Title: The emerging discourse of patient safety – the research and publication contribution of Frank Milligan

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“THE EMERGING DISCOURSE OF PATIENT SAFETY – THE RESEARCH AND PUBLICATION CONTRIBUTION OF FRANK MILLIGAN”

by

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ABSTRACT

Introduction - This thesis presents the portfolio of evidence required for the award of a PhD by publication at the University of Bedfordshire. The theme that runs throughout is the contribution of the work analysed to the discourse of patient safety in terms of the theoretical, educational, practice development and research contribution made by the author.

Aim and objectives - The aim of the portfolio is to provide a critical analysis of the contribution made by the author to the growing discourse of patient safety. The objectives were to synthesise those contributions through a narrative analysis of the publications with particular reference to:

1. The delineation of patient safety as a viable discourse in healthcare
2. The changing role of medicine as a profession within the context of patient safety
3. The centrality of human factors theory in improving future patient safety practice
4. Safety culture, its definition and problematic relationship with safeguarding
5. Education and healthcare practice.

The literature - The publications included here range in time scale from 1998 to 2017. Twenty-four pieces of literature are analysed and consist of a co-edited book, three research reports, four chapters from two different books and sixteen peer-reviewed journal articles. A citation summary for these publications is provided in Appendix 1.

Key themes - Early publications focused on a critique of western medicine in order to highlight the unnecessary harm that was occurring in medically dominated healthcare systems. This critique moved through the concepts of iatrogenesis and adverse events before settling on patient safety as the key concept through which to influence quality enhancement in healthcare practice. The range and scale of the authors publications reviewed here added value to concepts such as safety culture and the centrality of patient safety incident reporting in such cultural shifts. Other aspects of human factors theory were promoted, most notably the Human Factors Analysis and Classification System leading on to research in the field of medication safety, human factors and safety culture in the context of the nursing home setting. These and other recent publications have highlighted inconsistencies in the relationship between patient safety and safeguarding, and argue that safeguarding has led to something of a return to the blame culture that has been historically present in healthcare.

Conclusion - Patient safety is now a priority in healthcare, although one that has to operate within the political and financial constraints that are inevitably associated with healthcare provision. The evidence and analysis given here shows that the publication and research record generated has both reflected and facilitated the growing discourse of patient safety.

Authors declaration

I declare that this thesis is my own unaided work. It is being submitted for the degree of PhD at the University of Bedfordshire.

It has not been submitted before for any degree or examination in any other University.

Name of candidate: Francis J Milligan

Signature: 

Date: 24-10-18

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Acknowledgements

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List of abbreviations

DH	Department of Health
CQC	Care Quality Commission
HFACS	Human Factors Analysis and Classification System
NHS	National Health Service
NPSA	National Patient Safety Agency
NRLS	National Reporting and Learning System
OECD	Organisation for Economic Co-operation and Development
RCA	Root Cause Analysis
WHO	World Health Organisation

Use of the word 'patient'

The words patient and patients are used throughout this portfolio following the convention of denoting people who are the recipients of health-related care and treatment. No distinction is intended between people as people, and people as patients.

1. Introduction and background

1.1 Introduction

This thesis, which is presented as the portfolio of evidence required for the award of a PhD by publication at the University of Bedfordshire, focuses upon the theoretical, methodological, research and educational contribution made by the author to the growing discourse of patient safety. It constitutes a narrative synthesis and evaluation of author literature published on patient safety (See appendices 1 and 3). The unifying theme that runs throughout the portfolio is the contribution of the work analysed here to the discourse of patient safety.

There are five major sections addressing each of the objectives set out below. The portfolio opens by setting out an aim and objectives. It then discusses the origins of the discourse of patient safety and the place of the profession of medicine within that discourse and the challenges to medical power that the patient safety agenda has generated. Particular attention is then paid to the impact of the field of human factors theory in healthcare. The work closes through a re-visioning of the notion of safety culture and the role of safeguarding within this.

1.2 Aim and objectives

Aim

The aim of this portfolio is to provide a narrative analysis of the contribution made by the author to the growing discourse of patient safety.

Objectives

The objectives of this portfolio are to synthesise the contributions made through an analysis of publications made in the field with particular reference to:

1. The delineation of patient safety as a viable discourse in healthcare
2. Limits to medicine as a profession within the context of patient safety
3. The centrality of human factors theory in improving future patient safety practice
4. Safety culture, its definition and problematic relationship with safeguarding
5. Education and healthcare practice.

These objectives are dealt with in sections 2 to 6 and are reflected in the section headings.

1.3 The concept of discourse

The notion of discourse is important in terms of understanding the narrative analysis presented here. Discourse refers to the language and the way in which language is used to describe particular events and projects (Burr, 2015). Parker *et al*. (1999 p.3) defined it as referring "…to patterns of meaning which organize the various symbolic systems human beings inhabit, and which are necessary for us to make sense to each other". Discourse is therefore an important concept as healthcare will work towards certain goals, and with limited

resources this will inevitably be at the expense of other goals. To be viewed as a priority a concept needs to be identified within the broad discourse of healthcare practice and patient safety has only recently achieved such a position. Discourse is about power, as for example analysed in Michel Foucault's (1991) 'Discipline and Punish' and, importantly in terms of unnecessary harm in healthcare, in the critique of medicine offered in the book 'The birth of the clinic' (Foucault, 1991a). As Foucault suggested, discourse offers the possibility of certain kinds of identities and to be a priority patient safety would have to be seen as a relevant and viable discourse (Rowland and Kitto, 2014), thereby becoming part of the identity of some, if not all, healthcare practitioners. As will become evident in the narrative analysis given, being a proponent of patient safety, and the healthcare benefits that such an approach can bring, is a relatively new possibility brought about through the growing discourse of patient safety.

1.4 Defining patient safety

Patient safety is arguably a 21st century enterprise. There was a concept of patient safety before the year 2000, but it was the combination of a number of different events around the turn of the century that saw the emergence in this and other countries of the field of policy, research, education and practice we now know as patient safety (Emanuel, 2008; Walshe and Boaden, 2008; Rowley and Waring, 2011; Vincent and Amalbertie, 2016; Woodward, 2017). That history can be seen in book titles in that those mentioning patient safety were rare before the year 2000 (See appendix 2). In the UK, the move towards using the phrase patient safety can be linked to the creation of the National Patient Safety Agency (NPSA) in 2001. As an arm's length body of the Department of Health its establishment was an acknowledgement of the high levels of unnecessary harm that were occurring in the NHS (DH, 2000; DH, 2002). The functions of the NPSA, on its closure, were transferred to NHS England in 2012 and now sit with NHS Improvement (2017).

Patient safety is defined by the World Health Organisation as "…the reduction of risk of unnecessary harm associated with health care to an acceptable minimum" (WHO, 2012, p.3). The same document defines a patient safety incident as "…an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient" (p.3). A concept analysis from a nursing perspective was completed by Kim *et al*. (2015) and concluded that the defining attributes were the prevention of medical errors and avoidable adverse events (an incident where a patient is harmed (WHO, 2012). In a helpful text titled 'What exactly is patient safety?' Emanuel *et al*. (2008) define it as "… a discipline in the health care sector that applies safety science methods toward the goal of achieving a trustworthy system of health care delivery" and continues, "… it minimizes the incidence and impact of, and maximizes recovery from, adverse events", a position more recently supported by Woodward (2017). The term adverse event is often used interchangeably with patient safety, which it pre-dates, and refers to unintended injury caused by medical management and not the disease process (Vincent, 2010). The term can be found in classic patient safety literature such as the Bristol

Royal Infirmary Inquiry[1] (2001; Kennedy, 2001) and 'An Organisation with a memory' (DH, 2000; 2002) where the phrase patient safety was largely absent.[2] Common examples of patient safety incidents include surgical operations on the wrong patient (or wrong part of a patient), medication errors including wrong drug and wrong dose, and healthcare acquired infections.

Progress towards more positive levels of patient safety arguably remain disappointingly slow (Rowland and Kitto, 2014; Woodward, 2017). The Organisation for Economic Co-operation and Development (OECD) has calculated that harm related to patient safety incidents is the 14th leading global disease burden, comparable to tuberculosis and malaria (Slawomirski *et al*., 2017). Hogan *et al*. (2012) in a retrospective case review of hospital patient records calculated 11,800 preventable deaths in English hospitals were due to problems in care. The Hogan *et al*. work is interesting in that the terms patient safety incident, adverse event and error were combined within the operational concept of 'problems in care'.

Some patient safety incidents are termed 'never events'. They are defined as "…serious, largely preventable patient safety incidents that should not occur if existing national guidance or safety recommendations have been implemented by healthcare providers" (NHS Improvement, 2016 p.3). Never events are clearly specified, with 14 identified under current guidance from wrong site surgery to scalding of patients with hot water and are, theoretically at least, preventable (NHS England, 2015). Even in this highly monitored aspect of provision in 2014 there were 83 wrong site surgery events reported (operations on the right person, but the wrong place on that person), 42 wrong implant/prosthesis events and 130 retained foreign surgical object events (NHS England, 2014). Provisional data from an eight-month period in 2016 showed that a total of 270 surgical Never Events had been reported (NHS Improvement, 2016). Calculating from these figures for a full twelve months gives an estimate of around 360 never events, which would be a rise of the 2012/3 figure.[3]

1.5 Summary

With this background in mind a critical narrative analysis of my publications is now given following the five objectives stated above.

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[1] The 'Bristol Royal Infirmary Inquiry' (2001; DH, 2002), is widely acknowledged as a turning point in patient safety in this country. The report carried similar messages to 'An organisation with a memory' (DH, 2000), in that significant failings leading to unacceptable levels of serious injury and preventable death were occurring to babies and small children being treated with cardiothoracic surgery at the hospital.

[2] The report, 'An organisation with a memory' (DH, 2000; 2002), was commissioned by the then Labour Government as an expert groups evaluation of the state of the NHS. A theme in the report was the notion that the NHS did not have a memory when it came to errors impacting on patient health.

[3] That rise might be attributable to ongoing improvements in reporting, particularly with regard to Never Event reporting (NHS Improvement, 2016).

2. Objective 1 - The delineation of patient safety as a viable discourse in healthcare

2.1 Introduction

This section is the first of four that presents a narrative analysis of the objectives set out in the introduction. It opens by exploring the notion of harm in healthcare and the need to differentiate between harm that is a necessary consequence of care and treatment and harm that is unnecessary – patient safety incidents. It traces the origins and development of the discourse of patient safety and the writing and research that I was generating within that discourse.

2.2 Necessary and unnecessary harm in healthcare

There is an assumption in the history of medicine and nursing that healthcare should 'do no harm' to the patient. Early efforts to deal will disease and ill health were sometimes more dangerous than the problems being treated (Sharpe and Faden, 1998). In the preface to the 1863 edition of the book 'Notes on hospital design', Nightingale opened by saying "It may seem a strange principle to enunciate as the very first requirement in a Hospital that it should do the sick no harm" (Nightingale, 1863 p.iii). Some, such as Woodward (2017) in a recent book analysing the current state of healthcare, name her as a key figure in patient safety history. Sharpe and Faden (1998) in their comprehensive analysis of medical harm defined iatrogenic illness as doctor generated harm. They went back to the Hippocratic oath written over two thousand years ago, which they note is often simplified to read 'first do no harm'. The analysis given shows that medicine as a profession has a long history of causing harm to patients, both necessary and unnecessary. With regard to unnecessary harm Sharpe and Faden note that this has been caused through its methods, but also through structural means in that professional aims have been put above those of the patient. More recent evidence on this can be found in the book by Mukherjee (2011) that gives a history of cancer treatment and some of the failings in medical and research practice that are part of that history. Mukherjee, as well as Marsh (2015)[4] who wrote a recent reflection on his career as a neurosurgeon, makes it clear that both necessary and unnecessary harm are intrinsic to medical practice.

My first publication on what would now be called patient safety was an article titled 'The iatrogenic epidemic' (Milligan, 1998). The article, which in terms of method was a narrative analysis, was unusual in that there was little in the way of a substantial discourse on the

[4] The text by Marsh is interesting in that he describes what are clearly, on some occasions, patient safety incidents, but does not identify them as such.

concept of unnecessary harm in healthcare.[5] It sought to highlight the levels and types of unnecessary harm occurring utilising the concept of iatrogenesis. In a medically dominated healthcare system, a notion that was analysed in more depth in the later chapter titled 'Defining medicine and the nature of iatrogenic harm' (Milligan, 2003a), the concept of iatrogenesis was contentious as it turned the focus on causes of unnecessary harm towards medicine.

My article drew on the work of Ivan Illich (1990), an emotive and controversial writer who identified three types of iatrogenesis: clinical, social and cultural. These were used in the article to establish some practical and everyday links with unnecessary harm in healthcare. The examples ranged from the pragmatic in terms of clinical iatrogenesis, the errors and misdiagnosis that can occur,[6] to the stress generated through health screening and the alienation associated with cultural iatrogenesis. This first article brought together a number of ideas that were to feature in later research and publications, not least of which were the concepts of unnecessary and inappropriate surgery.[7]

The most common use of the concept of iatrogenesis at that time was in relation to problems in the management of medication, although the important text by Sharpe and Faden (1998) mentioned above was to be published later in that year. Another important book was published the following year by Rosenthal *et al*. (1999) containing a chapter by Leape (1999) that did identify a range of earlier research pointing to significant levels of unnecessary harm.[8] As with Sharpe and Faden (1998) the phrase patient safety was not utilised by Rosenthal *et al*. The notion of unnecessary harm was, with hindsight, the most important idea within my first publication (Milligan, 1998), although couched within the concept of iatrogenesis which was limited by definition to harm caused by the profession of medicine and not other disciplines or aspects of healthcare. A second article (Milligan, 2000) on problems being encountered with the large general hospital followed and is dealt with in detail in section 3.

2.3 The birth of a discourse of patient safety

With hindsight those early publications (Milligan, 1998; 2000) were both a part of and reflective of, the emerging discourse of what was to become known as patient safety. A number of key patient safety events and publications occurred between the years 1999 and 2001. Those events included, amongst others, publication in the UK of 'An organisation with a memory' (DH, 2000), the 'Bristol Royal Infirmary Inquiry' (2001) and the Kohn *et al*. (2000)

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[5] The article was being written at the same time as the publication by Sharpe and Faden.

[6] Khullar and Jena (2016) cite a diagnostic errors rates of up to 15% with Graber (2007) citing evidence of 10% diagnostic error rates found at post-mortem.

[7] The problems of unnecessary and inappropriate surgery would be highlighted and analysed further in Milligan 2003a and Milligan 2007. The issue was highlighted again recently through the case of the surgeon Ian Patterson, who was convicted of the unlawful wounding of women during breast surgery. His case is analysed later in this portfolio.

[8] The book by Rosenthal, Mulcahy and Lloyd-Bostock (1999), titled 'Medical mishaps' pieces of the puzzle', was published in 1999. It reflects the lack of a clear focus that existed at the time in terms of speaking of unnecessary harm in healthcare. There is brief mention of the concept iatrogenic injury, but it does not use the phrase patient safety.

report ‘To err is human’ in the USA.[9] These and other publications of the time highlighted the high error and preventable death rates that were occurring in healthcare systems (Woodward, 2017). They coincided with the conviction of the General Practitioner and mass murderer Harold Shipman in the year 2000 (Baker, 2001; Smith, 2005). Although Shipman’s case was unusual (it is dealt with in more detail in section 3), healthcare practitioners rarely murder patients, the case contributed to a growing wave of cultural unease with regard to the quality and safety of healthcare provision. The delays in detecting Shipman’s practice were given as an example of cultural iatrogenesis in a later chapter exploring issues related to organisations, professions and patient safety (Milligan, 2007).

2.4 Limiting harm in healthcare

It was against the increasing acknowledgement of the unnecessary harm occurring in healthcare at the turn of the century that the motivation for the book ‘Limiting in harm in healthcare: a nursing perspective’ (Milligan and Robinson, 2003) developed. Although the project arose from unease with aspects of healthcare, particularly the role and place of the medical profession in achieving broader public health and health promotion goals, cross-disciplinary support, including from medicine itself (Richardson, 2003), and an experienced co-editor were quickly secured. The book was founded on the notion of unnecessary harm and made extensive use of the concept of iatrogenesis. The key aims were: to critique the effectiveness of western medicine in terms of its contribution to healthcare; clarify the nature and extent of iatrogenic harm; explore the expanding scope of nursing practice; and finally, to offer suggestions on ways of reducing the levels of unnecessary harm being seen. In terms of method, it was an attempt to consolidate and broaden the discourse on unnecessary harm in healthcare. Although the concepts of iatrogenic harm and medical gaze (Foucault, 1991) were not used to structure all the chapters they did act as a foundation for the overall analysis given.

2.5 Consolidating a discourse of patient safety

The analyses given in the book delivered a fuller evaluation of the concepts iatrogenesis and unnecessary harm from a range of different perspectives. The outcome in terms of my own writing was a reduction in the use of the concept iatrogenesis in favour of the concepts adverse event and patient safety. This shift represented both an appreciation of the limits of iatrogenesis as a means through which to promote patient safety and the emergence of the new patient safety discourse. The creation of the National Patient Safety Agency in 2001, and its ongoing work with what was to become the National Reporting and Learning System[10]

[9] The Kohn (2000) report was an evaluation of the state of medical error, what would now be termed patient safety or adverse events, in the USA at the time and reached similar conclusions with regard to preventable harms and death to those reported in ‘An organisation with a memory’ (DH, 2001).

[10] Creation of the National Reporting and Learning Service was a key aspect of NPSA work. The principles upon which the NRLS was based, an open, fair and anonymous system of patient safety incident reporting, were derived in part from the recommendations of ‘An organisation with a memory’ (DH, 2000).

(NRLS), saw the increasing and widespread use of the phrase 'patient safety', a position I sought to reflect in my writing.

Further publications were secured to help reach a broader audience (see Milligan and Bird, 2003; 2003a and Bird and Milligan 2003; 2003a). These marked a shift away from use of the concept iatrogenic harm in favour of the term adverse event. An emphasis was placed throughout the series on defining the extent of the problem, citing examples of unnecessary harm in the need to move away from the blame culture that had been so common in healthcare. Another important concept given priority was the near miss, where a patient safety related error is avoided but not reported. At that point in time the reporting of near events in healthcare was rare. The third article (Bird and Milligan, 2003) anticipated a rise in the number of error reports being made in the NHS due to the increasing complexity of treatment, the ageing population and the increasingly rapid throughput of in-patients. The closing article (Milligan and Bird, 2003a) explored the challenge of a blame–free culture, a notion that would be amended during later work at the NPSA where an 'open and fair' culture was to become the policy implemented.[11] This article also spent some time on lessons being learned from aviation, an area that would be developed further in the article on the Human Factors and Analysis Classification System as applied to medication administration errors (Milligan, 2007a) and in more recent research into medication errors (Milligan *et al*. 2015; 2015a).

In a further attempt to broaden the discourse of patient safety an article was written with a midwifery colleague (Madden and Milligan, 2004). It sought to raise awareness of the relevance of patient safety, the phrase was now used in my writing in preference to iatrogenesis or adverse event, in maternity practice where there was little discussion or literature available on unnecessary harm at the time. As with the Milligan and Bird series above the significance of near miss events was emphasised highlighting a difference in the definition of the concept between the field of patient safety and maternity services. In the Confidential Enquiries[12] of the time (CESpi, 2001) the term related to situations in which a woman nearly died as opposed to a patient safety incident where an error almost occurs but is avoided. It was argued that the inclusion and analysis of further incidents where death did not occur, a more accurate use of the term near-miss in patient safety work, would aid future learning in maternity practice. The article, consistent with other publications analysed here, promoted a systems approach to explanations of error.

Further consolidation of the discourse of patient safety was achieved in articles written during a part-time secondment at the NPSA as one of two clinical specialty advisors for nursing (Milligan and Dennis, 2004; 2005). The first article set-out the nature and purpose of the NPSA and the role of clinical specialty advisor. The notion of safety culture was again

[11] More recently this position has been consolidated within 'The professional duty of candour' for medical and nursing staff (GMC/NMC, 2016).
[12] For further details on the history and development of the Confidential Enquiries at that time see Weindling (2004).

analysed emphasising the need to move away from blame towards a more open and fair culture. The potential impact of the patient safety agenda on the working conditions of staff was analysed, pre-dating the later arguments that human factors is very much the friend of staff – it improves working conditions (Milligan, 2007a; Carayon, 2012). The first article (Milligan and Dennis, 2004) closed with an acknowledgement that all staff are involved in harm to patients, but that some of that harm is unavoidable being an inevitable consequence of care and treatment, yet other harm is avoidable – patient safety incidents. The second article reiterated the definition of patient safety, the importance of near-miss events in terms learning from incidents and then concentrated on the notion of safety culture (Milligan and Dennis, 2005).

2.6 Discussion

The call to do no harm in the history of healthcare demonstrates an appreciation of the risks inherent in care and treatment delivery. In with this there has been a long-standing appreciation of the possibility of error, inadvertent harm and malicious practice, but that understanding lacked focus and open discussion; a discourse through which to theorise and operationalise what we would now refer to as patient safety research and practice. My early publications sought to surface the concept of unnecessary harm, drawing on the evidence that was available and generating new evidence, thereby further consolidating a discourse of patient safety. The concepts of iatrogenesis and adverse events were the background to my early writing, but it was patient safety that was to give the dialogue on unnecessary harm in my work, and the wider literature, the clarity we now see.

3. Objective 2 - Limits to medicine and the discourse of patient safety

3.1 Introduction

Inevitably the emerging discourse of patient safety was a challenge to medicine. Western healthcare had very much been built on the profession of medicine and its biomedical positivist philosophy and methods (Foucault, 1991). Any critique of healthcare remains, therefore, a challenge to medicine as the two are so inextricably linked and my early writing, as seen below, sought to consolidate that challenge.

3.2 The decline of the large general hospital?

Building on my 1998 article analysed above, a second article was published offering a critique of the general hospital (Milligan, 2000). The title, 'Anticipating the decline of the large general hospital' was deliberately contentious in an attempt to draw attention to the unnecessary harm that medically dominated healthcare can generate. It was suggested in the article that the general hospital as designed and utilised at the time, was becoming outdated in terms of effectively meeting the health needs of the public. The examples used in the article included the rising threat of hospital acquired infections, increasing information and computer technology use, the rise in the population size and the problems of the public travelling to centralised hospital facilities. Illich (1974) had talked of the disabling nature of cars, in that we see cars as both a consequence of and means to liberation, but we end up stuck in traffic, disabled in a sense by the sheer numbers of people who have access to cars. Information and computer technology improvements were highlighted (Milligan, 2000) as a means of taking diagnosis and treatment to people rather than obliging people to go to the hospital, although there were to be significant delays in the adoption of information and computer technology as seen in the goals set by the then Labour government (NHS Executive, 1998). These points were used to argue that smaller, local provision was perhaps a better way forward in future healthcare provision.

The critique offered on the large general hospital[13] also explored the notion of it as a symbol of medical professional power, and that technological changes such as the internet were emerging threats to that power, a point repeated in the concluding chapter of the book

[13] Hospital design continues to evolve in response to healthcare acquired infections and the rise of antibiotic resistant bacteria. Authors such as Urich and Zimring (2004) in a review of research on the impact of the physical hospital environment on patient outcomes, suggested a move towards much more side-room provision, a challenge to Nightingale (1863) influenced hospital design. They also emphasised the impact of the hospital environment on staff efficiency and morale.

'Limiting harm in healthcare' (Milligan and Robinson, 2003b). In both the article and the chapter it was argued that if a foundation of profession status is knowledge, then what happens to status and the power that goes with it when the public have more open access to a professions knowledge (Milligan, 2000; Milligan, 2003a).

The concept of the biomedical gaze and the limitations it has brought to healthcare were analysed in the chapter 'Defining medicine and the nature of iatrogenic harm' (Milligan, 2003). In this, with regard to the use of information and computer technology,[14] it was argued that the delay in adoption in the NHS was in part about the reluctance of the medical profession to see a move away from human - the professionals diagnosis, towards computer supported diagnosis, even though good evidence existed at the time that this would be a positive step forward for the patient, a point analysed in the chapter 'Defining medicine and the nature of iatrogenic harm' (Milligan, 2003).

3.3 Professions, organisations and unnecessary harm

The chapter in the book 'Understanding patient safety' constructed a critique of professionals, professions and organisations in the context of the patient safety agenda (Milligan, 2007). So as not to fall into the trap of writing something potentially uninvolving for an often-pragmatic healthcare audience, the decision was made to analyse some of the more extreme examples of unnecessary harm that have occurred and the professional and organisational repercussions that arose from them. The notion of healthcare professionals 'doing no harm' (Nightingale 1863; Sharpe and Faden, 1998) was again analysed in the chapter to reinforce the emerging discourse of patient safety. It was reiterated that harm is inevitable in attempts to improve public health through the care and treatment delivered by health services. In dealing with medicine as a profession, its place and position in healthcare had to again be acknowledged and analysed. As with the earlier chapter (Milligan, 2003a) the assertion was that medicine was, and remains, the most powerful profession in healthcare and, therefore, any explanation as to why rates of unnecessary harm are acknowledged as being high ought to turn to medicine for part of the explanation. Research for the chapter included documentary analysis of the former General Practitioner and multiple murderer Harold Shipman in with three other medical staff who had committed malicious and inept acts; Rodney Ledward, Richard Neale and Peter Green (Milligan, 2007).

The chapter opened by claiming that patient safety was a 21st century enterprise, something now widely accepted in this (Rowley and Waring, 2011; Vincent and Amalberti, 2016; Woodward, 2017) and other countries (National Patient Safety Foundation, 2015; OECD, 2017). It reiterated key parts of the patient safety agenda, such as the levels of unnecessary harm estimated to be occurring and consolidated patient safety as an important discourse that all healthcare practitioners should be conversant with, a position subsequently

[14] The 'Information for health' (NHS Executive, 1998) strategy had set a goal of lifelong electronic patient records that would be available across different healthcare sectors, something that is still yet to be achieved.

consolidated through the international patient safety curriculum guide published by the World Health Organisation (WHO, 2011).

Details of the four medical practitioner case studies were used to give substance to the arguments put forward with the bulk of the analysis being given over to the former GP and multiple murderer Harold Shipman. It cannot be certain exactly how many patients he murdered, most often by injection of an opiate overdose, but estimates of around 250 people, mostly elderly women, are broadly accepted (Baker, 2001; Smith, 2005). The other cases analysed included another GP convicted of 9 counts of sexual assault on his patients and two consultant gynaecologists who had high complication rates in their surgery with one, Rodney Ledward (Ritchie Report, 2000), performing significant levels of unnecessary and inappropriate surgery on women (Milligan, 2007).

An argument was constructed in the chapter that suggested healthcare cannot rely on professional status alone to protect patients from patient safety incidents. Many patient safety incidents are linked to error in its various forms, but some, as these and other cases have shown (See Ian Patterson below) are due to a lack of competence (I used the term inept practice) and/or criminal activity (I used the term malicious practice). The four case studies demonstrated the potential dangers of an over reliance on professional status and the trend, in professions, to protect the professional first then the patient. It was shown that it can be difficult for the public and healthcare practitioners to raise concerns about medical staff. The typical picture seen in the cases analysed was one of incompetent and/or malicious practice over an extended period of time with failures to detect that practice, or a failure of managers and organisations to act upon evidence of malicious or inept practice. This was clearly the case with both Shipman (Smith, 2005; Peters, 2005) and Ledward, (Ritchie, 2000) and was seen again recently in the case of the surgeon Ian Patterson (Kennedy, 2015).

The evidence cited and the conclusions offered in the chapter were critical of professional regulation and argued that the medical profession can at times protect its membership at the expense of public safety. In the conclusion, it was suggested that staff consider putting the patient first, not the profession or the organisation, a position reflected in the recent GMC/NMC (2015) Duty of Candour guidance. This places an obligation on staff and organisations to be honest with patients when patient safety incidents occur. The guidance makes it clear that medical and nursing staff must tell the patient (or carer where relevant) when something has gone wrong. A theme that evolved on reviewing the four cases in the chapter was that staff were sometimes reluctant to disclose concerns, and in some ways anticipated the need for some of the surveillance strategies seen in the safeguarding agenda as discussed in section 5. It was the ideas formulated in this chapter that also shaped and supported the subsequent literature review on students raising concerns with the quality of practice they encounter on clinical and social care placements (Milligan *et al*. 2016; 2017). Reflecting back on the chapter on professions and patient safety the concept of safeguarding was absent as it had yet to consolidate its own discourse, yet a similar chapter if written now would have to utilise the concept of safeguarding. This is important in that safeguarding was

to have a significant influence on later research conducted on medication errors in the nursing home setting as seen in the next section (Milligan, *et al*. 2015; 2015a).

3.4 Limiting unnecessary and inappropriate treatment

The issue of unnecessary and inappropriate treatment has been returned to at the time of writing this thesis with regard to Ian Patterson (Kennedy, 2015), a surgeon who was convicted of 17 counts of wounding with intent and three counts of unlawful wounding. He was sentenced to 15 years in goal.[15] An investigation into his practice (Kennedy, 2015) found that he was, over a long period of time, able to perform inappropriate and unnecessary surgery. His case reflects findings and conclusions reached in the chapter on professions and patient safety (Milligan, 2007). Kennedy found a failure of the employing organisation to manage concerns about Patterson's practice, leading to delays in his being called to account for his poor performance. As with the cases of Richard Neale and Rodney Ledward (Milligan, 2007), there was a failure to follow up on earlier concerns with performance by managers struggling to control Patterson's activities. His status as a medical professional awarded him a level of protection that inhibited attempts to accurately evaluate and manage his work. The obtaining of and adherence to consent gained from patients was another aspect of Paterson's practice that caused concern. He had been performing operations that did not reflect the consent given by patients, and through the tissue sparing mastectomies he completed it was concluded by Kennedy that Paterson had placed his patients under additional risk of recurrence of their malignancy. As in the case of Rodney Ledward there was a lack of clarity with regard to assessing his poor performance in part due to the fact that he worked in both the NHS and private care sectors (Ritchie, 2000; Milligan, 2007). It is likely that an enquiry into his practice will be convened although at the time of writing that has not been confirmed.

3.5 Discussion

The place of the medical profession in healthcare is under increasing scrutiny in the context of the discourse of patient safety. Limits to healthcare, such as high error rates and the other forms of unnecessary harm that are increasingly acknowledged and subject to scrutiny, generate significant challenge and these are discussed further in the next section. My contribution to this aspect of the discourse included challenges to the dominance of the large general hospital as a focus for healthcare provision. It went on to critique medicine as a profession and the repercussions of an unquestioning reliance on professional status in supporting and promoting patient safety. I have argued that reliance on professional status has limits in terms of the possibility and management of unnecessary and inappropriate treatment (Milligan, 2007), a problem that closed this section and that has returned to current debate through the case of Ian Patterson (Kennedy, 2015).

[15] The gaol sentence was subsequently extended on review to 20 years. See https://www.theguardian.com/uk-news/2017/aug/03/breast-surgeon-ian-paterson-sentence-for-needless-operations-unduly-lenient (Accessed 4-9-17).

4. Objective 3 - The centrality of human factors theory in improving patient safety practice

4.1 Introduction and definition

In the previous section on limits to medicine the early critique of healthcare in my writing focused on the medical profession and its position of power at the top of the healthcare hierarchy. Having explored and applied concepts such as iatrogenic and unnecessary harm (Milligan, 1998; Milligan and Robinson, 2003), and acknowledging that the problems of unnecessary harm went beyond the profession of medicine in that analysis (Milligan, 2003), it was patient safety that came to dominate my writing, a position consistent with acceptance of the concept as a viable international discourse in healthcare (See for example Vincent, 2010; WHO, 2011). It was to be human factors theory that would give a more grounded approach to my writings in terms of offering a critique of, and possible solutions to, some of the unnecessary harm in healthcare provision. It has been historically common to blame the practitioner at the 'sharp end' when things go wrong as opposed to accepting the primacy of system explanations in healthcare, the so called 'blunt end' (Cook and Woods, 1994). Human factors theory and the focus that it brings to 'blunt end', perhaps better known as system, explanations of error has been key in moving healthcare towards a more positive safety culture. Human factors is defined by the International Ergonomics Association[16] as "...the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimize human well-being and overall system performance" (Carayon, 2012 p.4).

4.2 The National Patient Safety Agency

Attempts to improve patient safety involve links with safety critical industries such as aviation and those industries have used human factors theory to dramatically improve safety. Early texts such as Bognor (1994) and Rosthenthal *et al*. (1990), drew heavily on aviation when judging the failings in safety and the high rates of error encountered in healthcare. These influences were seen when I was working at the NPSA (circa 2004) in the use of human factors theory in the work the organisation was planning and delivering. Publication of the Seven Steps to Patient Safety (NPSA, 2004; 2004a)[17] was clear evidence of that influence. It espoused the need to build a positive safety culture, move away from blame when error

[16] In some human factors literature the terms ergonomics and human factors are used interchangeably.
[17] Further versions of the guide were subsequently produced by the NPSA for primary care, mental health and general practice.

occurred, promoted the value of incident reporting and sought to enhance learning from error (NPSA, 2004), a position promoted in my writing (See for example Milligan and Bird, 2003a and Milligan and Dennis, 2004). There was no direct mention of human factors theory in the NPSA Seven Steps document and it was to be more practical parts of human factors theory, as opposed to the rather esoteric concept of culture (see section 5), that were a focus in my later writings. The most prominent of these was error, its inevitability and frequency, in with the historical preference, both within and outside of healthcare, to blame the individual when things go wrong rather than to look to systems explanations. The Incident Decision Tree (NPSA/NHS Confederation, 2003) clearly set this out in a flow chart designed for managers investigating patient safety incidents. The tool made it clear that the majority of patient safety incidents would be due to system failures and not individual practitioners, a theme promoted in my writing and in the research I later developed and delivered (Milligan *et al*. 2015; 2015a).

Further evidence on the balance of error explanation and where it should sit can be found with authors such as Gwande (2010). In explaining development of the World Health Organisation Surgical safety checklist, he estimated 75% or more of errors as being system related. Reason (1990; 2008), a widely respected expert in applying human factors in healthcare, puts the figure nearer 90% with Norman (2013), in an analysis of error and the impact of good design on reducing error, suggesting that 99% of the explanation for error sits with system and design factors and not with the individual. Such assertions were promoted through publications such as Milligan and Bird (2003), Milligan and Dennis (2004) and Madden and Milligan (2004). The latter, as previously mentioned, analysing the propensity of error and system explanations of that error, in the maternity setting.

4.3 The Human Factors Analysis Classification System (HFACS)

In Milligan (2007a) I sought to draw together important aspects of human factors and directly link them to the common problem of drug administration errors committed by nursing staff. The article, after a definitional analysis of human factors, focused on a framework used in accident investigation, the Human Factors Analysis and Classification System (HFACS) (Weigmann and Shappell, 2003). The framework offers a method through which to go beyond simply blaming the person present when an accident occurs. It explores the nature of the incident, the error (or errors within it), and a range of potential contributory factors. It is based on a number of important human factor concepts the most notable of which is Reason's 'accident causation model' (Reason, 1990). In that model, it is argued that where there are failures in a system the product of that system is adversely affected. In aviation, the product of concern is passenger and staff safety, whereas in healthcare it is patient safety.

HFACS is used widely in aviation and other safety critical industries, for example the maritime and oil/pipeline industries (Celik and Cebi, 2009; Theophilus *et al*. 2017).[18] A central tenet on

[18] The article that linked the HFACS system to drug administration errors (Milligan, 2007a) has been cited widely including the maritime (Celik and Cebi, 2009) and pipeline industries (Theophilus *et al*. 2017). See appendix 1 for citations linked to publications analysed within this portfolio.

which HFACS is based is that errors vary in type - there are different causes of error, and that factors other than those related to the operator (the nurse in drug administration) are significant. The four levels are:

- Unsafe actions of the operator (error type)
- Pre-conditions for unsafe acts
- Supervisory factors
- Organisational factors.

HFACS theory was combined with a theoretical analysis of drug administration errors in the article (Milligan, 2007a). A key point in HFACS is that the cause of error usually lies outside the operator – in the case of drug administration the nurse (Milligan, 2007a). Applying human factors theory and HFACS to medication administration in this way helped to consolidate the relevance of the concepts in the emerging discourse of patient safety. It was again argued in my writing that the historically common blaming of staff involved in medication errors was a flawed approach with emphasis being placed on the inevitability of error, a notion that still remains counterintuitive to many in healthcare.

Reference was made in the HFACS article (Milligan, 2007a) to a book by Duffy and Saull that analysed ways through which maximising learning from errors had been achieved within safety critical industries. Duffy and Saull described the characteristics of a learning environment as being a "… a 'culture' that reinforces and rewards safe operation" (Duffy and Saull, 2003, p.1010). The article (Milligan, 2007a) pointed clearly to the importance of education in generating and sustaining such a learning culture. It was in 2012 that the World Health Organisation published its 'Patients safety curriculum guide'. This listed 11 key concepts that should be delivered to all healthcare practitioners, number one being 'What is patient safety', and number two was 'Human factors theory' (WHO, 2012). These fit with aspects of my writing and the more recent research conducted on errors in NHS systems supplying medication to residents in the nursing home sector.

4.4 Understanding medication error through the human factors theory

The theoretical and methodological understanding gained through research and publication on human factors contributed to later work that linked patient safety incident reports to medication errors in the treatment of people with diabetes mellitus (Milligan *et al*. 2011; Milligan, 2012). Knowing the importance of understanding systems as espoused in human factors (See for example Dekker, 2011) I was able to anticipate that incident reports from NHS staff would contain reference to the care/nursing home[19] sector as NHS systems both discharge and receive patients from those facilities. NHS systems also provide the prescriptions for residents and supply the medication. On this assumption, a Freedom of Information Act request was made to the NPSA and data obtained showing that the care

[19] The Care Quality Commission criteria for a care home service with nursing was used to differentiate between residential and nursing homes for the purposes of the study (CQC, 2010).

home sector was indeed involved in patient safety incidents related to residents with diabetes. It was not known if the incidents originated in the care home setting or the NHS, but showed for the first time that the NRLS was indeed gathering data on care home provision.

These two publications (Milligan *et al*.,2011; Milligan, 2012), and ongoing clinical governance experience on medication safety, led to the development of research in medication error affecting people with diabetes (Milligan *et al*., 2014; Milligan *et al.* 2015b). The research method selected combined the tried and tested human factors investigation tool, Root Cause Analysis[20] (RCA), with the notion of investigating medication errors in the nursing home setting. The combination proved attractive and funding was secured from the National Institute for Health Research[21] to support a 2.5 year study into NHS medication errors affecting nursing home residents with diabetes (Milligan *et al*., 2014; 2015; 2015a; 2015b).

The study was the first of its type to support both the NHS and the nursing home sector in attempts to secure the enhanced reporting of, and learning from, medication errors. Data collection and subsequent data analysis within the RCA process was structured around the four levels of the HFACS system. Error theory in the shape of error classification was similarly reflected in data collection and analysis. The first article on this study sought to analyse the problems encountered in the data collection process in that the blame culture nursing homes were operating in was hindering the reporting of errors (Milligan *et al*., 2014).[22] A second publication (Milligan *et al*. 2015) contained further details on the findings, and utilised the notion of organisational influences from HFACS to argue that patient safety incident reporting from the primary care sector could be integrated into the NRLS. As nursing homes sit outside the NHS they have no formal access to the facility and are therefore not included in feedback mechanisms. Changing policy to allow access would, it was argued, enhance system understanding of medication processes and the failures that can occur within them (Milligan *et al*., 2015b). GPs are central to the prescribing process for care home residents, yet they were known to be 'poor reporters'. The timing of the study coincided with an initiative from NHS England that sought to increase GP reporting through publication of a guide on patient safety incident reporting (NHS England, 2015a). A computer desktop icon that could be downloaded was also made available. This would sit on the GP computer desktop allowing prompt access to the reporting form (NHS England, 2015b).

4.5 Discussion

Through my writing and research I have sought to utilise, and encourage others to utilise, theoretical and methodological approaches common to safety critical industries such as aviation. Establishing and sustaining a discourse of patient safety is inevitably linked to the concept of safety culture and the need within such a culture to train and educate on

[20] Root Cause Analysis was heavily promoted by the NPSA as a means of investigation patient safety incidents.
[21] Total grant awarded by the Research for Patient Benefit Programme for the 2.5 year project, £205,782 (Grant number PB-PG-1010-23040).
[22] This research and the issue of blame culture is returned to in the next section.

knowledge, skills and attitudes relevant to safety. To be considered a viable and sustainable discourse patient safety needs to be a valued part of the education and training that healthcare practitioners undertake. The World Health Organisation (2011; 2012) has accepted this through the curriculum guidance it has produced, with human factors being the second of the eleven key topics identified. To paraphrase Duffy and Saul (2003), a safety culture is a learning culture and training and education are therefore integral to the discourse of patient safety. As an educationalist and a proponent of patient safety I understood this, hence the comparatively early attempt in my work to directly link methods such as the HFACS to the problem of drug administration errors by nurses (Milligan, 2007a). The four levels within HFACS, as with other human factors theory, point to the broader system explanations of error. This understanding of the importance of error theory and system explanations when things go wrong led to the methodological innovation of applying RCA and error theory within research directed at medication management errors occurring in the NHS nursing home interface.

5. Objective 4 - Safety culture and its problematic relationship with safeguarding

5.1 Introduction

As mentioned above achieving a more positive safety culture is a fundamental goal of human factors in the safety critical industries (Reason, 2008). The establishment of a more positive, learning-oriented safety culture reduces the chances and severity of error and improves the working lives of staff (Milligan, 2007a; Carayon, 2012). The rise of the concept of safeguarding in the UK over the last decade has occurred as part of the emerging discourse of patient safety and reflects concerns with the detection and prevention of incompetent and malicious practice (See Milligan and Robinson, 2003; Milligan, 2007). Historically healthcare has operated a culture of blame – when things go wrong it is an individual or a collection of individuals that are seen to be at fault (Vincent, 2010; Dekker, 2011). Yet blame is inconsistent with the goal of achieving a positive safety culture as industries such as aviation have discovered (Reason, 2008; Gordon *et al*., 2013). As discussed in section 2, if harm to patients is accepted as inevitable, both in terms of necessary harm in attempts to maximise health, and unnecessary in the form of patient safety incidents, shifting patient safety discourse towards safeguarding and the blame associated with it could be counterproductive. This disconnect between being open and fair and the blame inherent in safeguarding, forms the focus of this final section.

5.2 What is safety culture? Being open, being fair

Although definition of safety culture remains problematic, it is clear that 'the way things are done around here', probably the simplest explanation of what safety culture means (Reason, 2008), has changed for healthcare internationally.[23] My early publications, utilising the concept of iatrogenesis (Milligan, 1998; Milligan, 2000; Milligan and Robinson, 2003; Milligan, 2003), were an attempt to question the way things were done in a medically driven healthcare system and sought to analyse the unnecessary harm in caring for and treating patients. As discussed in section 2, the critique of medicine offered by Illich (1990) identified three types of iatrogenesis, the last of which was cultural. Illich argued that modern medicine imposes a particular cultural view of health and the treatment of disease on people, a view that prioritises the biomedical and professional priorities of western medicine (Milligan, 2003). The book 'Limiting harm in healthcare' attempted to consolidate aspects of that critique and closed by saying "... the harm described in this book through the examples and evidence cited has

[23] A summary analysis of safety culture and climate and the impact of these on patient safety has been provided by The Health Foundation (2011).

been about more than mistakes[24] – it has been about culture… It is now appropriate and necessary to change this culture" (Milligan and Robinson, 2003 p.270). It has been the shift away from routinely blaming staff when patient safety incidents occur, together with the profound increase in the reporting of patient safety incidents (as promoted in Milligan and Bird, 2003b; Bird and Milligan, 2003; Milligan and Dennis, 2005; Milligan *et al*., 2015), that have perhaps been the most obvious aspects of the cultural change seen (NHS Improvement, 2016; 2017). It was made clear by the former NPSA (2004) in the Seven Steps to Patient Safety, that a culture of 'being open' (NPSA, 2009), being able to raise concerns and report patient safety incidents, was required of the NHS. The creation of the National Reporting and Learning Service (NRLS) had consolidated attempts to create a more open culture[25] and in the twelve years since its inception has fundamentally changed the culture of incident reporting in the NHS.

The 'Being open initiative' asked staff and organisations to apologise and explain when a patient safety incident occurred (NPSA, 2005; NPSA/NRLS, 2009). This was promoted, again under the heading of safety culture, through an article written whilst at the NPSA (Milligan and Dennis, 2005) and was further reflected in publication of audit data on the care and treatment of people with acute coronary syndrome (Coughlin and Milligan, 2007). Even though the clinical audit data showed that just over 50% of the patients audited had been either over or under treated the hospital was still prepared to support publication, a sign of a more open NHS culture. More recently the joint GMC/NMC (2015) Duty of Candour guidance has placed an obligation on staff and organisations to be honest with patients when things go wrong. That obligation was reflected in the Council of Deans of Health research analysed below (Milligan *et al*. 2016; 2017).

5.3 The conflation of safeguarding and patient safety

The Care Quality Commission website defines safeguarding as "… protecting people's health, well-being and human rights, and enabling them to live free from harm, abuse and neglect" (CQC, 2017 no page number). Review of the document, which sets out the CQC's responsibilities, shows that wider patient safety considerations are part of the CQC role, including the monitoring of standards of quality and safety. There are then two key functions the CQC fulfils - safeguarding, in the sense of dealing with issues of abuse and neglect by staff and organisations (CQC, 2015), and the monitoring and reporting of standards achieved in relation to the concept of patient safety.

The rise of safeguarding in the last decade in some ways reflects concerns with regard to shortcomings in systems for detecting incompetent and malicious practice (See for example

[24] Error would have been a more accurate word here but at the time my knowledge of error theory was yet to be enhanced through an understanding of human factors theory. Mistakes are a type of error (see for example Reason (2008) and Norman (2013)).

[25] It is now common for practitioners to acknowledge and report incidents with around 2 million reported in England in 2016 (NHS Improvement, 2016; 2017).

Milligan, 2007). Prior to the demise of the NPSA in 2012[26] there had been a clearer separation between the concepts of safeguarding and patient safety.[27] The NPSA was largely patient safety focussed with issues of safeguarding and quality monitoring sitting elsewhere in other Department of Health bodies such as the then Healthcare Commission.[28] As discussed in an earlier section, some patient safety incidents involve incompetent and malicious practice (Milligan, 2003a; Milligan, 2007), but they remain a small part of the overall burden of unnecessary harm generated through patient safety incidents.

5.4 The impact of blame on medication error reporting

The research described in section 4 in the nursing home sector was to illustrate the problem of conflation between patient safety and safeguarding (Milligan *et al*, 2015; 2016). The Freedom of Information Act request to the NRLS team mentioned in section 4 demonstrated that medication incidents were occurring and that NHS staff were being diligent in reporting them (Milligan *et al*. 2011; Milligan, 2012), yet care home staff had no formal mechanism through which to report into the NRLS. [29]

Using theory and research methodology from human factors and the data retrieved from the NRLS described above (Milligan et al. 2011; Milligan, 2012), I was able to lead a successful bid for research funding[30] to analyse the origins of NHS medication management errors as experienced in the nursing home sector. The research drew on elements of human factors including error theory,[31] Root Cause Analysis (RCA) and the importance of promoting incident reporting (Milligan et al. 2014; Milligan *et al*. 2015). Elements of HFACS were also integrated into the data collection and analysis processes (Wiegmann and Shappell, 2003; Milligan, 2007a). Despite efforts to increase incident reporting throughout the study only 23 medication errors were reported. RCA was completed on two of those incidents.[32] Medication errors in the nursing home sector were classified, using NICE guidance (NICE, 2015), as safeguarding issues. An example was suggested in the final report (Milligan *et al*. 2015a), that if a nurse made an error in insulin administration in the nursing home sector it would be classified as a

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[26] The functions of the NPSA were passed to various other Department of Health bodies including the NHS Commissioning Board and at the time of writing sit with NHS Improvement.

[27] Although the discourse of patient safety includes the abuse and inept practice practitioners might inflict on patients it was functional to have two separate entities as the NPSA sought to promote patient safety incident reporting within a more open and less blaming culture (NPSA, 2005).

[28] In 2009 the Care Quality Commission came into operation combining the functions of the Healthcare Commission and the Commission for Social Care.

[29] At the time of the study it was possible for patient safety incidents occurring in the care home sector to be reported directly into the NRLS through the NPSA on-line public reporting facility. This function was utilized during the research (Milligan *et al*. 2015) and all the incidents in the study were reported anonymously through the NRLS, but care home staff and managers were not aware of its availability. Further to this, there was no formal mechanism of feedback to care homes for any incidents reported by them into the NRLS system.

[30] National Institute for Health Research, Research for Patient Benefit Programme, grant number PB-PG-1010-230-40

[31] The term error theory here is used to denote the academic field of theory research and into the nature, cause and prevention or errors (See for example Reason (2008) and Carayon (2012).

[32] Evidence from the review of the literature undertaken as part of the study clearly indicated that much higher levels of medication error would be occurring (See for example Barber *et al*. 2009; Avery *et al*. 2012).

safeguarding issue, but the same error in the NHS would likely be classified as a patient safety incident. The latter would likely be dealt with more positively, for example through application of the 'Incident decision tree' (NPSA/NHS Confederation, 2003) and within a more open culture. A conclusion reached was that it would be appropriate to have medication errors in the care home setting classified as patient safety incidents, and that NRLS reporting systems should be open to the care home sector (Milligan *et a*l., 2015; 2016).[33]

5.5 Disclosure and blame in a safety culture

The importance of patient safety and concepts related to it, and the problematic conflation of it with safeguarding, formed the basis of a bid to complete a systematic literature review for the Council of Deans of Health on healthcare students reporting concerns with the quality of practice (Milligan *et al*., 2016; 2017). The issue of students raising concerns is important as they, like all healthcare practitioners, have an increasingly important role to play in generating and delivering feedback on quality. Students, to repeat the analogy drawn in the Francis report (2013), bring a fresh pair of eyes to practice environments and this can allow them to see, sometimes more clearly than permanent staff, the limitations and strengths of the care and treatment being delivered. They may not always evaluate the quality of care accurately, perhaps due to a lack of knowledge and experience (Duffy *et al*., 2012), but as transitory participants they bring a different and potentially useful perspective (Francis, 2015).

In the findings of the systematic review (Milligan *et al*., 2016; 2017) it was concluded that the place and contribution of students in raising concerns required further research, both in relation to the experiences of students (what happens to them once they raise a concern) and the systems within which they are expected to raise concerns. It was suggested that students are in a stronger position now than they have been in the past, in terms of having the concerns they raise listened to, as a more open safety culture has become the norm. The report re-iterated the recent 'Freedom to Speak Up' report (Francis, 2015), in arguing for a further cultural shift, a shift in which the raising of concerns of whatever type is increasingly encouraged and even obliged in some situations. The review concluded that reporters are generally being dealt with more positively, yet this remains a complex area, one that lacks clarity around the meaning of concepts central to that reporting process - raising concerns, whistle-blowing and where these sit within the patient safety and safeguarding agendas. The reviews findings (Milligan *et al*. 2016) will be used by the Council as a basis for judging support for further research in this area (Council of Deans of Health, 2016).

5.6 Discussion

The research and publication narrative analysed in this section demonstrate that the conflation of patient safety and safeguarding within the remit of the CQC has been shown to be problematic through the writing and research described above. Malicious and inept

[33] Several attempts to raise this issue in personal communication with senior NRLS staff were made, but at the time of writing it is unlikely that the NRLS will be extended to the care home sector.

practice are inevitably part of the patient safety agenda as they are a cause of unnecessary patient harm, yet they are but a small, if emotive part (Kennedy, 2015), of the total burden (Milligan, 2007). With its long history of blame when things go wrong there is perhaps some intuitive attraction for healthcare staff in utilising safeguarding as a way of dealing with patient safety incidents, yet blame is clearly inconsistent with the goal of achieving a positive safety culture (see for example Reason, 2008; Dekker, 2011). A culture of blame has, as has been shown here, hindered medication error reporting in the nursing home setting and limited progress on understanding the root causes of such error (Milligan *et al*. 2014; 2015). As the literature review for the Council of Deans showed, there are significant drivers in place to increase learning from patient safety incidents (GMC/NMC, 2016) and these are shifting healthcare towards a less blaming and more safety positive culture.

6. Objective 5 – Education and practice

6.1 Introduction

This section draws on aspects of the first 4 objectives analysed above and provides further evidence on how the emerging discourse of patient safety, the publication and research activity undertaken within this, has been integrated into my educational, research and clinical work. The section is further supported with detail regarding related conference presentations.

6.2 Educational provision

As evidenced in the previous sections there has been an ongoing and substantial link between my academic and research interest in the discourse of patient safety and my educational practice. Using those early publications as substantiation of the emerging evidence on unnecessary harm in healthcare I was able to successfully argue for increasing usage of patient safety and human factors related concepts in educational practice. In the early stages of my educational career this was arguably indirect in terms of highlighting evidence on unnecessary harm, for example the concept of iatrogenic harm (Milligan, 1998) and the potential disadvantages of the general hospital setting (Milligan, 2000). As time moved on, however, the links between my writing and research interests became more structured as demonstrated through the book 'Limiting harm in healthcare' (Milligan and Robinson, 2003) and later research on medication safety. The relevance of the concept of unnecessary harm in terms of healthcare curriculum development was specifically highlighted in the closing chapter of the book (Milligan and Robinson, 2003b) and the heavily cited article on nurses committing drug administration errors (See appendix 1).

These and other early publications, for example Milligan and Bird (2003; 2003a) and Bird and Milligan (2003; 2003a) were to add weight to the arguments being made during curriculum development at the University of Bedfordshire and, as seen below, helped me gain a post with the National Patient Safety Agency. In 2007 I successfully planned and delivered a new MSc course title 'Enhancing quality through patient safety'. The course, based on a modular system, included units specifically dedicated to patient safety and human factors theory as was the final dissertation required of the degree.

The position at the time of writing is that all pre-registration healthcare programmes in the University of Bedfordshire, including nursing, midwifery, paramedic science and perioperative practice, deliver content on patient safety and human factors theory. The WHO (2011) patient safety curriculum guide continues, with my support, to be used to structure that provision. The current University MSc Advanced Clinical Practice (nursing, midwifery and paramedic science) course, a replacement for the earlier MSc 'Enhancing quality through patient safety', contains a core unit titled 'Human factors and design for patient safety'. Other post-

registration healthcare provision at the University, such as community practice programmes and the non-medical prescribing course, have patient safety and human factors elements integrated within them. Table 1 shows conference presentations demonstrating the promotion of patient safety discourse in educational provision.

Table 1 - Conference presentations related to educational provision

June 2015	Conference presentation	*Patient safety and the concept of care.*	iCare 2015, University of Bedfordshire
May 2011	Invited presentation	*Developments in patient safety.*	Bedford Hospital Trust, Bedford
September 2005	Conference Core Paper	*Establishing a culture for patient safety – the role of education.*	Nurse Education Tomorrow, Grey College, Durham
September 2004	Conference Core Paper	*The patient safety agenda in healthcare curriculum development,*	Nurse Education Tomorrow, Grey College, Durham

6.3 National and international links

Research and writing on issues related to patient safety, perhaps most notably the co-edited book 'Limiting harm in healthcare' (Milligan and Robinson, 2003), supported me in gaining a post as one of two nurse advisors at the National Patient Safety Agency in 2004. Working at the NPSA allowed me to both better understand the emerging discourse of patient safety and actively contribute to the work of the agency in terms of some of the policy and guidance it generated. Articles written around that time sought to further consolidate the discourse of patient safety and promote the efforts of the NPSA within that discourse (Madden and Milligan, 2004; Milligan and Dennis, 2004; 2005). Examples of specific projects contributed to include the NPSA Foresight package (NPSA, 2008), an initiative to help practitioners become more error wary, and the later Insulin passport work produced by the NPSA (NPSA, 2009; 2010). Table 2 shows the conference presentations completed in relation to NPSA work. Links with the NPSA were further utilised within the MSc Enhancing Quality Through Patient Safety course, for example in designing the two hour unseen examination on error theory used as part of the human factors unit.

Table 2 - Conference presentations related to NPSA activity.

June 2005	Conference Presentation	*The patient safety agenda and the work of the NPSA.*	Nursing Times Careers Event, London.
April 2005	Conference Presentation	*Patient safety and the work of the NPSA*.	Royal College of Nursing Congress, Harrogate.
November 2004	Seminar presentation	*The role of the NPSA in patient safety (England Management Team, RCN).*	Royal College of Nursing, London
June 2004	Joint conference presentation	*The patient safety agenda and the work of the NPSA.*	Nursing Times Careers Convention, Earls Court, London.

More recently I was invited to be an expert member of an advisory group for Health Education England charged with producing medication guidelines for the NMC on the new Associate Nurse role (HEE, 2017). As part of the group I was able to encourage the use of concepts

such as ‘safety critical medications’ and ‘safety culture’, terms which can be seen within the published guidance.

As an experienced member of academic staff at the University of Bedfordshire I was able to secure a five month sabbatical in 2014. I used this opportunity to further consolidate my clinical experiences of patient safety, firstly by working as a staff nurse for a day a week on a haematology ward, and secondly by arranging a visit to the Anhui Medical University in Hefei, China. Having taught patient safety on a range of courses to international students from different countries I felt it would be helpful to gain more direct experience of patient safety in another country – to experience patient safety as in international agenda. The Anhui Medical University staff were very helpful and supportive and facilitated a range of visits to clinical areas in two different hospitals in Hefei leading to the sharing of number of ideas and experiences on patient safety (see Table 3). The two Universities subsequently signed a partnership agreement (University of Bedfordshire, 2015) and exchange visits by students from both institutions took place in 2016.

Table 3 - Conference presentations completed as part of international patient safety work.

March 2016	Invited presentation	*Patient safety, 2014 to 2016.*	First affiliated hospital, Hefei, China
April 2014	Invited presentation	*Human factors and patient safety.*	Anhui Medical University School of nursing, Hefei, China
March 2014	Invited presentation	*Patient safety, an international concern.*	First affiliated hospital, Hefei, China

6.4 Clinical governance

An integral part of promoting patient safety has been supporting a range of clinical governance initiatives, including long term membership of an acute trust Safer Medication group, which more recently became a Medication Safety Group as required under NHS patient safety guidance. A number of conference presentations were generated through this medication group work (see table 4) which also supported development and dissemination of the research findings on the medication error research I have lead (Milligan *et al*., 2014; 2015; 2015a; 2015b). The clinical link between my research and writing on patient safety became clearly evident when I attended a clinical governance meeting at which audit data was presented on adherence to clinical protocols when treating patients with acute coronary syndrome. Working with the junior doctor who collated the data I was able to facilitate publication of the audit thereby promoting good practice with regard to protocol use and development. Publication of the audit data also demonstrated the more open culture NHS hospitals are working within (Coughlin and Milligan, 2008). Working as a staff nurse during the sabbatical mentioned above also allowed me to gain practical experience and an up-to-date view on medication management in the acute hospital setting, both of which have been valuable in enhancing my contribution to medication management strategies.

Table 4 - Medication safety related conference presentations.

November 2016	Invited presentation	*Root Causes of Medication Errors in Nursing Home Residents with Diabetes: Enhancing Safety in NHS Medicines Management systems.*	Diabetes Professional Care, Olympia, London
September 2016	Conference presentation, core paper	*Going beyond blame: reporting NHS medication errors in nursing home residents with diabetes*	Nurse Education Tomorrow conference, Cambridge
March 2015	Poster presentation	*Root Causes of Medication Errors in Nursing Home Residents with Diabetes.*	Diabetes UK national conference, London
March 2015	Symposium presentation	*Root Causes of Medication Errors in Nursing Home Residents with Diabetes: Enhancing Safety in NHS Medicines Management.*	RCN Older Peoples Forum. Renaissance conference centre, Manchester
May 2013	Invited presentation	*Patient safety and error; a health promotion issue.*	256 City of London Field hospital, Territorial army, London
October 2006	Joint presentation	*Reducing medication errors: the role of a Safer Medication Group.*	Reducing medication errors conference, London
February 2006	Joint presentation	*Safer medication in the acute hospital.*	Patient Safety 2006 conference, Birmingham
November 2006	Joint conference presentation	*Involving service users in the work of a Safer Medication Group.*	Risk 2006 conference, London.

6.5 Discussion

The section adds to gaining an understanding on how my research, education and clinical governance work has contributed to the emerging discourse of patient safety. It shows that the contribution has been consistent over a prolonged period of time and in itself reflects the growth of a patient safety discourse and my contribution and place within that discourse.

7. The emerging discourse of patient safety - Discussion and conclusion

7.1 Discussion

When I started researching and writing about the limitations of healthcare in terms of unnecessary harm in its various guises there was no coherent discourse of patient safety. As shown in this portfolio there was some debate and research on unnecessary harm prior to the turn of the century, but not within a rubric of patient safety as now seen. The limitations of medically influenced healthcare, in terms of the high levels of unnecessary harm occurring evidenced in those early publications (Milligan 1998; 2000), were to be critiqued in more depth through later publications and research that sought to analyse, theorise and challenge aspects of healthcare that appeared inefficient, prone to error and unnecessarily harmful for the patient. At the turn of the century concepts such as iatrogenesis (Illich, 1990), adverse events (Kennedy *et al*., 2000; DH, 2000) and the medical gaze (Foucault, 1991) were in use, but it was the subsequent delineation of a discourse of patient safety that brought those concerns into focus. As Burr (1995) suggested, a discourse is a particular way of representing things, and there is now, as evidenced through the literature and research subject to narrative analysis here, a coherent discourse of patient safety. Put simply, unnecessary harm in healthcare, harm that is either of no health benefit or potential benefit for the patient, is now conceptualised as patient safety, a term now in common usage in both public and healthcare discourse. The research, publication, education and clinical governance record reviewed here has both supported and added to that usage.

The application of aspects of human factors theory and methods to healthcare has helped to articulate for a wider audience the complex nature of errors and the superficiality of quickly and uncritically blaming those involved in error (see for example Milligan, 2007a; Milligan *et al*. 2015; 2015a). The rise in use of human factors methods and theory has challenged medicine through its emphasis on a more critical and theory-based approach to team working and flattening the hierarchy to improve communication (Gwande, 2010; Gordon *et al*., 2013). My work has through the research methods used, including Root Cause Analysis and systematic reviews of the literature, actively promoted aspects of human factors including RCA, the Human Factors Analysis and Classification System and error theory. This was particularly the case in the research on medication errors in the nursing home setting (Milligan, 2007a; Milligan *et al*. 2015; 2015a). Further challenges to the profession of medicine include support, through the writing and research analysed here, for increased accountability for the profession by highlighting the possibility and consequences of inept and malicious practice, both for the profession itself and individual practitioners (Milligan, 2007a). The increasing use of human factors in healthcare has also led to a more substantial critique

of safety culture, its definition and problematic relationship with safeguarding, something that has been a long-standing theme in my work (Milligan and Robinson, 2003; Milligan and Bird, 2003a; Madden and Milligan, 2004; Milligan and Dennis, 2005; Milligan *et al*. 2016; 2017). These concepts have been made more accessible to healthcare staff through the promotion of them in educational provision as seen in section 6.

Understanding the complexity of NHS medicine management systems and the frequency of error were the motivation for the research into errors in the nursing home setting. As it transpired it was to be the fear of blame directed to those involved with, or simply associated with, the errors being sought for the study that led to the small number of incidents finally gathered, a number lower than that predicted by research (see the analysis given in Milligan *et a*l., 2015; 2015a; 2015b). The research led to the critique of the safeguarding agenda recently espoused in my writing in that it is still too common for practitioners to seek blame when a patient safety incident occurs. One of the conclusions reached through this research was that a medication error committed by a nurse in the NHS community or hospital settings is likely to be classified as a patient safety incident, but if that same error occurs in a nursing home the incident is likely to be classified as a safeguarding event. Inevitably the latter carries more blame and a culture of blame holds back the level of safety culture achieved. It is argued here that this discrepancy is symptomatic of the unresolved nature of the relationship between patient safety and safeguarding in the UK.

7.2 Future research and publication

At the time of writing I am developing another research project titled, “The effectiveness of Medicines Use Reviews (MUR) in medicines optimisation for older patients with diabetes and respiratory diseases: a realist evaluation of pharmacist recommendations, GP medicines management and patient outcomes”. This research will seek to further analyse mediation errors in the community context and generate a better understanding of the medicine management process within what is a complex interaction of healthcare systems. Two further publications will also be generated from the process of collating this portfolio. One will explore the conflation of patient safety and safeguarding in more detail, and the second will seek to revisit points made in the chapter on malicious and inept medical practice and lessons that might be learned from the recent Ian Patterson case (Kennedy, 2015).

7.3 Conclusion

Over the last two decades the language used to identify, define and explain the unnecessary harm that can occur to patients has evolved into a much more coherent discourse. This portfolio has provided a critical analysis of the theoretical, methodological, educational, practice and research contributions made by the author to that discourse. Patient safety is now a priority in healthcare, although one that has to operate within the political and financial constraints that are inevitably associated with care and treatment provision. The evidence and analysis given here shows that my publication and research record has both reflected and influenced that discourse. It demonstrates that a meaningful publication and research

record is in place, a record that continues to evolve and contribute to the growing discourse of patient safety.

Word count = 12,906

8. The selected literature upon which the portfolio is based[34]

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[34] All these publications were completed, in part at least, whilst employed at the University of Bedfordshire. A declaration of the authors contribution to joint authored works can be found in appendix 4.

*Only authored and co-authored elements of this book are included in Appendix 3.

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9. Appendices

Appendix 1 – Citations of author literature analysed in this portfolio

Citations indicated on Google Scholar as at 24-5-18 and 'Reads' on ResearchGate, 24-5-18.

Short reference	Article/chapter Title	Number of citations*
Milligan, F. (2007a) *Nurse Education Today*, 27 pp.95-102.	Establishing a culture for patient safety – the role of education.	123 (373)
Milligan, F. and Dennis, S. (2004) *Nursing Standard*, 19 (7) pp.33-36	Improving patient safety and incident reporting.	42
Milligan, F. and Dennis, S. (2005) *Nursing Standard*, 20(11) pp.23-29.	Building a safety culture.	26
Milligan F, Krentz, A, and Sinclair, A. (2011) *Diabetic Medicine*, 28 (12) pp.1537-1540.	Diabetes medication patient safety incident reports to the National Reporting and Learning Service – the care home setting'.	14
Bird, D. and Milligan, F. J. (2003) *Professional Nurse*, 18 (10) pp.572-575	Adverse health-care events: Part 2. Incident reporting systems.	9
Milligan, F. Robinson, K. (eds) (2003) Oxford: Blackwell Science.	Limiting harm in health care: a nursing perspective.	7
Madden, B. and Milligan, F. (2004) *British Journal of Midwifery*, 12 (10) pp.643-647.	Enhancing patient safety and reporting near misses.	5
Milligan, F. and Bird, D. (2003) *Professional Nurse*, 18 (9) pp.502-505.	Adverse health-care events. Part 1: The nature of the problem.	5
Bird, D. and Milligan, F. J. (2003a) *Professional Nurse,* 18 (11) pp.621-625.	Adverse health-care events: Part 3. Learning the lessons.	5
Milligan, F. and Bird, D. (2003a) *Professional Nurse*, 18 (12) pp.705-709.	Adverse health-care events: Part 4. Challenge of a blame-free culture.	5
Milligan, F. (1998) *Nursing Standard,* 13 (2) pp.46-47.	The iatrogenic epidemic.	4
Milligan, F. (2012) *Nursing Standard*. 26 (29) pp.38-43.	Diabetes medication incidents in the care home setting.	3
Milligan, F. (2003b) In Milligan, F. J. Robinson, K. (eds) *Limiting harm in health care: a nursing perspective.* Oxford: Blackwell Science. pp.255-273.	Limiting harm in future health care – the role of nursing.	2 (5)
Milligan, F. *et al*. (2014) *Nursing and Residential Care*, (11) 16 pp.617-621.	Reporting medication errors: residents with diabetes.	2
Coughlin, S and Milligan, F. (2007) *Clinical Governance: an international Journal*. 13 (2) pp.138-141.	An audit of acute coronary syndrome assessment (TIMI scoring) and treatment	2

*Literature with a single citation has been excluded. Figure in brackets is 'Reads' as found on ResearchGate, 24-5-18

Appendix 2 – Selected books demonstrating the growing discourse in patient safety

Title	Author	Year of publication
Patient safety in anesthetic practice	Calkins	1997
**Limiting harm in healthcare: a nursing perspective*	Milligan and Robinson	2003
The patient safety handbook	Youngberg and Hatlie	2003
Patient safety: research into practice	Walshe and Boaden	2006
Understanding patient safety	Currie (UK)	2007
Understanding patient safety	Watcher (USA)	2008
Practical patient safety	Reynard *et al*.	2009
Health care errors and patient safety	Hurwitz and Sheikh	2009
Patient safety	Vincent	2006 (2010)
Patient safety: a human factors approach.	Dekker	2011
Patient safety: an engineering approach	Dhillon	2011
Innovating for patient safety in medicine	Lawton and Armitage	2012
Patient safety: an essential guide	Gluyas and Morrison	2013
Patient safety and managing risk in healthcare	Fisher	2013
Patient safety: a case-based comprehensive guide	Agrawal	2014
Patient safety culture: theory, methods and application	Waterson	2014
Rethinking patient safety	Woodward	2017

*The use of the phrase ‘patient safety’ was considered by the editors and authors of the book ‘Limiting harm’ was not used due to the infrequent use of the concept at that time. The table illustrates the earliest published book with patient safety in the title and the increasingly common use of the phrase since the turn of the century.

Appendix 3 – Copies of the literature analysed within the portfolio

In order not to breach copyright regulations the copies of the materials listed on page 30-31 have been removed from this version of the thesis.

Appendix 4

Declaration of contribution to joint authored works

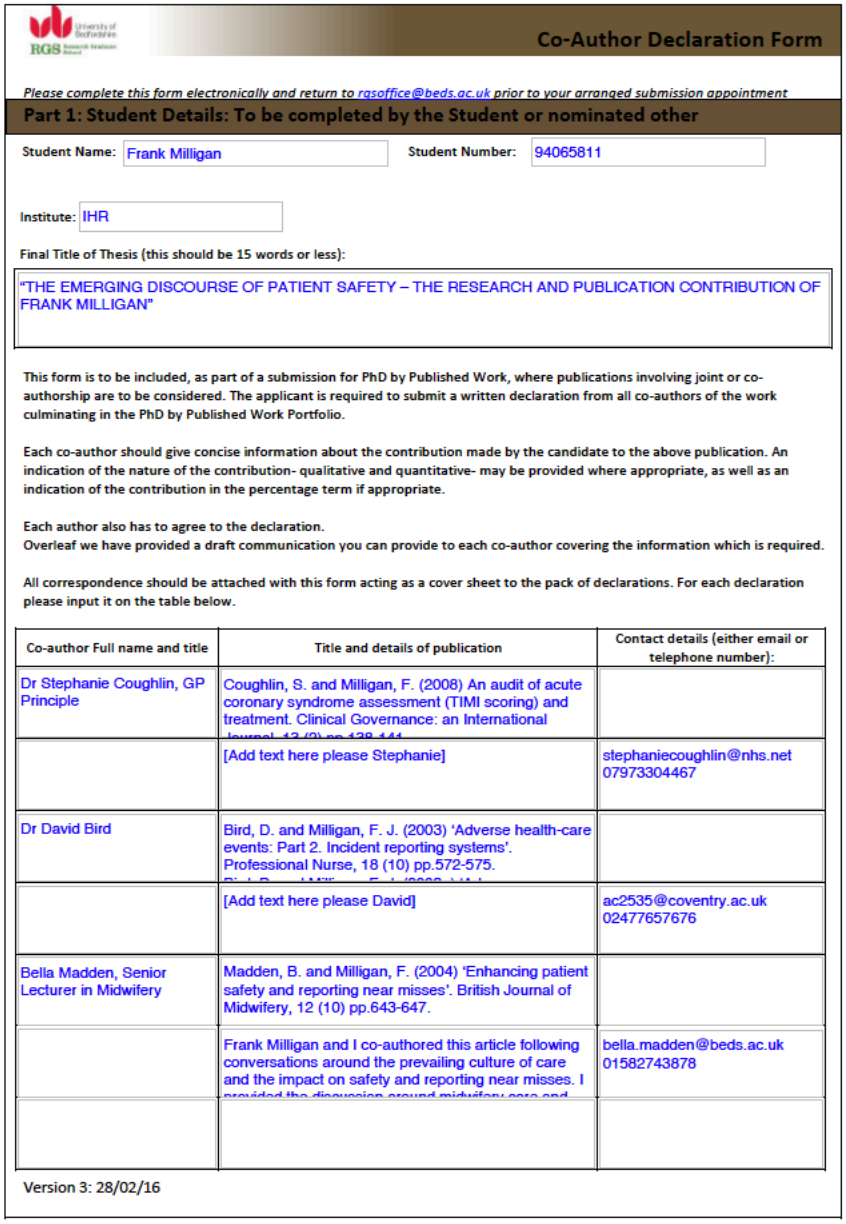
Reference for jointly authored publications	Declaration/clarification
Milligan, F. and Robinson, K. (eds) (2003) *Limiting harm in health care: a nursing perspective*. Oxford: Blackwell Science.	I instigated the approach to Blackwell Science with regard to this type of text being produced and secured support from Professor Kate Robinson as co-editor. I fulfilled the role of lead editor and liaised with the publishers throughout the process of completion of the text. Meetings and communication with the various authors was again coordinated and led by myself.
Milligan, F. Robinson, K. (eds) (2003a) Introduction, aims and mapping health care. In: *Limiting harm in health care: a nursing perspective*. Oxford: Blackwell Science. pp.1-16.	As above in that this introduction set out my vision for the text as agreed with Kate Robinson and the writing team. I produced a completed draft chapter that we then co-edited and agreed for final production.
Milligan, F. and Robinson, K. (2003b) Limiting harm in future health care – the role of nursing. In: Milligan, F. and Robinson, K. (eds) *Limiting harm in health care: a nursing perspective.*	This was the concluding chapter for the book and involved the process described above.
Milligan, F. and Bird, D. (2003) 'Adverse health-care events. Part 1: The nature of the problem'. *Professional Nurse,*18 (9) pp.502-505. *Bird, D. and Milligan, F. J. (2003) 'Adverse health-care events: Part 2. Incident reporting systems'. *Professional Nurse*, 18 (10) pp.572-575. *Bird, D. and Milligan, F. J. (2003a) 'Adverse health-care events: Part 3. Learning the lessons'. *Professional Nurse*, 18 (11) pp.621-625. Milligan, F. and Bird, D. (2003a) 'Adverse health-care events: Part 4. Challenge of a blame –free culture'. *Professional Nurse*, 18 (12) pp.705-709.	I agreed the idea for these publications with David and approached the editorial team from Professional Nurse to secure the possibility of publication. The structure and progression of the four pieces was agreed with David with responsibility for opening and closing the series sitting with me. The bulk of the writing for the first and last articles sat with myself, with David leading on the other two.
Milligan, F. and Dennis, S. (2004) 'Improving patient safety and incident reporting'. *Nursing Standard*, 19 (7) pp.33-36.	Sharon and myself agreed that publication on the role of the nurse advisor at the National Patient Safety Agency would be beneficial. I led the writing and coordinated final production of the text for the journal
*Madden, B. and Milligan, F. (2004) 'Enhancing patient safety and reporting near misses'. *British Journal of Midwifery*, 12 (10) pp.643-647.	This idea, to broaden the debate around patient safety in midwifery practice, came up in our discussions as work colleagues. As the article was about midwifery we agreed that Bella should be the lead author, although the production and writing process was led by myself.

Continued over page.

Reference for jointly authored publications	Declaration/clarification
*Coughlin, S. and Milligan, F. (2008) An audit of acute coronary syndrome assessment (TIMI scoring) and treatment. *Clinical Governance: an International Journal*, 13 (2) pp.138-141.	The audit data reported in this article had been generated within the hospital by Dr Stephanie Coughlin. The original data was presented at the hospital trust as part of local clinical governance work. I suggested publication and coordinated adaptation of the original report for publication.
Milligan F, Krentz, A, and Sinclair, A. (2011) 'Diabetes medication patient safety incident reports to the National Reporting and Learning Service – the care home setting'. *Diabetic Medicine*, 28 (12) pp.1537-1540.	The original idea of approaching the NRLS for the data reported originated from my understanding of error theory and work at the NPSA. With the support of Professor Alan Sinclair and Alan Krentz, who worked for the Institute of Diabetes for Older People (IDOP), I was able to generate and deliver the article as part of patient safety work at the Institute.
Milligan, F. Gadsby, R. Ghaleb, M. Ivory, P. McKeaveney, C. Newton, K. Randhawa, G. Smith, J. and Sinclair, A. (2014) 'Reporting medication errors: residents with diabetes'. *Nursing and Residential Care*, 16 (11) pp.617-621. Milligan, F. Gadsby, R. Ghaleb, M. McKeaveney, C. Newton, K. Smith, J and Randhawa, G. (2015) 'Going beyond blame: reporting NHS medication errors in nursing home residents with diabetes'. *British Journal of General Practice*, 65 (636) pp.372-373. Milligan, F. Edovic, M. Gadsby, R. Ghaleb, M. Ivory, P. McKeaveney, C. Smith, J. Newton, K. Randhawa, G. (2015a) *'Root causes of medication errors in nursing home residents with diabetes: enhancing safety in NHS medicines management'*. Luton: University of Bedfordshire. Milligan, F. Randhawa, G. McKeaveney, C. Ghaleb, M. Smith, J. Gadsby, R. Ivory, P. and Edovic, M. (2015b) *NIHR Research for Patient Benefit (RfPB) Programme Final Report Form*. London: National Institute for Health Research.	I was invited by Professor Alan Sinclair at the Institute of Diabetes for Older People to lead on developing a piece of research that combined patient safety theory with medication problems encountered in people in the care home setting. My role was to lead the development team and coordinate generation and submission of the research bid. Once funding was received I took on the role of research manager for the study and led on tasks such as ethical approval and day to day management of the project. When Professor Sinclair left the University I was asked to take on the role of Chief Investigator. All publications associated with the study were initiated, drafted and coordinated for publication by myself.
Milligan, F. Wareing, M. Preston-Shoot, M. Pappas, Y. and Randhawa, G. (2016) *Supporting nursing, midwifery and allied health professional students to raise concerns with the quality of care: a systematic literature review*. London: Council of Deans of Health. Milligan, F. Wareing, M. Preston-Shoot, M. Pappas, Y. Randhawa, G. and Bhandol, J. (2017) 'Supporting nursing, midwifery and allied health professional students to raise concerns with the quality of care: a review of the research literature'. *Nurse Education Today*, 57 pp.29-39.	I led the team with creation, writing and submission of the bid for the funding to undertake this systematic review of the literature. Once the bid had been secured I again led the team and coordinated completion and publication of the review. Contact with the Council of Deans of Health was coordinated by myself and was the final drafting of all published material.

*David Bird, Bella Madden and Stephanie Coughlin have been contacted with regard to completion of this portfolio and the wording of this declaration has been agreed with them (See appendix 5).

Appendix 5 - Co-author declaration forms



Co-Author Declaration Form

Please complete this form electronically and return to rgsoffice@beds.ac.uk prior to your arranged submission appointment

Part 1: Student Details: To be completed by the Student or nominated other

Student Name: Frank Milligan Student Number: 94065811

Institute: IHR

Final Title of Thesis (this should be 15 words or less):

"THE EMERGING DISCOURSE OF PATIENT SAFETY – THE RESEARCH AND PUBLICATION CONTRIBUTION OF FRANK MILLIGAN"

This form is to be included, as part of a submission for PhD by Published Work, where publications involving joint or co-authorship are to be considered. The applicant is required to submit a written declaration from all co-authors of the work culminating in the PhD by Published Work Portfolio.

Each co-author should give concise information about the contribution made by the candidate to the above publication. An indication of the nature of the contribution- qualitative and quantitative- may be provided where appropriate, as well as an indication of the contribution in the percentage term if appropriate.

Each author also has to agree to the declaration.
Overleaf we have provided a draft communication you can provide to each co-author covering the information which is required.

All correspondence should be attached with this form acting as a cover sheet to the pack of declarations. For each declaration please input it on the table below.

Co-author Full name and title	Title and details of publication	Contact details (either email or telephone number):
Dr Stephanie Coughlin, GP Principle	Coughlin, S. and Milligan, F. (2008) An audit of acute coronary syndrome assessment (TIMI scoring) and treatment. Clinical Governance: an International	
	[Add text here please Stephanie]	stephaniecoughlin@nhs.net 07973304467
Dr David Bird	Bird, D. and Milligan, F. J. (2003) 'Adverse health-care events: Part 2. Incident reporting systems'. Professional Nurse, 18 (10) pp.572-575.	
	[Add text here please David]	ac2535@coventry.ac.uk 02477657676
Bella Madden, Senior Lecturer in Midwifery	Madden, B. and Milligan, F. (2004) 'Enhancing patient safety and reporting near misses'. British Journal of Midwifery, 12 (10) pp.643-647.	
	Frank Milligan and I co-authored this article following conversations around the prevailing culture of care and the impact on safety and reporting near misses. I	bella.madden@beds.ac.uk 01582743878

Version 3: 28/02/16

I confirm that I have read and understand the Co-author information outlined above.

Signature Date 02/02/18

Part 3: Research Graduate School Use Only

Checked By:

Date:

Example email to Fellow publication authors:

Dear

I am about to submit my PhD by Published Work Portfolio for examination at the University of Bedfordshire and a I am writing to request your consent to include the below publication within the Portfolio.

Publication title:
Date of Publication:

As part of providing your consent can you please provide a statement covering the below information which is a requirement of the University and programme of study:

- A statement indicating the nature of the contribution- qualitative/quantitative
- A percentage indication of the contribution (if appropriate)

I look forward to receiving your response.

Best regards

Version 3: 28/02/16

Co-Author Declaration Form

Please complete this form electronically and return to rgsoffice@beds.ac.uk prior to your arranged submission appointment

Part 1: Student Details: To be completed by the Student or nominated other

Student Name: Frank Milligan Student Number: 94065811

Institute: IHR

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"THE EMERGING DISCOURSE OF PATIENT SAFETY – THE RESEARCH AND PUBLICATION CONTRIBUTION OF FRANK MILLIGAN"

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Each co-author should give concise information about the contribution made by the candidate to the above publication. An indication of the nature of the contribution- qualitative and quantitative- may be provided where appropriate, as well as an indication of the contribution in the percentage term if appropriate.

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Co-author Full name and title	Title and details of publication	Contact details (either email or telephone number):
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	[Add text here please Stephanie]	stephaniecoughlin@nhs.net 07973304467
Dr David Bird	Bird, D. and Milligan, F. J. (2003) 'Adverse health-care events: Part 2. Incident reporting systems'. Professional Nurse, 18 (10) pp.572-575.	
	[Add text here please David]	ac2535@coventry.ac.uk 02477657676
Bella Madden, Senior Lecturer in Midwifery	Madden, B. and Milligan, F. (2004) 'Enhancing patient safety and reporting near misses'. British Journal of Midwifery, 12 (10) pp.643-647.	
	[Add text here please Bella]	bella.madden@beds.ac.uk 01582743878

Version 3: 28/02/16

I confirm that I have read and understand the Co-author information outlined above.

Signature SC Date 24/02/18

Part 3: Research Graduate School Use Only

Checked By:

Date:

Example email to Fellow publication authors:

Dear

I am about to submit my PhD by Published Work Portfolio for examination at the University of Bedfordshire and a I am writing to request your consent to include the below publication within the Portfolio.

Publication title:
Date of Publication:

As part of providing your consent can you please provide a statement covering the below information which is a requirement of the University and programme of study:

- A statement indicating the nature of the contribution- qualitative/quantitative
- A percentage indication of the contribution (if appropriate)

I look forward to receiving your response.

Best regards

Version 3: 28/02/16

University of Bedfordshire RGS Research Graduate School

Co-Author Declaration Form

Please complete this form electronically and return to rgsoffice@beds.ac.uk prior to your arranged submission appointment

Part 1: Student Details: To be completed by the Student or nominated other

Student Name: Frank Milligan Student Number: 94065811

Institute: IHR

Final Title of Thesis (this should be 15 words or less):

"THE EMERGING DISCOURSE OF PATIENT SAFETY – THE RESEARCH AND PUBLICATION CONTRIBUTION OF FRANK MILLIGAN"

This form is to be included, as part of a submission for PhD by Published Work, where publications involving joint or co-authorship are to be considered. The applicant is required to submit a written declaration from all co-authors of the work culminating in the PhD by Published Work Portfolio.

Each co-author should give concise information about the contribution made by the candidate to the above publication. An indication of the nature of the contribution- qualitative and quantitative- may be provided where appropriate, as well as an indication of the contribution in the percentage term if appropriate.

Each author also has to agree to the declaration.
Overleaf we have provided a draft communication you can provide to each co-author covering the information which is required.

All correspondence should be attached with this form acting as a cover sheet to the pack of declarations. For each declaration please input it on the table below.

Co-author Full name and title	Title and details of publication	Contact details (either email or telephone number):
Dr David Bird	Bird, D. and Milligan, F. J. (2003) 'Adverse health-care events: Part 2. Incident reporting systems'. Professional Nurse, 18 (10) pp.572-575.	ac2535@coventry.ac.uk 02477657676
	FM "I agreed the idea for these publications with David and approached the editorial team from Professional Nurse to secure the possibility of	
	I agree that this statement is correct and a true reflection of both our contributions to the series of articles as published by Professional Nurse.	
	I	

Version 3: 28/02/16

I confirm that I have read and understand the Co-author information outlined above.

Signature

Date

28/03/18

Part 3: Research Graduate School Use Only

Checked By:

Date:

Example email to Fellow publication authors:

Dear

I am about to submit my PhD by Published Work Portfolio for examination at the University of Bedfordshire and a I am writing to request your consent to include the below publication within the Portfolio.

Publication title:
Date of Publication:

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- A statement indicating the nature of the contribution- qualitative/quantitative
- A percentage indication of the contribution (if appropriate)

I look forward to receiving your response.

Best regards

Version 3: 28/02/16

Appendix 6 – Ethical issues form

UNIVERSITY OF BEDFORDSHIRE

Research Ethics Scrutiny (Annex to RS1 form)

SECTION A To be completed by the candidate

Registration No: 94065811

Candidate: Frank Milligan

Degree of: PhD by publication

Research Institute: Institute for Health Research

Research Topic: Patient Safety

External Funding: None. Funded by the IHR.

The candidate is required to summarise in the box below the ethical issues involved in the research proposal and how they will be addressed. In any proposal involving human participants the following should be provided:

- clear explanation of how informed consent will be obtained,
- how will confidentiality and anonymity be observed,
- how will the nature of the research, its purpose and the means of dissemination of the outcomes be communicated to participants,
- how personal data will be stored and secured
- if participants are being placed under any form of stress (physical or mental) identify what steps are being taken to minimise risk

If protocols are being used that have already received University Research Ethics Committee (UREC) ethical approval then please specify. Roles of any collaborating institutions should be clearly identified. Reference should be made to the appropriate professional body code of practice.

The research for this PhD by publication involves reflection on literature and research I have previously published. That reflection will form part of the portfolio of evidence I am required to generate to meet the assessment requirements for this award by the University of Bedfordshire. Where ethical approval was required in that previous research and literature it was obtained and the work was carried out in accordance with the ethical criteria specified at the time.
With regard to ongoing research for the award of PhD by publication that process will require analysis of previous literature and generation of the portfolio and the new publications within it. This work will not involve patients or other human subjects and will be completed through review and analysis of published materials. As part of my patient safety role I link with various NHS organisations and that experience may inform some of that new writing. Where that experience might be used appropriate permissions from the NHS organisation will be gained and no patient or staff data will be disclosed, apart from co-authorship when that might be relevant. The confidentiality and data protection requirements of those organisations will be adhered to. Patient safety, errors in healthcare, is a sensitive topic but I have extensive experience of handling the topic.

October 2014

Answer the following question by deleting as appropriate:

1. Does the study involve vulnerable participants or those unable to give informed consent (e.g. children, people with learning disabilities, your own students)?
   No

   If **YES**: Have/will Researchers be DBS checked?
   Yes No = Not applicable

2. Will the study require permission of a gatekeeper for access to participants (e.g. schools, self-help groups, residential homes)?
   No

3. Will it be necessary for participants to be involved without consent (e.g. covert observation in non-public places)?
   No

4. Will the study involve sensitive topics (e.g. sexual activity, substance abuse)?
   Yes

5. Will blood or tissue samples be taken from participants?
   No

6. Will the research involve intrusive interventions (e.g. drugs, hypnosis, physical exercise)? **No**

7. Will financial or other inducements be offered to participants (except reasonable expenses)? **No**

8. Will the research investigate any aspect of illegal activity?
   No

9. Will participants be stressed beyond what is normal for them?
   No

10. Will the study involve participants from the NHS (e.g. patients) or participants who fall under the requirements of the Mental Capacity Act 2005?
    No

If you have answered yes to any of the above questions or if you consider that there are other significant ethical issues then details should be included in your summary above. If you have answered yes to Question 1 then a clear justification for the importance of the research must be provided.

*Please note if the answer to Question 10 is yes then the proposal should be submitted through **NHS research ethics approval procedures** to the appropriate **NRES**. The UREC should be informed of the outcome.

Checklist of documents which should be included:

Project proposal (with details of methodology) & source of funding	See attached
Documentation seeking informed consent (if appropriate)	Not applicable
Information sheet for participants (if appropriate)	Not applicable
Questionnaire (if appropriate)	Not applicable

(Tick as appropriate)

October 2014

Applicant declaration
I understand that I cannot collect any data until the application referred to in this form has been approved by all relevant parties. I agree to carry out the research in the manner specified and comply with the statement of ethical requirements on page 1 of this form. If I make any changes to the approved method I will seek further ethical approval for any changes.

Signature of Applicant: Date: .....25-11-16..

Signature of Director of Studies: Date: ...25-11-16

This form together with a copy of the research proposal should be submitted to the Research Institute Director for consideration by the Research Institute Ethics Committee/Panel

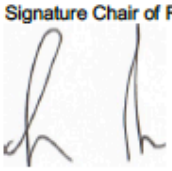
Note you cannot commence collection of research data until this form has been approved

SECTION B To be completed by the Research Institute Ethics Committee:

Comments:

Approved

Signature Chair of Research Institute Ethics Committee:



Date: 21/2/18

PROFESSOR GURCH RANDHAWA
This form should then be filed on the student's record

This form together with the recommendation and a copy of the research proposal should then be submitted to the University Research Ethics Committee

October 2014

End