involved. . When I refer to 'situated position' I mean it as Madge (1993) and Haraway (1991) suggest, which is where the researcher's role of 'self' (in terms of race, nationality, age, gender, social and economic status amongst other attributes) influences the data. This refers to a 'situated position' offering a type of 'situated knowledge' which shows where the power dynamic, which is generated from the data, is actually situated. In other words, for this study, the power was between myself, as a psychology focused researcher, and the patient. However, this was a conscious decision, following the development of the method, as initially, the nurse experts and research team had the 'power' over the data, because they knew about how patients developed pressure ulcers from a clinical perspective. However, I made decisions (in using the patient interviews per se, rather than using excerpts from them in my coherent account) to keep the 'power' with the patient throughout the data analysis. Much of the method became about addressing these power dynamics between participants (see Chapter 3 for detailed discussion about this). I was determined not to override the patients' versions of events, as they were very different from the health professionals' perspective. In doing so, this allowed me to explore the concept of a 'best explanation' rather than data as 'truth'. The impact of the findings around contrasting perspectives, has led to developmental work, as part of my current role, to incorporate the patient as shared decision-maker in pressure ulcer care. I see this as a positive step forward, which arose from my reflections on the PhD.

9.10 Discussion

I have discussed prospective and retrospective reflexivity in context, but there is also potential for much more exploration of reflexivity at other theoretical levels of interaction. For example, it would be possible to investigate whether the findings that I reported as significant were the same as the answers to the research questions with which I had started the study. The varying disciplines I drew on for my explanations offered perspectives, but if I had focused less on psychological explanation and more on a sociological one, would I have found different answers to my research questions?

If, for example, I had focused more on the political environment around pressure ulcers and health policy, I might have offered recommendations at a more policy oriented level. I chose instead, to remain at the position of frontline, within the NHS system. Underneath the umbrella of inter-disciplinary questions, are also those around which 'situated position' to take when data is being collected. Again, I may have found different answers had I allowed the health professionals more power during the course of analysis, and if I had more nursing knowledge at the outset to draw upon.

I could also have considered a different methodological approach to analysis rather than a realist-based one. I chose to interpret the data as 'facts'. An Interpretative Phenomenological Analysis, for example, might have focused more on the meanings generated by the patients and staff and what a severe pressure ulcer meant to them. However, my choice to focus on 'explanations' meant that I was searching for the best explanation, taken as truth, that I found 'at the time', with the evidence I gathered, (which was as exhaustive as I could manage, although this is open to scrutiny and critique) incorporating the notion of reflexivity of who I am as a researcher. The quest for the explanation was therefore the nearest to my 'truth' or politics of location, or 'situated position' as I could articulate it.

Reflecting encourages the researcher to articulate the understanding that emerges from experience, and to take responsibility for the raised awareness as he or she identifies a desired direction of travel. Then, the researcher must pursue the knowledge needed to help with this direction. I have lost count of the times that this happened within my PhD study. Sandywell (1996) notes that reflexive action changes the self, and a reflexive practice never returns the original self. A developmental approach to reflexivity has therefore potential both to enrich the researcher's experience and shape learning and progress (Attia and Edge, 2016).

A developmental approach to reflexivity also recognises the value of reflection as a means of capacity-building, as it supports creativity and innovation by encouraging the researcher to discern methodological opportunities within his or her own environment, and to be purposeful in decision-making and analysis. In doing so, a study's findings, generated with reflexive insight, can highlight new ways of looking at a phenomenon, and highlight alternative avenues for research. This journey, if anything, is what is central to a PhD journey.

Chapter 10 Conclusion

10.1 Chapter summary

This chapter draws the four previous discussion chapters together in one concluding chapter beginning with a discussion of the strengths and limitations of the research study. It examines the fundamental role of the environment and decisions which impact on the development of severe pressure ulcers in patients. It revisits the literature review in terms of sociological, psychological and organisational views of patient safety.

The chapter then discusses how using a combination of these inter-disciplinary views may offer an improved method of investigating the causes of severe pressure ulcers, and how this in turn may offer improvements to current investigative tools and processes. It briefly revisits the theories of coherence and correspondence, the Theory of Explanatory Coherence (TEC) and inference to the best explanation, in relation to a retrospective case study method. It considers how the use of these reasoning and analysis techniques may lead us towards supporting the concept of a 'Safety III'. The chapter concludes with how the application of the findings to the study of severe pressure ulcers may help to point towards a future direction for health care investigation techniques.

10.2 The background and rationale revisited

This study aimed to explore and explain the reasons why patients develop severe pressure ulcers and whether the organisational environment contributed to their development. These ulcers are seen as a major burden to patients, carers and the healthcare system, affecting an estimated 1 in 10 hospital and 1 in 20 community patients (Gunningberg, 2006, Bredesen et al., 2015b, Vanderwee et al., 2011, Schuurman et al., 2009a). Before this study was conducted, we knew that immobility was a significant clinical risk factor (National Institute for Clinical Excellence, 2001a, EPUAP/NPUAP, 2009, Nixon and McGough, 2001, Nixon, 2009, Briggs et al., 2013). However, what we did not know enough about was why some severe pressure ulcers develop in patients which cannot be explained by clinical risk factors alone. There were suggestions from previous literature that organisational environments may have an influence, and that associated clinical negligence may also contribute (Bennett et al., 2004, Nixon, 2009, Department of Health, 2000).

Additionally, and reiterating points made in Chapters 1 and 2 of this thesis, a narrative review conducted in 2010 on UK patient safety research (Waring J et al., 2010) found

that much research attention has been focused (since the growth of the patient safety movement) on solutions such as checklists, guidelines, re-training and technological innovation. However, studies included in the literature review in this thesis showed that these initiatives are also influenced by wider socio-organisational factors, and that greater thought and attention should be given to translating techniques typically used in other industries to health care (Hollnagel et al., 2013, Waring J et al., 2010, Vincent et al., 2017). The narrative review also called for greater focus on the connections between services, and patients' and carers' roles in patient safety (Waring J et al., 2010). These issues continue to raise concerns to date in the search for better investigation techniques in health care (Vincent et al., 2017).

Therefore, questions about the organisational environment, pressure ulcers and socioorganisational factors in patient safety formed the rationale for this study. These questions were specifically; Why do patients develop severe pressure ulcers? And does the healthcare environment contribute?

10.3 Strengths and limitations of the study

10.3.1 Retrospective study

One of the main limitations of this study however, is that it was retrospective in nature. Although steps were taken by the researcher to reduce hindsight bias, which included the sense checking review process, the sequence of events chronology and the use of 'good usual care', the study was not able to counteract this problem fully. This issue was debated in Chapter 3 in detail, so will not be reiterated here. Associated issues with hindsight bias also included historical accuracy of accounts from all participants and the sample, which was not a randomised sample, but patients chosen who had already developed severe pressure ulcers.

10.3.2 Sample and data collection issues

The data collection phase of this study took two years to complete, which highlights issues with the length of time spent collecting data deemed useful enough to investigate. This could have potential negative impact on the future usability of the study. The sample size was also small (n=8), which highlights the strongly debated issue with generalisability associated with small sample sizes in qualitative research (Hammersley, 1992, Emmel, 2013). Again, this was debated in Chapter 3, so will not be revisited here.

I wanted to represent the evidence in the most accurate way to get the most suitable explanation. However, I faced several smaller challenges while trying to do this. I found, while carrying out interviews with each patient that, although he or she was witness to most of what happened, there were other people's versions of events which he or she was not witness to, such as decisions made by nurses, physiotherapists and consultants. This meant that data collection was substantial and I had to gather numerous and varied sources of evidence for each patient to make sense of what had happened.

However, the small sample did allow a very thorough investigation of each case, not associated with larger scale survey style investigations. Focusing on a small sample also offered the opportunity to refine and develop candidate explanations. The intention was never to generalise to a larger population, but to offer possible candidate explanations and possible theories from which to better understand how severe pressure ulcers develop.

10.3.3 Issues with reflexivity

Issues with reflexivity were debated in Chapter 9 and explored questions around which approach I took. For example, if I had focused less on psychological explanation and more on a sociological one, would I have found different answers to my research questions? Or had I focused more on the political environment around pressure ulcers and health policy, I might have offered recommendations at a more policy oriented level. I chose instead, to remain at the position of frontline, within the NHS system. Whether this was the best choice is always debatable.

10.3.4 Defensiveness and time constraints of participants

As the study was observational, and mainly carried out on NHS sites, most of the field work took place on busy hospital wards, where staff members had little time to spare to help with my research. A number of informants were defensive, given the issues around severe pressure ulcers and patient safety indicators, so some didn't give enough time, and others did not attend their arranged interviews. I used the on-site TVNs as gatekeepers to overcome the defensiveness of staff, and mostly this was useful, however, the outsider issue always presents a difficulty as for field researchers and can only be overcome to an extent.

I was non-clinical and some aspects of the information were not understandable, but I overcame these issues with the use of a parallel clinical review by the TVN (explained

earlier). I therefore had an on-site account of what had happened, from the TVN's clinical perspective. However, this still presented a challenge, as sometimes I did not understand fully the clinical issues, and had to have these clarified by the TVN, and project team.

10.3.5 Patient story bias

In each case I chose the patient's story to structure the timeline. The bias towards timelines according to staff members had been part of the issues with current investigative tools (such as RCA). I realised that if I wanted to improve current practice I needed to minimise the effect of different perspectives of events. Although I knew each of the accounts was not perfect and couldn't offer the 'right' answers, I still strived for a best explanation of what happened (Lipton, 1991, Haig, 2009). However, this was from the perspective of the patient and it was often difficult to navigate through which 'true' account to accept. This issue was covered in Chapter 9; however, this was overcome by a method of staged analysis which became a strength of the study (see below).

10. 4 Strengths of the study:

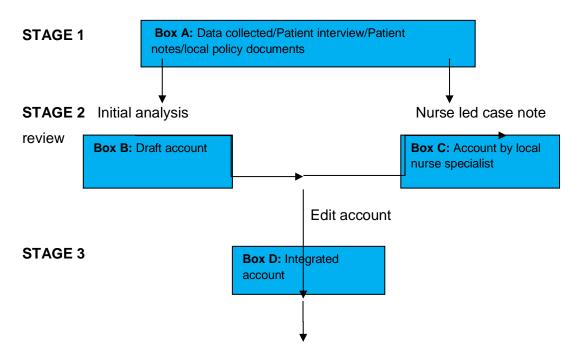
10.4.1 The stages of analysis

The data was subjected to detailed scrutiny (Shadish et al., 2002, Guba and Lincoln, 1989, Hammersley, 1991, Lipton, 1991). I used the analytical review process to develop my coherent account for each patient, to counteract different perspectives and to compare the coherent account of what happened with good usual care seen on a ward. The expert witnesses offered their verdict on whether good usual care had been followed. I knew I wanted to be open to all disciplines (see Chapters 2 and 3) when explaining how a severe pressure ulcer developed. Applying this was more difficult. I used the review process as a forum for applying different cross disciplinary explanations (see Table 1 below), and asked the team to choose which ones, if any, they thought were the most appropriate. I asked them to read each patient's coherent account with the explanations in mind.

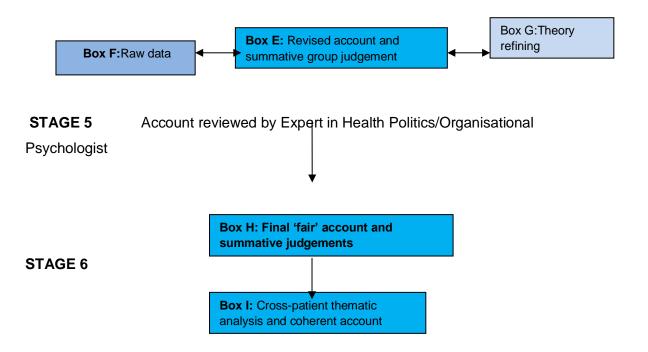
10.4.2 The key role of the expert witnesses

The staged review process that this method used and the expert witnesses' accounts were also key to the study's findings, in that they internally validated the coherent accounts (Hammersley, 1991, Campbell and Stanley, 1966). Figure 3.4/10.1 reminds the reader of the staged analysis process:

Fig 3.4/10.1: Review Process



STAGE 4 Review by expert witnesses group (2 Tissue Viability Nurses (TVNs; not on-site) 1 hospital 1 TVN; I community TVN; 2 academics)



The final coherent account; having gone through six stages of member-checking (Hammersley, 1991), had considerable internal validity (see debate in Chapter 3 for the preference of this term over more qualitative language) which was strengthened

through the analysis process. The associated summative judgements for each coherent account validated by each review stage, allowed me to make a more plausible judgement about the validity of each coherent account for each patient. At the same time extensive recording of empirical data through analysing different types of data sources meant that the audit trail was easy to monitor for any discrepancies or inaccuracies (see Chapters 3 and 4). It becomes clear that the correspondence and coherent approaches complement each other and both are needed to support an investigation around why severe pressure ulcers occur in a complex system.

More importantly, the expert witnesses provided an account of 'good usual care' for all cases which does not form part of an RCA investigation. An RCA method tends to focus on idealised practices and how a system can be altered to rectify the errors which occurred (NHS Direct, 2011). However, the expert witnesses judged what was 'good usual care' and not idealised care. This is a subtle but important difference in focus. This was a key element of the method's contribution to the debates in patient safety (Vincent et al., 2017).

The expert witnesses within the study offered me their accounts of 'good usual care' for every patient involved in the study. The methodology was at the outset made explicit to the people involved in judging each case (see Chapter 3) in that I was not looking for perfect care, but the care that they, as experts in their field, would have expected as good everyday care (see Chapters 3 and 4)). The expert witnesses included two tissue viability nurse specialists who were not involved with the patients or employed at the NHS sites. An academic with expert knowledge in nursing also helped to review the account. The tissue viability nurses and academic, who were all experienced expert witnesses in legal proceedings, provided an account of 'good usual care' which was a benchmark against which the care of the patients could be judged. I provided the expert witnesses with raw data, alongside coherent accounts, so that they could compare the accounts with the original sources of information. They recorded departures from treatment and care that each individual might reasonably have expected to receive. This is similar to how evidence is used within a coroner's inquiry (see Chapter 3), and was indeed the basis for the whole of my study. For example for Bernie, who had a number of complex needs such as contracted legs and cognitive impairment due to a stroke, one expert witnesses noted that, 'For Bernie there was no mention at all of physiotherapists and Occupational Therapists – (Agreement from Expert witnesses A and C) – or the physios being involved in repositioning.'

For Glenn, who was a paraplegic gentleman, who had been on a long journey via ambulance to a specialist healthcare centre and developed his severe pressure ulcer following this episode of care, the expert witnesses discussed his case and provided a consensus of opinions as follows:

Expert witness A: So, we're assuming that what we're looking at is the ischial pressure ulcer.

Expert witness B But if he was elevated slightly in the ambulance, given that he's so thin, is there not that potential that although he's not sitting directly on his ischium, that actually, there would be...

Expert Witness C But I don't agree... if you sit like that and you're thin -

Expert Witness A You still miss your ischials

Expert witness B Yes, you still miss your ischials.'

The similarity to a coroner's method of analysing a case, would be where an expert witness would be called to explain and compare what had happened in a particular investigation, where normal good practice and deviances from this normal good practice might have occurred. Somewhere between the judgements for each patient's case in this study, the team of experts and I drew the best explanations we could elicit, given the evidence analysed, about causal inferences relating to each case. The expert witnesses offered me the hypothetical 'positive deviance' alongside the adverse event analysis. Interestingly, Hollnagel et al (2013) also refer to their concept of Safety II in a similar way as this study's concept of 'good usual care' when they refer to looking at 'work as done', rather than 'work as imagined' and note 'normal' practice. In other words, they want us to focus on systems that are real (or in my study 'good usual care') rather than ideal (Hollnagel et al., 2013).

In executing the method, the explanations became consistent and transparent and added validity to the data collection and method.

I recognise that this technique of investigating complex adverse events is a time-consuming and multi-method approach (on average taking three months at two days per week) and that issues of time constraints and tools of adverse event investigation have already been documented in research (Waring, 2007, Nicolini et al., 2011). Nevertheless, I have found that using this approach offered interesting insights unavailable from other methods of error investigation. There has, until now, been no

way of discovering the causes of a complex event such as a severe pressure ulcer, which focuses on the patient's view of events rather than an in-house investigation, based on health care professionals' views. Although studies in patient safety are starting to address this issue (O'Hara et al., 2018). This type of thorough investigation has been called for in patient safety literature (Waring, 2007). I felt that this study addressed this issue.

What has been shown by this study is how to address the organisational culture (to an extent, given the exploratory nature of the research), and yet remain close to the primary sources of evidence. The method allows us to formulate candidate explanations of what happened, which remain grounded in primary evidence (Pawson, 2006). For this thesis, the explanations I refer to aim to offer a degree of abstraction from observable and measurable data, but these could be applied to real world settings, while at the same time I do not make grand claims of generalizable rules (Merton, 1968). This time-consuming method of looking at the whole picture alongside raw data may not be transferred per se into practice, however, this new way of examining and understanding evidence suggests a way to incorporate psychological, sociological and organisational research and offer a more holistic, multi-method way of studying patient safety than has ever been practised before (Waring J et al., 2010).

The use of evidence gathering and making sense of the data corresponds to a coroner's or large scale inquiry, see Mid-Staffordshire NHS Foundation Trust Inquiry (Francis, 2013, Secretary of State, 2001); and the Bristol Inquiry; (Kennedy, 2001). However, the difference between this study and recent large scale inquiries is that it does not conclude with a list of recommendations which can be difficult to put into practice. In contrast, in this study I used the evidence in a coherent way; in the form of an account of events, which also allowed me to refer back to corresponding evidence in the primary data. This gives a transparent audit trail for my choice of explanations and strengthens the evidence, accountability and stability of findings.

10.5. Final discussion

Overall, this study found that the main plausible explanation for patients who develop severe (Category 3 and 4) pressure ulcers was that the environment made their development more likely (see Chapters 2, 3, 4, 5, 6, 7 and 8). This was in some cases in combination with a sequence of events (see Table 10.1/4.3).

Table 10.1/4.3

Patient	Unavoidable	Single/isolated	Sequence	Environment	Other
		event	of events	made	explanation
				development	
				more likely	
1 Alex				•	
2 Bernie			•	•	
3 Chris		•		•	
4 Danni			•	•	
5 Elliott				•	
6 Frankie			•	•	
7 Glenn				•	
8 Hilary	•				

Table 10.1 shows that for three patients (Bernie, Danni and Frankie) the best explanations for the development of a severe pressure ulcer, following the staged analysis, were that there was a combination of a sequence of events and the environment. For another three patients (Alex, Elliott and Glenn) the environment was judged as solely the cause of their severe pressure ulcer. For one patient (Chris) there was a precipitating isolated error in combination with the environment. For the final patient (Hilary) the severe pressure ulcer was seen to be outside health services, therefore in terms of analysis, was unavoidable.

10.5.1 Four emerging candidate explanations

As well as the main finding that environmental influences do contribute to the development of severe pressure ulcers, the study then began to highlight four discrete emergent candidate explanations arising from further coding and analysis of the data (see Chapters 3 and 4). These have been explored separately in the four previous discussion chapters. These were i.patient (and carer) voices not being heard; ii. difficulties with decision making in a complex environment; iii. a 'mindless' safety culture, and iv. diffusion of responsibility, poor communication and coordination between staff, wards and health care services. This discussion now compares these four candidate explanations in the light of how to apply them to health care practice and

how the application of these may improve our approach to studying severe pressure ulcers. The four explanations link together and this chapter suggests a logic model which may analyse and predict a patient's pathway if he or she presents with high risk of skin damage.

As I analysed the data, it became apparent that the four candidate explanations also linked with other literature in a layered, or multi-tiered way (see Figure 9.1 below). This mirrored my initial questions around trying to understand why patients developed severe pressure ulcers, and my initial analysis of the data. For example, the explanation that patients' voices were not heard worked better at an individual or micro level of analysis, and links with the literature at an individual, patient focused level were more helpful to understand this area (Blegen et al., 1998, Coleman et al., 2013b). The next theoretical explanation, that decisions about pressure ulcer management were difficult to make in complex environments, fitted better with the psychological literature at a psycho-social level (Benner and Tanner, 1987, Klein, 2008, Thompson and Dowding, 2009). The third candidate explanation, that there was a mindless safety culture, linked with more socio-cultural level thinking and literature, and insights from that area of research were more useful in this area, to understand and define my explanation (Ausserhofer et al., 2013, Goldenhar et al., 2013, Weick et al., 2008). Finally, the diffusion of responsibility, and poor communication was better understood in terms of organisational level literature (West, 2000, Hollnagel et al., 2015, Edmondson, 1999).

The role of the patient (and his or her carer) has been highlighted in the findings of this thesis as a key candidate explanation in the development of severe pressure ulcers; which has often been overlooked to date in patient safety (Bazin et al., 2016, Vincent and Coulter, 2002, Berger et al., 2014). This study supports the possible view that health care staff were not listening enough to patients and often treated them as 'non-compliant' and 'passive', disregarding their role in their care (see Chapter 5). These tentative findings have implications for current investigation techniques within the patient safety field, given the links between pressure ulcers and patient safety (2008, Bredesen et al., 2015b, McMaster, 2005, Salcido, 2007). Staff could engage patients more fully in their care, and move towards a more concordant approach, if we want to work towards the prevention of severe pressure ulcers (see Chapter 5).

The findings of this study also suggest that the dialogue between doctors, nurses, and the wider MDT, needs to incorporate the social environment that they make decisions in. Decision-making regarding pressure ulcer prevention ought to be clear and

understandable, to make it equal for professions, and more open to scrutiny, so that we can learn how to make the best choices for high risk patients within uncertain, time pressured environments (see Chapter 6). Alternatively, it maybe that some of these decisions are inherent within the system and no amount of retrospective investigations would equip the staff with the foresight (Klein, 2008, Perrow, 1984, Vaughan, 1996). However, rather than individuals simply being accountable for decisions they make, it may be that expectations, time to decide and awareness are not high enough around prevention and management of pressure ulcers and staff need to be equipped with more clarity of process and decision making analysis. Although, the conclusions drawn from this study need to be interpreted with a degree of caution, given its exploratory design, it suggests that staff (particularly nursing staff) should be empowered, encouraged and supported to make those decisions around pressure ulcer prevention and management, while recognising the complex environment they make decisions in. This complexity was discussed in more depth in Chapters 6, 7 and 8.

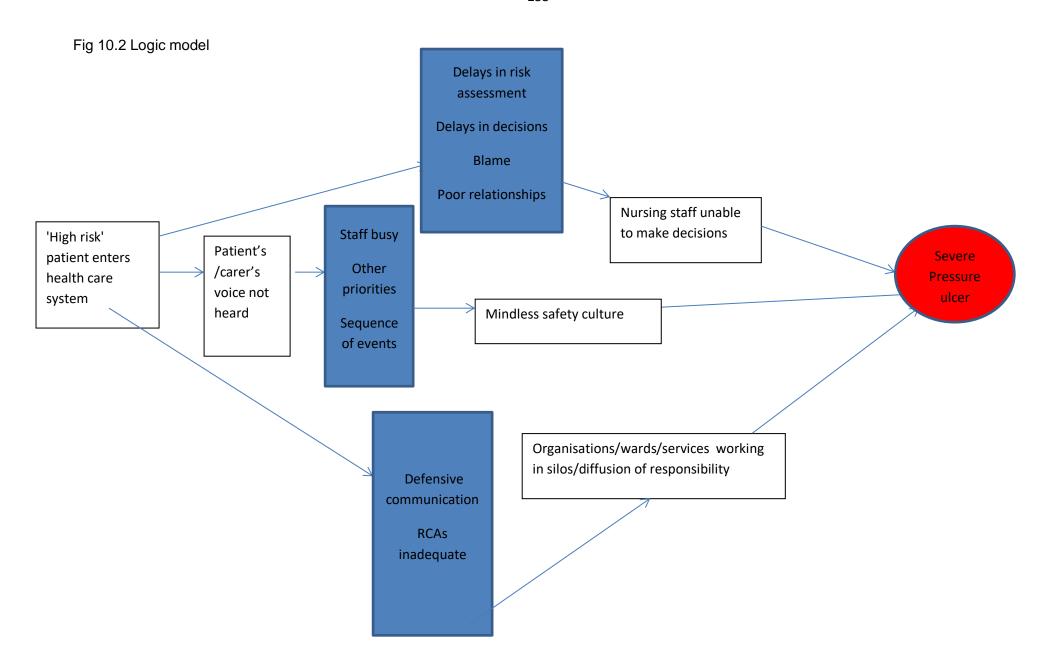
Examination of the data in terms of sequences of events highlighted delays in response by staff members towards pressure ulcer risks in patients. In these cases specific events played a role; however these occurred in organisational environments which hindered the staff in doing their work to their best ability (see Chapters 7 and 8). Above all, the responses and decisions made for all of the patients appeared to point towards a mindless (Weick et al., 2008, Weick and Sutcliffe, 2001) as opposed to a mindful awareness regarding skin care. To reiterate, when I refer to 'mindless', it is not a detrimental term in the commonly used sense, but acts as a psychological term, meaning opposite to 'mindful awareness', such as when an actor goes into a 'mindless state' and acts in an 'auto-pilot' mode (Weick et al., 2008, Weick and Sutcliffe, 2001). Weick et al. (2008) note that when people within an organisation are in mindless mode they face confusing signals and rely on past ways of doing their work, and hold on to their perspective without awareness that things could be different. The authors add that this is more likely to happen when people are distracted, hurried or overloaded.

When I examined the sequences of events and delays in response alongside the organisational environment, it appeared, while interpreted with a degree of caution, that staff members' actions and responses within organisational contexts led them to be less aware or mindless of pressure ulcer risks, for various reasons, including being distracted and hurried. It also appeared from the findings that pressure ulcer care is not as high on nurses' priorities as it should be, which is supported by other literature in this field and examined in Chapters 7 and 8 of this thesis (Samuriwo and Dowding, 2014).

Part of the 'mindless' state of awareness is that there seemed to be poor communication on hospital wards, between wards and between multi-disciplinary professional groups (Goulding, 2011) (see Chapter 8). Although this was not true of all locations or services. The tentative findings, to further explore, from my exploratory study, suggest that, if no one takes responsibility within a large complex system, and passes patients on from ward to ward, for example without a clear handover process (which happened for several of the patients in this study) this may impact on the care of a patient, and is more likely lead to the development of a severe pressure ulcer. This finding also supports the theory of diffusion of responsibility set out earlier in Chapter 8 of this thesis (Latané and Darley, 1970). Conversely, key areas for safety and prevention of pressure ulcers, arising from the findings of this study appear to be good coordination and communication, including the patient's and carer's views, to provide information.

10.5.2 Model of high risk patients' pathway through hospital

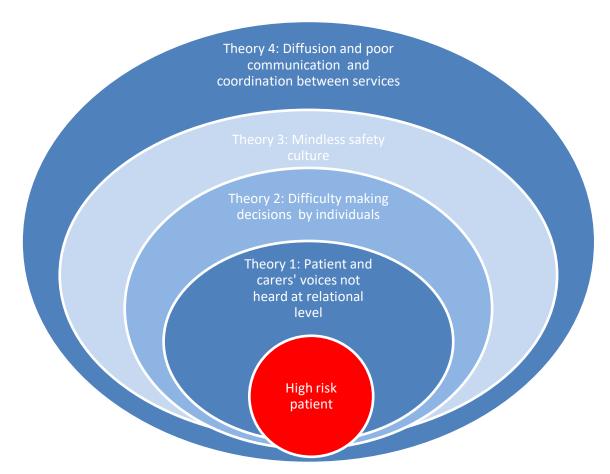
One of the main findings of this thesis relative to frontline health care practice is the mapping of a typical high risk patient as he or she enters the healthcare system, and the organisational influences which are more likely to result in a severe pressure ulcer. The logic model below (Figure 10.2) describes a typical high risk patient's pathway through care. In the context of both a lack of awareness and mindless safety culture, the issues may escalate to impact on the likelihood of a patient's skin deteriorating. The logic model highlights in stages the effects of health care practices on the high risk patient as he or she enters health care (such as the patient and carer's voice not being heard and delays in risk assessments) and the likelihood, according to these effects, of the patient then developing a severe pressure ulcer.



10.5.3 Four candidate explanations in one model

However, there are also relationships between the patient and the different candidate explanations set out above. The four areas are discrete but relate to each other in that they represent different *tiered* levels regarding pressure ulcer prevention and management. What I mean by 'tiered levels' is a hierarchical health care structure graduating away from the patient, but still impacting on him or her. Central to this model is the 'high risk' patient, and at varying outer layers are the influences on the patient's severe pressure ulcer development. These are shown in the diagram below (Figure 9.2). At the centre is the patient, and at a micro-social level there is the impact of staff not listening to their patient's needs. Surrounding this are the decisions made by staff in relation to the patient at a sociocultural level, which must be supported and acted on to prevent deterioration of a patient's skin condition. Surrounding this level is the safety culture within which the staff work, and surrounding this is the macro, or service/governance level supporting mechanism. Although the model does not quite follow familiar sociological tiers (micro, meso and macro) it does echo these levels to an extent.

Fig. 10.3 Four tiers



The high risk patient, at the centre, is affected directly by relationships with those around him or her (namely frontline health care staff and carers). If the patient's or carer's voice is not heard, or their concerns not heeded at a one to one relational level, this affects the decision-making around the patient and vice versa. Decisions made by individuals who operate within a mindless safety culture appear to be more difficult, although this finding is tentative given the exploratory nature of the study (see Chapters 5 and 6). Coupled with this however, if communication and coordination between services at this wider, more macro level is lacking then the patient will most likely develop a severe pressure ulcer.

Although some of this argument is likely to be seen as common sense, it is useful to see a visual model of the support systems (or lack of) surrounding a patient and it is easier to target areas for training or service improvement based on this, which may be deficient or weaker.

Illuminatingly, there are recent models used within patient safety which have set out similar relationships to analyse adverse events at a more general level of analysis. Lawton et al.'s Yorkshire Contributory Factors Framework (2012) offers domains to analyse adverse events based on a systematic review of factors which contribute to patient safety incidents. The framework consists of active failures (at individual level), situational factors, local working conditions, latent/organisational factors and latent/external factors. The framework is set out below:



Factor	Definition		
Active failures	Any failure in performance or behaviour (eg, error, mistake, violation) of the person at the 'sharp-end' (the health professional)		
Communication systems	Effectiveness of the processes and systems in place for the exchange and sharing of information between staff, patients, groups, departments and services. This includes both written (eg, documentation) and verbal (eg, handover) communication systems		
Equipment and supplies	Availability and functioning of equipment and supplies		
External policy context	Nationally driven policies / directives that impact on the level and quality of resources available to hospitals		
Design of equipment and supplies	The design of equipment and supplies to overcome physical and performance limitations		
Individual factors	Characteristics of the person delivering care that may contribute in some way to active failures. Examples of such factors include inexperience, stress, personality, attitudes.		
Lines of responsibility	Existence of clear lines of responsibility clarifying accountability of staff members and delineating the job role		
Management of staff and staffing levels	The appropriate management and allocation of staff to ensure adequate skill mix and staffing levels for the volume of work		
Patient factors	Those features of the patient that make caring for them more difficult and therefore more prone to error. These might include abnormal physiology, language difficulties, personality characteristics (eg, aggressive attitude).		
Physical environment	Features of the physical environment that help or hinder safe practice. This refers to the layout of the unit, the fixtures and fittings and the level of noise, lighting, temperature etc.		
Policy and procedures	The existence of formal and written guidance for the appropriate conduct of work tasks and processes. This can also include situations where procedures are available but contradictory, incomprehensible or of otherwise poor quality		
Safety culture	Organisational values, beliefs, and practices surrounding the management of safety and learning from error		
Scheduling and bed management	Adequate scheduling to manage patient throughput minimising delays and excessive workload		
Staff workload	Level of activity and pressures on time during a shift		
Supervision and leadership	The availability and quality of direct and local supervision and leadership		
Support from central functions	Availability and adequacy of central services in support the functioning of wards/ units. This might include support from Information Technology and Human Resources, portering services, estates or clinically related services such as radiolophlebotomy, pharmacy.		
Task characteristics	Factors related to specific patient related tasks which may make individuals vulnerable to error		
Team factors	Any factor related to the working of different professionals within a group which they may be able to change to improve vatient safety		
Training and education	Access to correct, timely and appropriate training both specific (eg, Task related) and general (eg, Organisation related)		

Fig. 10.4 Yorkshire Contributory Factors (Source Lawton et al. 2012)

When I compared my findings, and my subsequent model, regarding the patients in my study who develop severe pressure ulcers, with the Yorkshire Contributory Factors Framework, it became apparent that there was some overlap with the domains. In the centre of both models sit errors at individual level, surrounded by decisions made at team level, then surrounding these on both models are cultural factors, and then at the outer tier there are external factors or service communication issues.

The similarities, while not an exact replication, i) provide support for the findings in my thesis around individual level factors, and socio-cultural factors, then service level findings; and ii) highlight that the model generated in this thesis may have value in offering analysis for investigating patients who develop severe pressure ulcers. This has implications for the RCA technique of analysis currently used in health care when examining adverse events. This is discussed in detail below.

10.5.4 The inadequacies of Root Cause Analysis

As has been mentioned earlier in this thesis (Chapters 1 and 2), over the last decade Root Cause Analysis (RCA) and other methods of error investigation have become the main tools for analysing adverse events such as severe pressure ulcers in health care (NHS Direct, 2011, Ovretveit, 2005). Originally used in high risk industries such as nuclear power and aviation (Carroll JS and Edmondson AC, 2002) RCA was adopted in 2001 by the National Patient Safety Agency, (now NHS Improvement) arising from the Department of Health's report 'An Organisation with a Memory' (2000). RCA still remains the most recommended method in health care which is used to examine clinical incidents retrospectively, and to devise strategies to change practice (Public Administration and Constitutional Affairs Committee, 2017, NHS England, 2015). It is designed to work towards preventing future adverse events based on the learning achieved from incident investigations.

Normally, an RCA is undertaken when an incident is reported, however, this requires correct and accurate reporting of incidents, and not all adverse events are easily reported and measured (Benn et al., 2009, Evans et al., 2006). Pressure ulcers, for example, as we have seen in this study, often do not have an easily identifiable beginning, and tend to happen on wards gradually, where the staff are sometimes not aware of their initial development (Evans et al., 2006). Currently, as has been discussed previously in Chapters 2 and 7, the tools (such as RCA) which are used to examine the causes of severe pressure ulcers, are based more around, or at least interpreted as, psychological and reductive perspectives rather than focused on an organisational, coherent view (Nicolini et al., 2011, Peerally et al., 2017, Waring J et al., 2010, Vincent et al., 2017). This study has suggested that this way of investigating incidents is not helpful if we are to gain a coherent, whole system perspective on what happens when a patient develops a severe pressure ulcer. This then can affect associated learning and service improvements.

10.5.5 The method's contribution to RCA

In collecting and analysing data using an adapted George and Bennett process-tracing methodological approach (George and Bennett, 2005), this study found that the most plausible explanations contributing to the development of severe pressure ulcers were environmental, rather than clinical or isolated causes. These included poor communication and service coordination, staff not listening to patients, decision making in uncertain, complex climates, and a less than ideal safety culture. These explanations place the findings firmly within the realms of organisational, human factors and socio-cultural theory rather than clinical literature around pressure ulcers.

The study has shown that there are more complex causal influences than factorial 'root causes' regarding patient safety issues such as severe pressure ulcers. This calls into question the search for 'root causes' of them. This also adds weight to the framework of investigation offered by Lawton et al., (2012). Aside from frontline managers' views in healthcare, other knowledge and judgements are needed to fully understand the organisational issues which impact on patients developing pressure ulcers (Wallace et al, 2009; Nicolini et al, 2011), yet frontline managers, debatably, still remain the most popular staff group who are currently directed to conduct RCA investigations (Vincent et al., 2017, NHS England, 2015). The chronology for this study took the perspective of the patient rather than a service level view, and this offered a different lens from which to view the system of healthcare. This study has suggested that the views of patients and carers, and experts who can compare investigations to typical good usual standards of care, could be successfully incorporated into investigations. However, these elements are overlooked currently in investigations (Evans et al., 2006, Lawton et al., 2017, Greenwood and McGinnis, 2016), although things are changing with more interest in the patient's view in patient safety (O'Hara et al., 2019). However, these would be areas in which to test the theories generated by the findings of this thesis. Although one study aimed to do this, in one NHS Trust, following the results of earlier publication of this thesis' findings (Greenwood and McGinnis, 2016), the study was limited in its scope and the authors note that the systems and organisational explanations were limited in the study. However, supporting this thesis' findings, they also noted that patient and staff interviews offered more insight into care delivery issues, and that the quality of the RCA process is improved when it is completed by someone external to a patient's care as it minimises bias (Greenwood and McGinnis, 2016, Health Services Investigation Branch, 2017).

10.6 Implications of the thesis' findings

Reviews of patient safety research have noted the need for multi and mixed method approaches to researching what is such a diverse and complex area (Waring J et al., 2010). Patient safety experts have also suggested that improvement should involve specialist expertise in incident investigations, including using underlying theories, human factors and hands-on experience of analytical methods in the patient safety field (Vincent et al., 2017). The focus on human factors has started to be addressed through the National Patient Safety Strategy (NHS Improvement, 2019b). Human factors has come to the fore in the NHS since the signing of the human factors concordat in November 2013 by the members of the National Quality Board (NQB) including Health Education England, the General Medical Council, Nursing and Midwifery Council and NHS England (Nationa Quality Board, 2013). This area of work is fast developing and this study's findings have supported the consideration of this wider view of investigating serious incidents (in this case, severe pressure ulcers). To an extent this issue has also been addressed by the recent formation of the Health Services Investigation Branch (HSIB), which aims to take investigations away from the frontline and offer a professional human factors approach to a selection of incidents (Health Services Investigation Branch, 2017).

The HSIB movement is in its early stages, having been created in April 2017, and its value has yet not been evaluated to date; however, this study's findings support the introduction of techniques of investigation which the HSIB aims to employ, which are human factors-based and organisational theory approaches, and which also include patients and or carers more actively in an investigation. The HSIB notes that 'patients, families and staff must be active participants in the process of investigation and must be engaged with and supported compassionately and respectfully investigations' and it also notes that investigations 'must be led by experts'. Both of these aims are findings within this thesis and support current developments to practice.

The need for an improved approach is partly because, as stated earlier in this thesis, a linear, reductionist approach to isolate 'root causes' has been shown in the RCA evaluation literature as too simple an approach to understand and learn from the causes of such complex events as severe pressure ulcers (Vincent et al., 2017, Perrow, 1984). The approach may be helpful in investigating isolated, time delineated events such as medication errors, but is inadequate regarding more complex patient safety events (Evans et al., 2006). Studying the complex organisational system, and

the culture which surrounds the patient, are both required to fully understand these phenomena. As highlighted above, work has already been started in patient safety which considers this cultural system with the advent of the Yorkshire Contributory Factors Framework (Lawton et al., 2012).

10.6.1 Perrow's contribution to investigating severe pressure ulcers

As I have demonstrated in this thesis, Perrow's analytical view is that the complex adaptive system sets an actor up to 'fail' within a complex system (Perrow, 1984). There is often no way of predicting where and how the failure will occur. This view is a more coherent perspective than a reductionist view. Perrow instead allows the system itself to cause the error, rather than a local actor or system at a micro level. An actor within a system may behave in a way that he or she thinks is rational, given the knowledge he or she has available at the time. For example, within the NHS system, a nurse may receive a frail patient who has transferred from another ward. The focus would be on their prevailing symptoms, which may or may not have been handed over clearly by staff on the previous ward. What they were likely not informed of, however, was the underlying skin damage that the patient may have been exposed to alongside their co-morbidities, such as lying on a trolley in the Emergency Department (ED), or how far the patient was able to comply with frequent turns, or how unwell they became when undergoing previous surgery. The person on the frontline often has no idea about the underlying systemic issues which have also impacted on the patient presenting to them. This not only links to a theory of diffusion of responsibility discussed earlier (see Chapter 8), but also shows us that, for the patients involved in this study, information loss often occurred over time. What was lost was not fully apparent to staff at each handover; consistent with Reason's 'swiss cheese model' (Hollnagel et al., 2015) but also consistent with the Normal Accidents theory that errors become 'normal' within a large system and are not always preventable in real time (Perrow, 1984). Perrow's 'Normal Accidents' theory argues that big accidents almost always have very small beginnings. Such events appear trivial to begin with to those at the frontline before cascading unpredictably through a system to create a large event with severe consequences. With the slow onset of decline in skin integrity, starting from small beginnings, namely Category 1 or 2 skin damage, this can have consequences if staff are not aware constantly of changes to skin status. These subtle systemic issues echo the findings of this thesis relating to a complex sequence of events, which was particularly valid for three of the patients. Poor communication and awareness on hospital wards, between wards and between multi-disciplinary professional groups was apparent in this study for various reasons. The findings above show us that, if no one

takes responsibility, or is indeed able to take responsibility due to the failings within a large complex system, this may impact on the care of a patient, which is more likely to lead to the development of a severe pressure ulcer.

The study's sequence of events also differs from usual investigations conducted currently in health care, in that the chronology was based around the patient's perspective, not the health care professionals', and thus aimed to provide a more coherent picture of the development of severe pressure ulcers. Although this has been discussed previously, Perrow's (1984) view about the systemic and 'Normal Accidents theory' therefore helps us to understand in part what happened for the patients in the study who developed severe pressure ulcers, in that the structure of the organisation can be such that a patient will develop a severe pressure ulcer due to factors outside the control of frontline staff. Perrow's insights help us to see that systems are more than 'components or equipment'; they can also be human constructions and decisions (Perrow, 1984). Typically, health services are systems based around human constructions in tandem with equipment and tools.

The analysis of the health care system using Perrow's Normal Accident Theory (1984) helps us towards a slightly depressing view that all complex systems will cause errors eventually, despite criticism of this theory from other authors, such as Weick et al. (Weick et al., 2008) who argue that it is possible to prevent errors with more mindful awareness (discussed below). Applying Perrow's analysis to health care however; and in particular regarding the development of severe pressure ulcers, makes us see that good coordination and clear communication, which include the patient's and carer's view to provide information, should be part of that system to provide consistency, transparency and clarity. In this study, the analysis showed that these factors were missing overall from the eight cases investigated.

10.6.2 Safety I and Safety II-are these concepts enough to understand safety?

The concept of Safety I has been explored in detail within my study, as the study's method allowed a retrospective investigation of cases where patients developed severe pressure ulcers (seen as adverse events in UK health policies, 2000 to date) which aimed to uncover causal explanations for these 'adverse events'. I spent several months collecting research evidence using timelines or sequences of events, in a similar manner to how Root Cause Analysis is undertaken in healthcare, examining the evidence causally, alongside interviews with everyone involved in a patient's care and documentary analysis. The findings showed interesting insights into how far the concept of Safety I could offer explanations.

For example, when I examined Danni's case, I found that the practice nurse admitted she should have referred Danni more promptly for more specialist care regarding her severe pressure ulcer, rather than repeatedly meeting with her in the GP's practice but not examining her wound or seeking specialist advice. This delayed decision was not picked up by the nurse herself until the retrospective analysis of the case and associated timeline of events highlighted this issue to her. This is without doubt one of the useful offerings of the Safety I approach (Waring J et al., 2010, Nicolini et al., 2011). The nurse noted that 'in hindsight she would have referred Danni earlier'. However, the question is, does knowing this detail actually affect our judgement of this situation or its final outcome? Although we understand in retrospect what happened in terms of sequences of events following detailed investigation into the case, given that practice nurses are often only given ten minute appointments to treat their patient, and patients within the GP's practice in Danni's case are ordinarily required to visit the practice if they use a wheelchair; this means that this issue would be very likely to be repeated in future. This is in spite of us knowing the detail of why the delay in referral happened. NHS healthcare policies and local GP's policies would not necessarily facilitate longer, more considerate appointments with patients, so this becomes less about examining the sequence of events which were so carefully examined, and more about the organisational cultural influences at work. No amount of causal analysis could change the way the patient was treated. Fischkoff reminds us (1975, 2003) that in situations where information is limited, surprises and failures are inevitable, as does Perrow in his study of disasters (1984) where he says accidents are 'normal' within a complex system, and we are unable to 'find and fix' them (Waring J et al., 2010).

Detailed system descriptions do not appear to fit today's world as well, either in industries or in health care (Hollnagel et al., 2015). In health care in particular, systems such as an intensive care or emergency setting cannot be systematised easily in a componential way, although attempts have been made along the way. There are often unexpected events and decisions to be made (see Chapter 7, and Bernie's case). To date, major policy drives using Safety I as a basis have offered few convincing reductions in risk, harm, serious error or death with the harm ratio of patients who are cared for through healthcare remaining at 1 in 10 since 2000 (NHS England, 2015; Vincent, 2004; Carson-Stevens et al, 2016). This has led some researchers in the field to call for different thinking, such as what has been currently termed Safety II (Hollnagel et al, 2015) which is described below. Indeed, as this thesis has also found, alongside its analysis of causal sequences of events, that everyday clinical work can

be variable and flexible, not easily systematised, with a need for situational awareness among frontline staff (see Chapters 6 and 7 on decision making and culture).

10.6.3 Safety II

Safety II focuses its investigations on gaining an understanding of how things usually go right, since that is the basis for explaining how things occasionally go wrong (Hollnagel et al., 2013). Hollnagel and colleagues, remind us that, in contrast to the tried and tested Safety I style tools of investigation, the situation is different for the many more events that go right. Despite the suggested importance and interest in this area, these events receive less attention in safety management activities such as risk identification, safety assurance and safety promotion. There are no current requirements from authorities and regulators to look at what works well (although things appear to be changing with the advent of positive deviance; (Lawton et al., 2017). Possible exceptions are audits and such where good practice is celebrated (NHS Wales, 2010). A system (for example, a hospital) is said to be unsafe if there are several adverse events; alternatively, a system is said to be safe if such adverse events occur rarely or not at all. This is, by logic, an indirect definition because safety is being defined by its opposite, by what happens when it is absent rather than when it is present (Hollnagel et al., 2015). Hollnagel et al. (2015) posit that we analyse and try to learn from situations where, by definition, there was a lack of safety and although 1 in 10 admissions to healthcare globally result in an adverse event, by the same logic, 9 in 10 or 90 per cent do not result in an adverse event-a large difference.

Safety II has argued this issue; instead of only looking at the few cases where things go wrong, this approach askes that we look at the many cases (90 per cent) where things go right and try to understand instead how that happens (Hollnagel et al., 2013); Lawton, 2017). The Safety II movement advocates that clinicians are often able (90 per cent of the time) to adjust their work to conditions. Resilience engineering (Hollnagel et al., 2013) also acknowledges this, and argues that the reason why people are able to work more or less effectively is that they continually adjust their work to current conditions. We have seen this portrayed earlier in this thesis when staff made decisions based on acute presentations of patients; particularly for patients such as Bernie, where staff focused on her stroke rather than her skin integrity-with catastrophic consequences. Thus, as health care systems expand, these continual adjustments by staff at the frontline become increasingly vital for safety and therefore present both a challenge and an opportunity for safety management (Weick et al., 2008). Yet, it is not just about the person at the frontline making adjustments, which is

where this thesis offers evidence for focusing on a more abstract level of analysis. The environmental influences for the patients involved in this study appeared to be important and caused the patients to develop their severe pressure ulcers, according to the evidence collected.

To fully understand these environmental influences, I return to and discuss the following authors' positions (Vaughan, 1996, Hollnagel et al., 2013, Weick et al., 2008). These authors all focused their analysis on socio-cultural, organisational influences at play when errors occur, which is where the most plausible explanations lay, according to this study's findings (see previous chapters). These influences were the case for every patient involved in the study, according to the analysis. These are opposed and contrasted in this thesis with a more logical and system focused view, which was seen to be applicable to three patients in the study, and more associated with graphical models discussed above such as Reason's (1999) Swiss Cheese model, and with the Safety I approach.

The findings from this study first suggest that the 'safety culture' within most patient cases was lacking, particularly with reference to a lack of 'mindful' thinking. Vaughan also found a 'mindless' safety culture contributed to the poor decisions made in her study of the Challenger disaster (Vaughan, 1996). To reiterate earlier discussions from this thesis (Chapters 2 and 6) Vaughan referred to NASA's technical culture altering into a culture which merged bureaucratic, technical and cost efficiency mandates. This included a tolerance for low-lying problems because of the focus on resources and efficiency drives over technical issues. This normalised a 'deviant' safety culture within the organisation (Vaughan named this 'normalisation of deviance') which led to the disastrous consequences of the Challenger crash. Vaughan argued that deviant behaviour, such as was the case for NASA leading up to the Challenger crash, becomes normal over time to people working within a culture, and it is only in hindsight, or to those outside the system, that this deviance is apparent. In light of the findings of my research, Vaughan's work has a particular resonance, despite hers being about a technical industry. She is able to draw on perspectives around organisational culture, but also she used a historical ethnography as a methodology, to systematically examine the evidence. This was less about causal inferences, but about the cultural influences. This also became the method my study used overall to examine the data collected, and although my analysis aimed to draw in both psychological and sociological perspectives (see my five initial explanations), the analysis suggested that my final explanations lay in more sociological domains, similar to Vaughan's conclusions.

The lack of recognition of safety culture is also alluded to by Weick and colleagues (Weick et al., 2008). Interestingly, despite Weick achieving a psychology degree, when he remained to study his PhD, the Ohio university department eventually built a degree based partially on Weick's theories (Weick and Sutcliffe, 2001), calling it an 'Organizational Psychology' degree. This highlights a move away from traditional psychological theories and analysis. Weick et al. first noted (1999), amongst other organisational theories, the concept of mindfulness within an organisation, which they developed from Langer's previous work (Langer, 2016) (see Chapter 8) and suggest that the adoption of this concept cultivates safer cultures and improved system outcomes. However, in contrast to this, they suggest that, within organisations when fewer cognitive processes are activated less often, in a less safe culture, then an actor goes into a 'mindless state' and acts in an 'auto-pilot' mode. This automatic processing is in response to repetitive and non-dangerous tasks which would elicit a prompt reaction, and is thus a mindless, automatic response. Others have argued instead that this is also a 'failure to rescue' (see Chapter 7) (Hollnagel et al., 2013). However, this theory appears to support some of the findings within this thesis, particularly around staff not noticing pressure ulcers developing, when preoccupied instead with other acute or organisational conditions (such as was the case for Bernie-her stroke, Chrishis rehabilitation and Frankie-the hospital alterations). Weick et al. (1999) suggest that a safe culture should have a preoccupation with dynamic 'non-events' to prevent the state of automatic response, in a similar vein to Hollnagel's suggestions above. This means again that rather than focusing on things which go wrong, we emphasize those which are going right, which is thus termed Safety II (Hollnagel et al., 2015).

Weick et al.'s (1999) approach, and the perspective based on my study's findings, are similar to other new perspectives which identify 'positive deviant' approaches instead to focus on (Lawton et al., 2014). The positive deviance approach has its origins in nutrition research in the 1970s. Researchers observed that, despite the poverty levels in a community, some poor families had well-nourished children. The idea of the positive deviance approach is that it operates within the specific cultural context of a given community (village, business, schools, ministry, department, hospital) and is therefore appropriate to their needs. It provides to community members the "social proof" that a behaviour can be adopted by all because it is already practiced by a few within the community. The solutions come from the community itself, therefore avoids the experts' offerings such as best practices that are often unsuccessful in promoting sustained change (Heckert and Heckert, 2007). Advocates of the positive deviance approaches thus argue that, rather than focusing on error detection, we should focus

instead on using how things go right, and not think in terms of 'error' using the good practice sustained in other areas of similar identity and spread this to less effective areas. The aim is to repeat the 'good practice' noted in the positively deviant' areas and use it in other comparable sites. These new approaches recognize that in current patient safety climates, unlike the often publicised and newsworthy stories which surround adverse events, the delivery of safe care under complex and difficult circumstances is often not recognised. This was apparent in the findings within Chapter 6 of this thesis, where nursing staff and doctors made decisions about complex patients within a complex environment without decision aids or other such tools. In the main, these decisions naturally go unnoticed (or every patient would develop a severe pressure ulcer when they arrive into hospital).

10.6.4 Issues with Safety II as an entity

Despite all the positivity, detecting safe patient care is nevertheless a huge challenge because of the lack of validated measures of safe care, (Lawton et al., 2014, Hollnagel et al., 2013). This is in spite of small scale 'Before and After' quality improvement studies regarding pressure ulcer care noted in the literature review in this thesis (Goldenhar et al., 2013, Baier et al., 2008, Berlowitz et al., 2003, Bredesen et al., 2015b). The positively deviant areas noted in the studies referred to in the literature review, were already succeeding and were not healthcare providers which were poor performers and then made changes. It has already been noted that areas which are 'organisationally ready' to improve will improve more readily than other areas (Berlowitz et al., 2005). This evidence has also been supported by recent shifts in Care Quality Commission (2017; 2018) and NHS Improvement drives (2019). Hughes et al. (2019) have tentatively identified positively deviant orthopaedic care in one NHS health provider who would not usually noted to be an outlier regarding safe systems of care (Patient Reported Outcomes, 2015, (Davis et al., 2011). This study offers an interesting development to this debate. It highlights that organisational readiness to improve and good leadership are factors which are crucial if a culture is to be positively deviant. Interestingly, mindful awareness is also a factor which is apparent in the study site that was found to be positively deviant.

However, in contrast, when my study examined errors which occurred (in this case severe pressure ulcers), I found there to be several causal links with high risk patients, who present with complex needs, being coupled with a lack of empowerment for nurse-led decision making (see Chapters 6 and 7). The cultural influences which were uncovered as the best explanation, still allowed important reasons (however small) for

studying adverse events, and not departing too much from Safety I in practice where healthcare is not organisationally ready. The analysis of the sequences of events helped to uncover and contrast alternative safer perspectives (for example in the cases of Bernie, Chris and Frankie).

Additionally, in terms of public health interest in safety in healthcare, and following interest in such as the Wayne Jowett case (Toft, 2001) which led to changes in how healthcare treats patients who receive chemotherapy, the public would be disappointed not to honour those that have suffered due to errors in healthcare. To not look at a story of a patient's experience of harm inflicted by the health system is departing from the core value of respect and the 'Duty of Candour' which asks frontline staff to openly admit mistakes to patients and families and apologise personally to them (Secretary of State, 2014).

The issue around whether to use adverse events, in my opinion, following the tentative findings from this study, is that few reliable ways have been found to strengthen *how* learning from adverse events is used to improve our healthcare systems in a way that sustains a risk reduction. This resonates with the concerns of other important voices in the patient safety field (Waring J et al., 2010, Vincent, 2010). There has also been a lack of knowledge around undertaking detailed investigations of incidents of the kind that are needed to help develop interventions (Waring J et al., 2010, Waring, 2007). It has already been argued elsewhere, and repeatedly, in this thesis (see Chapter 8) that frontline staff are not always best placed to conduct RCAs on their patients (Waring J et al., 2010). In addition to this, whilst research groups have provided insights into which incidents to focus attention on, many have been reluctant to take the difficult step of moving to intervention development, implementation and testing (Carson-Stevens et al., 2018). This research study has nevertheless made attempts, however small, to develop a possible method of approach which can offer insights into this area, and one of the key strengths has been in its use of expert witnesses (as highlighted above).

10.7 A composite model

This study's findings were that for all eight patients the organisational, environmental influences were the best overall explanation for a patient developing a severe pressure ulcer, twinned with a causal sequence of events for three of the eight patients (see Chapters 3 and 4). These conclusions suggest that there is a place for examining what goes wrong (Safety I) alongside what goes right (Safety II) using a compare and contrast style of analysis. Some, not all, advocates of Safety II acknowledge that things inevitably do go wrong in complex systems, and suggest that we shouldn't need to

differentiate at all between those that 'go wrong' and those that 'go right' (Hollnagel et al., 2013). They argue that one of the issues is that Safety I (error focused) and Safety II (good practice focused) use fundamentally different approaches to learning in patient safety. The trick, they say, is to rid ourselves of any distinction at all between the two. They suggest instead that outcomes of adverse events may, for instance, be due to transient conditions that only existed at one particular point in time and space. For example, local healthcare politics may be antagonistic on one particular day because two adjoining departments were arguing over resource allocations. This idea of 'transience' resonates with some of the findings of my thesis, particularly regarding Frankie's experience of being hospital when the wards she was admitted onto were changing their identity and moving site. Hollnagel et al (2015) argue, quite convincingly, that these example conditions may, in turn, have emerged from other transient or emergent phenomena. Again, in the case of Frankie, some decisions were made about her care (not to admit her onto a High Dependency Unit, where she would have received more one to one care) based on the ward upheavals mentioned above.

However, despite Hollnagel et al.'s (2015) offerings, other authors in the field have argued that they do little to explain Safety II properly, instead focusing too much on what Safety II isn't (Sujan, 2018). The main text from which the Safety II approach is based on, devotes most of its emphasis on describing the issues with Safety I and doesn't develop the detail around how to study Safety II. Nevertheless, aside from this criticism, Hollnagel et al (2013; 2015) conclude, as does this thesis, that a mixture of the two approaches, in whatever guise, is probably necessary to really understand adverse events and learn from them, and to reconstruct them to understand safety. The discussion of the two approaches is described further below.

10.8 Towards Safety III: a middle ground.

So what if we looked slightly differently at the contrasting safety approaches? Instead of trying to work out the difference between Safety I and Safety II as separate entities, combining the two approaches could instead be seen as conjoining a correspondence approach (Safety I) with a coherent approach (Safety II). Chapters 2, 7 and 8 in this thesis suggest that both Safety I and II approaches can complement each other for the best outcome, as Sutcliffe and Weick asked us to consider in Hollnagel et al. (2013). Hollnagel and colleagues (2013) suggested that for health care to become resilient, we should use a twin lens of a complex adaptive system, and within it study the localised patterning of culture. However, I aim to develop this debate further and use another, alternative lens to help with understanding these issues instead of simply debating

Safety I and Safety II. To do this we return to the theory of correspondence versus coherence, which underpinned the method for this study.

10.8.1 Correspondence v coherence.

To highlight the idea of coherence versus correspondence theories in relation to this study, I will reiterate the difference between the two. The correspondence theory of judgement focuses on empirical accuracy, and whether a person, or approach achieves this. A coherence theory, in contrast, focuses on whether a judgement or approach to data achieves logical rationality during the process. Thus for correspondence we are aiming for accuracy, and for coherence we aim for explanatory rationality (Hammond, 1996). Neither offer 'truth' per se. According to the Stanford Encyclopaedia of Philosophy, for coherence theorists, the truth conditions of propositions consist in other propositions, relative to a constructivist view. The correspondence theory, however, states that the truth conditions of propositions are not propositions, but instead objective features of the world, more consistent with a positivist view. Although coherence and correspondence theories are fundamentally opposed in this way, they both present a conception of empirical truth. Regarding health services, I have already demonstrated in the literature review and method in this thesis that the correspondence theory of truth, associated with positivism and hard evidence still dominates in current research debates and is more readily accepted within health care than supposition or coherent versions of truth (Hammond, 1996; Pawson (2006).

However, while correspondence theories explain the observation and verification component of scientific reasoning, and internal validity, along with supporting evidence, coherence theories try instead to explain explanatory hypotheses and counterhypotheses, along with their supporting arguments. Coherence theories posit that science, along with any system of beliefs, is simply a philosophical model. Therefore, for coherence theorists, the "actual world" referenced by someone or some theory is just the largest maximally consistent and minimally inconsistent set of propositions held by that person or theory. So when we refer to "facts", or "states of affairs", we are really just referring to the dominant explanatory model.

This is how the coherent account was arrived at within this study. I was not asserting that it was the 'truth' but that it was the most 'truthful' or 'best' explanatory account of what happened given the evidence we had (see section in Method chapter on Theory of Explanatory Coherence) and the dominant explanation was 'judged' to be the most useful. However, in isolating aspects of empirical evidence to further validate each

coherent account within this study, this supplemented each account with correspondence evidence and thus satisfies all audiences of 'truth' in receipt of such evidence. Again, the evidence was collected following a patient centred approach, which brought forward alternative evidence than purely health service based investigations. For example, regarding this study, the correspondence approach focused on the sequence of events and retrospective evidence collected from data sources, whereas the coherence approach focused on the judgements and logical suppositions about why the severe pressure ulcers developed. Nevertheless, both versions of truth are grounded in empirical evidence. In terms of healthcare, the positivist focus (Pawson, 2008) and insistence on Evidence Based Medicine means that healthcare professionals are more comfortable with using correspondence evidence to make decisions, or form the basis of an intervention. The logic of this is that a tool such as Root Cause Analysis, with its emphasis on finding causality to explain an adverse event, (Safety I) would be a method chosen over the explanation or theoretical building, or more coherent analysis of an adverse event. Surely then, frontline healthcare professionals would feel more comfortable with a composite model which twins correspondence evidence (in this study the sequences of events) and coherence evidence (in this study the coherent account and 'best explanations').

Perrow (1984) made an excellent attempt at portraying these two lenses to some extent in his work 'Normal Accidents'; when he examined the disasters at Chernobyl. His findings were that the technology and human error were conjoined to produce 'normal accidents' within a system (see Chapter 2); however he did not focus in great detail on examining the socio-cultural influences at play, although they were implied, and his socio-technical approach examining disasters within technological industries was never applied to the study of medical error. However, if we were to combine Perrow's socio-technical approach with Vaughan's (1996) and Weick's (Weick et al., 2008) socio-cultural approaches, and incorporate Hollnagel et al.'s (2013) using the lens of correspondence versus coherence instead of all of the other approaches to understanding safety, we can also apply the approaches to error in health care with more intellectual insight. For example, we can use the empirical accuracy of the correspondence approach of Safety I to add internal validity to the findings, but the coherence approach, with its emphasis on logical rationality, helps understand the emergent 'story', and situates it so that it becomes more meaningful to staff working and trying to learn from mistakes. In addition this 'coherence' view allows us to understand the Safety II's focus on 'good usual care.' This idea was first introduced in the methods section (Chapter 3) of this thesis, and has been executed in the analysis

and subsequent findings (see Chapters 3, 4, 7 and 8). These approaches can, and ought to be considered in parallel if we are to improve methods of investigating incidents such as severe pressure ulcers. If we can understand how and why the theories of correspondence and coherence can offer insights into healthcare perspectives and decision making, we can understand better how to deal with adverse events. This thesis has attempted to do just that.

10.9 Conclusions and recommendations for future practice

Part of the coherent story behind examining severe pressure ulcers, is allowing the 'story' to be understood. The discrepancies between data sources highlight gaps in the current approaches to studying adverse events. The whole story means including the views of the patients, not only in apologising following an error (as is now evident in current RCA practice), but in genuinely seeking out and using their version of events, as this study has shown that these often differed from the views of staff.

To include the patient in an investigation and as part of preventative treatment, one suggestion would be that a detailed shared treatment plan is firstly drawn up between staff and patient. Currently these are used variably in practice (National Institute for Healthcare and Clinical Excellence, 2005), although there are NHS England and several other drives to work towards a better process of consent (Montgomery v Lanarkshire Health Board UKSC 11 (UKSC), 2015). However, an additional improvement might be that a consent form is also used as a tool for achieving concordance.

Patients currently often receive an information leaflet about pressure ulcer risks and treatment (usual practice in NHS settings, following NICE guidance and recommendations). NICE guidance for patients suggests questions for patients to ask about their care, but there is no way of knowing or auditing whether a patient gets the chance to ask these questions. Question examples are given on the NICE website as follows: Can you tell me if I am at risk of getting a pressure ulcer? What are the symptoms of a pressure ulcer? How do you check my skin to see if I'm likely to get a pressure ulcer?

Following the findings of this study, a useful development for pressure ulcer prevention could also be a process similar to a research ethics-based consent system (UKREC), (see Appendices for examples of this) where a shared care agreement is offered to patients about pressure ulcer risks and management. These type of agreements are in their early stages in a few NHS Trusts, but the process is far from embedded and

remains at local level. This process would require commitment and signatures on both sides (patient, carer, or advocate) and agreement with statements, rather than an expectation that patients will ask questions voluntarily. For example, statements might include the following: 'I have read the Patient Information leaflet about my pressure ulcer risks and care, and have had opportunities to ask questions'. Further questions might be 'The health care professional has explained to me the risks involved with my choices.' and 'I will inform the health care professional if there are any changes in my skin status in terms of increasing pain or skin breakdown.'

This process encourages a more interactive, 'concordant' approach with patients (Hobden, 2006, McKinnon, 2013), relating to pressure ulcer care, and a responsibility from both sides to 'sign up' to a shared agreement. This can empower the patient (Stevenson et al., 2004) and offer a documented partnership centred approach.

Rather than ignoring issues around the uncertain nature of complex patients, which seems largely the case for the patients involved in this study, who get lost within a decision-laden system, there could be a more effective way to make intuitive decision making more transparent, particularly for nursing staff in the earlier stages of a patient's pathway. For some staff (where they used a decision tree in other studies regarding pressure ulcers) it appeared to be a useful aid (Samuriwo and Dowding, 2014b). Future work could focus on this area regarding high risk patients who present to health care services.

In this study staff didn't appear to respond with enough awareness and recognition to patients who were all high risk of skin damage, although this wasn't true of all staff. This could be seen as 'mindlessness', or a dysfunctional awareness of a changing external environment, and the inner state of the people working in the organization (Weick and Sutcliffe, 2001). Mindlessness closes us off to possibility, and prevents needed change (Filo, 2013, Weick et al., 2008). It suggests the opposite of 'mindful' awareness, and future work would look towards encouraging mindful awareness regarding pressure ulcer prevention and management. This could, and has to an extent already included, changes in risk assessments to focus on the main issues which affect high risk patients (Coleman et al., 2013b). Also useful, according to these findings, would be to encourage staff safety briefs which include awareness-raising around patients at high risk of pressure ulcers (Goldenhar et al., 2013).

For the patients involved in this study, information loss often occurred over time, what was lost was not fully apparent to staff at each handover, consistent with the 'normal accidents' theory that errors become normal within a large system. With the slow onset

of decline in skin integrity, starting from small beginnings, namely Category 1 or 2 skin damage, this can have consequences if staff are not aware constantly of changes to skin status. Keeping pressure ulcers at the forefront of health care staff's minds would be a useful service improvement to prevent severe pressure ulcers developing or deteriorating. This could also be through the continued use of safety huddles or briefs.

10.10 Conclusive comments

Overall, this thesis has highlighted the role of the organisational environment as a main contributing explanation for the development of the patients' severe pressure ulcers involved in the study. Although more specific explanations are around safety culture, decision making, the patient voice not being heard, diffused responsibility and communication issues, these also combine, as shown in the models above, to highlight the possible role of the organisation. This finding has never been explored before in the study of pressure ulcers. There would be scope in exploring this finding further.

Investigations into severe pressure ulcers do not currently focus enough on the whole organisational system regarding their development. This study suggests that the current investigative approach should be widened to include (where resource allows) experts in organisational studies, alongside frontline staff, who are often too close to the issues, and often not equipped, in terms of training, to make informed human factors based judgements about the development of severe pressure ulcers. This is partly because current investigative analysis is more similar to that carried out by engineers, not staff who are not trained in standardisation and reliability of processes.(Vincent et al., 2017, Vincent et al., 2014). Although things are changing and the need for human factors training is increasingly being recognised in health care systems (NHS Improvement, 2019b).

Currently, this novel method has only been applied to pressure ulcer research, and it could be applied to other types of clinical area to see if it works in the same way to produce coherent explanations. It could also be tested alongside current or newer adverse event investigation tools, such as the Yorkshire Contributory Factors tool (2012), to see how it compares in practice, or alternatively, it could also be tested out in areas of good practice to see if it generates similar results.

The study has answered its research question that the environment does contribute to the development of severe pressure ulcers, although how far this is applicable needs further exploration. The findings suggest that incorporating the patient's view, using expert witnesses, or a staged review process and focusing on the wider organisational perspective could be helpful in improving current investigative approaches.

The retrospective case study method also offers a possible, and testable, new theoretical lens to allow the concepts of Safety I and II to be combined semantically and theoretically in a Safety III paradigm, and to examine evidence in a practical way, which should appeal to all parties, and which can be helpful for future investigators and theorists.

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Chapter 12. Appendices

Appendix 1

(Delete this line then print on Trust headed paper- given with study information)

PATIENT AGREEMENT TO RESEARCHER CONTACT

Name of researcher:	Lisa Pinkney	
	Centre for Health and Social Care	
	University of Leeds	
	Leeds Institute of Health Sciences	
	101 Clarendon Road	
	Leeds	
	LS2 9LJ	
	0113 343 0828	
Name of consultant/nurse:		
Contact number:		
Why do patients develop severe pressu	re ulcers? Patient interviews	
Please initial the boxes:		
I have read the information sheet (v	version 1) and kept a copy.	
 I am happy to be contacted by telepting discuss the study further 	phone by the above named researcher to	
allocate and etady farmer		
OR		

• I am happy for my nurse to arrange a time for me to meet with the researcher on the ward

Please complete your contact details in the space provided

Patient name		
Address		
	Postcode	
Telephone Number		
Preferred contact time		
OR		
Hospital name		
Ward		
Date and time of visit		

Thank you for completing this form. Please return to Lisa Pinkney at Centre for Health and Social Care, Room 2.02, LIHS, University of Leeds, 101 Clarendon Road, Leeds, LS2 9LJ or phone 0113 343 0828

(Delete this line then print on headed paper)

PATIENT CONSENT FORM

Why do patients develop pressure ulcers?

Na	me of researcher: Lisa Pinkney		
	Idress: Centre for Health and Social Care, University of Leeds, Institute of Heiences, 101 Clarendon Road, Leeds, LS2 9LJ	alth	
Те	Telephone: 0113 3430828		nitial b
1.	I confirm that I have read and understand the information sheet for the above Version 1 dated 17/12/2008 and have had the opportunity to ask questions.	study	
2.	I understand that my participation is voluntary and that I am free to withdraw time without giving any reason, without my nursing care being affected.	at any	
3.			
4.	I agree that my interview will be tape recorded and typed out, maintaining anonymity.		
5.	I agree to allow any information arising from this study to be used for hear and/or medical research purposes. I understand that my identity will anonymous.		
6.	I consent to the storage including electronic, of personal information for the purposes of this study. I understand that any information that could identify no be kept confidential and that no personal information that could identify me wincluded in the study report or other publication.		
7.	I understand that a copy of this Consent Form will be sent to the Centre for Fand Social Care and my GP.	lealth	

8. I agree to take part	in the above study.		
Name of Patient	Date	Signature	
I have given written info who has freely given the		al explanation to the person named abo pate.	ve
Name of Person taking consent	Date	Signature	
(When completed, 1 for	patient, 1 for patier	t file; 1 for CHSC)	

Appendix 3

(Delete this line then print on headed paper)

STAFF CONSENT FORM

Why do patients develop pressure ulcers?

Name of researcher: Lisa Pinkney

Address: Centre for Health and Social Care, University of Leeds, Institute of Health

Sciences, 101 Clarendon Road, Leeds, LS2 9LJ

Telephone: 0113 3430828

Please initial box after each question

9.	I confirm that I have read and understand the information sheet for the above study <i>version 1 dated 17/12/2008</i> and have had the opportunity to ask questions.	
10.	I understand that my patient is aware that I will be asked to participate in the study and that he/ she has given consent for me to be approached in regard to	
	this. I have seen a copy of my patient's consent form confirming this	
11.	I understand the purpose of the study and know that my participation is voluntary and that I am free to withdraw at any time without giving any reason.	
12.	I agree that my interview will be tape recorded and typed out, maintaining anonymity.	
13.	I agree to allow any information arising from this study to be used for healthcare and/or medical research purposes. I understand that my identity will remain anonymous.	

purposes of this s will be kept confid	tudy. I understand th	at any information that could identify me resonal information that could identify me other publication.	_
15. I understand that a Health and Social		nt Form will be sent to the Centre for	
16. I agree to take pa	rt in the above study.		
Name of Staff member	Date	Signature	
Name of Person taking consent	Date	Signature	

(When completed, 1 for Caregiver, 1 for patient file; 1 for CHSC)

(Delete this line then print on headed paper) Interview Topic Guide

'Why do Patients develop severe pressure ulcers?' study.

Researchers: Lisa Pinkney, Professor Justin Keen, Dr. Jane Nixon.

Address: Centre for Health and Social Care, University of Leeds, LS2 9LJ

Tel: 0113 343 0828

Interview Topic Guide: Patients

(verbal introduction....) Have you any questions about this study? Are you happy to start the interview?

This interview will be unstructured and informal and guided by you, not by a set of questions.

However, as an opening question....

Introductory question:

'Why do you think you developed a severe pressure ulcer?'

Some topics which will be covered, but which are only tentative topics and will be developed as the research progresses:

Background/history of events

Severe pressure ulcer description

Timeline of events-micro, mezzo and macro levels

Interpersonal level

People involved

Support systems-persons, services

Clinical risks

Unexpected events

Communication

Service involvement

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a direct line: 0113 343 0828

fax: 0113 343 0862

■ email: l.m.pinkney@leeds.ac.uk

21 January 2009

Dear Sir or Madam

NIHR Study: Why do patients develop severe pressure ulcers?

Ethics ref:

We are writing with regard to the above study, funded by the National Institute for Health Research. We are researchers from Leeds University Centre for Health and Social Care (Lisa Pinkney and Professor Justin Keen). Local Tissue Viability Nurses will be working with us to identify appropriate patients.

Our study aims to uncover some of the non-clinical reasons why patients develop severe pressure ulcers, i.e. full thickness cavity pressure ulcers. One of the purposes of this research is to see whether the causes may be down to healthcare system weaknesses, rather than individual weakness or blame. The study also aims to help produce a risk assessment tool, which will try to help prevent severe pressure ulcers from developing. There is an information sheet with this letter should you wish to read further details.

As part of our investigation we have gained consent from i	identified patients in the
Yorkshire area to access their healthcare records. One of	your patients in the
study	
	has given their consent to
participate in the study. We have completed an interview v	•
like your permission to review their GP records in order to	examine potential triggers

preceding the development of the severe pressure ulcer. We enclose a copy of the patient's consent form with this letter.

We were hoping to arrange a time that is convenient for you for us to search through the records.

The study has ethical approval from Leeds West Research Ethics Committee (date/details.....) and we enclose a copy of the letter of ethical approval.

We will contact you in the next few days by phone to try and arrange a mutually convenient time to search patient records.

If you have any queries about the study, or need any further information, please do not hesitate to contact us on 0113 343 0828 or by email l.m.pinkney@leeds.ac.uk.

Yours faithfully,

Lisa Pinkney

Research Officer

Justin Keen

Professor of Health Politics

Centre for Health and Social Care

Leeds Institute of Health Sciences

University of Leeds

Charles Thackrah Building

101 Clarendon Road Leeds LS2 9LJ Tel: 0113 343 0828

(Delete this line then print on Trust headed paper)

Participant Information Leaflet and Consent Form

Why do patients develop severe pressure ulcers? Patient interviews (community based)

We would like to invite you to take part in a research project. Before you decide to take part, it is important for you to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully and discuss it with your relatives and your ward nurse or carer if you wish. Ask us if there is anything that is not clear or if you would like more information.

(Part 1 tells you the purpose of this project and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study).

Part 1

What is the purpose of the study?

The development of a severe pressure ulcer (PU), also called a bed sore or pressure sore, has serious consequences for everyone involved. For patients, they cause much suffering and pain. For staff involved in the care of someone with a severe pressure ulcer, they are now seen as what is called a 'serious clinical incident', and require investigation into the causes. For carers they are a major worry, and an obstacle to caring.

This study is about trying to find out the reasons why people develop severe pressure ulcers which may not always be clinical ones. One of the purposes of this study is to see whether the causes may be down to healthcare system weaknesses, rather than to individual weaknesses or blame. The study involves interviewing patients like yourself, and all the people involved in your care throughout the development of your severe pressure ulcer, to see if there are any general underlying patterns which lead to developing a severe pressure ulcer. The study also aims to uncover any other reasons for developing a severe pressure ulcer, which may have not yet been noticed. The final aim of the study is to help produce a risk

assessment tool, which will try to help prevent severe pressure ulcers from developing.

Why have I been invited?

You have been chosen to take part because we are interested in talking to people who have experience of having severe pressure ulcers. Any person who has, or has had in the past, a severe pressure ulcer, from a sample of either hospitals or within the community, will be asked to participate.

Do I have to take part?

You are under no obligation to take part in this study, it is up to you to decide. We will describe the study to you and go through this information sheet. If you agree to take part we will then ask you to sign a consent form to show that you have agreed to take part. You will be given a copy of this information sheet and the consent form for you to keep. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive. If you do not wish to take part this will not affect the care that you are currently receiving.

What will happen to me if I take part?

If you agree to take part, you will be introduced to the researcher, who will be accompanied by the tissue viability nurse. This will give you an opportunity to ask questions about the study. If you then still wish to take part, the researcher will arrange an interview with you. It is expected that the interview will take about an hour. We will make sure the interview takes place in as private a place as possible, either in your own home or on the ward where you are admitted, at a time convenient for you. The interview will be informal, in a conversation style, rather than a list of questions.

The researcher will also seek permission to access and analyse your case notes, to look into what possibly led to you developing a severe pressure ulcer. Your nurses and carers/relatives will be approached to participate in the research and provide information relating to your care.

No further involvement from you is required.

The discussion that you have with the interviewer, with your permission, will be tape recorded and transcribed to help us analyse it. The tape recording will be used only by researchers involved in the project and it will be stored in a locked cabinet. As soon as the information on the tapes in analysed, the tapes will be destroyed.

What are the possible disadvantages and risks of taking part?

We do not foresee any disadvantages or risks to you in taking part in this study. However, you are being asked to give some of your time and you will need to reflect on your personal experience of having a severe pressure ulcer and what your experience of care has been. There is a possibility that you may find this distressing. The interview can be stopped at any point if you feel you do not want to continue. If necessary, a referral can be made to your nurse or other healthcare professionals if you are distressed at all by the interview.

What are the possible benefits of taking part?

We hope that being given the opportunity to take part in this study would give you some satisfaction that you are contributing to increasing knowledge about the reasons and risks behind why people develop severe pressure ulcers. We hope that the information we get from the interviews will help to inform healthcare services about patterns in a person's care pathway which may be more likely to lead to the development of a severe pressure ulcer. We also hope to help produce a risk assessment to help prevent severe pressure ulcers from occurring.

Will my taking part in this study be kept confidential?

Yes. All information which would be collected about you during the course of the study will be kept strictly confidential. We will follow ethical and legal practice and all information about you will be handled in confidence. In the event that any evidence of poor practice, neglect or abuse is identified during the course of the interview, the researcher might need to disclose details to a third party outside of the interview. This would not be done without discussing it with you first. Details are included in Part 2.

This completes part 1.

If the information in Part 1 has interested you and you are considering participation,

please read the additional information in Part 2 before making any decision.

Part 2 What will happen if I don't want to carry on with the study?

You are free to change your mind at any point up to, during or following the interview. You will not be able to be identified in the study results but if you wish to withdraw any data already collected prior to publication of the results then arrangements can be made for the interview tape to be destroyed and your discussion excluded from the study.

Will my taking part in this study be kept confidential?

The procedures for handling, processing, storage and destruction will be according to the Caldicott principles and the Data Protection Act 1998.

Lisa Pinkney and her supervision team have a duty of confidentiality to you as a research participant and will do their very best to meet this duty. Any information that is collected about you will have your name and address removed so that you cannot be recognised from it. All information will be kept in locked cupboards and will only be accessible by members of the research team. No names or details that would identify specific people will be included in the outputs from this study. Outputs, including quotations from interviews, may be used in reports, presentations and papers, and for healthcare and/or medical research, but these will not be traceable to specific individuals. All published and unpublished reports will disguise the identity of people.

What will happen to the results of the research study?

Participants will not be identified in any report or publication. The study results will be used to inform healthcare provision, and to help produce a risk assessment tool, based on the information gathered from participants. Information from this study will be included in a final report and published in a scientific journal.

Who is organising and sponsoring the research?

This study is funded by the National Institute of Health Research, which is part of a larger pressure ulcer research programme aimed to reduce the impact of PUs on patients, and to produce a risk assessment framework to help prevent pressure sores.

This study is also being undertaken as part of a PhD qualification supervised by the University of Leeds.

Who has reviewed the study?

This study has been peer reviewed by the National Institute of Health Research before approval for funding was given. In addition, all research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given approval by the (name of REC) Research Ethics Committee.

What do I do now?

Once you have read the information and if you would like to take part in the study, please tell your district nurse or tissue viability nurse who provided you with this information leaflet. They will complete the Agree to Researcher Contact Form at the end of this leaflet and send it back to the researcher, Lisa Pinkney, who will contact you upon receiving the form, to discuss this study further (with your tissue viability nurse present) and then arrange a time for the interview.

Further information and contact details

Thank you for taking the time to read this leaflet and for considering this study. If you would like to discuss the study further or have any questions about the study at any time, please contact the researcher, Lisa Pinkney on 0113 343 0828 or the study supervisor, Professor Justin Keen on 0113 3436941 or speak to your district nurse or tissue viability nurse who provided you with this information sheet.

(Delete this line then print on Trust headed paper-given with study information)

PATIENT AGREEMENT TO RESEARCHER CONTACT

Name of researcher:	Lisa Pinkney Centre for Health and Social Care University of Leeds Leeds Institute of Health Sciences 101 Clarendon Road Leeds LS2 9LJ 0113 343 0828	
Name of consultant/nurse:		
Contact number:		
Why do patients get sever interviews Please initial the boxes:	re pressure ulcers? Patient	
I have read the information sheet	t (version 1) and kept a copy.	
 I am happy to be contacted by th study further (with a tissue viabili 	ne above named researcher to discuss the ity nurse present)	
Please complete your contact details	in the space provided	
Patient name		
Address		
	Postcode	
Telephone Number		
Preferred contact time		

Thank you for completing this form. Please return to Lisa Pinkney at Centre for Health and Social Care, Room 2.02, LIHS, University of Leeds, 101 Clarendon Road, Leeds, LS2 9LJ or phone 0113 343 0828

Leeds (West) Research Ethics Committee

A/B Floor, Old Site

Leeds General Infirmary

Great George Street

Leeds

LS1 3EX

Telephone: 0113 3923181

Facsimile: 0113 3922863

26 February 2009

Full title of study: Why do patients develop severe pressure ulcers?

REC reference number: 09/H1307/8

Thank you for your letter of 03 February 2009, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

The Committee has designated this study as exempt from site-specific assessment (SSA). The favourable opinion for the study applies to all sites involved in the research. There is no requirement for other Local Research Ethics Committees to be informed or SSA to be carried out at each site.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission at NHS sites ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date	
Indemnity Letter	1	18 December 2008	
Insurance Details	1	02 October 2008	
Flowchart of Research Design	1	17 December 2008	
Appendix K - Interview Topic Guide	1	18 December 2008	
Appendix G - Interview Topic Guide	1	18 December 2008	
Participant Consent Form: Appendix F1 - Staff Consent	1	17 December 2008	
Participant Consent Form: Appendix E1 - Caregivers Consent	1	17 December 2008	
Participant Consent Form: Appendix D	1	17 December 2008	
Participant Consent Form: Appendix C	1	17 December 2008	
Participant Consent Form: Appendix B	1	17 December 2008	
Participant Information Sheet: Appendix F	1	17 December 2008	
Participant Information Sheet: Appendix E	1	17 December 2008	
Participant Information Sheet: Appendix D	1	17 December 2008	
Participant Information Sheet: Appendix A	1	17 December 2008	
GP/Consultant Information Sheets	1	17 December 2008	
Letter from Sponsor	1	17 December 2008	
Covering Letter	1	17 December 2008	
Protocol	1	17 December 2008	
Investigator CV	1	17 December 2008	
Application	5.6	17 December 2008	
Grant Letter	1	17 December 2008	

Timeline	1	17 December 2008	
GP/Patient consent form	1	17 December 2008	
Response to Request for Further Information		03 February 2009	

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "After ethical review –guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

09/H1307/8	Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely

Mr Jon Silcock

Chair

Appendix 9 Initial protocol for study authored by Lisa Pinkney (sent via email to Jane Nixon and Justin Keen 30/10/2008)

Why do patients develop severe pressure ulcers? A Retrospective Study.

Chief Investigators:

Care,

Professor Justin Keen, Centre for Health and Social

University of Leeds, Leeds Institute of Health

Sciences,101

Clarendon Road, Leeds, LS2 9LJ;

Dr Jane Nixon, Clinical Trials Research Unit, University of Leeds, 71-75 Clarendon Road, Leeds, LS2 9PH

Project Team/Authors: Lisa Pinkney, Centre for Health and Social Care,

University of

Leeds, Leeds Institute of Health Sciences.



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1 LIST OF ABBREVIATIONS

2 SUMMARY

This study will investigate the hypothesis that severe pressure ulcers may result from whole system weaknesses in the organisation of health care. Rather than concentrating on individual and organisational risk 'factors' as separate measurable entities, it will aim to gain insight into the whole picture, in order to uncover possible unexplained risks, and thus enhance knowledge about why certain high clinical risk patients develop severe pressure ulcers, when others do not.

3 BACKGROUND

Pressure ulcers are both reportable as a clinical incident in the NHS, and associated with quality implications (DH, 2001; DH 2001b). They can also contribute to the deaths of patients. Severe pressure ulcers are now seen as a serious clinical event. Although the main clinical risk factor: immobility, occurs particularly in elderly, medical, cardio/vascular surgical, orthopaedic, intensive care, spinal cord injured, long-term care and community care populations (Nixon et al; 2001), implications are that clinical negligence can also be a factor (Bennett et al, 2004).

Very recent work by Gorecki et al. (2008) has examined the formation of PUs in relation to clinical risk factors, and advocates the use of appropriate and rigorous tools in dealing with patients, however additional 'outlying' reasons which can contribute to severe PU development currently remain unexplained solely by clinical risk, and are not always attributable to negligence (Fox, 2002; Langemo; 2000). Although patients may belong to similar high risk groups of patients with a propensity for developing a severe PU, some go on to develop one, and some do not, or recover, despite belonging to a high clinical risk category (Nixon et al, 2007).

In the light of these findings, and with litigation predicted to increase, due to both societal trends, and with proposed changes in legislation in investigating PUs as markers of institutional and professional neglect of vulnerable adults (DfES, 2006; DH, 2001; AEA, 2008; No Secrets, 2000; The Mental Capacity Act, 2005; Safeguarding Vulnerable Groups Bill, 2006), there has been growing demand for uncovering all unexplained reasons why patients should develop severe pressure ulcers despite consideration of all clinical risk factors.

Following concerns that severe PUs could indeed be indicative of 'inadequate care' there have been recent developments around guidelines for PU treatment. They have been identified as a NHS quality indicator and priority through DH policy (see DH, 2001; DH, 2001a), with subsequent development of national guidelines (NICE, 2001; 2003; 2005; RCN, 2001). A main focus of the guidelines was in identifying patients at risk, through risk assessment of all patients on admission to acute hospitals and community nursing services, with a parallel focus on preventative care. The guidelines also highlighted a consequential need for improved risk assessment and prevention (NICE, 2005), but were largely based on consensus, and less on a specific evidence base.

Therefore, there is also a requirement for development of a rigorous and thorough risk assessment tool as a preventative measure, and to provide a detailed understanding of the possible individual and organisational factors which may contribute to risk, but equally, how the whole system may contribute. Recent literature has suggested that the propensity for 'errors' in healthcare is 'hard-wired' into the system (see Institute Of Medicine, 2001), and that although individual staff do make mistakes or 'active errors' (Reason, 1990), recurrent errors are more likely to result from weaknesses or 'latent errors' in the whole system organisation of health care (see Bristol Inquiry, 2000), and although every member of staff may act in their patients' best interests, and in the most professional manner possible, there still remain issues in healthcare which are difficult to attribute to individual blame (see Laming Inquiry, 2003).

There have been a number of retrospective, methodologically robust studies by well respected academics which have examined systems failures in fine detail, including the Three Mile Island nuclear reactor (Perrow, 1984) and the Challenger space shuttle disaster (Vaughan, 1996). Recently these innovative methods of investigation have been applied to studies of safety in healthcare (Waring et al, 2006) highlighting the 'tightly-coupled' (Perrow, 1984) organisational relationships, based on timely information exchange, services and resources, which are required for the delivery of health care, and can lead to failures or 'breakdowns' in the system. These 'breakdowns' can be due often to staff working quickly rather than safely. The above methods can similarly be applied to the exploration of why patients develop severe PUs, in order to elicit underlying causal 'mechanisms' (Pawson, 2006) which may 'yield to multiple explanations' (Pawson, 2008, p7), yet nevertheless may follow a similar underlying process for different patients.

The above approach allows for thorough investigation of all the issues involved in the development of severe pressure ulcers, while allowing for any 'outlying' reasons which may have influence. Hammond's (1996) work on human

judgement emphasises the tension between 'coherence' and 'correspondence' and is relevant to the research in its theorising on professionals having to make judgements about healthcare amongst uncertainty. A 'correspondence' approach to making judgements, and offered by years of studying human decision-making by psychologists highlights the 'functional' and 'cognitive' approaches to human judgement and emphasises 'empirical accuracy', whereas 'coherence' highlights that a judgement is made using an 'intentional rationality' to find a 'best fit' for a judgement under the particular circumstances. The tension which exists between the two approaches is symbolic of the tensions which exist for professionals working and making decisions within a culture, and which may have a bearing on the decisions made as to whether a patient develops a pressure ulcer or not.

In addition, Vaughan (1996) applied a 'decision chronology' to examine retrospectively the decisions made at certain points in time by all the people involved in the Challenger disaster, and found that although all the decisions were made using the professionals' best judgements they nevertheless contributed one by one to the huge disaster. This concept, of a 'decision chronology' will also underpin this study, to try and explore why patients develop severe pressure ulcers.

4 AIMS AND OBJECTIIVES

The main aim of the research study is to identify the unexplained reasons which may contribute to development of severe pressure ulcers, using innovative methods of investigation (Vaughan, 1996; Perrow, 1984; Waring et al., 2006; Pawson, 2006; 2008). It also aims to develop a critical incident adult neglect investigation methodology.

5 STUDY DESIGN

5.1 Brief overview of research design

The research study will assume a realist approach (Pawson and Tilley, 1997; Pawson, 2006; Pawson, 2008) and consist of a multi-centre retrospective case study design (see Ragin, 2005). It will incorporate two phases, in order firstly to develop a thoroughly detailed understanding of the system weaknesses, and patterns or mechanisms which may lead to the development of severe pressure ulcers, then to examine, and test the data generated in terms of which 'mechanisms' are at work (Pawson, 2006; 2008).

5.2 Phase 1

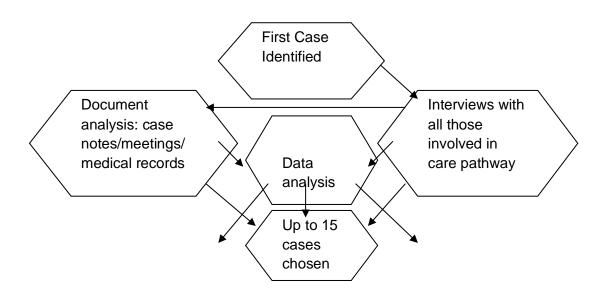
Design

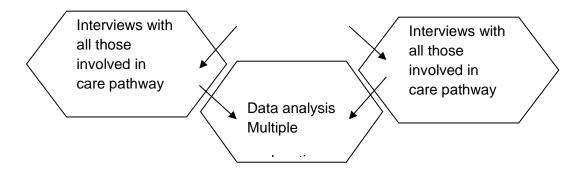
This will consist of a retrospective multiple case study, following the line of an inquiry (see Laming, 2003; Bristol Inquiry, 2000) in order to gain a detailed insight into unexplained influences and patterns involved in the development of severe pressure ulcers, exploring in terms of the 'whole system', and informed by detailed studies of systems failures (see Vaughan, 1996; Perrow, 1984).

This phase will include retrospective analysis of all documentary evidence available and relevant to the pressure ulcer process, and involve conducting semi-structured interviews with all patients (where applicable), carers and professionals involved in the process of the development of a pressure ulcer, in order to produce a thorough, detailed and 'sense-making' account of the multiple explanations, or causes of why severe pressure ulcers occur, including why decisions were made historically and under what circumstances (see Vaughan, 1996, for her 'historical ethnography' and 'decision chronology' terms.) This can also be aligned to the 'process-tracing' type method (George and Bennett, 2005; Cherkel, 2006), which consists of tracing the operation of causal mechanism(s) at work in a given situation. The process is carefully mapped, and the extent to which it coincides with prior, theoretical expectations about the workings of the mechanisms is explored.

An initial case study will be carried out as part of Phase 1 in order to elicit the amount of data to be generated. This will then inform the case sample size. It is anticipated that the sample will be approximately 12 - 15 cases dependent upon time resources. The initial case will be chosen to maximise the range of patient and service characteristics. Further cases will then be chosen using a purposive or 'building block' approach to sampling (Blaikie, 2000; Pawson, 2006) in order to refine the sample, locating cases best able to develop explanation. Data will be collected until saturation is reached. Each case study will involve documentary analysis (medical records, case notes, meeting minutes and so on) and interviews with all stakeholders involved in the patient's 'care pathway' from his or her present circumstances, tracing back until the point in time where the pressure ulcer first occurred.

A list of potential plausible explanations will be generated as a result of the thick descriptive data.





Phase 1

6 ELIGIBILITY

6.1 Inclusion Criteria

Patients from participating acute and community trusts will be included if they have had or have currently a severe PU (Grade 3-4; EPUAP), including hospital in-patients, hospital out-patients, intermediate care or community patients under the care of community nursing services.

The sample will be chosen to be as diverse as possible; and may include the following broad categories of patients from high clinical risk groups:

Acute
Acute on chronic (eg old age + acute illness)
Palliative Care
ICU
Chronic-planned
Chronic –frail.

The sample will be taken from multiple NHS sites incorporating a range of services, including Acute Trusts, Intermediate Care hospitals, PCTs, Community Nursing Services and District General Hospitals. (are these all the sites?!)

If the above high risk patients have developed a severe PU(Grade 3-4; EPUAP) they will be assigned to group 1; if their severe PU has healed despite their high clinical risk they will be assigned to group 2. Check with Jane/Justin

Table 1

Grade 1	Non-blanchable erythema of intact skin. Discolouration of the skin, warmth, oedema, induration or hardness may also be used as indicators, particularly on individuals with darker skin.
Grade 2	Partial thickness skin loss involving epidermis, dermis, or both. The ulcer
	is superficial and presents clinically as an abrasion or blister.
Grade 3	Full thickness skin loss involving damage to or necrosis of subcutaneous
	tissue that may extend down to but not through underlying fascia.
Grade 4	Extensive destruction, tissue necrosis, or damage to muscle, bone, or
	supporting structures with or without full thickness skin loss.

The sample may also include participants who lack mental capacity both fluctuating and permanent, and strict guidelines according to the Mental Capacity Act, 2005 will be followed (see **Recruitment and Consent**).

6.2 Exclusion Criteria

Patients will be excluded from the study if the following criteria apply:

They have not developed a severe pressure ulcer although they are high clinical risk.

Patients who it would be ethically inappropriate to approach, for example, those where death is imminent (any patient who is on or meets the criteria of the Liverpool Care Pathway for the dying) will not be approached.

7 RECRUITMENT AND CONSENT PROCEDURE

7.1 Patients (who are able to consent for themselves) and any person involved in their care 'pathway', for example their informal carer, advocate, nursing staff, paid carer, other healthcare provider.

Patients will be sampled purposively (up to 15 cases depending on pilot study data) in order to represent high clinical risk (Nixon et al, 2007), ensuring, where possible, representation of patients with grade 3 and 4 severe pressure ulcers, and representing different service provisions in different geographical areas.

Members of the tissue viability team (TVT) which includes the local principal investigator and other members of their local team (i.e. tissue viability and clinical research nurses) at participating trusts will identify potential patients through critical incident reporting systems, and referrals. Those who meet the broad eligibility criteria will be approached by a member of the TVT, informed about the study, and provided with a project information leaflet (appendix A) which includes details about the rationale, design, and personal implications of the study, and an 'agree to be contacted by the researcher' form (including either telephone contact or a visit at the ward (appendix B). Members of the TVTs at participating trusts will also provide a record of those identified as potentially eligible, approached to participate, refusals, and consenting patients.

Following information provision, patients will have as much time as they need to discuss the study with their family, advocate, carers, and healthcare provider (up to two weeks expected turnaround). They will be asked to complete the 'agree to researcher contact' form, which will be posted back to the Centre for Health and Social Care). The TVT and the researcher will be available to answer any questions that patients might have about the study. After receiving the signed 'agreement to be contacted' form from the patient, the researcher will telephone the patient, carer, healthcare professional etc to arrange a time for the interview. The researcher will provide information about the study and interview process and will answer any questions before gaining verbal consent and arranging an interview at a mutually convenient time. For in-patients who cannot be contacted by telephone and who are expected to be in the hospital during the interview, with the patient's permission, the TVT member will liaise with the researcher and patient to arrange a mutually convenient time for the researcher to see the patient on the ward to discuss the study further.

The researcher will interview patients in their own home, in the out-patient clinic, or in-patient ward, as determined by the patient's circumstances and preferences at the time of the interview. It is anticipated that a similar number of community and hospitalised patients will be interviewed. Before the interview, each participant will be given a further verbal explanation of the study by the researcher, informed that the interview will be recorded but that all identifiable information will remain anonymous, reminded that they can withdraw from the study at anytime without it affecting their care, and then invited formally to participate. They will be given an opportunity to ask any questions and then if they agree to take part, the participant will be asked to sign the consent form (appendix C). A copy of the consent form will be given to the patient to keep or filed in the patient hospital notes, and one copy kept by the researcher to take back to the Centre for Health and Social Care.

The right of the patient to refuse consent without giving reasons will be respected. Further, the patient will remain free to withdraw from the study at any time, again, without giving reasons and without prejudicing any further treatment.

After the patient has been approached, given consent and interviewed, other professionals involved throughout their care pathway will be sought out through examination of the patient's case notes, files and documentation concerned with their care, and using an approach similar to that of patient recruitment, except that staff and carers will be approached directly (face to face or by phone) and asked if they would be interested in participating. Information will be provided about the study (Appendix D) and a 'cooling off' time will be allowed before they their consent is sought to take part. The guidelines will follow those of the patient consent procedure apart from this initial difference in approaching participants. A snowballing technique will be used to enlarge the sample until data saturation is reached.

Patients requiring an advocate for assisted consent

All procedures will be followed as above; however, if the patient requires additional help with consenting, this will be identified by the Tissue Viability Nurse, and an additional 'personal consultee' will be chosen, who will not be a member of staff concerned with the patient's care. In accordance with the Mental Capacity Act (MCA), 2005; Section 32-33, this specified person will then be asked to assist with the consent procedure (Appendix E) to determine whether the person would be included in the study, and could proceed with an interview, (again subject to MCA, 2005; Section 32). The person may also be a 'nominated consultee' or IMCA (Independent Mental Capacity Advocate), and who will help act either in the 'best interests' of the person as part of the research study, or assist the patient with giving their own consent.

Data Collection

Phase 1

Once an initial patient is identified using our initial broad sampling procedure, and given his or her consent to taking part in the study, a fine detailed inquiry will be undertaken. This will take the following format:

- 1. Semi-structured interviews with the patient (this way of using a bottom-up strategy avoids the researcher absorbing any pre-conceived ideas held by staff and allows a non-biased focus)
- 2. Accessing patient case notes/medical records to examine them retrospectively and using the format below to record details in terms of the shaping influence of multi-layers at Individual, Interpersonal, Institutional, and Infra-structural levels (Pawson, 2006, see fig 1).

The following methods of collecting data will be used:

- a. Tabular timelines (monthly/ weekly/yearly) to record the data collected (Appendix F),
- b. Person grids to record who was where and when in terms of staff, carers and any other input from people (Appendix F),
- c. Incident sheets to record in more detail the data collected (Appendix G).
- 3. Semi-structured interviews with staff, carers and all other 'stakeholders' within the patient's care pathway depending on the data found within patient notes, and through talking to the patient themselves.

The initial case inquiry will be analysed thematically, yet inductively, to look for patterns and possible explanations or causal mechanisms, and which will inform the next case choice using the 'purposive sampling' strategy mentioned earlier. The rest of the cases will follow the same format above in terms of data collection, until data saturation is reached and there appear no other routes to look for causal explanations.

6.5 Data analysis

Phase 1

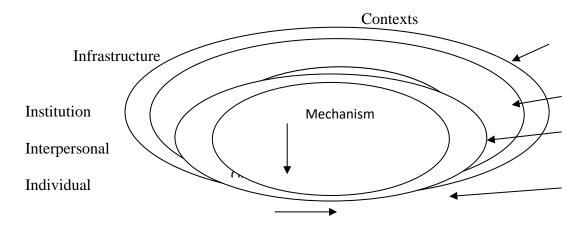
Thematic analysis of information collected from interviews will be ongoing, and conducted as soon as possible after each interview during the initial case study, but at minimum after every few interviews. This will enable an inductive analysis process to commence, (using a computer assisted software package, NVivo 7; QSR) to start to identify a) the key patterns which may lead to development of a severe pressure ulcer, and b) the potential causes. The analysis nevertheless will be iterative, and will be mainly to articulate ideas, at this stage, about the potential causes, both individual and organisational, of severe pressure ulcers. As the data set builds, the process of analysis will be refined and more causal explanations will be generated until saturation point is reached.

Reason's Model of Organisational Accidents(1990), Perrow's theory of 'tight and loose coupling' (1984), using Vaughan's 'decision chronology' and Hammond's Coherence account (1996) will all be applied to aim to produce a general explanation of the structures involved along the care pathway of a patient developing a severe pressure ulcer.

5.2 Phase 2

The data generated by phase 1 will then subjected to Pawson's mid-range theory of causal mechanisms (2008), in order to explicitly test out which 'mechanisms' are at play in the development of severe pressure ulcers. This will consist of a comparison between the multiple case studies to examine the different mechanisms, patterns and contexts as they fit different scenarios of pressure ulcer development.

Fig 1. Layers of contextual influence in Pawson's mid range theory (2006; 2008)



This will also be combined with Reason's Organizational Accident model (1990), and applying Hammond's (1996) theory of Coherence, which may help define potential explanations, in terms of the structures and mechanisms involved in the process of a severe pressure ulcer development. Cases will be compared (Ragin, 2005) for points of commonality.

The findings and conclusions drawn will thus provide a structured, theory informed basis from which to develop an adult incident critical incident methodology and risk assessment protocol.

Competing explanations of events will then be evaluated to identify the most convincing one using Yin's elimination of hypothesis method (Yin, 2003).

Phase 2

The causal 'mechanisms' or patterns, found in Phase 1, and explained in terms of the above theories will then be tested out as part of Phase 2, to examine whether the explanations and models produced can offer insight into why patients develop severe pressure ulcers.

8 CONFIDENTIALITY

Any information which would allow individual patients, healthcare professionals, carers to be identified will not be released. All the participating hospitals, community services, and the Centre for Health and Social Care and CTRU at the University of Leeds will comply with all aspects of the Data Protection Act 1998. All participants will be assigned a project number, and confidentiality will be maintained throughout the duration of the research and dissemination. Any data stored electronically will be password protected. Any hard data will be locked away.

All information collected during the course of the study will be kept strictly confidential. Information will be held securely on paper and electronically at the Centre for Health and Social Care (CHSC). The CHSC will comply with all aspects of the 1998 Data Protection Act, operationally this will include:

- consent from patients to record any personal details (i.e. name, date of birth, address and telephone number) appropriate storage, restricted access and disposal arrangements for patient recorded interviews and personal or clinical details
- consent from patients for access to their medical records by responsible individuals from the research staff or from regulatory authorities, where it is relevant to study participation
- consent from patients for the data collected for the study to be used for training purposes and for developing new research
- Patient name and address will be collected on a separate 'contact details' form and patient name will be collected on the consent form. All questionnaire data collected will be coded with a study number. This will include two patient identifiers, usually the patient's initials and date of birth

If a participant withdraws consent from further study participation their data will remain on file and will be included in the final study analysis.

9 ARCHIVING

At the end of the study, data will be securely archived at the CHSC and participating centres for a minimum of 5 years. If a participant withdraws consent for their data to be used, it will be confidentially destroyed immediately.

10 ETHICAL CONSIDERATIONS

This project will recruit patients with severe PUs and will therefore include elderly and highly dependent patients considered as vulnerable. The study will also incorporate patients who may have mental capacity issues. Ethical issues relate to the involvement of vulnerable adults/elderly patients with high levels of comorbidity including acute and chronic illness. The study also raises ethical issues in relation to recruiting patients who may have fluctuating, and a permanent lack of capacity. It is important to include these participants, as they are over represented in terms of developing severe pressure ulcers, is there a ref for this Jackie?

The ethical issues surrounding these potentially vulnerable patients have been addressed through the study design and include a thought out consent process, which also follows current Mental Capacity Act guidelines.

The study will be submitted to and approved by a flagged Research Ethics Committee (REC) prior to identifying eligible patients. The CHSC will provide the REC with a copy of the final protocol, patient, staff and informal caregiver information leaflets, consent forms, and all other relevant study documentation.

11 STATEMENT OF INDEMNITY

The study is sponsored by the LTHT (?) which will be liable for negligent harm caused by the design of this study. The NHS has a duty of care to patients treated, whether or not the patient is participating in a study, and the NHS remains liable for clinical negligence and other negligent harm to patients under this duty of care. The University of Leeds does not accept liability for negligence on the part of the employees of hospitals. This applies whether the hospital is a NHS Trust or not, and the University of Leeds cannot be held liable for any breach in the hospital's duty of care.

12 STUDY ORGANISATIONAL STRUCTURE

Research Governance- All approvals including R&D and ethical approvals will be in place at participating centres prior to patient enrolment.

Project Team (PT) The Project Team will report 6 monthly progress to the Programme Management
Group, and on an annual basis to the independent Programme Steering Committee.

13 TIMELINES OF STUDY

Months 1-6 Sep 2008-Feb 2009	Set up	Protocol developed Ethical Approval sought Advisory group set up Centre identification R&D MREC/SSI Research Sponsorship Meeting/study schedules agreed				
Phase 1 Months 7-18 March 2009-Feb 2010	Recruitment and analysis	Pilot study commences (months 7-8) Sample identified Main study Phase 1 commences (months 9-18) Progress reports produced? Interim advisory group meeting				
Phase 2 Months 19-24 March 2010-Aug 2010	Implementatio n and pilot	Phase 2 fieldwork (pilot) commences				
Months 25-31 Sep 2010-March 2011	Implementatio n roll out	Phase 2 implementation of risk assessment commences				
Months 32-36 April 2011-Aug 2011	Write up and dissemination	Dissemination activity				

14 PUBLICATION POLICY

The success of the study depends upon the collaboration of all participants. For this reason, credit for the main results will be given to all those who have collaborated in the project, through authorship and contributorship. Uniform requirements for authorship for manuscripts submitted to medical journals will guide authorship decisions. These state that authorship credit should be based only on substantial contribution to:

- conception and design, or acquisition of data, or analysis and interpretation of data
- drafting the article or revising it critically for important intellectual content
- and final approval of the version to be published and that all these conditions must be met (www.icmje.org).

In light of this, the Chief Investigator and relevant project team members will be named as authors in any publication. In addition, all collaborators will be listed as contributors for the main study publication, giving details of roles in planning, conducting and reporting the study. Individual participants must not publish data concerning their patients which is directly relevant to the questions posed in the study until the main results of the study have been published. Data or any findings will not be released prior to the end of the study, for publication or presentation purposes, that might detrimentally affect the progress of the study or bias further data collection for analysis.

DISSEMINATION

Overall outcomes of the study:

- To feedback the results to local NHS teams responsible for critical incidents and adult protection issues. Through participation in implementation groups and networks, we will work with teams to identify any practical changes they can make to their own work.
- To develop a critical incident/adult neglect review protocol underpinned by a Minimum Data Set to standardise review of individual risk factors and critical organizational factors.
- To implement the critical incident/adult neglect review protocol as a pilot in a designated lead acute (Bradford) and lead community trust and then roll out to participating centres.
- To disseminate recommendations for multi-agency service improvements aimed at promoting patient safety, reducing system failures for patients and risk of NHS prosecution.

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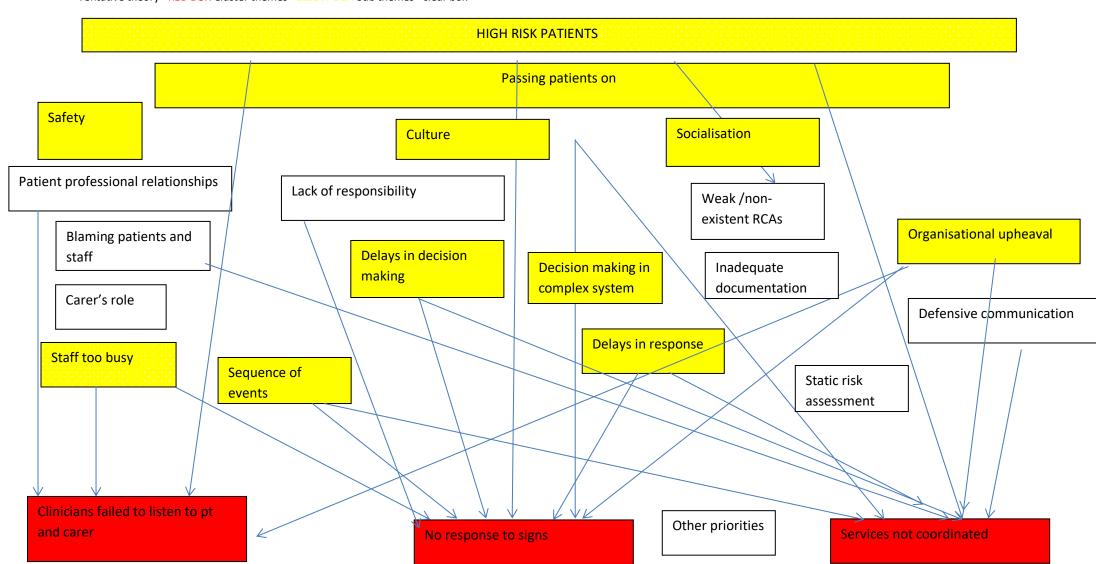
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Appendix 10 Raw data example

4 A	В	С	D	E F	G	Н	I	J	K	L	М
ID	Nursing_Notes_1	Medical_Notes	Patient_Version	tient_Date_Time	Wound_Care	Nursing_Notes_2	Organisational_Issues	Clinical_Risk	nsultant_Vers	r Dr_Vers	Ward_Manager_Version
115				1							
72				1							
83		not for AB at moment, Rehab botox injections to hip-DATE		1	S 1, left Buttock 1, rt buttock 4, ankle 1						
88		no change in legs		1							
98				1							
113				1					I The case		
	Admitted frm	atient Timed No	oteSet +				Obs noted that it is a very busy chaotic ward. The impression was that no one has any time. All staff rush around, and no one was very keen to be interviewed. There were always interruptions to interviews, and most		mix on the ward has changed, from rehab ward where there were mixed group of people where there were some with very very		It is a very pyhsical ward-I am continuously at numbers, most days you are a pair of hands and you don't have cahnce to oversee what is happening, and you have got

Appendix 11: Thematic structure analysis

Tentative theory = RED BOX Cluster themes YELLOW BOX Sub themes = clear box



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