The prevention of patient falls in healthcare settings, with particular emphasis on the effect of bedrail use on falls and injury as part of multi-faceted interventions

In one volume

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DECLARATION

I declare that this doctoral statement is my own work and I have correctly acknowledged any work of others, in accordance with University and School guidance on good academic conduct, and that no part of the material offered has been previously submitted for a degree of other qualification in this or any other University. Where joint work is submitted, the part of it that is my independent contribution is outlined within the appropriate co-authorship forms.

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ABSTRACT

This doctoral statement links previously published original research and places this in the context of the wider literature. Analysis of a national database identified over 200,000 patient falls, including 1,000 fractures, reported from hospitals in England and Wales during 2005/06, leading to excess morbidity, mortality, healthcare costs, litigation, distress and anxiety. Mean falls rates for acute hospitals were 4.8 falls per 1,000 occupied bed days, falls were most likely to be reported as occurring between 10:00 and 12:00, and in relation to bed occupancy, patients aged over 85 years and males were at greatest risk. Although the only such study on a national scale, its findings were congruent with earlier smaller studies. A cluster randomised trial of multifactorial interventions carried out in acute and rehabilitation wards for older people identified a significant reduction in rate of falls between intervention and control groups (incident rate ratio 0.59 95% CI 0.49-0.70). The use of a ward-based multidisciplinary approach and several components of the intervention were found in review of other successful trials of hospital falls prevention. A systematic review identified that both routine bedrail use and unselective bedrail elimination appear to increase the risk of falls and injury, and that direct injury from bedrails, including fatal entrapment, is primarily related to outdated equipment design, and poor fitting and maintenance. The dominant orthodoxy in the literature that bedrails are harmful and unacceptable appears to have become detached from the empirical evidence and patients' views. A multi-hospital overnight survey of bedrail use found 25.7% of patients had full bedrails raised, with immobility the most significant factor associated with bedrail use on logistic regression (OR 62.5 95% CI 27.4-142.8). These findings were disseminated through publications for the National Patient Safety Agency and through additional journal publications, and influenced policy in UK hospitals and internationally.

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CONTENTS

APPENDICES

INTRODUCTION: A RESEARCH APPRENTICESHIP

In this doctoral statement I will demonstrate that my previously published work is the result of a sustained level of recent research activity in the field of the prevention of falls in hospitals to which it makes an original contribution. I will also place my research in the context of the wider literature. My research career has involved responding to areas where a lack of evidence creates challenges for patient care. Because these challenges arose from my clinical and managerial roles and interests, I will introduce my published work by describing my career pathway and the research activity arising at different stages of it, and explain how the support, guidance and supervision I received amounted to an apprenticeship in the design, conduct, analysis, interpretation and publication of research.

<u>Early involvement in research</u>

I underwent non-academic general registered nurse training followed by registered mental health nurse training in the 1980s. I had a young family, worked part-time, and did not undertake any significant post registration development until 1993, when I undertook a certificate level course in clinical nursing management. This coincided with my appointment as a deputy ward sister for a joint assessment ward (an acute hospital ward for older people with acute and complex physical illness and mental health needs). This patient group had high levels of falls and multiple fallers, and was where my interest in falls prevention first arose.

As part of the certificate course I had support to undertake a small study using research techniques, and I undertook a retrospective analysis of reports of falls to determine whether injuries were more or less likely on carpeted or vinyl areas within wards. This was clinically relevant as local wards were undergoing refurbishment and had to choose flooring types. This study (Healey 1994; see Appendix D) was published in a peer-review nursing journal and continues to be cited in articles related to the role of flooring in injury prevention (e.g. Drahota et al. 2007).

<u>Research in tissue viability</u>

I was then seconded for a year to work as a specialist nurse in tissue viability, with pressure ulcer prevention and treatment my core responsibility. The role was based in the nursing research department so I had access to support and advice on research methodology. As a relatively new speciality, there were many unanswered questions for clinical practice. One early challenge was the national recommendation of a new pressure ulcer grading scale (the Stirling scale) (Reid and Morrison 1994) which had been developed through expert consensus, but had not been tested for inter- or intra-rater reliability, and the utility of which was unclear given its greater complexity than any existing scale. As a result of these concerns I undertook an inter-rater reliability and utility test with the support of six nurse specialists in other trusts who collected observations from 109 registered nurses. I was able to draw on the help and advice of Jon Deeks (now Professor of Health Statistics at the University of Birmingham) for statistical analysis, extending my knowledge of statistical techniques, and published the study (Healey 1995; see Appendix D) in the *Tissue Viability Journal*. It was later included in a systematic review (Kottner et al. 2009) where its quality score of eight out of ten was one of the highest of 24 included studies.

A further clinical challenge was deciding which pressure ulcer risk prediction tool to introduce in the hospital. Although the Waterlow score (Waterlow, 1985) was the most popular tool in use in UK hospitals, there was little data on its sensitivity or specificity, so I planned an evaluation of this alongside its introduction on a pilot basis. Through the mechanism of a format for recording risk assessment and skin condition with a carbon copy I collected data on over 7000 admissions, and was able to describe a pressure ulcer incidence rate and also to identify that using Waterlow with a cut-off point of 15 optimised specificity and sensitivity. These findings were published in Healey (1996a & 1996b; see Appendix D) and continue to be cited in systematic reviews of pressure ulcer risk prediction tools (e.g. Serpa et al. 2009). For these studies I was able to access support and advice from established researchers in the speciality on the editorial board of the *Tissue Viability Journal*. I also developed my research skills through attending a module at the University of Hull in the Understanding and Application of Research approved by the English National Board for Nursing, Midwifery and Health Visiting (ENB 870) in 1995 and I completed an Open University Diploma in Health and Social Welfare in 1996. Although the funding for my nurse specialist post ended after twelve months and I returned to a generic nursing role, I continued to occasionally publish in the field of pressure ulcer prevention (Healey 2000, Healey 2006, Healey 2010) and sat on the editorial board of the *Tissue Viability Journal* from 2004 to 2007.

Research in falls prevention in York

In the late 1990s I worked as a ward manager and as Assistant Director of Nursing and by 2000 had completed a Bachelor of Science degree in Health Studies with the University of York, taking hospital falls prevention as my dissertation subject, and thus further refining my critical appreciation of the evidence base. In 2001 I became Directorate Manager for Elderly Services at York Hospitals NHS Trust. As would be expected in elderly medicine, our falls rate was higher than in other directorates with younger patient populations, and there was a need to review and refresh our approach to falls prevention. Because of the lack of clear evidence we could identify from the prior literature on what measures were effective in falls prevention in hospital settings, and because of my own interest in research, we sought to do this within a research framework rather than as a service improvement project. This led to the development of the cluster randomised controlled trial (RCT) of multifactorial falls prevention which will be explored in Chapter Two of this doctoral statement. This was published in *Age and Ageing* as Healey et al. (2004) 'Using targeted risk factor reduction to prevent falls in older in-patients: a randomised controlled trial.' My fellow authors were all practicing clinicians (a consultant geriatrician, matron, registrar, and physiotherapist) but my research apprenticeship was furthered by the support and advice of Dr Caroline Mozley in the trust's research department and by statistical advice from Dr Daphne Russell and Dr Jeremy Miles who were lecturers in biostatistics at the University of York. My contribution to the RCT was substantial, comprising 80% of design, 90% of the conduct, 80% of the analysis of outcome and 75% of the preparation for publication (see co-authorship forms Appendix B). Our study was the first published RCT of multifactorial interventions for falls prevention in an acute hospital setting, and remains one of only five published RCTs of multifactorial interventions in hospitals (Cumming et al. 2008, Haines et al. 2004, Healey et al. 2004, Koh et al. 2009, Stenvall et al. 2007) and the only such trial to date led by clinicians rather than academics.

Research work with the National Patient Safety Agency

In 2003 I moved to the National Patient Safety Agency (NPSA) as a Patient Safety Manager. The NPSA was founded in 2001 in response to *An organisation with a memory* (Department of Health, 2000) which set out aspirations for a national reporting system to inform action to improve patient safety and this was initiated in 2003 as the National Reporting and Learning System (NRLS). It was in this context that I developed the studies and publications that I will describe in Chapters One, Three, Four and Five of this doctoral statement.

The study that will be discussed in Chapter One was a detailed analysis of over 200,000 falls reported to the NRLS and was published in *Quality and Safety in Healthcare* as 'Falls in English and Welsh hospitals; a national observational study based on retrospective analysis of 12 months of patient safety incident reports' (Healey et al. 2008a). In Chapter Three I will discuss 'The effect of bedrails on falls and injury: a systematic review of clinical studies' (Healey et al. 2008b) which was published in *Age and Ageing*. In Chapter Four I will discuss 'Bedrail use in English and Welsh hospitals' (Healey et al. 2009) which used logistic regression to identify patient and equipment characteristics associated with bedrail use based on an overnight survey of patients in seven trusts and published in the *Journal of the American Geriatric Society*. As I will discuss later, for each of these studies I made substantial contributions ranging from 70% to 95% of design, 75% to 95% of the conduct, 60% to 90% of the analysis of outcome and 75% to 80% of the preparation for publication (see co-authorship forms Appendix B). The three studies I undertook for the NPSA, and the RCT I undertook in York, will each be discussed separately, beginning with an outline of the background literature for each, and discussing commonalities and differences between their findings and the wider literature.

Within Chapter Five I will discuss three associated NPSA publications:

- Healey and Scobie for NPSA (2007) *Slips trips and falls in hospital*
- Healey and Stevenson for NPSA (2007) *Using bedrails safely and effectively*
- Healey for NPSA (2007) *Resources for reviewing or developing a bedrail policy*

These publications used the evidence from the four research projects to recommend changes in clinical practice, and this chapter will explore the combined impact of these journal papers and the associated NPSA publications, using a range of independent sources of data.

Throughout this period I worked under the supervision and direction of Professor Richard Thomson within the NPSA's Patient Safety Observatory (PSO), and when Professor Thomson left the NPSA in 2008, I secured appointment as an Honorary Research Associate at the University of Newcastle and continued preparation of these papers under his supervision. This period of academic support, both at the NPSA and subsequently, was the most sustained and valuable part of my research apprenticeship and continued when Professor Thomson took on a formal role as my supervisor when I registered for my doctorate. As part of my doctorate I have also been able to attend taught courses, including a year's module on Health Statistics, which has been very valuable in extending my knowledge of selecting appropriate statistical methodology for the interpretation of results.

Additionally, my research apprenticeship was furthered by collaboration with Professor David Oliver. He was our peer reviewer for the RCT described above, and wrote an accompanying editorial (Oliver 2004 see Appendix J) and acted as second or third co-author for three of the original research publications described above. His support and advice was particularly instrumental in enhancing my research skills, particularly in conducting systematic reviews and in the ethical and legal issues relevant to falls prevention.

Other publications

In addition to the four original research papers and three NPSA publications that this doctoral statement centres on, I have collaborated with Professor Oliver on a number of additional papers and journal letters (Oliver & Healey 2006, Healey & Oliver 2006, Healey et al. 2007, Healey & Oliver 2008, Healey & Oliver 2009a, Oliver & Healey 2009, Healey & Oliver 2009b; see Appendix C) making good use of our complementary perspectives as researchers from medical and nursing backgrounds. I have also been the sole author for additional journal publications related to falls or bedrails (Healey 2006, Healey 2007, Healey 2009a, Healey 2009b, Healey 2010a, Healey 2010b; see Appendix C) and I have given 22 plenary and concurrent presentations on falls prevention and bedrails at international, national and regional conferences between 2006 and 2009 (see Appendix F). I was the lead author for Royal College of Nursing guidance on restraint *Let's talk about restraint* (RCN 2007). I am currently completing a commissioned clinical review of the evidence on falls prevention in hospitals for a special falls prevention edition of *Clinics in Geriatric Medicine* (Oliver, Healey & Haines in press) that draws on the analysis of the literature I prepared for this doctoral statement, and preparing a chapter on falls prevention in care homes for the *Oxford Desk Reference for Geriatric Medicine*.

I also acted as co-author of the Patient Safety First campaign's *'How to' guide for reducing harm from falls* (Patient Safety First 2009; see Appendix E) and I am currently involved in disseminating this and supporting its implementation. The campaign has a membership of 98% of acute hospital organisations in England, and the *'How to' guide* takes the recommendations and evidence in *Slips trips and falls in hospital* (Healey & Scobie for NPSA 2007a) and subsequent research as its basis, breaking these down into specific actions for trust Boards and frontline staff with associated sets of process and outcome measures. It also replicates the care plan from Healey et al. (2004) and draws on *Using bedrails safely and effectively* (Healey & Stephenson for NPSA 2007b). The *'How to' guide* will be used to underpin falls prevention work by the Department of Health as a potential High Impact area of service improvement for nursing and within the Quality, Innovation, Productivity and Prevention workstream.

<u>Continued work in the area of falls prevention</u>

My involvement in the field of falls prevention continues through a range of roles. I am a steering group member for the Royal College of Physician's National Clinical Audit of Falls and Bone Health in Older People (2009) and have chaired and presented at their regional workshops. I am a member of an expert group led by the Social Care Institute for Excellence (SCIE) that is disseminating guidance and educational packages (SCIE 2009) related to restraint and to bedrail use in care homes that draws on our literature review (Healey et al. 2008b) and the RCN restraint guidance I co-authored (RCN 2007). I continue to act as a peer reviewer for a number of journals including *Journal of the American Medical Association, Quality and Safety in Health Care, Age and Ageing, The Journal of Clinical Epidemiology, The International Journal for Quality in Health Care, Evidence-based Nursing Journal, Nursing Times,* and *CME Journal of Geriatric Medicine.*

I was also a successful co-applicant on behalf of the NPSA for a bid to the Health Foundation on 'Closing the gap' between evidence and clinical practice in inpatient falls prevention. This secured funding of £380,000 in late 2009. I act as a steering group member for the project, and expect to play an active role in the education of the change agents in the study wards and units. I sit on the steering group of a current study into the role of flooring in reducing injury (University of Portsmouth 2009) and a proposed study into falls prevention in mental units (Research for Patient Benefit 2010) and I am currently involved in preparing a research proposal aimed at integrating expertise in clinical and environmental risk factors for falls with the Health & Safety Laboratory.

I continue my employment with the NPSA as Head of Patient Safety (Medical Specialties). Whilst this is a broad role, falls prevention is one of five overarching topics adopted as patient safety priorities by the NPSA for 2010 and 2011 and I will spend the majority of my time fulfilling my responsibility for leading the development of NPSA strategy for preventing harm from falls and linking with collaborating organisations. The strategy will include devising updated and additional analysis of NRLS data, a potential Alert related to the aftercare of hospital patients who fall, and the development of further service improvement and educational resources for NHS staff.

CHAPTER ONE: REPORTS OF FALLS AND INJURY IN HOSPITALS

1.1 INTRODUCTION

In this chapter I will focus on our study ‘Falls in English and Welsh hospitals; a national observational study based on retrospective analysis of 12 months of patient safety incident reports’ (Healey et al. 2008a). This study is the most appropriate of my papers with which to open my doctoral statement, as it provides importance context on the scale of harm caused to patients by falls in hospital settings, before I move on to examine falls prevention in hospitals, including the role of bedrails.

I will begin with an overview of the scale and consequences of falls. I will then focus on studies of inpatients published prior to our national observational study, including all identified studies on the incidence of falls and subsequent injury in hospitals, with a particular focus on studies from UK hospitals. I will then examine those studies that included additional data on the characteristics of patients who fell.

Having created a picture of the evidence published prior to our observational study, I will briefly describe the purpose and function of the National Patient Safety Agency (NPSA) and its National Reporting and Learning System (NRLS) from which data were collected. I will then go on to discuss the strengths and limitations of our study, with a particular emphasis on the limitations of incident reporting as a source of data.

I will then, most importantly, discuss the commonalities and differences between the evidence presented prior to our observational study, and the evidence within it. Key to this discussion will be the scale of our study, our findings on injury and time of day, and our use of patient population data to contextualise our findings on the age and gender of patients who fell. Variability in falls rates between individual organisations providing acute hospital care, community hospital care and mental health unit care will also be discussed.

I will then summarise key findings from research published subsequent to our observational study. Finally, I will indicate what our observational study has added to the understanding of the issue, including the implications for clinical practice and directions for future research.

1.2 REPORTS OF FALLS AND INJURY IN HOSPITALS PRIOR TO 2007

1.2.1 Introduction

Falls are recognised internationally as a major health issue disproportionately affecting older people, with estimates that between one in three and one in two community-dwelling older people fall each year, of whom around 5% need hospitalisation (American Geriatrics Society et al. 2001). In the UK, with a population of over four million people aged over 75 years (Office of National Statistics (ONS) 2010), around 700,000 older people attend emergency departments following a fall each year (Royal College of Physicians (RCP) 2009) and around 230,000 fragility fractures are treated, of which around 75,000 are hip fractures (proximal femur fractures) (National Institute for health and Clinical Excellence (NICE) 2010). Deaths attributable to falls are difficult to assess because of the complex co-morbidities present in many older people who fall, but around 10% of people fracturing their hip die within a month, and around a third die within twelve months (NICE 2010). Costs for hospital and social care subsequent to hip fracture in the UK are estimated at approaching two billion pounds (Torgerson et al. 2001).

The consequences of a fall for the individual older person can be immense. Hip fracture is the injury most feared by older women (Salkeld et al. 2000) and with good reason; around half of those able to walk independently before a hip fracture will never walk independently again, and most will be dependent on others for one or more activities of daily living (Osnes et al. 2004), with the hip fracture triggering admission to a care home for between 10% and 20% (NICE 2010). Even falls resulting in little or no physical harm can mark the beginning of a negative cycle where fear of falling leads an older person to limit their activity, with consequent further losses of strength and independence (Tinetti et al. 1994).

Whilst slip or trip hazards can cause falls even in young and healthy adults, most falls in older people (or in younger patients with long term health problems) arise out of a complex interaction between risk factors. Over 300 individual risk factors for falls and injury have been identified (Todd & Skelton 2004) with the most consistently identified factors across studies including muscle weakness, previous falls, gait disorder, balance disorders, impaired vision, arthritis, dependence for activities of daily living, depression, cognitive impairment, age over 80 years (American Geriatric Society et al. 2001), polypharmacy, psychoactive medication, cardiovascular medication (Hartikainen et al. 2007), and specific illnesses such as Parkinson's disease, epilepsy and stroke (NICE 2004).

Various risk factor classifications exist, including division into environmental and individual factors, or extrinsic and intrinsic risk factors (American Geriatric Society et al. 2001). These divisions may over-simplify the synergy between risk factors; for example, a home with trip hazards (environmental) may be the result of a person with dementia mislaying their possessions (individual), whilst medication (extrinsic) may be prescribed in response to a symptom or disease (intrinsic). The DAME classification (Disease, Ageing, Medication & alcohol, Environment) (Oliver 2008) is more helpful, particularly in recognising the risk factors inherent even in healthy ageing, such as changes in vision, balance, and strength. However, a further category of Personality & lifestyle (Healey & Scobie for NPSA 2007a) is a useful addition to encompass the identified risk factors around older peoples' choices and behaviour, including intentionally restricting activity through fear of falling (Tinetti et al. 1994). Whilst any risk factor applying to older people in the community can also apply to inpatient fallers, the risk factors most consistently found in hospital patients are impaired or unstable mobility, incontinence or urinary frequency, dependence on staff to use the toilet, a history of previous falls, agitation with confusion, and psychoactive medication, particularly night sedation (Oliver et al. 2004).

Most authors (e.g. American Geriatrics Society et al. 2001, Oliver et al. 2007, Coussement et al. 2008) suggest that rates of falling are much higher in hospital patients than in community dwellers and that outcomes of injury are likely to be much worse, because of the co-morbidity inherent in falling whilst already suffering from a condition sufficiently serious to need hospitalisation (Murray et al. 2007). Despite this acknowledgement that falls in hospitals are a significant problem, and numerous studies seeking to identify risk factors specific to hospitals fallers (as reviewed by Oliver et al. 2004), information on the scale and consequences of falls in hospitals is difficult to locate in the literature. Even scholarly papers (e.g. Cameron et al. 2010, Coussement et al. 2008, Oliver 2008, Haines et al. 2004, Oliver et al. 2004, Oliver et al. 2007) offer only one to four references for hospital inpatient falls or injury rates and these are often secondary references to very outdated studies (e.g. Coussement et al.'s (2008) citation of Mahoney (1998) which cites sources from the 1970s), or refer to rates from very small and specialised units (e.g. Cameron et al.'s (2010) reference to Nyberg et al. 1997).

Therefore, to provide the context of what was known about rates of falls in hospital settings before the publication of our national observational study, I undertook a systematic search of the literature for any articles published between 1987 and 2006 that included key words related to falls rates in hospital or mental health unit settings (detail of the search strategy can be found in Appendix G). The key content of all identified studies (whether observational or intervention studies) that included a falls rate or an injury rate were abstracted. All falls rates were standardised to per 1,000 occupied bed days (OBDs), and injury rates were standardised to the percentage of falls resulting in injury. The studies were sorted into the following settings:

- acute whole hospital studies
- studies of selected acute wards within acute hospitals
- studies of rehabilitation wards, units and hospitals
- studies from Mental Health units

Each of these settings will be discussed in more detail below.

1.2.2 Data on the incidence of falls and injury in acute hospitals prior to 2007

Data taken from whole hospital studies will be presented first, followed by data from studies limited to specific acute wards within acute hospitals (e.g. internal medicine, acute geriatric wards).

1.2.2.1 Data from whole acute hospital studies prior to 2007

The search identified thirteen observational studies describing falls rates or the proportion of falls resulting in injury or fracture across all adult inpatients in an acute hospital setting. These studies are summarised below in Table 1a.

TABLE 1a: Whole acute hospital falls rates and/or injury rates 1987–2006

Reference	Study design[i]	Study aims	Setting	Fall incidence findings	Injury findings
Barrett et al. 2004	Retrospective observational study	To assess a falls prevention intervention	Acute general hospital in England	Falls given as whole numbers only, no OBDs denominator	27% (3,087/11,508) resulted in some injury of which 0.8% (95/3,087) fractures
Brandis 1999	Before-and-after study	To assess a falls prevention intervention	500 bed acute hospital in Australia	1.61 to 1.74 falls per 1,000 OBDs	51.1% (138/270) had some injury including fractures in 3.0% (8/270)
Dunton et al. 2004	Retrospective observational study	To identify any correlation between nurse staffing and reported falls	Multi-hospital: 282 acute and rehabilitation hospitals in the USA	3.73 falls per 1,000 OBDs	*“approximately 30% involved some injury”*
Enloe et al. 2005	Retrospective observational study	To report falls incidence	471 bed acute academic hospital in the USA	2.63 falls per 1,000 OBDs	39% some injury including 9% *“moderate or severe”* injury
Fischer et al. 2005	Retrospective observational study	To report falls incidence	An acute academic hospital in the USA	3.1 falls per 1,000 OBDs	6.1% caused serious injury[ii] 1.0% caused fracture or dislocation[iii]
Gaebler 1993	Retrospective observational study	To compare the characteristics of single and multiple fallers	680 bed acute hospital in Australia	Falls given as whole numbers only, no OBDs denominator	59% (229/382) some injury on first fall (injury from all falls not stated)
Halfon et al. 2001	Retrospective observational study	To inform a falls prediction model	800 bed acute academic hospital in Switzerland	2.67 falls per 1,000 OBDs First falls 2.2 per 1,000 OBDs	37% (234/634) some injury of which 2.2% (14/634) fracture

[i] NOTE: unless otherwise stated, studies were based on falls reported to incident reporting systems.
[ii] Defined as any bleeding or bruising or fracture
[iii] Calculated from figures given that of the 6.1% serious injury, 15.9% were fractures or dislocations

Reference	Study design[i]	Study aims	Setting	Fall incidence findings	Injury findings
Hitcho et al. 2004	Prospective observational study using falls reported, recorded in notes, or recalled by patients or nurses	To report falls incidence	1,300 bed acute academic hospital in the USA, (children included)	3.3 to 3.4 falls per 1,000 OBDs overall	*"42% of first falls resulted in some type of injury"* (injury from all falls not stated) 1.1% (2/183) of first falls resulted in fracture 1.1% (2/183) of first falls resulted in subdural haematoma
Kilpack et al. 1991	Before-and-after study	To assess a falls prevention intervention	An acute academic hospital in the USA	3.0 to 3.6 falls per 1,000 OBDs	
Nadkarni et al. 2005	Retrospective observational study	To assess the costs of orthopaedic injuries sustained in inpatient falls	Acute hospital in England	Falls numbers or rate not reported	4.6% (42/900) falls resulted in *"orthopaedic injury"* 2.0% (18/900) hip fracture 1.0% (9/900) fatalities
Rohde et al. 1990	Retrospective observational study	To report falls incidence	1,000 bed acute academic hospital in the USA	3.1 falls per 1,000 OBDs	
Schwendimann et al. 2006a	Before-and-after study	To assess a falls prevention intervention	300 bed acute hospital in Switzerland	8.9 falls per 1,000 OBDs	33.6% (1290/3842) some injury of which 3.9% (148/3842) major injuries[iv] of which 1.7% (64/3842) fracture of which 0.8% (31/3842) hip fracture plus 0.3% (12/3842) intracranial bleeds
Tan et al. 2005	Retrospective observational study	To identify injury and restraint chair and bedrail use	700 bed acute academic hospital in Ireland	1.32 falls per 1,000 OBDs	
SUMMARY	**13 studies**	**4 studies whose primary focus was to describe falls incidence**	**2 UK studies**	**Range 1.3 to 8.9 falls per 1,000 OBDs (10 studies)**	**Range 27% to 51% some injury (6 studies)** **0.8% - 3% fractures (5 studies)** **0.8% to 2% hip fractures (2 studies)**

[iv] Major injury undefined but examples include multiple haematoma

Only one of the identified studies (Dunton et al. 2004) used reports of falls from more than one hospital, but because this was a study focused primarily on staffing issues, only the combined mean falls rate of 3.7 falls per 1,000 OBDs was described. The remaining nine studies (Brandis 1999, Enloe et al. 2005, Fischer et al. 2005, Halfon et al. 2001, Hitcho et al. 2004, Kilpack et al. 1991, Rohde et al. 1990, Schwendimann et al. 2006a, Tan et al. 2005) reported a wide range of falls rates from 1.3 to 8.9 falls per 1,000 occupied bed-days. None of these studies came from UK hospitals, and the relevance of falls rates from other countries to the UK may be limited due to differences in the age profile of their populations and in their healthcare provision; for example, around three quarters of inpatients in some hospitals in the USA are aged under 65 years (Morse 1996) whilst almost three quarters of inpatients in UK acute hospitals are aged over 65 years (Hospital Episode Statistics 2008).

Eleven studies reported either the overall proportion of injuries, or focused on specific types of injury. Overall proportions of falls resulting in injury were included in only six studies (Barrett et al. 2004, Brandis 1999, Dunton et al. 2004, Enloe et al. 2005, Halfon et al. 2001, Schwendimann et al. 2006a), which reported a range of 27% to 51% of falls resulting in some injury. Where terms such as 'major injury' or 'severe injury' were used, definitions differed between studies and so direct comparison is not possible. Five studies reported proportions of falls resulting in any fracture (Barrett et al. 2004, Brandis 1999, Fischer et al. 2005, Halfon et al. 2001, Schwendimann et al. 2006a) with a range from 0.8% to 3%, but in some cases this was based on very small numbers of fractures (e.g. eight fractures in Brandis 1999). Two report hip fracture rates ranging from 1.1% to 2.0% (Nadkarni et al. 2005, Schwendimann et al. 2006a). Two studies identified rates of intracranial bleeds ranging from 0.3% to 1.1% of falls (Hitcho et al. 2004, Schwendimann et al. 2006a) but again based on very small numbers (e.g. two subdural haematomas in Hitcho et al. 2004). One study (Nadkarni et al. 2005) identified a death rate of 1% from falls, although it is unclear from the methodology whether this included only deaths directly attributable to falls injury. Only two of these studies came from a UK setting (Barrett et al. 2004, Nadkarni et al. 2005).

1.2.2.2 Data from wards or specialities within acute hospitals prior to 2007

The search identified twelve observational studies describing falls rates or the proportion of falls resulting in injury or fracture within specific inpatient departments or specialties in an acute hospital setting. These studies are summarised below in Table 1b.

TABLE 1b: Acute hospital falls rates and/or injury rates restricted to subsets of wards 1987 – 2006[v]

Reference	Study design	Study aims	Setting	Incidence findings	Injury findings
Fonda et al. 2006	Before-and-after study	To assess a falls prevention intervention	Four elderly care acute and rehabilitation wards within an acute hospital in Australia	10.1 to 12.5 falls per 1,000 OBDs	Falls resulting in serious injuries[vi] 5.8% (27/465) in 2001 3.5% (17/489) in 2002 1.7% (7/413) in 2003
Giles et al. 2006	Before-and-after study	To assess the effect of volunteer companions	Two medical wards in acute hospitals in Australia	14.5 to 15.5 falls per 1,000 OBDs	
Healey et al. 2004	Cluster RCT	To asses the effects of multi-faceted interventions	Two rehabilitation hospitals and six acute elderly care wards within an acute general hospital in England	11.38 to 19.92 falls per 1,000 OBDs	22.4% (236/1,039) some injury
Kilpack et al. 1991	Before-and-after study	To assess a falls prevention intervention	One neuroscience and one oncology/renal unit in an acute academic hospital in the USA	4.4 to 4.7 falls per 1,000 OBDs	
Mitchell & Jones 1996	Before-and-after study	To assess a falls prevention intervention	32 bed medical ward in an acute hospital in Australia	4.42 to 7.77 falls per 1,000 OBDs	
Oliver et al. 2002	Before-and-after study	To assess a falls prevention intervention	Elderly medical unit within an acute academic hospital in the UK	11.1 to 13.8 falls per 1,000 OBDs	25.4% (168/661) some injury
Powell et al. 1989	Retrospective observational study	To assess the effects of a body restraint reduction initiative	Geriatric wards within a general hospital in the USA	7 .0 to 8.7 falls per 1,000 OBDs	
Schwendimann et al. 2006b	Before-and-after study	To assess a falls prevention intervention	Internal medicine wards within an acute hospital in Switzerland	17.2 falls per 1,000 OBDs in internal medicine sub group	

[v] i.e. not whole hospital studies, which are described in Table X above, nor studies reporting data only from rehabilitation wards or units, which are described in Table X below

[vi] Defined as fractures, head injuries, or fatalities related to falls

Reference	Study design	Study aims	Setting	Incidence findings	Injury findings
Semin-Goossens et al. 2003	Retrospective observational study	To assess the effect of service improvement	Internal medicine and neurology wards within an acute hospital in the Netherlands	Between 8 and 9 falls per 1,000 OBDs in internal medicine and between 13 and 15 in neurology	
Sweeting 1994	Retrospective observational study	To assess the effect of service improvement	231 beds on geriatric wards in a small acute hospital in England	Overall falls given as whole numbers only, no OBDs denominator	1.7% (5/300) fractures of which hip fractures 0.7% (2/300)
Tutuarima et al. 1997	Retrospective observational study	To report falls incidence	720 patients admitted with stroke to 23 hospitals in the Netherlands	8.9 falls per 1,000 OBDs	*"Approximately 25% caused slight-to-severe injury"* Hip fracture in 1.7 % (3/173)
Von Renteln-Kruse & Krause 2004	Retrospective observational study	To report falls incidence	145 beds on geriatric wards with an acute academic hospital in Germany	Overall falls given as whole numbers only, no OBDs denominator Rates for specific diagnostic groups (e.g. stroke, Parkinson's disease) 36-57 per 1,000 OBDs	0.6% (10/1,596) fractures
SUMMARY: ACUTE SPECIALIST WARDS	**12 studies**	**2 studies whose primary focus was to describe falls incidence**	**3 UK studies**	**Range 4.4 to 19.9 per 1,000 OBDs (10 studies)**	**Range 22% to 25% some injury (2 studies)** **0.6% to 1.7% fractures (2 studies)** **0.7% to 1.7% hip fractures (2 studies)**

As shown in Table 1b above, twelve additional studies limited to particular wards or patient groups within acute hospitals were identified (Fonda et al. 2006, Giles et al. 2006, Healey et al. 2004, Kilpack et al. 1991, Mitchell & Jones 1996, Oliver et al. 2002, Powell et al. 1989, Schwendimann et al. 2006b, Semin-Goossens et al. 2003, Sweeting 1994, Tutuarima et al. 1997, Von Renteln-Kruse & Krause 2004). These came from a range of settings but predominantly wards described as geriatric or elderly care wards (six studies (Fonda et al. 2006, Healey et al. 2004, Oliver et al. 2002, Powell et al. 1989, Sweeting 1994, Von Renteln-Kruse & Krause 2004)) or described as medical wards or internal medicine wards (Giles et al. 2006, Mitchell & Jones 1996, Schwendimann et al. 2006b, Semin-Goossens et al. 2003), where a higher proportion of older patients and patients with long term ill health or disability, and therefore a greater vulnerability to falls and injury, might be expected. Falls rates are reported in ten studies (Fonda et al. 2006, Giles et al. 2006, Healey et al. 2004, Kilpack et al. 1991, Mitchell & Jones 1996, Oliver et al. 2002, Powell et al. 1989, Schwendimann et al. 2006b, Semin-Goossens et al. 2003, Tutuarima et al. 1997) and ranged from 4.4 to 19.9 falls per 1,000 patient days, higher than the range seen in the whole hospital studies. Overall injury rates are reported in only two studies (Healey et al. 2004, Oliver et al. 2002), and ranged from 22% to 25% of falls. Fracture rates are reported in only two studies (Sweeting 1994, Von Renteln-Kruse & Krause 2004) and ranged from 0.6% to 1.7% of falls, with hip fracture rates reported in two studies (Sweeting 1994, Tutuarima et al. 1997) as 0.7% and 1.7%, but again the numbers of fractures that the percentages are calculated from are very small (no more than ten in any one study). Only three of the studies came from the UK (Healey et al. 2004, Oliver et al. 2002, Sweeting 1994) and these were all based on elderly care wards.

Because the healthcare service provided and the criteria for admission and discharge to specialist wards or departments may differ markedly between hospitals, these studies based on specialist units cannot be generalised. This is particularly true for elderly care and medical wards which may be accepting patients on an integrated, age-related or needs-related basis, and may or may not have access to intermediate care or early discharge schemes (Department for Health 2001). However, they do provide confirmation that the patients most vulnerable to falling are unlikely to be equally distributed across all wards, but tend to be concentrated on particular types of wards where falls rates are likely to be higher than whole-hospital falls rates.

1.2.2.3 Other sources of data on falls rates in acute hospitals

The many studies published on numerical inpatient falls risk prediction tools (Oliver et al. (2004) identified 47 papers) might be expected to provide a rich source of information on falls rates in hospital, but this proved not to be the case, as almost all compared fallers with an equally sized group of non-fallers, rather than using the whole inpatient population, or presented number of falls or fallers without contextual data on OBDs.

All but one (Hitcho et al. 2004) of the studies reported above relied solely on analysis of falls reported to local incident reporting systems (a methodology with limitations that will be discussed in more detail later in Chapter 1.4.2). An alternative source of information on falls rates would be case note review undertaken as part of studies with a wider focus on all types of adverse incidents. The methodology for case note review was established by Brennan et al.'s (1991) landmark study, and defined adverse events as those resulting in some harm to the patient, and so would only be expected to identify injurious falls, rather than all falls. However, even with this focus, the 20 harmful falls the authors identified from the review of 30,195 case notes (Leape et al. 1991) and the 66 falls from 14,179 case notes in Australia reported by Wilson et al. (1999) seem implausibly low given the rates reported from hospitals in the USA and Australia in Table 1a above. A sub-analysis (Thomas and Brennan 2000) of a similar adverse event study in Utah and Colorado (Thomas et al. 2000) extrapolates their findings to all hospital patients in the two states, and state that of patients aged over 65 years, 0.10% (one in 1,000) admissions) suffered *"preventable falls",* whilst of patients aged under 65 years, 0.01% (one in 10,000) suffered *"preventable falls".* Similar studies in Denmark (Schioler et al. 2001), New Zealand (Davis et al. 2003), Canada (Baker et al. 2004) and Spain (Aranaz-Andres et al. 2007) did not provide detail at a level that identified falls. In the UK, the earliest adverse event study (Vincent et al. 2001) was expanded by Neale et al. (2001) described three falls, two resulting in fractured neck of femur, from review of 1014 case notes. A Scottish adverse event study (Williams et al. 2008) identified only one fall in 348 admissions, despite a methodology that included adverse events causing no physical harm. In contrast, a later UK study (Sari et al. 2007) identified 48 falls causing at least *"emotional harm"* from review of 1,006 case notes, although the higher rate in that study might partly be explained by the low threshold for defining harm. The contrast between studies based on case note reviews and falls reported to incident reporting systems, and possible explanations for the lack of congruity between them, will be discussed later in Chapter 1.4.2, but in terms of providing a useful source of data on the extent of falls and injury in hospitals, case note reviews appear relatively unhelpful.

Given the historic perception of falls as a Health and Safety issue rather than a clinical concern (Oliver 2008), it could be theorised that studies of hospital falls incidence may be published in risk management journals which are not peer-reviewed or indexed on clinical databases. A hand search of Healthcare Risk Review from January 2008 to December 2009 did not, however, support this theory; of six articles related to falls (three case studies of litigation, two local service improvement stories, one commentary on an NPSA publication) none described falls rates (see Appendix G).

Therefore, although falls are acknowledged as comprising the most frequently reported type of patient safety incident in all developed countries (Joint Commission for the Accreditation of Healthcare Organizations 2009, NPSA 2007a, Australian Council on Safety and Quality in Healthcare 2005), prior to 2007 there was very limited information on falls or injury rates in acute hospitals available from peer-reviewed publications, and almost none from UK settings.

1.2.3 The incidence of falls and injury in rehabilitation hospitals

Studies describing falls and injury rates in rehabilitation hospitals are summarised below in Table 1c.

TABLE 1c: Studies of rehabilitation units falls and/or injury rates 1987–2006

Reference	Study design	Study aims	Setting	Incidence findings	Injury findings
Aisen et al. 1994	Retrospective observational study	To report falls incidence	Patients admitted to a neurological rehabilitation unit in a rehabilitation hospital in the USA	3.9 falls per 1,000 OBDs[vii]	15.3% (18/117) minor injury 2.6% (3/117) lacerations requiring suturing No fractures
Barry et al. 2000	Before-and-after study	To assess the effect of a falls prevention intervention	95 bed rehabilitation and long stay hospital for older people in Ireland	Overall falls given as whole numbers only, no OBDs denominator	In each of three years 32.3% (23/71) 25.0% (14/56) 11.0% (4/36) some injury of which fractures in 11.3% (8/71) 1.8% (1/56) 0% (0/36)
Falkenbach et al. 2006	Retrospective observational study of reported falls made to an insurance body	To report falls incidence	Rehabilitation unit in Austria	0.6 falls per 1,000 OBDs[viii]	*"Surgical treatment"* required for 12% (17/140)
Haines et al. 2004	RCT	To assess the effect of multi-faceted falls prevention	Three sub-acute wards within an elderly care/rehabilitation hospital in Australia	11.2 to 16.1 falls per 1,000 OBDs	20.8% some injury, of which 1.6% (4/254) fractures, in subjects consenting to randomisation
Hanger et al. 1999	Before-and-after study	To assess the effect of bedrail reduction	135 bed rehabilitation hospital in New Zealand	16.5 to 19.2 falls per thousand OBDs	18.6% (148/792) minor injury or extra observation 0.8% (6/792) fractures (all hip fractures)
Mayo et al. 1994	RCT	To assess the effect of alert wristbands	120 bed rehabilitation hospital in the USA	7.33 per 1,000 OBDs	16.7% (8/48) *"resulted in injury"* in subjects consenting to randomisation

[vii] Calculated from rate given as 1,439 falls per 1,000 patient years: 1,439/365 = 3.94 falls per 1,000 patient days
[viii] Calculated from 140 falls and 234,502 OBDs

Reference	Study design	Study aims	Setting	Incidence findings	Injury findings
Nyberg & Gustafson 1995	Retrospective observational study	To report falls incidence	A stroke rehabilitation unit in Sweden	15.9 falls per 1,000 OBDs	29% (44/153) some injury 4% (6/153) fractures
Nyberg et al. 1997	Retrospective observational study	To report falls incidence	A geriatric rehabilitation unit in Sweden	9.2 falls per 1,000 OBDs in the geriatric rehabilitation unit	38% some injury 5% major injury
Schmid 1990	Retrospective observational study	To assess the effect of service improvement	A military rehabilitation hospital in the USA	4.1 falls per 1,000 OBDs	
Vassallo et al. 2004	Before-and-after study	To assess the effect of a falls prevention intervention	Three wards in a rehabilitation hospital in England	11.5 to 12.3 falls per 1,000 OBDs	37.3% (56/150) some injury
Vassallo et al. 2005	Retrospective observational study	To identify risk factors for injury from falls	825 consecutive admissions to geriatric rehabilitation wards in England	Falls given as whole numbers only, no OBDs denominator	30.0% (73/243) some injury of which 6.8% (5/243) of *“major severity”*
Vlahov et al. 1990	Retrospective observational study	To identify risk factors for falls	151 bed rehabilitation hospital in the USA	Falls given as whole numbers and rate per admission only, no OBDs denominator	13% sustained injuries
Summary	**12 studies**	**4 studies whose primary focus was to describe falls incidence**	**2 UK studies**	**Range 3.9 -19.2 falls per 1,000 OBDs (9 studies)**	**Range 13% to 37% of falls resulting in injury (7 studies)** **0% to 11.3% resulting in fracture (5 studies)** **0.8% resulting in hip fracture (1 study)**

Twelve studies (Aisen et al. 1994, Barry et al. 2000, Falkenbach et al. 2006, Haines et al. 2004, Hanger et al.1999, Mayo et al. 1994, Nyberg & Gustafson 1995, Nyberg et al. 1997, Schmid 1990, Vassallo et al. 2004, Vassallo et al. 2005, Vlahov et al. 1990) based in rehabilitation units were identified, of which two were from a UK setting (Vassallo et al. 2004, Vassallo et al. 2005). Only nine studies gave a falls rate (Aisen et al. 1994, Falkenbach et al. 2006, Haines et al. 2004, Hanger et al.1999, Mayo et al. 1994, Nyberg & Gustafson 1995, Nyberg et al. 1997, Schmid 1990, Vassallo et al. 2004). Falkenbach et al.'s (2006) study identified a rate of only 0.6 falls per 1,000 OBDs, but the data source was an insurance claims system which was likely to detect only falls associated with complaints or costly treatment. The remaining eight studies based on reports of falls reported a wide range from 3.9 to 19.2 falls per 1,000 OBDs. Seven studies (Hanger et al. 1999, Mayo et al. 1994, Nyberg & Gustafson 1995, Nyberg et al. 1997, Vassallo et al. 2004, Vassallo et al. 2005, Vlahov et al. 1990) gave overall injury rates, which again showed a wide range, with from 13% to 37% of falls reported as resulting in some injury. Fracture rates were provided in five studies (Aisen et al. 1994, Barry et al. 2000, Haines et al. 2004, Hanger et al. 1999, Nyberg & Gustafson 1995) but showed even more marked variation, from no falls resulting in fracture to 11% of falls resulting in fracture, although again based on small numbers (no more than eight fractures in any study). Only Hanger et al. (1999) reported on the proportion of falls resulting in hip fracture (0.8%).

Overall, whilst almost as many studies on falls and injury rates could be located from rehabilitation settings as from acute hospital settings, the studies showed a degree of variation that leaves the overall picture of harm unclear.

1.2.4 The incidence of falls and injury in mental health units

The search identified five observational studies describing falls rates or the proportion of falls resulting in injury or fracture in mental health units. These studies are summarised below in Table 1d.

TABLE 1d: Studies of mental health units falls and/or injury rates 1987–2006[ix]

Reference	Study design	Study aims	Setting	Incidence findings	Injury findings
Blair & Gruman 2005	Retrospective observational study	To report falls incidence	A psychogeriatric ward in the USA	Falls given as whole numbers only, no OBDs denominator	49% (22/45) some injury of which 2% (1/45) fracture
Gowdy & Godfrey 2003	Retrospective observational study	To assess the effect of adult mobility aids (*'merry walkers'*)	A 10 bedded psychogeriatric ward in the USA	28 to 67 falls per 1,000 OBDs[x]	
Nyberg et al. 1997	Retrospective observational study	To report falls incidence	A psychogeriatric unit in Sweden	17.1 falls per 1,000 OBDs	Only injury figures combined with neighbouring geriatric rehabilitation unit presented
Poster et al. 1991	Retrospective observational study	To report falls incidence	A neuro-psychiatric hospital in the USA; eight wards of which four were children's or adolescent wards	4.1 falls per 1,000 OBDs	38% (187/494) *"had some consequential outcome"* 1% (5/497) *"serious"*
Weintraub & Spurlock 2005	Retrospective observational study	To assess the effects of reducing use of body restraints	767consecutive admissions to a psychogeriatric unit in the USA	18 to 21 falls per 1,000 OBDs	
SUMMARY	**5 studies**	**3 studies whose primary focus was to describe falls incidence**	**No UK studies**	**Range 4.1 to 67 falls per 1,000 OBDs (4 studies)**	**Range 38% to 49% some injury (2 studies)** **2% fracture (1 study)**

[ix] Savage & Matheis-Kraft's (2001) study was a potential additional source, but because their psychogeriatric unit, although located in a hospital, was used for continuing care and had a mean length of stay of four years, it is more appropriate to consider it to be a care home study.

[x] This 10 bed psychogeriatric unit was located within a 400 bed acute general hospital, and falls rates for the whole hospital of 2.6 to 6.1 falls per 1,000 OBDs are also presented in the paper. However, the whole hospital rate was so heavily influenced by the 10 psychogeriatric beds, which accounted for 58% of all reported falls, that the overall hospital rate was not included above in Table 1d.

As shown in Table 1d, only five studies (Blair & Gruman 2005, Gowdy & Godfrey 2003, Poster et al. 1991, Nyberg et al. 1997, Weintraub & Spurlock 2005) were located, four of which were based in psychogeriatric units (Blair & Gruman 2005, Gowdy & Godfrey 2003, Nyberg et al. 1997, Weintraub & Spurlock 2005), where a high prevalence of dementia might be expected to lead to an increased risk of falls. Reported rates were reflective of this increased risk, ranging from 17 to 67 falls per 1,000 OBDs. Only one of these studies (Blair & Gruman 2005) reported the proportion of falls resulting in some injury (49%) or fracture (2%), but the study was small and the latter percentage is based on a single fracture. One study (Poster et al. 1991) was from an unusual setting of a hospital providing neurological and psychiatric care, where half the patients were children or adolescents. This reported a rate of 4.1 falls per 1,000 OBDs, with 38% resulting in some injury. Gowdy & Godfrey 2003 also reported a falls rates for the whole 400 bed mental health hospital of 2.6 to 6.1 falls per 1,000 OBDs. However, the whole hospital rate was heavily influenced by the 10 psychogeriatric beds, which accounted for 58% of all reported falls.

1.2.5 Summary: data on falls and injury in hospitals prior to 2007

Table 1e below summarises the key findings from all the settings discussed above.

Table 1e: Summary ranges of reported falls rates and injury proportions in hospitals pre-2007

Setting	**Falls rate per 1,000 OBDs (range)**	**Proportion of all falls resulting in some injury**	**Proportion of all falls resulting in fracture**	**Proportion of all falls resulting in hip fracture**
Acute whole hospital (13 studies)	1.3-8.9 (10 studies)	27%-51% of falls resulting in any injury (6 studies)	0.8%-3.0% (5 studies)	0.8%-2.0% (2 studies)
Acute specialist units (12 studies)	4.4-19.9 (10 studies)	22%-25% (3 studies)	0.6%-1.7% (2 studies)	0.7%-1.7% (2 studies)
Rehabilitation units (12 studies)	3.9-19.2 (9 studies)	13%-37% (7 studies)	0%-11.3% (5 studies)	0.8% (1 study)
Mental health units (5 studies)	4.1-67 (4 studies)	38%- 49% (2 studies)	2% (1 study)	-
Combined **(42 studies)**	**1.3-67** **(33 studies)**	**13%-51%** **(18 studies)**	**0%-11.3%** **(13 studies)**	**0.7%-2.0%** **(5 studies)**

This summary demonstrates that prior to 2007, despite 42 published studies, there was no clear picture of the number of falls in hospital settings, with more than tenfold variations between lowest and highest reported falls rates and the lowest and highest proportion of falls reported to result in fracture, and fourfold variations in the proportion of falls resulting in injury or hip fracture. Much of the variation was potentially attributable to differences in the inpatient population (between countries and between specialist areas of inpatient care) and to inadequate power for assessing the proportion of falls and injury resulting in fractures.

1.2.6 Age and gender of patients who fall

A limited number of the studies identified through the search strategy reported above also included data on the age or gender of patients who fell, and this is summarised in Table 1f.

TABLE 1f: Studies including data on age or gender of hospital fallers 1987- 2006

Reference	Study design	Study aims	Setting	Age of fallers	Gender of fallers
Brady et al. 1993	Retrospective observational study	To assess the effect of service improvement	172 geriatric rehabilitation beds within an acute hospital in the USA	*"the largest percentage of falls were in the 70 to 79 age range"*	*"males were predominant"*
Brandis 1999	Before-and-after study	To assess the effect of a falls prevention intervention	500 bed acute hospital in Australia	37% of fallers 60-79 years 40% of fallers 80+ years	
DeVincenzo & Watkins 1987	Retrospective observational study	To report falls incidence	150 bed rehabilitation unit in the USA	Falls peaked in the 60-69 age group	*"Males predominate in younger age groups, with female predominance increasing from age 60 upwards"*
Falkenbach et al. 2006	Retrospective observational study based on reports made to an insurance body	To report falls incidence	Rehabilitation unit in Austria		*"Females fell more frequently than males"*
Fischer et al. 2005	Retrospective observational study	To report falls incidence	An acute academic hospital in the USA	Median age of fallers 62 years	
Gaebler 1993	Retrospective observational study	To compare characteristics of single and multiple fallers	680 bed acute hospital in Australia	Mean age of fallers 71.9 years (SD=15.11)	
Govier & Kingdom 2000	Retrospective observational study	To report injury from falls in relation to bedrail use	206 beds on *'high risk wards'* in an acute hospital in England	40% aged 76-85 years 38% aged 86+ years	
Halfon et al. 2001	Retrospective observational study	To inform a falls prediction model	800 bed acute academic hospital in Switzerland	Rates per 1,000 OBDs: Age 56-65 1.72 Age 66-75 2.29 Age 76-85 4.15 Over 85 5.61	Rates per 1,000 OBDs: Female 2.25 Male 2.64
Hitcho et al. 2004	Prospective observational study using falls reported, recorded in notes, or recalled by patients or nurses	To report falls incidence	1,300 bed acute academic hospital in the USA, adults and children included	40.0% (74/183) of first fallers aged 70 years+ 24.0% (44/183) aged 60 to 69 years 35.5% (65/183) aged below 60 years (but no context of OBDs by age and children included)	45.4% (86/183) first fallers male (but no context of OBDs by gender)

Reference	Study design	Study aims	Setting	Age of fallers	Gender of fallers
Poster et al. 1991	Retrospective observational study	To report falls incidence	A neuro-psychiatric hospital in the USA; eight wards of which four were children's or adolescent wards	48% of fallers aged >60 years	*"No gender effect after adjusting for age"*
Vassallo et al. 2000	Retrospective observational study	To compare the impact of different ward designs on the circumstances of falls	Three integrated medical wards in an acute hospital in England	72.9% aged over 65 years	61% of fallers were male
Summary	**11 studies**	**-**	**2 UK studies**	**10 studies report age of fallers**	**7 studies report gender of fallers**

Ten studies provided some data on the age of fallers (Brady et al. 1993, Brandis 1999, DeVincenzo & Watkins 1987, Fischer et al. 2005, Gaebler 1993, Govier & Kingdom 2000, Halfon et al. 2001, Hitcho et al. 2004, Poster et al. 1991, Vassallo et al. 2000) but in some studies (Brady et al. 1993, DeVincenzo & Watkins 1987) this was approximate and in other studies it was based on very broad age bands (e.g. under or over 60 years in Poster et al. 1991). Only one study (Halfon et al. 2001) contextualised the age of fallers by presenting the rates of falls by age over a denominator of OBDs by age, and this study demonstrated a falls rate that rose steadily with each age band, and was at its highest in patients aged over 85 years, whose falls rate of 5.61 falls per 1,000 OBDs was more than double that of patients aged 66 to 75 years (2.29 falls per 1,000 OBDs). The remaining studies failed to provide any contextual data on the age profile of their inpatients overall, essentially rendering the information on the age of fallers impossible to interpret.

Seven studies provided some data on the gender of patients who fell (Brady et al. 1993, DeVincenzo & Watkins 1987, Falkenbach et al. 2006, Halfon et al. 2001, Hitcho et al. 2004, Poster et al. 1991, Vassallo et al. 2000) with a fairly equal division between those noting more fallers were male (Brady et al. 1993, Halfon et al. 2001, Vassallo et al. 2000), those noting more fallers were female (Falkenbach et al. 2006, Hitcho et al. 2004) and those noticing no gender effect overall (DeVincenzo & Watkins 1987, Poster et al. 1991). However, once again, most of these studies failed to provide any contextual data on the gender mix of their patients, with only one study (Halfon et al. 2001) that presented the rates of falls by gender over a denominator of OBDs by gender. This study indicated that males were slightly more likely to fall, with rates of 2.25 falls per 1,000 OBDs for females and 2.64 falls per 1,000 OBDs for males.

Therefore, by 2007, only one study (Halfon et al. 2001) had provided meaningful data on the age profile and gender of fallers in hospital settings.

1.2.7 Time of falls

A limited number of the studies identified through the search strategy reported above also included data on the time that patients fell, and these are summarised in Table 1g below.

TABLE 1g: Studies including the time of day of hospital falls 1987- 2006

Reference	Study design	Study purpose	Setting	Time of falls
Brady et al. 1993	Retrospective observational study	To assess the effect of service improvement	172 geriatric rehabilitation beds within an acute hospital in the USA	Peak between 14:00-15:00
DeVincenzo & Watkins 1987	Retrospective observational study	To report falls incidence	150 bed rehabilitation unit in the USA	Peaks at 08:00 and 11:00
Govier & Kingdom 2000	Retrospective observational study	To report injury from falls in relation to bedrail use	206 beds on *'high risk wards'* in an acute hospital in England	74% between 22:00 and 08:00 26% between 08:00 and 22:00
Halfon et al. 2001	Retrospective observational study	To inform a falls prediction model	800 bed acute academic hospital in Switzerland	Peaks between 09:00-11:00 and 17:00-18:00
Hanger et al. 1999	Before-and-after study	To observe the effects of bedrail reduction	135 bed rehabilitation hospital in New Zealand	Falls peaked at 00:00
Kerzman et al. 2004	Retrospective observational study	To report falls incidence	Psychiatric, elderly care and rehabilitation departments within a 2,000 bed acute hospital in Israel	*"most of the reported falls occurred during the morning shift"* ($p<0.001$)
Poster et al. 1991	Retrospective observational study	To report falls incidence	A psychiatric hospital in the USA; eight wards of which four were children's or adolescent wards	Peaks at 07:00, 15:00, 19:00
Sweeting 1994	Retrospective observational study	To assess the effect of service improvement	231 beds on geriatric wards in a small acute hospital in England	*"peaks in falls"* at 10:00-11:00, 13:00-14:00, 23:00-01:00 and 03:00-04:00
Tutuarima et al. 1997	Retrospective observational study	To report falls incidence	720 patients admitted with stroke to 23 hospitals in the Netherlands	*"most falls occurred during the day"*
Von Renteln-Kruse & Krause 2004	Retrospective observational study	To report falls incidence	145 beds on geriatric wards with an acute academic hospital in Germany	*"patients with stroke had their maximum of falls 09:00-12:00"*

Most of the ten studies identified provided limited descriptive data, with some using as the unit of measurement 'shifts' or 'night and day' whose start and finish times are not reported (Kerzman et al. 2004, Tutuarima et al. 1997) or comparing periods of unequal length (e.g. Govier & Kingdom's (2000) comparison of a ten hour night-time period with a fourteen hour daytime period). Three studies report a peak of falls in the morning (DeVincenzo & Watkins 1987, Kerzman et al. 2004, Von Renteln-Kruse & Krause 2004), one study an afternoon peak (Brady et al. 1993), one study a ‘daytime’ peak (Tutuarima et al. 1997) and two studies a night-time peak (Govier & Kingdom 2000, Hanger et al. 1999). The remaining studies (Halfon et al. 2001, Poster et al. 1991, Sweeting 1994) give a picture of several peak times for falls distributed over morning, afternoon and night.

Taken together, the differences in peak times of falls reported by the studies suggest that the timing of falls may be influenced by local circumstances specific to each hospital studied, and no clear overall picture of the time of day that patients are most vulnerable to falling emerges.

1.3 A NATIONAL REPORTING AND LEARNING SYSTEM

1.3.1 The National Patient Safety Agency (NPSA)

Before moving on to report our analysis of falls in hospital, I will set the context for our paper by describing the origins of the NPSA and its National Reporting and Learning System (NRLS). The NPSA was founded in 2001 in response to *An organisation with a memory* (Department of Health, 2000) which set out aspirations for a national reporting system to inform national learning and action to improve patient safety. By the time the NPSA was established, almost all acute hospitals and mental health units (and most primary care organisations) in the UK had invested in commercial Local Risk Management Systems (LRMS); software that allowed them to enter incident reports made either through web portals or on paper forms and to categorise, analyse and produce reports on these.

1.3.2 The National Reporting and Learning System (NRLS)

After widespread consultation and piloting (NPSA 2003) the way forward decided on for England and Wales was to build a National Reporting and Learning System which used the LRMS established in most NHS organisations as its primary data source. This approach had many advantages, the greatest of which included no need for duplicate reporting by frontline staff and national access to the full range of all types and severity of incidents reported locally. Equally importantly, it supported the key patient safety concept (NPSA 2003) that almost all incidents will require local action to manage their consequences or reduce future risks, regardless of whether or not they also require action at a national level.

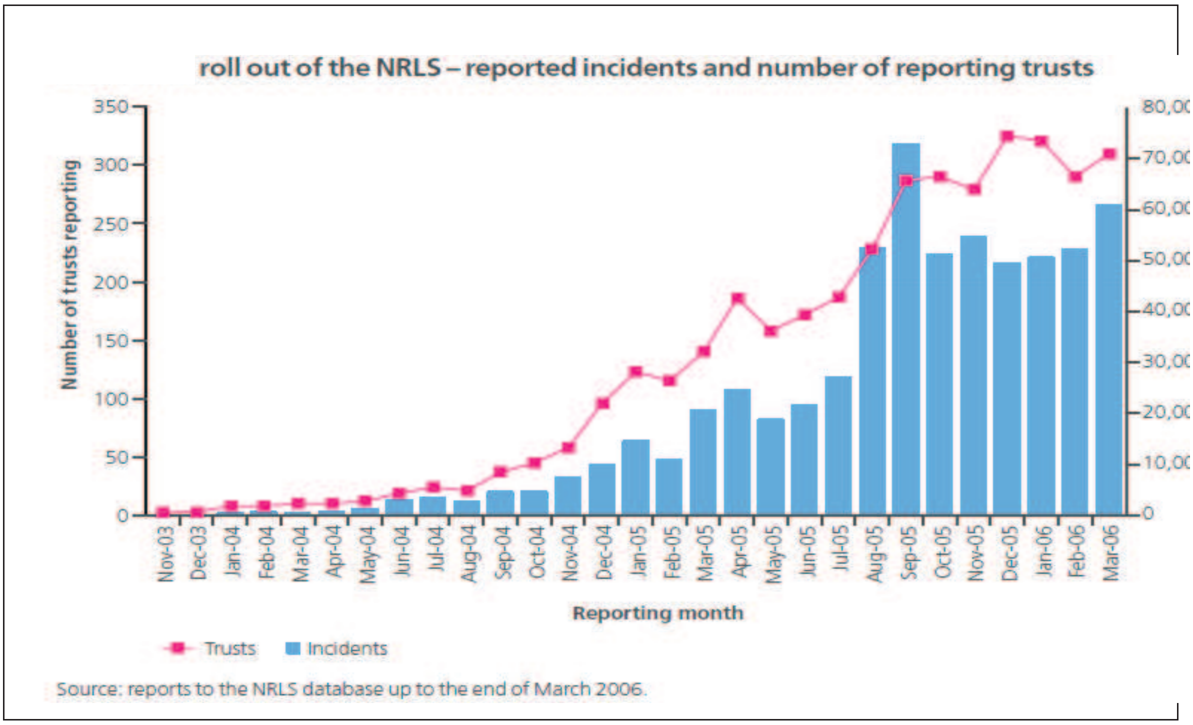
However, this approach also held challenges. The LRMS in use in NHS organisations were provided by several different commercial organisations, and each provided a different taxonomy, which could then be further adapted by the NHS organisation that had purchased it.[xi] Despite the challenge posed to a national reporting system from these multiple locally varying taxonomies, individual NHS organisations did not want to see any substantial changes to their local taxonomy, as this would impair their ability to compare current reporting with past trends. Because of this, a system of mapping local taxonomies to an agreed national taxonomy (the NRLS dataset) was adopted, where a link from each local category to its best match[xii] within the NRLS dataset was built into each LRMS. This operated to automatically substitute the national taxonomy for the local taxonomy at the point where data was uploaded by local organisations to the NRLS.

The strength of this approach in terms of national access to high volumes of reports was apparent at an early stage; within months of the first major commercial vendor releasing compliant software late in 2004, the NRLS was receiving 20,000 reports per month (Figure 1a).

[xi] A useful analogy is to consider each of the commercial vendors of LRMS (*Datix, Ulysses,* etc.) as speaking different languages, but then each organisation changing the language slightly into a local dialect. This meant that at the time of the introduction of the NRLS, there were four languages spoken by the majority of NHS organisations (the most commercially successful of LRMS vendors), six minority languages (vendors with a niche market) and over 500 local dialects (one from each of the acute, mental health, or primary care trusts in England and Wales).

[xii] To continue the analogy used above, the NRLS taxonomy was the 'Esperanto' or artificial language in which all the languages and local dialects could establish a common communication.

FIGURE 1a: Increase in trusts connecting and reporting to the NRLS 2004 - 2006 (NPSA 2006)



However, the mapping approach also had disadvantages. Firstly, as duplicate reporting had been eliminated, the quality of data received by the NPSA was completely dependent on the quality of data collected locally, which varied between organisations and at the inception of the NRLS was poor in many (NPSA 2005). Also, to be able to create meaningful linkages with the range of LRMS taxonomies, the NRLS dataset had to be at a relatively high level. For inpatient falls, this meant a single incident type of ‘Slips trips and falls’ to which all relevant local incident types (e.g. ‘falls from bed’ or ‘found on floor’) were mapped, and for level of harm, a generic classification of no harm, low harm, moderate harm, severe harm or death, rather than outcomes specific to falls such as bruising or fracture. To compensate for the limitations imposed by this high level mapping, the NRLS also included powerful search engines (initially Autonomy™ and later SAS™) which could also scrutinise the free text describing the incident for keyword combinations.

<u>1.3.3 Analysis of reports of slips trips and falls: background and purpose</u>

The first published analyses drawn from the NRLS were broad overviews of all patient safety incidents types (NPSA 2005, NPSA 2006) presenting quantitative analysis drawn from NRLS categorical data, with the free text of individual incidents used as illustrative examples. However, the predominance of slips, trips and falls incidents, which accounted for around a third of all incidents reported to the NRLS (Healey et al. 2008a), made this an ideal topic for the first NPSA publication focused on a particular incident type. Our aims were to report *“the documented characteristics of reported accidental falls in English and Welsh hospitals with respect to frequency (and variability [between care settings and between individual hospitals]); related harm; timing; age and gender of patients who fell; and to draw general lessons from this analysis, which might inform falls prevention strategies”* (Healey et al. 2008a p. 425). Additionally, this focus on a particular incident type provided an opportunity to showcase the capacity of the NRLS to provide detailed learning.

‘Falls in English and Welsh hospitals: a national observational study based on retrospective analysis of 12 months of patient safety incident reports’ (Healey et al. 2008a) can be found in Appendix A

1.4 STRENGTHS AND LIMITATIONS

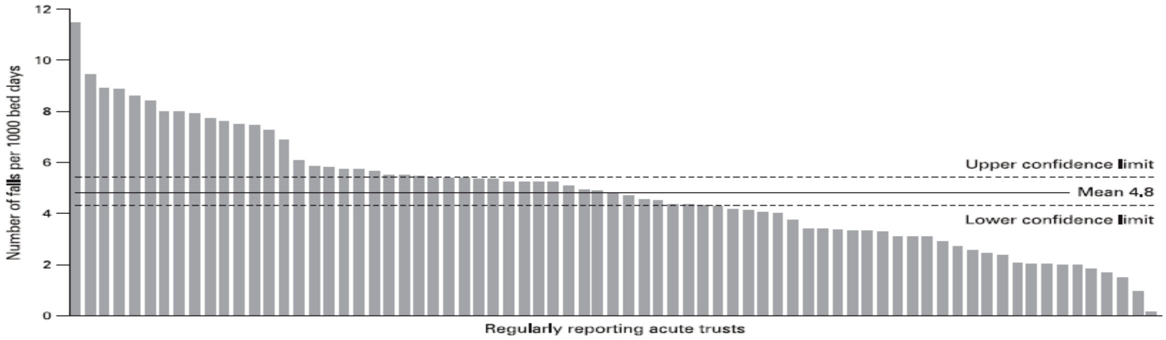
1.4.1 Strengths of our national observational study

A key strength of our analysis of reported falls was its size and power; it was the first multi-hospital study to provide more than minimal and approximate data and drew from over 200,000 reported falls, compared to fewer than 12,000 falls in the previous largest study (Barrett et al. 2004). This scale allowed our analysis to detect patterns and trends unlikely to be noticeable in smaller scale studies, such as the changes in reports of falls by hourly bands reported in our paper. Its scope was also much wider, incorporating not only the acute and rehabilitation hospital settings that had been the subject of most previous analyses, but also mental health units. Importantly, our study was the first study to report rates of falls across the whole patient cohort in acute hospitals based on data from a UK setting, and the first to report falls rates across the whole patient cohort in typical mental health units internationally.

It was the first study to illustrate the variability of rates of reported falls between individual acute hospitals, community hospitals and mental health units by using denominator data of OBDs in each organisation. Despite the popularity of ‘benchmarks’ providing comparative rates in other areas of patient safety, such as Healthcare Associated Infection (Health

Protection Agency 2007), this was an innovative approach, since a collection of reported falls on the scale of the NRLS, in a country where detailed denominator data on healthcare activity at a national level were also available (through Hospital Episode Statistics), had never previously existed. Their graphical presentation was also a strength, as our figures (Healey et al. 2008a p 426 – 427 and reproduced below as Figure 1b to 1c) visibly demonstrated the extremes of variation within the range. (Note upper and lower confidence limits refer to 95% confidence intervals.)

Figure 1b: Mean reported falls rates from regularly reporting acute hospitals



Reported falls per 1000 bed days from regularly reporting acute hospitals. Source: The rate of reporting and the number of NHS organisations reporting to the NRLS have increased over time. Trusts were therefore included if they reported consistently (defined as 100 or more reports every month based on incident date) between December 2005 and May 2006. Seventy-three acute organisations were regular reporters and are included in the chart above. Occupied days taken from hospital episode statistics 2004/2005.

Figure 1c: Mean reported falls rates from regularly reporting mental health units

Reported falls per 1000 bed days from regularly reporting mental health trusts. Source: The rate of reporting and the number of NHS organisations reporting to the NRLS have increased over time. Trusts were therefore included if they reported consistently (defined as 100 or more reports every month based on incident date) between December 2005 and May 2006. Sixteen mental health organisations were regular reporters and are included in the chart above. Occupied days taken from hospital episode statistics 2004/2005.

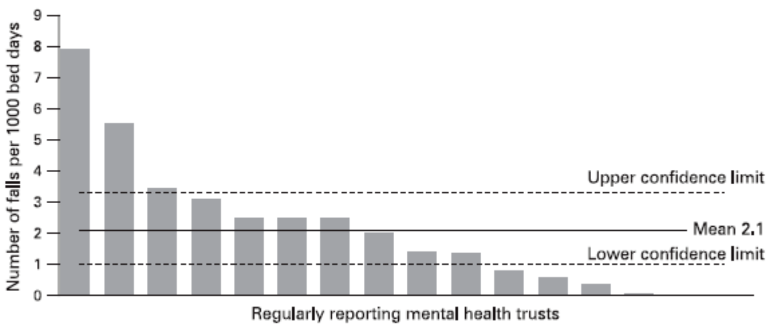
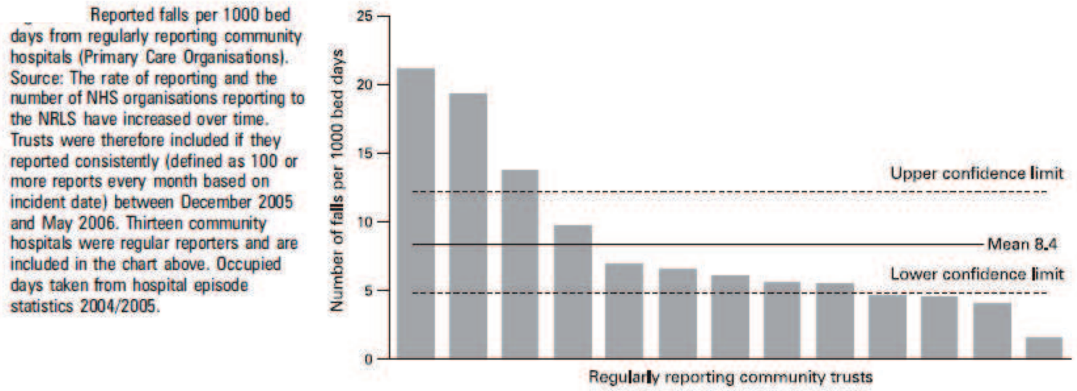


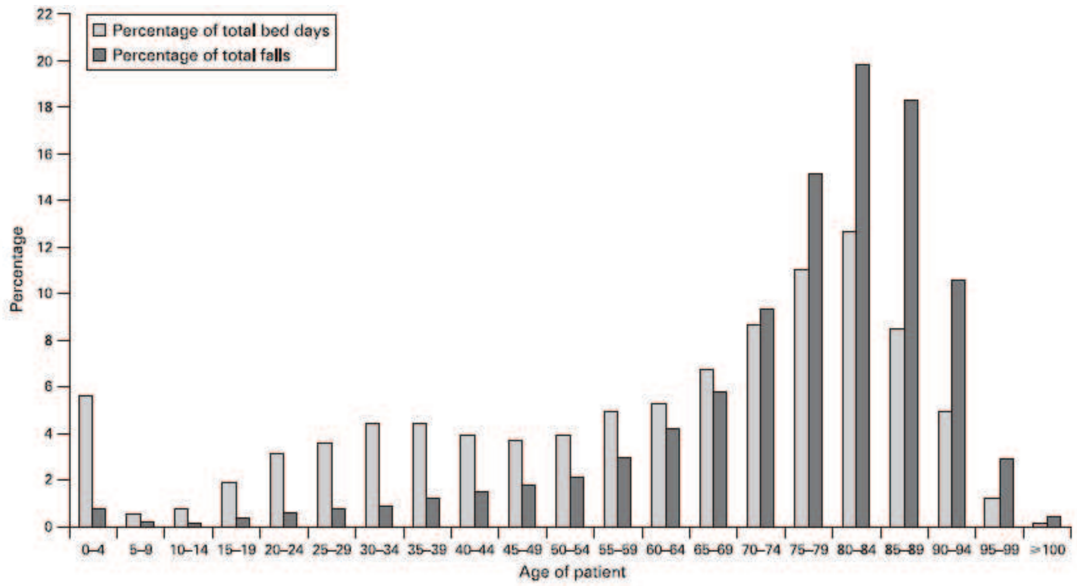
Figure 1d: Mean reported falls rates from regularly reporting community hospitals



Reproduced from Healey et al. 2008a p. 426 – 427

A further strength was the use of denominator data to provide context for falls reported by age and by gender. As reported above in Chapter 1.2.6, this had only previously been provided in a single hospital study (Halfon et al. 2001), even though data on the proportions of fallers by age or gender is meaningless without the context of their proportions within the inpatient population studied. By providing context of OBDs we were able to identify that patients aged over 85 years were proportionately the most vulnerable to falling, and that the proportion of falls in male patients exceeded the proportion of OBDs occupied by males in all settings except mental health. A further strength was clear graphical presentation of this age data across five year bands ranging from newborns to centenarians (Healey et al. 2008a p. 428).

Figure 1e: proportion of reported falls by age compared to OBDs by age



Age of patients who fell compared with age of all patients. Source: Falls in hospital locations reported to the NRLS between 1 September 2006 and 31 August 2006, where age reported and within a valid range (108 360 incidents, 52.5% of total). Hospital episode statistics on occupied bed days from 2004/05.

In contrast to the earlier studies reported above, that relied on analysis of categorical date alone, or were sufficiently small for every included fall to be individually reviewed, we made full use of search engines[xiii] to conduct keyword searches of the free text of individual incident reports. The methodology for analysing NRLS data in this way was developed and refined in the course of producing *Slips trips and falls in hospital* and is superficially similar to keyword methods used for literature searching. However, in incident data, keywords may need to encompass not only correct medical terminology but the abbreviations of these used in common practice, misspellings, symptoms indicative of the condition, and actions or treatments used in response to the condition, and this is an iterative process, with initial sets of incident reports scrutinised to identify any further terminology specific to the issue and search strategies refined accordingly. A strength of our paper was using these techniques to quantify specific injury types (including lacerations, hip fracture and other fractures) through constructing keyword searches[xiv] followed by review of random samples. We also ensured these random samples were of sufficient size to provide extrapolations to the whole dataset with small confidence intervals. We estimated 11,824 lacerations, with 95% confidence intervals (CI) from 11,265

[xiii] Initially Autonomy™ and later SAS™

[xiv] The eventual keyword combinations identified and used for our paper are reported within ‘Methods’ on p. 425 of Healey et al. 2008a.

to 12,181, 528 fractured neck of femur (95% CI 447 to 626) and 443 other fractures (95% CI 381 to 512). These specific searches were in addition to our presentation of levels of reported severity of outcome from each care setting and from all care settings combined (Healey et al. 2008a p. 428 and reproduced below as Figure 1f).

Figure 1f: Degree of harm from reported falls by type of hospital and overall

Degree of harm from falls by type of hospital

Degree of harm		Location: Acute hospital	Community hospital	Mental health units	All locations
No harm	No	101199	17760	14458	133417
	%	66.5%	63.0%	55.4%	64.7
Low	No	44806	9139	10199	64144
	%	29.5%	32.4%	39.1%	31.1
Moderate	No	5008	1172	1326	7506
	%	3.3%	4.2%	5.1%	3.6
Severe	No	1022	123	85	1230
	%	0.7%	0.4%	0.3%	0.6
Death	No	21	1	4	26
	%	<0.1%	<0.1%	<0.1%	<0.1%
All falls	No	152056	28195	26072	206323

Source: All incidents categorised as slips, trips and falls in hospital locations reported to the NRLS between 1 September 2005 and 31 August 2006. Incidents reported as deaths have been reviewed to correct for miscoding of severity, or location: 16 incidents have been excluded which were fatal collapses, not falls, eight incidents were miscoding where reports clearly indicate the patient survived, and in three cases the fatal fall occurred outside hospital care.

A further strength was our appropriate use of statistical analysis, in line with the approach urged by Brennan and Croft (1994 cited in Altman et al. 2000), who caution against the over-emphasis of tests of statistical significance when these are based on purely observational data. They advise that p values should not be published, with confidence intervals presented only as an indication of the possible influence of chance on the result. Using this approach, we identified a number of areas where our findings were unlikely to be due to chance. These included a lower falls rate from regularly reporting mental health units (2.1 falls per 1,000 OBDs 95% CI 1.0 to 3.3) than from regularly reporting acute hospitals (4.8 falls per 1,000 OBDs 95% CI 4.3 to 5.4) and community hospitals (8.4 falls per 1,000 OBDs 95% CI 4.8 to 12.0). We also identified injury rates in mental health units (44.5% 95% CI 43.9% to 45.1%) which exceeded those in community hospitals (37.0% 95% CI 36.4% to 37.6%), which in turn exceeded those from acute hospitals (33.4% 95% CI 33.2% to 33.7%). Potential explanations for these observed differences will be discussed later in Chapter 1.5.

We also produced the first fully reported analysis of time of falls by hourly bands (Healey et al. 2008a p.429). Unlike the studies reported earlier in Chapter 1.2.7, where mention is made of selected peaks (without data on how greatly these differed from other time periods) or comparison only takes place in time segments of eight or more hours, we analysed the data by hourly bands.

A further strength was our grounding of our findings within the wider evidence on falls risk factors, falls prevention and clinical practice. Whilst these aspects will be discussed in more detail later in the context of commonalities and differences, our paper included debate around potential behavioural and physiological reasons for our findings, such as the higher proportion of fallers who were male, and the higher proportion of injury found in community hospital and mental health units (p. 427) and the likelihood of additional deaths consequent to fractured neck of femur occurring in the weeks and months following the original injury (p. 429). We also placed our findings on peak times for falls within the context of diurnal physiological changes and clinical activity (p. 428).

We also suggested that the wide variation between individual trusts' reported falls rate went beyond what could be plausibly explained by differing case mix or differences in falls prevention practice, given the success rates of published falls prevention trials,[xv] and therefore speculated that differences in reporting practice were very likely to have contributed to this. Given the association found by other studies between high incident reporting rates and other indicators of organisational safety (Hutchinson et al. 2009) we made the observation that units that *"units which take the problem [of falls] seriously may be more likely to record and report falls assiduously, leading to a spuriously lower apparent falls rate in hospitals less committed to reporting and learning"* (Healey et al. (2008) p. 427 citing Gibson et al. 1987).

1.4.2 Limitations of our national observational study

For any observational study based on reported incidents, an issue of key importance is how affected the data are by under-reporting, both in absolute terms, and in terms of whether incidents are less likely to be reported in particular circumstances, thereby making the reported data unrepresentative. Both these issues will therefore be examined in detail below.

[xv] These will be discussed in depth later in Chapter 2.

1.4.2.1 The under-reporting of falls to incident reporting systems

For patient safety incidents overall, large scale case note reviews (as outlined earlier in Chapter 1.2.2.3) are accepted as the 'gold standard' for indentifying harm associated with healthcare treatment, with suggestions that they identify up to six times as many incidents as voluntary reporting systems (Sari et al. 2006) although other commentators would suggest definitional differences between adverse events (which include iatrogenic illness in the absence of error) and reportable incidents may account for much of the disparity (Haller 2007). But case note review also has limitations. These include issues with inter-rater reliability; in a systematic review of inter-rater reliability in case note review, Lilford et al. (2007) found mean Kappa values ranging from 0.32 to 0.70, and whilst they considered reviews of specific outcomes (such as adverse events) generally had better inter-rater reliability than reviews of processes, inter-rater reliability still appears weak in some adverse event studies. For example, Wilson et al. (1995) found that reviewers disagreed with each other on 32.6% of occasions on whether or not an adverse event had occurred. A further drawback is the relatively rarity of such studies. For example, in England, only two studies (Vincent et al. 2001, Sari et al. 2006), each involving the review of around 1,000 case notes, have been conducted within a decade in which around 100 million inpatient treatment episodes have occurred (Hospital Episode Statistics 2007).

At the level of reported *falls*, a different picture of whether incident reporting or case note review is the most accurate source of data may emerge, as some studies have been constructed to allow a more direct comparison of the relative accuracy of case note review and reported incidents. Sari et al. (2007) undertook a direct comparison for a cohort of 1,006 patients admitted to an acute hospital in England of incidents detected in case note review and/or reported to a local incident reporting system, and reports on a subset of these that were falls. The published article (Sari et al. 2007) indicates that of 48 falls detected in case note review, only 29 (60.4%) were also reported as incidents (i.e. 19 falls were detected solely by case note review). However, the converse comparison, whilst not included in the published article, indicated that 17 falls were reported as incidents but not detected in case note review (personal correspondence). Therefore, for falls (unlike adverse events overall) this study would suggest both case note review and incident reporting systems identified similar numbers (48 falls v. 46 falls[xvi]) but that both methods under-identified the 'true' number of falls by 26% and 29% respectively.[xvii] A similar study in an acute academic hospital in the USA (Naessens et al. 2009) compared routine clinician review of small samples of case notes with reported incidents and concluded *"events considered to be nursing issues [including] hospital falls"* were most likely to be identified through being reported as incidents (p. 305). Their findings that case note review appeared more complete than incident reporting for adverse events related to medical or surgical treatment, whilst incident reports appeared the more complete source for events reported by nurses may explain the implausibly low falls rates reported by most of the large scale case note review studies discussed above in Chapter 1.2.2.3.

Some additional studies are specific to falls. Williams et al. (2007) used both reported falls and falls recorded in case notes in an Australian acute hospital to assess the impact of a falls prevention intervention and found that 127 falls were reported as incidents but only 88 falls recorded in case notes. Because the reporting system was an anonymous one, the degree of overlap (falls reported both as incidents and in case notes) could not be determined. Cumming et al. (2008) collected outcome data for a cluster RCT of falls prevention through case-note review and questioning of staff and found that 3% (12/381) of falls verbally reported by staff were not recorded in case notes; carbon copies of incident reports of falls were filed in the case notes and so case note review encompassed both reported falls and falls described in medical or nursing chapters of the notes. Hill et al. (2010) compared case note review, questioning of patients, and falls reported as incidents in two Australian acute hospitals and found that case note review was the most reliable method (case notes captured 227 (92.65%) of falls, incident reporting systems captured 185 (75.51%) of falls and patient recall captured 147 (60.25%) of falls). However, the study also suggested a variation between the two hospitals in terms of how well falls were captured by incident reporting systems, with speculation this could be attributed to one hospital having an electronic reporting system but potentially inadequate numbers of computer stations for this to be easily accessed.

Taken together, these comparative studies provide a contradictory picture, with some suggesting incident reporting captures falls more accurately than case note review

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[xvi] 29 falls in both case note review and incident reporting systems + 17 falls in incident reporting system alone = 46 falls

[xvii] 29 + 19+ 17 = 65 falls overall. 48/65 = 73.8% detected by case note review, 26.2% not detected. 46/65 = 70.7% detected by incident reporting, 29.3% not detected

(Naessens et al. 2009, Williams et al. 2007), some suggesting they are roughly equal (Sari et al. 2007) and some suggesting case note review is more accurate (Hill et al. 2010), although this does not appear supported by the low numbers of falls identified in larger adverse events studies (see Chapter 1.2.2.3). From the limited number of studies discussed above, it appears that incident reporting systems may capture around 70% (Sari et al. 2007) and 75% (Hill et al. 2010) of falls overall, but with variation seen between individual units and hospitals, and with other potential data sources also affected by under-reporting. Therefore we have to accept under-reporting as a limitation of our analysis of reported falls, as we do in both the introduction and discussion chapters of our paper (Healey et al. 2008a p. 425 and p. 427). This is in contrast to some other authors, who either omit to discuss the possibility that their data may be incomplete (e.g. Dunton et al. 2004, DeVincenzo & Watkins 19987, Sweeting 1994) or assert that it is complete without supporting evidence (e.g. Koh et al.'s (2009) assertion that their methodology identified all falls that occurred because the reporting of accidents is a legal requirement for nursing staff).

However, all the studies discussed above also suggest that in terms of access to data in normal clinical practice, reported incidents are likely to be the only source with sufficient numbers of reports to allow detailed analysis. Daily visits to question patients and staff are unfeasible outside a funded research study, and case note review is very labour intensive; in the context of local learning, where most hospitals are unlikely to review more than around 20 case notes a month (Institute for Healthcare Improvement 2005, Naessens et al. 2009), case note reviews could only be expected to identify very small numbers of falls. In contrast, acute hospitals are likely to receive over 1,000 reports of falls via their local incident reporting system each year (Healey & Scobie for NPSA 2007a), whilst the NRLS gave us access to over 200,000 reports of falls (an almost thousand-fold larger data set than the largest number identified in case note review (the 227 falls identified by Hill et al. (2010)).

1.4.2.2 Bias in reporting of falls to incident reporting systems

When assessing source data known to be affected by under-reporting, it is important to also attempt to assess whether the under-reporting is truly random (and therefore the reported incidents, though lower in numbers than true incidence, would be expected to share the same characteristics) or whether falls are particularly more or less likely to be reported in certain circumstances (thereby introducing selection bias to any analysis based on reported falls).

Some studies include data that can help assess bias in reporting. Williams et al. (2007) found 71.8% of falls overall, and 71.7% of injurious falls were captured by incident reporting systems, suggesting staff were no more or less likely to report a fall with or without injury. Hills et al. (2010) also found no significant difference between the likelihood of falls with or without injury being reported as incidents (75.5% of falls overall, and 78.3% of injurious falls). These findings appear to contradict Haines et al. (2008) who found that in interviews with over 200 hospital staff, whilst many said they would report all falls regardless of injury, a substantial minority (31% (66/212)) indicated they would be *"more inclined to complete an incident report if the patient was injured"* (p. 702). Cases identified in Sari et al.'s (2007) study (personal correspondence) might provide an explanation for this apparent dichotomy, as it was noted that whilst the intent of staff to report an injurious fall was high, they explained any failure to complete an incident report by having been distracted by the need to attend to the injury. This suggests the influence of a higher intent to report injurious falls in a subgroup of staff may be counterbalanced by distraction from doing so by the greater workload involved in responding to an injurious fall, and therefore no skewing of reported falls towards or against injurious falls results, although this can only remain a tentative theory given the very limited data available.

The only other data available on reporting bias specific to falls is provided by Hill et al. (2010). They combined case note review, questioning of patients, and falls reported as incidents in two acute hospitals, then compared the falls reported as incidents to the total falls identified by one or more of the three ascertainment methods. They found no significant differences between reported falls and all identified falls in relation to patient age, gender, diagnosis, first language, diagnostic group, care setting, location, or weekday of fall, or between witnessed and unwitnessed falls. However, they did identify falls were significantly less likely to be reported if they occurred in the period 06:00 to 10:00 (95% CI 0.29, 0.99) and significantly more likely to be reported if they occurred 14:00 to 18:00 (95% CI 1.05, 7.76).[xviii] Additionally, first falls were more likely to be reported than subsequent falls in the same patient (95% CI 1.07, 1.82).

[xviii] Note that the statement in the paper that *"Falls were less likely to be reported when they occurred in the morning or afternoon shifts and particularly between 6 and 10 am and 2 and 6 pm"* appears to be an error, as for the latter a higher rate, not a lower one, is reported.

The nature of the NRLS also potentially introduced reporting bias. Our study was produced at an early stage of its development, and potentially the 'early adopters' who were the first to supply incident data to us were not representative of typical NHS organisations, as their early connection might have resulted from more proactive attitudes to incident reporting. However, the main constraints on connection appeared to be the date on which vendors of commercial risk management systems made software updates available, and the workload capacity of key individuals acting as administrators for the systems in each hospital (NPSA 2005) rather than the maturity of the local reporting culture, and, by the time that data was being extracted for analysis for our paper, around 98% of NHS organisations had reported incidents (Healey & Scobie for NPSA 2007a), although intervals between uploads of incidents were very variable. To avoid those organisations who had not established regular reporting to us affecting mean rates, we calculated mean rates of falls only in those organisations who had established a regular routine of at least monthly reporting (Healey et al. 2008a p. 426-427).

A further potential source of bias was that, although a free text description of the fall and the severity of outcome were mandatory fields and therefore were completed in 100% of reports, our analysis of patient age and gender and time of falls was based only on the proportion of the data set where these fields were complete (52.5%, 52.5% and 84.5% respectively). However, the inclusion or otherwise of such data usually resulted from the software provided by different vendors of commercial risk management systems, rather than on what was included by frontline staff in the report of a fall, and so was unlikely to introduce bias.

1.4.2.3 Other limitations in our analysis of reported incidents

Because the NRLS is an anonymised database we were unable to distinguish patients who fell only once from patients with repeated falls. As we discuss in our paper (Healey et al. 2008a p. 429), this would have been a useful differentiation, as they may demonstrate different characteristics and require differently tailored interventions (Vassallo et al. 2002).

A further limitation was our reliance on grading of severity of outcome by the reporting organisation, a method that is potentially subject to human error both when frontline staff report the fall and when administrative staff enter the report onto a local database. However, we partly compensated for this by individual scrutiny of all incidents reported with an outcome of death. Additionally, our keyword searches for injuries including lacerations, hip fractures, and other fractures (as reported above in Chapter 1.4.1) helped provide more specific data on severity of outcome. A further limitation is that the early submission of incident reports is a central tenet of any local reporting system (so that local action to reduce the risk of recurrence is expedited) and therefore the longer term outcome (e.g. death some weeks later due to complications from a fractured neck of femur) is not usually included. We compensated for this limitation by referring to studies which indicated the higher level of late mortality seen in older people who sustain a fractured neck of femur as inpatients (Murray et al. 2007).

1.5 COMMONALITIES AND DIFFERENCES

1.5.1 Commonalities and differences: incidence of falls

As reported above in Chapter 1.2.2, in acute hospital settings internationally, a wide range of rates from 1.3 to 8.9 falls per 1,000 occupied bed-days had been reported, which, given only one or two studies came from most nations (with greater numbers of studies only in the USA), gave the impression of significant inter-country variation. However, the range of international rates fell within the range of rates from individual English and Welsh hospitals reported in our study (0.9 to 11.4 falls per 1,000 occupied bed-days) and our mean rate of 4.8 (95% CI 4.3 to 5.4) falls per 1,000 occupied bed-days is placed centrally within it. Given the much greater size of our study, and the normal distribution of rates reported from the 73 acute hospitals included in the analysis, this would suggest that the earlier international data may not be as inconsistent as it appeared prior to the publication of our study, but may represent various points within a similar range (as might be expected, given almost all these earlier studies were based on single hospitals).

However, the mean rate we reported was higher than the rates reported in six studies from hospitals in the USA (Dunton et al. 2004, Enloe et al. 2005, Fischer et al. 2005, Hitcho et al. 2004, Kilpack et al. 1991, Rohde et al. 1990). These six studies remain a small sample in comparison to the size of our study, but suggest that in addition to intra-nation differences in mean falls rates in individual hospitals, there may also be differences between nations. A lower falls rate in hospital patients in the USA in comparison to England and Wales might be anticipated given the lower age profile of hospital inpatients in the USA (as discussed above in Chapter 1.2.2.1).

For rehabilitation units, more commonality between nations might be expected, since, regardless of their population and healthcare provision, a similar group of older patients with impaired mobility might be expected to require rehabilitation. Again, the range identified in our study (2.1 to 21.4 falls per 1,000 occupied bed-days) encompassed the range reported earlier in Chapter 1.2.3 from prior international studies (3.9 to 19.2 falls per 1,000 OBDs) and our observed mean of 8.4 (95% CI 4.8 to 12.0) was fairly centrally placed within this range.

For mental health units our study was unique, with no previous publications describing falls rates from typical mental health units. Although our mean rate of 2.1 (95% CI 1.0 to 3.3) is much lower than the studies from psychogeriatric settings summarised above in Chapter 1.2.4, which reported rates ranging from 17 to 67 falls per 1,000 OBDs, this remains plausible given the majority of inpatient provision in mental health units is for working age adults (Department of Health 1999) whose vulnerability to falling would be low, driving down overall falls rates expressed as a rate of OBDs.

<u>1.5.2 Commonalities and differences: injury rates</u>

Our analysis of reported falls suggested the proportion of falls in acute hospitals resulting in some injury was 33.4% (95% CI 33.2% to 33.7%), which was consistent with the range of 30% to 51% reported from the limited number of previous studies in acute hospitals (Brandis 1999, Dunton et al. 2004, Enloe et al. 2005, Halfon et al. 2001, Schwendimann et al. 2006a). We identified a slightly higher proportion of falls in community hospitals resulting in some injury at 37.0% (95% CI 36.4% to 37.6%) just within the range described by prior studies in rehabilitation units of 13% to 37% of falls reported as resulting in some injury (Hanger et al. 1999, Mayo et al. 1994, Nyberg & Gustafson 1995, Nyberg et al. 1997, Vassallo et al. 2004, Vassallo et al. 2005, Vlahov et al. 1990). Because of our use of confidence intervals, our findings of higher proportions of injurious falls in community hospitals than in acute hospitals were unlikely to be due to chance, and they were clinically plausible given the older age profile of community hospital patients (Hospital Episode Statistics 2006) and greater vulnerability to injury with increasing age (Oliver 2008). The difference between acute and community hospital injury proportions was small and would be unlikely to be detected in studies on a smaller scale than ours.

In mental health units, the proportion of falls resulting in some injury was higher still at 44.5% (95% CI 43.9% to 45.1%). There was little prior data to compare this with, but a single study from a psychogeriatric unit also reported a high injury rate of 49% (Blair & Gruman 2005). Despite the generally younger overall age profile in mental health units discussed above, a higher proportion of injurious falls in mental health units was clinically plausible, given the concentration of reports of falls from psychogeriatric units where the prevalence of dementia and psychoactive medication would lead to impairment of reflexes and reactions that might in usual circumstances reduce the impact of a fall.

For all these care settings, an alternative explanation that must be considered is the potential for observed proportions of injury to be a product of bias in reporting (and therefore for the observed differences between care settings to be an artefact of selective withholding of reports of falls without injury). However, as outlined above in Chapter 1.4.2.2, speculation that falls without injury are less likely to be reported does not appear supported by a study that triangulated reported falls with case note review or questioning of patients (Hill et al. 2010).

No comparison of proportions of moderate or severe harm between our analysis of reported falls and earlier studies was possible, since these earlier studies either did not define their terminology of 'serious' or 'major' injury (e.g. Schwendimann et al. 2006a) or included in their definition of 'serious' injury conditions such as bruises (e.g. Fischer et al. 2005) which did not equate with the NPSA definition of severe harm as injury leading to permanent disability.   However, comparison at the level of reported fractures is possible.

Although the studies examined above in Chapter 1.2 reported the proportion of falls resulting in fracture as ranging from nil to 11%, these extremes appear likely to be due to chance given the small size of many of the studies, where one or two fractures could represent several percentage points. The only two large scale studies to clearly report fractures (Barrett et al. 2004, Schwendimann et al. 2006a) identified that 0.8% and 1.7% of reported falls resulted in a fracture, whilst the proportion identified in our study was around 0.5% (95% CI 828 to 1,138 fractures identified within 206,350 reports of falls).

Potential explanations for the lower fracture rate we identified could include differences between the inpatient population, particularly any differences in age profile, and in the proportion of beds occupied by females, given the influence of these factors on the risk of osteoporosis (NICE 2008). An alternative explanation could be incomplete recording of injury subsequent to falls, but this might be assumed to equally affect Barrett et al.'s (2004) and Schwendimann et al.'s (2006a) studies (which also used reported falls as their source of data) and our own. A further possibility is differences in diagnostic practice between nations in terms of thresholds for undertaking x-rays to identify fractures unlikely to require surgical intervention (e.g. fractures of ribs or pubic rami).

It is interesting to note that the proportion of falls resulting in fracture reported both by our analysis and by Barrett et al. (2004) and Schwendimann et al. (2006a) is substantially lower than the commonly cited statistic that 5% of falls in community dwelling older people result in fractures (Lord et al. 2007). It is highly unlikely that the inpatient population is inherently *less* vulnerable to fracture than community dwelling older people, given their greater age and co-morbidities. It also seems unlikely that fractures are more likely to remain undiagnosed in hospital patients than in community dwelling older people. The most plausible explanation is that in a community setting, there is a reporting bias towards falls that result in A&E attendance or require inpatient treatment, which may artificially inflate the apparent proportion of falls resulting in fracture. Our findings suggest the number of non-fracture falls in community dwelling older people may currently be greatly underestimated.

Approximately half the fractures we identified were hip fractures. This finding is highly congruent with the three prior hospital studies (Nadkarni et al. 2005, Schwendimann et al. 2006a, Sweeting 1994) that reported on both hip fracture and overall fracture, all of whom reported that around half of all fractures reported were hip fractures (respectively 2.0% v 4.6%, 0.8% v. 1.7%, 0.7% v. 1.7%). This ratio is, however, unlike the ratios seen in community settings in the UK, where around 230,000 fragility fractures, including around 70,000 hip fractures (NICE 2010), are treated annually in hospitals. Plausible explanations for this difference include the age profile of hospital fallers; Kanis and Johnell (2004) report a typical trajectory of wrist or ankle fractures occurring in early old age, with hip fractures occurring when the patient is in their eighties, and as reported above in Chapter 1.4.1, both the inpatient population overall, and fallers in particular, contain far greater proportions of the very old than would be seen in the community. Another explanation is different mechanisms of falling; inpatients are more likely to have physical disabilities, dementia or delirium, and be taking medication with sedating effects, all of which may make it less likely that they can put out a hand to break their fall (the classic mechanism of a Colles fracture (Owen et al. 1982)), with their fall potentially resulting in a hip fracture instead.

1.5.3 Commonalities and differences: age

As outlined above in Chapter 1.2.6, almost no meaningful information on the effect of age on incidence of falls in hospital inpatients existed prior to our analysis, since most studies that reported the age of fallers failed to provide contextual data on the age of their inpatient population. Our findings, which compared the proportion of falls with the proportion of OBDs by five year age bands, very closely matched the findings of the one study (Halfon et al. 2001) that also reported falls by age in the context of bed occupancy; we both found the incidence of falls to be at its highest in patients aged over 85 years. Our findings were also congruent with the increased incidence of falls with age in community dwelling older people (Oliver 2009).

1.5.4 Commonalities and differences: gender

As discussed above, only one study (Halfon et al. 2001) presented the rate of falls by gender over a denominator of OBDs by gender. This study indicated that males were slightly more likely to fall, with rates of 2.25 falls per 1,000 OBDs for females and 2.64 falls per 1,000 OBDs for males.

Our study also reported the gender of fallers in the context of OBDs by gender and identified that males were more likely to fall, with 50.8% (95% CI 50.5% to 51.1%) of reported falls occurring in males, although males occupied only 45.4% of OBDs. In hindsight, it would have been preferable for us to present this data as a rate per 1,000 OBDs divided by gender to allow direct comparison with Halfon et al.'s (2001) study, but the excess risk appears similar in both studies. Given the far greater size of our study in comparison to all earlier studies, it appears likely that earlier studies produced conflicting findings on gender and falls because they failed to consider bed occupancy, or because of local variations in the gender mix of their population.

In our study we debate possible reasons for males to be over-represented amongst hospital fallers (Healey e al. (2008) p. 428) including the possibility that males' greater muscle strength means they retain just enough functional reserve into older age to mobilise into situations where falling is a risk, in contrast to older females who may be too frail to mobilise at all. An alternative explanation is gender-related attitudes to risk; males on average are known to be less risk-averse than females in many activities (Bradley & Wildman 2002), and it is feasible that this attitude could persist in older age and manifest in male patients with impaired mobility taking more risks when they mobilise. Salkeld et al.'s (2000) finding that older females greatly feared hip fracture would tend to support this hypothesis.

Whatever the underlying reason may be, the reversal in hospital settings of the conventional wisdom that females are the most vulnerable to falls (perhaps because of the greater 'visibility' of their falls due to osteopaenic and osteoporotic fractures (NICE 2010)), has important clinical implications that are explored later in Chapter 1.7.

1.5.5 Commonalities and differences: time of falls

Our study found that more falls were reported on weekdays (with Tuesday showing the highest number of reported falls) and fewer at weekends (with Sunday showing the lowest numbers of reported falls). The difference between weekdays and weekends would be expected given variations in elective activity and admission patterns, but there is no obvious explanation why more falls are reported on Tuesdays. The only prior study to look at daily patterns (DeVincenzo & Watkins 1987) identified peaks on Monday and Friday. Subtle variations between weekdays in the balance of elective and emergency workload might create slight differences in patient vulnerability to falls, particularly if falls are concentrated at particular points of individual patients' stays, such as the first few days when the hospital environment may be more unfamiliar. However, there appears little evidence in the literature to establish if this is the case; Mahoney (1999) suggests that previous assertions that falls are more commonplace earlier in a hospital episode are based on misinterpretation of reported falls unadjusted for length of stay.[xix]

As outlined above in Chapter 1.2.7, only ten studies had previously reported the time of day of falls, and most of these provided only approximate findings describing 'peaks' in falls at varying time points over day or night, without quantifying the excess of reported falls at these times. Only one study tested for statistical significance, and noted falls in the *"morning shift"* were significantly higher ($P < 0.001$) (Kerzman et al. 2004).

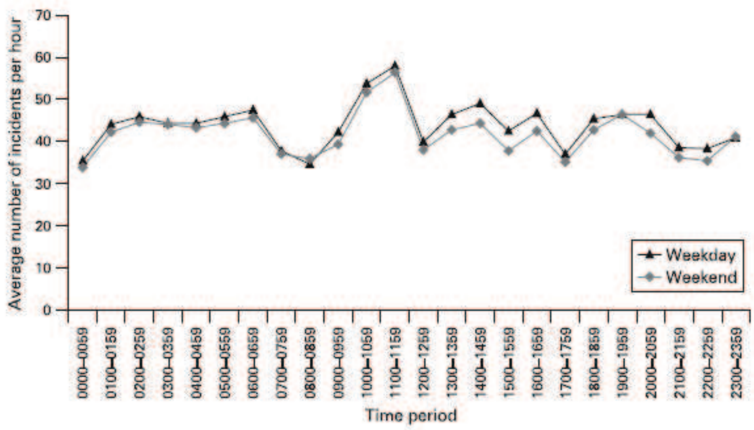
In contrast, our study analysed falls by hourly bands and tested variations for statistical significance, given a null hypothesis that falls were equally distributed across all 24 hours.

[xix] Without adjustment, day one will almost inevitably appear responsible for more falls than day two, since for every patient discharged before day two, there will be one less patient remaining in the hospital to fall, and if patients with stays over 30 days are very rare, reports of falls occurring after day 30 post-admission will be rare too, etc.

We identified that the proportion of falls was significantly lower than expected in the hours beginning 00:00, 01:00, 07:00, 08:00, 17:00, 21:00 and 22:00 and significantly higher than expected in the hours beginning 06:00, 10:00, 11:00, 13:00, 14:00 and 19:00. Of all these peaks, the most marked were the peaks in the hours beginning 10:00 and 11:00, where a fall was being reported each minute of each day from a hospital somewhere in England and Wales (Healey et al. 2008a p.429 and reproduced below).

Figure 1g: Time of falls for weekdays and weekends

Time of falls for weekdays and weekends. Source: Falls in hospital locations reported to the NRLS between 1 September 2005 and 31 August 2006, where time and date of incident were not unrealistic or missing (174 261 incidents, 85% of incidents).



A range of possible explanations for these variations are discussed in our paper (Healey et al. 2008a p. 428). These include: patient activity (e.g. mealtimes, when patients are likely to be limiting activity to sitting and eating, tended to show lower rates of reported falls, and falls were lowest in the early hours of the morning when most patients were likely to be asleep); patient physiology (an early morning peak in falls would fit plausibly with postural drops in blood pressure on first rising from bed, and a late morning peak with increased mobilisation to the toilet as diuretics take effect); and ward routines (e.g. nursing shift patterns and handovers, staff availability in relation to workload, and staff activity in relation to patient observation). A further potential influence is the times that relatives and friends are most likely to visit patients, given studies of the impact of volunteer companions (Donoghue 2005, Giles et al. 2006) which identified few if any patient falls occurred in the direct presence of the volunteers. However, in UK settings, visiting tends to be concentrated in afternoons and early evening, and this time period included two periods of higher reported falls rates (the hours beginning 14:00 and 19:00).

A further potential explanation for the variation in frequency of falls over the 24 hour cycle that we observed could lie with reporting bias. Haines et al. (2008) found in interviews with staff that some considered they were less likely to report falls when their workload was high, and Hill et al. (2010) identified that falls were significantly less likely to be reported as incidents if they occurred in the period 06:00 to 10:00 (95% CI 0.29, 0.99), a period where direct nursing workload is usually at its highest. The broader four-hour time bands used as units of analysis by Hill et al. (2010) do not equate directly with our analysis by hour, but it is plausible that the peak we observed between 10:00 and 12:00 may represent a period where nursing workload had dropped just sufficiently for falls that occurred to be more consistently reported. These possible influences on the time of hospital falls are almost impossible to disentangle, but will be discussed below in terms of questions they raise for future research.

1.6. REPORTS OF FALLS AND INJURY IN HOSPITALS 2007 ONWARDS

In Table 1g below, studies describing rates of falls and injury in hospital settings published subsequent[xx] to our analysis of reported falls are summarised. These studies were identified by the same search strategy reported above in Chapter 1.2 and Appendix G, but with a publication date between 1 January 2007 and 31 December 2009.

[xx] I divided Chapters 1.2 and Chapters 1.6 into studies published 1987-2006 and studies published from 2007 onwards because our analysis of reported falls was published first in February 2007 within *Slips trips and falls in hospital* (Healey and Scobie for NPSA 2007a) before being accepted by *Quality and Safety in Healthcare* in December 2007 and published by them in 2008.

TABLE 1g: Studies of hospital falls rates and/or proportions of injury 2008 - 2009

Reference	Study design	Study aims	Setting	Incidence findings	Injury findings
Barker et al. 2009	Before-and-after study	To assess a falls prevention intervention	An acute academic hospital in Australia	2.54 to 4.13 falls per 1,000 OBDs[xxi] over individual years within a 9 year study period	29% caused some injury
Cumming et al. 2008	Cluster RCT with falls as an outcome measure (based on reported falls, verbal reports from staff and review of case notes)	To assess the effect of a falls prevention intervention	24 elderly care wards across 12 acute hospitals in Australia	9.20 to 9.26 falls per 1,000 OBDs	Overall some injury in at least[xxii] 34.4% (131/381) including fractures in 0.5% (2/381)
Czernuszenko 2007	Retrospective observational study	To report falls incidence	353 stroke patients admitted to a neurological rehabilitation unit in Poland	5.02 falls per 1,000 OBDs	2% caused *"severe injury"*
Heinze et al. 2007	Retrospective observational study	To report falls incidence	Patients aged 65 or over in 40 hospitals in Germany	Counting first fall per patient only, 4.7 falls per 1,000 OBDs	
Koh et al. 2007 & 2009	Retrospective observational study and subset before-and-after study	To report falls incidence (all) and to assess a falls prevention intervention (subset)	Five acute care hospitals in Singapore with subset of two acute care hospitals	0.68 to 1.44 falls per 1,000 OBDs in individual hospitals	Injury rates ranged from 16.9% to 71.7% in individual hospitals
Krauss et al. 2007	Retrospective observational study (two cohorts: academic hospitals and non-academic hospitals)	To report any differences between the cohorts	One academic hospitals and eight non-academic hospitals in the USA	Overall falls given as whole numbers and per admission only, no OBDs denominator	3.7% of falls resulted in serious injuries[xxiii] in the academic hospital 2.2% of falls resulted in serious injuries in the non-academic hospitals

[xxi] These were smoothed rates calculated using a generalised additive model. Actual quarterly rates ranged more widely from around 0.2 falls per 1,000 OBDs to around 6.0 falls per 1,000 OBDs (Barker et al. 2009 Figure 1 p. 469).

[xxii] Because injurious falls are presented separately for single and multiple fallers in Table 3 within the paper, the overall proportion of injurious falls could be higher (if some multiple fallers were injured in more than one fall) but cannot be lower.

[xxiii] Defined as fractures, dislocations or head injuries

Reference	Study design	Study aims	Setting	Incidence findings	Injury findings
Krauss et al. 2008	Retrospective observational study	To assess the impact of nurse education on falls prevention	Medical wards in an acute hospital in the USA	3.81 to 6.64 falls per 1,000 OBDs	Overall injury ranging from 13% to 30%between units and quarters[xxiv]
Milisen et al. 2007	Prospective observational study	To assess the predictive qualities of the STRATIFY tool	16 selected medical, surgical, and geriatric wards within six Belgian acute hospitals	7.3 falls per 1,000 OBDs	
Quigley et al. 2009	Retrospective observational study	To assess the effect of service improvement	A veteran's acute hospital in the USA (predominantly male patients)	2.78 to 3.62 falls per 1,000 OBDs	Given as ranges of injuries per 1,000 OBDs per unit per month; unable to extract average.
Rabadi et al. 2008	Retrospective observational study	To report falls incidence	Stroke rehabilitation unit in the USA	8.2 falls per 1,000 OBDs	10% some injury 8% *"minor injury"* 2% *"serious injury"*
Schwendimann et al. 2008[xxv]	Retrospective observational study	To report falls incidence	A 300 bed acute hospital in Switzerland	Age-adjusted falls per 1,000 OBDs: 10.7 geriatrics 9.6 internal medicine 3.2 surgery	30.1% minor injury 5.1% major injury[xxvi]
Stenvall et al. 2007	Cluster RCT with falls as an outcome measure (based on review of case notes)	To assess the effect of a falls prevention intervention	Two wards caring for patients post fractured neck of femur in Sweden	6.29 to 16.28 falls per 1,000 OBDs	28.2% (22/78) some injury including 5.1% (4/78) fractures
Tzeng & Yin 2009	Retrospective observational study	To explore any correlation between falls rates and response time to call bells	Three medical or surgical units within an acute hospital in the USA	3.74 falls per 1,000 OBDs	4% *"moderate or major"* injury[xxvii]
Von Renteln-Kruse & Krause 2007	Before-and-after study	To assess a falls prevention intervention	145 geriatric beds within an acute academic hospital in Germany	8.2 to 10.0 falls per 1,000 OBDs	27.1% (369/1361) some injury including 1.4% (19/1361) fractures
Williams et al.	Before-and-after	To assess a falls prevention	89 beds in medical or	8.0 to 9.5 falls per 1,000	35.4% (87/246) some

[xxiv] Calculated from injury rates per 1,000 days and falls rates per 1,000 days, pre and post intervention, intervention and control (2.01/7.37,0.78/6.24, 1.14/3.81,1.28/6.64)
[xxv] Note that this study is a more detailed breakdown of data used in Schwendimann et al. 2006a
[xxvi] Note that in a earlier paper using the same data (Schwendimann et al. 2006a) different injury rates of 29.7% minor injury and 3.9% major injury are given
[xxvii] This is calculated from an average falls rate of 3.74 per 1,000 OBDs (n = 288) and 0.15 injurious falls per 1,000 patient OBDs (n not given).

Reference	Study design	Study aims	Setting	Incidence findings	Injury findings
2007	study	intervention	geriatric wards within an Australian academic hospital	OBDs	injury
Summary	**15 studies**	**4 studies whose primary focus was to describe falls incidence**	**No UK studies** **2 studies multiple whole acute hospitals** **3 studies single whole acute hospitals** **3 studies of specialist wards in multiple hospitals** **5 studies of specialist wards in single hospitals** **2 studies in rehabilitation units**	**Range 0.68 to 16.28 falls per 1,000 OBDs (12 studies)**	**Range of falls resulting in some injury 10% to 72% (9 studies)** **Range of falls resulting in fracture 0.5% to 5.1% (3 studies)**

Fifteen studies published from 2007 to 2009 were identified, but ten of these studies (Cumming et al. 2008, Czernuszenko 2007, Heinze et al. 2007, Krauss et al. 2008, Milisen et al. 2007, Rabadi et al. 2008, Stenvall et al. 2007, Tzeng & Yin 2009, Von Renteln-Kruse & Krause 2007, Williams et al. 2007) were based on selected specialist wards or diagnostic groups which, as discussed above in Chapter 1.2.2.2, are unlikely to reflect the average rates across whole hospitals, and cannot easily be generalised due to variations in admission criteria even where units have similar titles (such as 'stroke units' or 'geriatric wards'). One of these studies (Cumming et al. 2008), although restricted to geriatric wards, extended across twelve acute hospitals in Australia, and took a triangulation approach to data collection, using incident reports, case note review, and daily verbal questioning of staff. This methodology would be expected to reduce under-reporting and so it is interesting to note that the proportion of falls resulting in injury reported is almost identical to that seen in our study (34.4% v. 33.4%) as is the proportion of falls resulting in fracture (0.5% v. 0.5%).

Five studies reported data on falls across all specialities within acute hospitals, of which two were multiple hospital studies. Koh et al. (2007) reported falls rates in five hospitals in Singapore ranging from 0.68 to 1.44 falls per 1,000 OBDs (lower than any rates identified in previous whole hospital studies) and very variable injury rates, ranging from 16.9% to 71.7% in individual hospitals. The striking variations in the proportion of injuries suggest marked differences between the hospitals in either their patient population or reporting culture, but there is little information provided to help determine if this was the case. Krauss et al. (2007) compared one academic hospital with eight non-academic hospitals in the USA, but did not provide data on falls rates and reported only 'serious injury' without specific data on fractures, and therefore cannot easily be compared with previous studies. A single hospital study (Quigley et al. 2009) reported a falls rate ranging over time from 2.78 to 3.62 per 1,000 OBDs, which is very similar to the other rates reported from acute hospitals in the USA discussed earlier in Chapter 1.2.2, and Barker et al. (2009) reported rates varying from 2.54 to 4.13 falls per 1,000 OBDs from an Australian acute hospital, 29% of which caused injury. Schwendimann et al. (2008) consisted of sub-analysis of data from an earlier study reported above in Chapter 1.2.2, and therefore provided new data only at speciality level, rather than for the hospital as a whole.

The findings of these additional studies tend to support the discussion above in Chapter 5.1.1, that whilst it is feasible that the apparent inter-country variation in falls rates is no greater than the variation between individual hospitals seen within England and Wales, the relatively consistent rates reported from hospitals within the USA suggest an inter-country variation may exist.

Additionally, two studies provided some information on gender of fallers. Krauss et al. (2007) found female sex was associated with a reduced rate of injury (aOR 0.83 95% CI 0.71-0.97) and Williams et al. (2007) found *"no significant differences between falls and gender"* although neither p values nor confidence intervals are reported. These studies continue the pattern of varying but non-significant findings on gender of fallers reported in earlier small scale studies. No further studies provided data on age of fallers or time of day of falls.

In addition to the published studies above, early findings from an analysis of 84,144 falls reported to a national database in Ireland have been presented as a conference poster (O'Byrne-Maguire, 2009). This study makes a very useful comparator with our analysis of reported falls in England and Wales, since it is also based on a model where local reports are uploaded to a national agency, and the countries have similar nationally funded healthcare provision. Unlike our study (which calculated rates only from regularly reporting hospitals) falls rate was calculated on the basis of total reports and total OBDs at a national level, and reported a lower rate of 2.7 falls per 1,000 OBDs[xxviii] that the authors consider is heavily affected by a proportion of hospitals failing to upload data. The gender effect we saw in our study was repeated in the Irish study, with males aged 65 years or over significantly more likely to fall than females aged 65 years or over. Given the far greater size of the Irish study in comparison to all earlier studies except our own, it tends to confirm the increased occurrence of falls in males that we observed is real, but only likely to be detected in multi-hospital studies with access to large numbers of falls. Data on time of falls appeared to mirror the patterns reported in our study, with a late morning peak in reported falls and low rates around midnight.

1.7 IMPLICATIONS FOR CLINICAL PRACTICE

Perhaps the most important of the implications of our study for clinical practice was the reminder it provided of the scale of the problem of hospital falls and consequent harm; as we stated *"appreciating the scale of the problem of falls, and the human and organisational*

[xxviii] Data on injury rates is not yet available.

costs, should inspire healthcare organisations to renew their efforts on falls prevention" (Healey et al. 2008a p. 429). Our paper included a description of a falls prevention resource *Slips trips and falls in hospital*[xxix] (Healey & Scobie for NPSA 2007a), so that any such renewed efforts could be based on the current evidence base.

Additionally, the variation in reporting rates between trusts, and the proportion of reports which did not include information on the age or gender of patients who fell, highlighted priority areas where hospitals should seek to improve the quantity and quality of their incident reporting in order to extract more meaningful local learning.

Despite the possible impact of reporting bias on the time of reported falls (as discussed above in Chapter 1.4.2.2) our description of variation in falls rates over time bands allowed individual hospitals to compare their own trends with the national picture, a process that could identify when local activity or local staffing levels were having an impact on falls.[xxx]

Our findings on age and gender were important in the clinical context of targeting of falls prevention efforts to the patients most vulnerable to falling. Some falls risk prediction tools[xxxi] which remain in common use in hospitals in England and Wales[xxxii] ascribe a higher 'score' to females and reduce the 'score' once an age of over 80 years is reached (e.g. Cannard 1996). Our analysis of reported falls suggested the opposite is true, which may in part explain the poor sensitivity and specificity of such tools (Oliver et al. 2004). Our findings also demonstrated that the most vulnerable group is not merely older people as conventionally defined (age 65 years upwards (Department of Health 2001)) but that falls prevention efforts need to focus particularly on the 'oldest old' aged 85 years and above.

[xxix] This resource will be explored in more detail in Chapter 5.3.

[xxx] For example, O'Hart (2007) in a conference presentation reported how the identification of a local pattern of time of falls that contrasted with the national picture (with night-time falls predominating in a single hospital) was used to successfully make the case for increased staffing levels on night shifts; our data helped the hospital demonstrate that their higher night-time falls rate was not the norm.

[xxxi] These tools will be discussed in more detail in Chapter 2.2.3, but because the term 'risk assessment tool' in the context of falls prevention can be used to report both a checklist of modifiable risk factors with associated actions to address them (as in Healey et al. 2004) and a numerical scoring system used to prospectively categorise patients as at 'high' 'medium' or 'low' risk of falling (Oliver et al. 2004) I will for clarity use the term 'risk prediction tool' to describe the latter.

[xxxii] See Table 5b in Chapter 5.6.2.4.

1.8 DIRECTIONS FOR FUTURE RESEARCH

Our analysis identified a number of issues for future research, including exploration of the reasons behind any under-reporting or reporting bias, and exploration of the observed differences in falls by gender, and between settings in the rates of falls and proportion of falls resulting in injury (Healey et al. p. 429). If these mechanisms could be understood, they might inform more appropriate targeting of falls prevention interventions.

We suggested additional analysis that would be possible at local level where data do not need to be anonymised and therefore differences between single and repeat fallers could be identified.

We also highlighted as a promising research area exploration of the reasons underlying variation between falls rates in individual hospitals, in terms of what influences consistent and accurate reporting of falls, and in terms of local falls prevention practice. We also suggested exploring whether these aspects are interdependent i.e. if hospitals with consistent and accurate reporting of falls are using these to target and tailor their falls prevention efforts, and therefore are also more likely to have effective falls prevention practice.

The complex potential influences on why falls occur more frequently at some times of day may also be worthy of future research. Cross-correlation with other characteristics of the fall might help pinpoint underlying causes of risk (for example, identifying whether the observed peak of falls in the late morning included a greater proportion related to toileting needs in patients prescribed diuretics).

With other countries considering the establishment of national reporting systems (World Health Organisation 2005), further comparative research may become possible, with potential for exploring the impact of nationally contrasting approaches to falls prevention on falls rates. This could include exploration of whether the very low rate of falls reported by Koh et al. (2009) from hospitals in Singapore are replicated in other Asian countries with a tradition of a family caregiver remaining constantly at the bed side (Tzeng et al. 2007), or if falls rates differ in countries that routinely use vest, belt or cuff restraints.[xxxiii]

[xxxiii] The use of these devices on patients considered at high risk of falling in healthcare environments in most developed countries (except the UK, Republic of Ireland, and New Zealand) will be discussed later in Chapter 3.3.2.

1.9 CONCLUSION

Prior to our analysis of NRLS data, relatively little data on the rate of falls or injuries from falls in acute hospitals existed, with only twelve studies describing the rate of falls or injury across the whole patient population in individual hospitals, and a single multi-hospital study that gave only minimal data. Twelve studies from rehabilitation hospitals were also identified, but studies from mental health units were rare and focused on specialist units rather than the general mental health inpatient population. With the exception of Halfon et al. (2001) only broad descriptions of the time of falls or the age or gender of hospital fallers were available. Our study was therefore the most extensive source on falls rates and proportions of injury in acute and community hospitals, and a unique source for mental health units.

The 200,000 reports of falls we drew on provided analysis on a scale that has not yet been matched. Particular strengths of our study included graphic illustration of the variation in rates between individual hospitals and mental health units, falls by hourly time bands, falls in the context of patient age and gender, and the identification of levels of harm including fractured neck of femur. Whilst any voluntary reporting system is affected by under-reporting and the potential for inaccurate coding of severity, we appropriately acknowledged these limitations in statistical analysis and discussion, and scrutinised samples of reports to estimate specific types of injuries.

Whilst smaller single hospital studies showed wide variation, our findings on falls rates and proportions of injuries and fractures were generally congruent with the largest scale studies. Our study demonstrated that reported falls rates can vary greatly between individual hospitals within the same country, but there may also be variation between countries.

Our analysis was aimed at informing falls prevention strategies, particularly enabling NHS trusts to target their efforts to the patients most likely to fall. Our finding that patients who were aged over 85 years and who were male were the most likely to fall had important clinical implications given the use of falls risk prediction tools that suggested the opposite. Perhaps even more importantly, our study provided a reminder of the very high numbers of falls in hospitals, and the consequent distress, injuries and deaths. This could act as inspiration for clinical and managerial staff to renew their efforts to prevent harm from falls.

CHAPTER TWO: FALLS PREVENTION IN HOSPITALS

2.1 INTRODUCTION

Having described the scale and consequences of falls in hospital patients in Chapter 1, I will now focus on our falls prevention study 'Using targeted risk factor reduction to prevent falls in older in-patients: a randomised controlled study' (Healey et al. 2004).

I will begin with an overview of the evidence base for falls prevention in hospitals published prior to our Randomised Controlled Trial (RCT), including discussion of why falls prevention interventions used in community or care home settings cannot be generalised to a hospital environment, and clarification of the terminology used in falls prevention studies. I will discuss some of the general challenges of designing falls prevention studies in hospitals and describing and analysing their results, before exploring the various approaches taken in these earlier studies, alongside discussion of the statistical and clinical significance of their findings. This will provide an opportunity to discuss the challenges inherent in assessing complex interventions.

Having created a picture of the evidence published prior to our RCT, I will briefly describe the background to devising and undertaking it and then go on to discuss the strengths and limitations of our study, including the use of incident reports for outcome data. I will then summarise key findings from research published subsequent to our RCT, drawing on studies published from 2004 to 2009.

A discussion of commonalities and differences based on all identified hospital studies of multifactorial interventions will be an opportunity to hypothesise on why some interventions succeeded and some have not, including the risk factors addressed and their theoretical basis, whether interventions were applied by a single profession or were multi-disciplinary, and whether the interventions were applied by ward staff or research staff.

Discussion of four systematic reviews and meta-analyses (Cameron et al. 2010, Coussement et al. 2008, Oliver et al. 2007, Robertson & Campbell 2008) will provide an opportunity to explore the pooled effect of multifactorial interventions. Finally, I will discuss what our RCT has added to the understanding of falls prevention in hospitals, including the implications for clinical practice and directions for future research.

2.2 THE EVIDENCE BASE PRIOR TO 2004

2.2.1 Terminology

Before going on to describe the evidence related to falls prevention, it is important to clarify some terminology used in the context of falls prevention, as this terminology is not consistently used within the existing literature. Initially the terms 'multifaceted interventions' and 'multifactorial interventions' were intended as distinct and separate terms (Lamb et al. 2005), with the former intended to describe multiple but standardised interventions (e.g. the hip protectors, education pack, and exercise programme given to all participants in Haines et al. 2004) whilst the latter was intended to describe multiple interventions which were selected on the basis of risk factors in the individual, and therefore varied between participants. However, in practice these terms are now used interchangeably (e.g. Oliver et al. 2007 use the term multifaceted throughout their systematic review, whilst Cameron et al. (2010), Coussement et al. (2008) and Robertson & Campbell (2008) use the term multifactorial throughout theirs). Whilst the Prevention of Falls Network Europe (ProFaNE) attempted to establish a terminology of 'multiple interventions' for standardised packages and 'multifactorial interventions' for those tailored to individual risk factors (Robertson & Campbell 2008), the term 'multiple' was not distinctive and does not appear to have been widely adopted. For clarity in this doctoral statement, I will use the terms 'standardised multiple interventions' and 'individualised multifactorial interventions' as appropriate. The term 'single intervention' is self-explanatory, but there is no convenient term in current usage to describe studies using two interventions (e.g. Donald et al.'s (2000) study of exercise and carpeted flooring). For clarity I will refer to any such studies as dual intervention studies.

The term 'falls risk assessment' is used in the literature as an umbrella term and, in different contexts, may be used to describe numerical tools intended to predict the likelihood of an individual person falling, checklists that would prompt staff to consider individual risk factors in order to formulate a plan of care or treatment, and checklists used to assess slip and trip hazards in the environment (Oliver & Healey 2009). For clarity in this doctoral statement, I will avoid the term 'falls risk assessment' and use the terms 'falls risk prediction tool', 'modifiable risk factor checklist' and 'environmental risk factor checklist' as appropriate.

2.2.2 Links between types of falls assessment and intervention

The differences between falls risk prediction tools and modifiable risk factor checklists are interlinked to the differences between standardised interventions (whether single, dual or multiple) and individualised multifactorial interventions. The underlying theory behind falls risk prediction tools is that if 'high risk' patients can be identified, a standardised intervention that prevents either falls or injury can then be provided to them (Morse 1996). The clinical utility of falls risk prediction tools therefore depends on there being a standardised intervention that is applicable and effective for all 'high risk' patients, even though their high risk may result from very diverse risk factors. Whether such a standardised intervention exists for hospital patients will be explored throughout the rest of this chapter. Ironically, vastly more research effort has been directed towards the development of falls risk prediction tools that will enable the identification of 'high risk' patients so that 'something can be done' than has been spent investigating what the 'something' might be.[xxxiv]

In contrast, individualised multifactorial interventions are applied in response to one or more modifiable risk factors[xxxv] in the individual, for example a risk factor checklist could include questions related to urinary incontinence that would be used to identify and treat underlying causes such as urinary tract infection or pelvic floor weakness. Whilst the two types of tool can be used in tandem – with a falls risk prediction tool as a first stage screening, followed by a modifiable risk factor checklist applied to those patients with a high score - this raises practical and ethical questions; is it, for example, acceptable to ignore unsafe footwear simply because the patient has a low score on a falls risk prediction tool?

2.2.3 Are risk prediction tools accurate?

Over and above their clinical utility, there is the issue of whether falls risk prediction tools can discriminate sufficiently well between potential fallers and non-fallers, in terms of high

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[xxxiv] Oliver et al. (2004) identified 47 papers identifying falls risk prediction tools for hospital inpatients up to the end of 2002. In the same period only 13 hospital falls prevention studies were published (see Chapter 2.2.7).

[xxxv] See Chapter 1.2.1 for discussion of the risk factors most commonly noted in hospital patients.

sensitivity, specificity, positive and negative predictive value (see Box 2a) at a level which does not end up identifying a large percentage of the patient group as being at 'high risk'.

Box 2a: The validity of falls risk prediction tools

If a sample of patients is assessed using a falls risk prediction tool, and then observed to see if they subsequently fall, a matrix like the one below can be generated:

	Actually fell	**Did not fall**
Predicted to fall	A	B
Not predicted to fall	C	D

Using this matrix, the following predictive qualities can be calculated:

- Sensitivity (true positive) = A/A+C (proportion of patients who fell who had been predicted to fall)
- Specificity (true negative) = D/B+D (proportion of patients who did not fall who had been predicted not to fall)
- Positive Predictive Value (PPV) = A/A+B (proportion of patients predicted to fall who fell)
- Negative Predictive Value (NPV) = D/C+D (proportion of patients predicted not to fall who did not fall)

The Youden Index and Receiver Operating Characteristic (ROC) curves (Bland 2000) can be used to give statistical and graphical representations of the combined attributes (Total Predictive Value) of a tool. ROC curves can assist in selecting the point where sensitivity and specificity can be maximised, but the area under the curve also acts as a summary of the TPV. For the Youden Index and ROC curves, 1.0 represents perfect predictive value and zero no greater predictive value than might be expected by chance.

Few falls risk prediction tools have been subjected to any kind of validation and many appear 'home made' with arbitrary weightings (as described by Morse 2006, Oliver et al. 2004, Oliver and Healey 2009). Only two - the Morse falls score (Morse 1996) and the STRATIFY score (Oliver et al. 1997) - have been subjected to several external validations in different settings and patient groups. Haines et al. (2007a), in a systematic review and meta-analysis of all falls risk prediction tools for hospital inpatients, employed the Youden Index to describe their total predictive value. For both Morse and STRATIFY, Youden Index was approximately 0.2 and no better than the accuracy afforded by nurse clinical judgement, whilst other tools had undergone only limited validation. As the authors concluded, *"Heterogeneity between studies indicates that the Morse Falls Scale and STRATIFY may still be useful in particular settings, but that widespread adoption of either is unlikely to generate benefits significantly greater than that of nursing staff clinical judgment"* (Haines et al. 2007a p. 664). The evidence from systematic reviews and comparisons (Haines et al. 2007, Oliver et al. 2004, Scott et al, 2007, Schwendimann et al. 2006c, Vassallo et al 2005) on those falls risk prediction tools that have undergone some validation was discussed in a recent article I co-authored (Oliver & Healey 2009, see Appendix C).

2.2.4 Why evidence from community and care home settings is not directly generalisable to hospitals

A substantial body of evidence exists on falls prevention in the community, with 111 randomised controlled studies included in a recent Cochrane review (Gillespie et al. 2009) with the key findings suggesting that sustained group or individual exercise programmes appear effective, whilst individualised multifactorial interventions, gradual withdrawal of psychotropic medications, and provision of special footwear for icy conditions may also be effective. Interventions that may be effective in specific subgroups are Vitamin D supplementation in individuals with Vitamin D deficiency, pacemakers in individuals with carotid sinus hypersensitivity, first eye cataract surgery in individuals with cataracts, and home hazard assessment in individuals with severe visual impairment or higher risk of falling.

Unfortunately, much of this body of evidence cannot be utilised in a hospital setting. Some interventions are simply irrelevant (e.g. footwear for icy conditions or home hazard assessment) whilst others are impractical given the time period that a patient is in hospital (e.g. successful exercise programmes in community settings had durations of sixteen weeks (Sherrington et al. 2008)). Additionally, as explored earlier in Chapter 1.2.1, the risk factors for falls in hospital are unlikely to be identical to the risk factors for community falls, with the prevalence of acute and chronic illness, delirium and dementia inherently higher in a hospital population than a community population, even before the impact of hospital-specific risks factors such as the effects of anaesthesia are taken into account. Therefore it would be unsafe to assume that approaches successful in community settings are generalisable to hospitals without additional evidence.

These same constraints apply to care home studies, where the population and their risk factors are again likely to differ from hospital inpatients, and the timescales for intervention are much longer. A recent Cochrane review (Cameron et al. 2010) identified 26 RCTs of falls prevention in care home settings, and concluded multifactorial interventions may be effective if multidisciplinary (but not if solely nurse initiated interventions) in reducing both risk of falls and of femoral fractures, as may Vitamin D plus calcium supplementation and medication review by a pharmacist in reducing risk of falls.

Evidence on fracture prevention might be expected to be more easily generalisable from community or care home settings to a hospital setting, since the mechanism of a fall would not be expected to differ markedly. The evidence on the value of identifying and treating osteoporosis, particularly in those with a prior fragility fracture, is clear (NICE 2010) with a reduction of around 40% in the relative risk of a hip fracture in those who comply with treatment. However, the mechanism of osteoporosis treatment means that the reduction in fracture risk would not be noted until some months after treatment was initiated. Hip protectors might be expected to convey a more instantaneous benefit, but Cochrane reviews (Parker et al. 2005) suggest that *"accumulating evidence casts some doubt on the effectiveness of hip protectors in reducing the incidence of hip fractures in older people"* (p. 2), with no effects from pooled individually randomised studies and apparently significant benefits only seen in cluster randomised studies which the Cochrane review identified as having problems in terms of design or analysis, particularly a failure to adjust for clustering effects in statistical analysis in four early care home studies (Ekman et al. 1997, Harada et al. 2001, Kannus et al. 2000, Lauritzen 1993). Subsequent studies with analytical techniques that adjusted for clustering (e.g. Meyer et al. 2003, O'Halloran et al. 2004, van Schoor et al. 2003) saw null results. Subsequent to the publication of the Cochrane review, the continued failure of further studies (e.g. Bentzen et al. 2008, Kiel et al. 2007, Koike et al. 2009) to replicate the significant reductions seen in these early studies increasingly points towards them being affected by a Type 1 error. The significant reduction in upper arm fractures as well as hip fractures found by Kannus et al. (2000) would tend to support this, as there is no plausible mechanism by which a hip protector could have prevented these. Additionally, the Cochrane review identifies substantial problems with acceptance and adherence, but the counter-argument that significant effects would be noted if only compliance could be improved appears discounted by the null findings of Kiel et al.'s (2007) large (N=1042) and ingeniously designed study which recruited and randomised only patients who demonstrated high compliance in a pre-test period and randomised to the right or left hip in the same individual.

Therefore, despite the usefulness of community and care homes studies in suggesting interventions that merit exploration in research studies in hospital settings, their findings cannot be directly applied to hospital inpatients.

2.2.5 The challenges of designing falls prevention studies in hospital settings

As articulately argued by Oliver (e.g. in Oliver et al. 2007, Oliver 2004, Oliver 2008) there are a range of challenges in research design for hospital falls prevention. The practicalities of recruitment to individually randomised studies make it difficult to include the full length of hospital stay from the point of admission onwards, and the ethics of recruitment to individually randomised studies risk excluding those patients who are the most acutely ill and cognitively impaired, who may also be the patients most likely to fall. Interventions such as environmental improvements and staff education cannot be delivered on an individual patient basis. Where patients within the same unit are individually randomised, some interventions may have a negative rather than neutral effect on control group patients (including any interventions that potentially divert limited staff time and capacity away from patients randomised to control and towards patients randomised to intervention). Cluster randomised studies may therefore be of particular value, although data collection needs to assess for confounding differences in patient groups persisting despite randomisation at cluster level, and statistical analysis needs to allow for clustering effects, with increased sample size required for studies to be adequately powered. Before-and-after studies may also be useful, especially if using a contemporaneous control and describing confounding differences in patient groups over time. Studies extended for periods beyond those likely to be influenced by seasonal variations in hospital activity, or potentially influenced by a temporary 'Hawthorne effect' (Bland 2000), will be more useful than short term studies. As the Grading of Recommendations Assessment, Development and Evaluation (GRADE) guideline group have made clear (Guyatt et al. 2008) evidence from observational studies where the effect size cannot easily be attributable to confounders may be at least as valid as those from smaller, shorter RCTs.

Before-and-after studies that are based on local service improvement initiatives rather than planned as research studies have additional strengths and weaknesses. Positive attributes include that interventions delivered without dedicated research staff are more likely to be replicable in normal practice. Additionally, their size is generally much greater than in the prospectively planned research studies (e.g. 3,200 patients in Oliver et al. (2002) v. 23 patients in Savage & Matheis-Kraft (2001)) and their duration tends to be longer, with the potential to demonstrate sustained improvement. However, this longer duration also creates a risk that other changes in the patient population or service provision confound the effect of the falls prevention intervention, and to assess this at least minimal data on any contemporaneous changes in mean patient age, length of stay and dependency is desirable. Retrospective decisions to present the results of local service improvement as research papers can have problems additional to those of prospectively designed before-and-after studies, particularly the risk that the authors select those comparison periods that show the 'best' results, which is likely to increase the risk of Type I errors. There may also be publication bias, as clinical staff may not be motivated to write up service improvement initiatives that prove unsuccessful.

A further challenge is that, given the multifactorial causation of falls in hospital patients discussed in Chapter 1, multifactorial interventions are the most promising area of research, but then raise issues in terms of which combinations of interacting interventions are likely to have influenced the results. Guidance from the Medical Research Council (2007) defines complex interventions as those with several interacting components, and suggests cluster randomisation may be particularly appropriate given the higher level processes involved (e.g. changes in attitude or approach amongst staff groups). Design of the studies should include piloting and the development of methodologies for effective implementation, and through the use of process measures or qualitative data (e.g. interviews with staff applying the intervention) the researchers should endeavour to separate failure to implement interventions from the failure of implemented interventions to change outcomes. They also suggest variation in application should be measured and described but may be viewed as appropriate adaptation of the intervention to local circumstances rather than a failure to consistently apply the research protocol. Components within the interventions should have their theoretical basis described, and be linked to process measures intended to shed light on plausible clinical mechanisms for the impact of components of the intervention. For ease of replication and dissemination, clear and detailed description not only of the intervention content, but also the methods by which it was implemented should be included, and data should be collected on as wide a range of outcome measures (including potential adverse effects) as feasible.

Outcome data are also a challenge. As discussed earlier in Chapter 1.4.2, staff do not always agree on what scenarios constitute a fall, and even if an event is recognised as a fall it may not always be reported, whilst case note review (Sari et a. 2007) and patient recollection can also be inadequate (Hauer et al. 2006). Severity of injury, except at the specific level of fracture types, can be difficult to define and injuries can escape detection (for example, bruises under clothing). Additionally, the low proportion of falls that result in injury, and the very low proportion that result in fracture (as described in Chapter 1), mean extremely large sample sizes and intervention effects would be needed to detect any statistically significant changes; the power calculations for our RCT (Healey et al. 2004) indicated that 3,000 patients would only be adequate to detect a change in injuries at the 0.05 significance level if injuries were reduced by 50%. Given as few as 0.5% of hospital falls may result in fracture (Healey et al. 2008a), multiple hospitals participating over a time period of years would be required to obtain a sample of hospital patients large enough to detect more modest but clinically significant changes in fractures.

2.2.6 The challenges of analysing and interpreting falls prevention studies in hospital settings

Data presentation and statistical analyses also raise complex issues for falls prevention studies. A very wide variation in presentation of outcome data has been identified in falls prevention studies, accompanied by generally poor clarity and sometimes by inappropriate choices of statistical techniques (as described by Hauer et al. 2006 and Robertson et al. 2005).

Some of this inconsistency results from the challenge created by individual vulnerability to falls and the potential for each fall to have a different outcome. Whilst for most clinical outcomes, analysis at the patient level is statistically the most straightforward (and in falls prevention studies, is usually presented in terms of relative risk of being a faller) there is a real clinical interest in outcomes not only in terms of the number of fallers but the number of falls, as each fall carries its own risk of harm. For events which may occur frequently in individual patients (e.g. the number of seizures in patients with epilepsy), analysis of events per patient can be undertaken. However, for falls in hospital, presenting outcomes as the average number of falls per patient will not be very informative as there is usually a very positively skewed distribution, with almost all participants experiencing no falls or a single fall and only a very few outliers experiencing multiple falls. Unless intervention and control groups are identical in size and length of stay, direct comparison of whole numbers of falls is not possible. Therefore the rate of falls against a denominator of occupied bed days (OBDs) is an important outcome of interest (Lamb et al. 2005).

It is the statistical comparison between intervention and control of their respective rate of falls which appears to have resulted in the greatest confusion of terminology in the literature. A calculation of the ratio of the rate of falls per OBDs in intervention groups versus the rate of falls per OBDs in control groups is often described as relative risk, although this would more correctly be described as a rate ratio. Various steps are taken by different authors of systematic reviews to try to clarify the terminology, for example Coussement et al. (2008) use the terms 'relative risk of being a faller' and 'relative risk of a fall' (with footnotes indicating the latter was actually a rate ratio); although technically incorrect this wording has the advantage of being easily comprehensible to the clinician. Oliver et al. (2007) use the technically correct terminology of rate ratio and relative risk, relying on figure titles to clarify that the former relates to falls and the latter to fallers. Cameron et al. (2010) also use the technically correct terminology of rate ratio for falls and risk ratio (a synonym of relative risk) for fallers, although the similarity of the terms may not assist the clinical reader to understand their differences. Confusion may be increased by the use of the abbreviation RR to indicate any of these terms, although Coussement et al. (2008) use a more self-explanatory abbreviation of RR^{fall} and RR^{faller}.

As well as being clinically relevant, rate ratios ensure the size of the chosen denominator – e.g. per day, per month, per year or per 1,000 occupied OBDs, etc. - do not affect the results. Falls rate ratios may also be the most robust measure of outcomes for falls prevention studies; Haines & Hill (in press) in a recent comparative analysis suggests they may be the least likely to produce Type 1 or Type 2 errors.

However, comparisons of relative risk of being a faller and the rate ratio of falls also have their limitations for hospital-based studies, because of the complex relationship of falls with length of stay. Length of stay may interact with falls in any of the following ways:

- Length of stay may indirectly correlate with falls, because conditions such as delirium, dementia, and reduced mobility are likely to result in both a longer length of stay and an increased risk of falling (Oliver 2008). Differences in length of stay between control and intervention can therefore indicate confounding differences in terms of their patients' vulnerability to falls.

- If the rate ratio of falls is used to compare two groups with differing lengths of stay, an assumption that falls are equally distributed throughout the length of patients' stays is inherent. However, there is no clear evidence from the literature to confirm or refute this (see Chapter 1.5.5).
- Falls after discharge are not included as outcomes in hospital falls prevention studies; if two units had patients with the same vulnerability to falls and had the same falls prevention practice, but one unit was able to discharge patients sooner (perhaps because of better community aftercare provision) it would appear to have a low relative risk of patients being a faller.
- Length of stay could be extended by the consequences of falls (for example, a fracture from a fall will almost certainly increase length of stay (Nadkarni et al. 2005)) and therefore reductions in length of stay could be seen as a secondary outcome to successful falls prevention.

These interactions of falls with length of stay create interpretation difficulties. For example, when an intervention group shows both a lower rate of falls and a lower length of stay, it could be that the apparently reduced risk of falls was actually due to a confounding effect of the intervention group having less vulnerable patients. Alternatively, reduced length of stay may have resulted from the benefits of the intervention in preventing falls. Because of this, consensus guidance from the Prevention of Falls Network Europe (ProFaNE) suggests that to assist in interpretation a full range of outcome measures should be described in falls prevention studies (Lamb et al. 2005) which in the context of hospital studies would include number of falls, number of fallers, numbers of injurious falls by severity and type, denominator data in terms of admissions and OBDs, time to first fall, fallers as a percentage of admissions, relative risk of being a faller, falls per 1,000 OBDs, falls rate ratio, and injurious falls rate ratio. This can assist in interpretation in findings. For example, in the case above when an intervention group shows both a lower rate of falls and a lower length of stay, if this was attributable to improved falls prevention rather than confounding differences in their patients, an increased time to first fall should also be observed. However, multiple analyses of statistical significance also raises the risk of Type I error (Bland 2000) and so care must be taken in interpretation of results.

A further problem with the analysis and interpretation of hospital falls prevention studies is the inappropriate use of subgroup analysis (Assmann et al. 2000). Studies can present misleading data based on selecting the 'best' time period after intervention versus the 'worse' period pre-intervention (e.g. Gowdy & Godfrey 2003, Grenier-Sennelier 2002, Krauss et al. 2008). Multiple sub-analyses of different patient groups (e.g. patients in different age groups, or with different diagnoses, or different falls history) are also likely to be unreliable, as if enough subgroup analyses are undertaken chance will dictate that at least some will show 'significant' results (Sleight 2000).

Appropriate adjustment for clustering effects is also an important issue as analysing as though the participants were individually randomised can lead to Type 1 error (Christie et al. 2009). Comparing summary measures for each cluster is not statistically efficient as each cluster provides only one value, with subsequent challenges to producing a weighted summary statistic (Donner & Klar 2000). Individual level data can be analysed and corrected for design effect (Christie et al. 2009) but this technique would only be applicable to the risk of being a faller, and not to rate of falls. Multi-level modelling would therefore be a preferred approach for analysis of cluster randomised falls prevention trials (Christie et al. 2009). Where cluster randomised controlled trials do not appropriately adjust for clustering effects in original publications, subsequent meta-analyses endeavour to correct this. However, Haines & Hill (in press) suggest the techniques used in most meta-analyses of falls prevention studies (taking the number of clusters as the number of participants when sub-group data per cluster is not included in the original publication) extend confidence intervals excessively and result in Type 2 errors. Appropriate adjustments can be made more challenging by the hybrid methodology used by some studies (e.g. by Stenvall et al. 2007) whereby patients are individually randomised to either enter a specific ward chosen to apply the intervention or to enter a control ward, rather than being randomised directly to receive the intervention on whatever ward they were admitted to. This creates an analytical challenge given the ward is the unit of intervention but the patient is the unit of analysis.

In addition to the challenging areas of analysis and interpretation discussed above, many falls prevention studies make more basic errors in analysing or interpreting their results (as described by Haines & Hill in press, Hauer et al. 2006, Robertson et al. 2005). Where apparent errors affect studies discussed in this doctoral statement, the authors' original results will be described within the results column in tables with apparent errors discussed under comments.

2.2.7 Evidence from hospital settings prior to 2004

Despite the challenges discussed above, research on falls prevention in hospitals has been carried out and published in peer review journals. I will first explore evidence from studies of hospital falls prevention published prior to 2004 (when our RCT of falls prevention was published) and these are shown below in Table 2a.

Studies were included if identified by any of six systematic or semi-systematic reviews encompassing hospital falls prevention (Cameron et al. 2010, Coussement et al. 2008, Oliver et al. 2007, Oliver et al. in press, Robertson & Campbell 2008, Stern & Jayasekara 2009) and if carried out in acute or rehabilitation hospitals or mental health units; full details of search strategies and inclusion criteria are given in Appendix G.

TABLE 2a: Design and results of falls prevention studies in hospitals prior to 2004

Reference	Study design	Setting	Participants	Intervention	Participants' mean age (years)	Mean length of stay (days)	Quality score in Oliver et al. 2007	Quality criteria met in Coussement et al. 2008	Results I = Intervention (RCT/cohort) C = Control (RCT/cohort) B =Before A =After NS = not significant (no p value given) SNT = significance not tested
Barry et al. 2001	Uncontrolled before-and-after	Small long-stay and rehabilitation hospital in Ireland	All patients admitted to 95 beds for one year pre-intervention and two years post intervention	Individualised multifactorial	81	c. 200 [xxxvi]	10/31	-	B 156 admissions, 39 fallers, 71 falls, 15 minor injury, 6 hip fracture, 2 other fracture A Year One 172 admissions, 36 fallers, 56 falls, 13 minor injury, 1 hip fracture A Year Two 149 admissions, 26 fallers, 36 falls, 4 minor injury, no fractures *"Chi square test and Fischer exact test were used as appropriate"* Reduction in falls and fallers NS Only in Year Two v. pre-intervention, decrease in injurious falls p<0.01 In Year One and Year Two v. pre-intervention, decrease in fractures p<0.05
Boswell et al. 2001	Uncontrolled before-and-after	An acute hospital in the USA	Unclear how many patients had sitters	Paid companions	-	-	-	-	Falls per sitter shift of eight hours increased *"marginally"* by 0.0019 SNT
Brandis 1999	Uncontrolled before-and-after	An acute hospital in Australia (including paediatric wards)	All patients admitted to 500 beds for one year pre-intervention and second year post intervention (no data provided for first year of intervention)	Individualised multifactorial	-	-	5/31	-	B 201 fallers, 270 falls, 130 minor injuries, 8 fractures, 1.74 falls per 1,000 OBD A Year Two 190 fallers, 258 falls, 133 minor injury, 3 fractures, 1.61 falls per 1,000 OBD SNT

[xxxvi] Based on the authors description of 'about' 150 admissions a year, 90% occupancy and 95 beds

Reference	Study design	Setting	Participants	Intervention	Participants' mean age (years)	Mean length of stay (days)	Quality score in Oliver et al. 2007	Quality criteria met in Coussement et al. 2008	Results I = Intervention (RCT/cohort) C = Control (RCT/cohort) B =Before A =After NS = not significant (no p value given) SNT = significance not tested
Donald et al. 2000	RCT	Elderly rehabilitation ward within a community hospital in England	54 successive admissions (all consented to randomisation)	Vinyl or carpeted bedroom plus routine or additional physiotherapy	83	30	-	9/20	Vinyl + routine physiotherapy 0 falls Vinyl + additional physiotherapy 1 fall Carpet + routine physiotherapy 7 falls Carpet + additional physiotherapy 3 falls Relative risk of being a faller on carpet v. vinyl 8.3 (95% CI 0.95-73) $p=0.05$ (?) No fractures in any group Mean LOS in vinyl group 22.7 days and in carpet group 36.1 days. More of the carpet group had been admitted because of a fall (6 v. 4) and Barthel scores were higher than vinyl group
Grenier-Sennelier et al. 2002	Uncontrolled before-and-after	A 400 bed rehabilitation hospital in France	All admitted patients over two years before and two years after (c.800 admissions per year)	Individualised multifactorial	76	36	-	-	The proportion of patients who had one or more falls was declining significantly[xxxvii] before intervention (44.6% in 1995, 36.3% in 1996) and initially increased significantly ($p<0.01$) after intervention (40.7% in 1997) before decreasing to 31.0% in 1998. Multiple fallers also decreased between the two pre-intervention years and in 1995 v. 1998 ($p=0.03$)

[xxxvii] The authors describe $p<0.1$ as significant; they may have accepted a 90% probability level or this may have been a typographical error

Reference	Study design	Setting	Participants	Intervention	Participants' mean age (years)	Mean length of stay (days)	Quality score in Oliver et al. 2007	Quality criteria met in Coussement et al. 2008	Results I = Intervention (RCT/cohort) C = Control (RCT/cohort) B =Before A =After NS = not significant (no p value given) SNT = significance not tested
Haumschild et al. 2003	Uncontrolled before-and-after	Rehabilitation hospital in the USA	Intervention applied to all admissions one year before, one year after but analysis based on 200 random sample from each year	Pharmacist-led medication review and adjustment	79	-	-	-	Ambiguously worded and either falls or fallers *"the number of falls was reduced from 30 patients in the pre-intervention group to 16 post-intervention"* (p. 1031). P=0.05
Kilpack et al. 1991	Uncontrolled before-and-after	Two specialist medical wards within an acute hospital in the USA	All patients admitted to 79 beds for one year pre-intervention and one year post intervention	Individualised multifactorial	-	-	5/31	-	B 4.7 falls per 1,000 OBDs (number of falls or fallers not given) A 4.4 falls per 1,000 OBDs (111 falls in 89 patients) SNT
Mayo et al. 1994	RCT	Rehabilitation unit in the USA	134 patients with capacity to consent and at 'high risk' of falling	Application of a blue wristband to history of stroke, ataxia, multiple falls, or incontinence	72	70	25/31	11/20	I 27/65 fallers C 21/69 fallers Hazard ratio 1.34[xxxviii] (95% CI 0.76-2.38)
Mitchell & Jones 1996	Uncontrolled before-and-after	Acute and sub-acute medical ward within a small acute hospital in Australia	All admissions to a 32-bed ward with six months before v. six months after (no. of admissions not given)	Individualised multifactorial	74	-	13/31	-	B 42 falls 7.77 falls per 1,000 OBDs A 21 falls 4.42 per 1,000 OBDs One tailed t-test applied to rate – p=0.0558

[xxxviii] Whilst the authors call this a hazard ratio, it appears to actually be relative risk of being a faller (27 fallers out of 65 patients in I v. 21 out of 69 in C = relative risk of being a faller = 1.34). The hazard ratio would be 1.65 (27 fallers v. 38 non-fallers in I and 21 fallers v. 48 non-fallers in C).

Reference	Study design	Setting	Participants	Intervention	Participants' mean age (years)	Mean length of stay (days)	Quality score in Oliver et al. 2007	Quality criteria met in Coussement et al. 2008	Results I = Intervention (RCT/cohort) C = Control (RCT/cohort) B =Before A =After NS = not significant (no p value given) SNT = significance not tested
O'Connell et al. 2001	Uncontrolled before-and-after	Two elderly care wards in an Australian acute hospital	580 admissions in a six month before period and 485 admissions in a six month after period	Application of pink wristbands and bedside signs for patients with high Morse scores	-	-	-	-	B 92 fallers, 124 falls, 12.5 falls per 1,000 OBD A 80 fallers, 139 falls, 13.2 falls per 1,000 OBDs *"increase in falls rate was not significant"*
Oliver et al. 2002	Uncontrolled before-and-after	An elderly medical unit within an acute hospital in England	3,200 patients admitted annually; data collected for one year pre-intervention and one year post intervention	Individualised multifactorial	80	-	5/31	-	B 211 fallers, 294 falls, 11.1 falls per 1,000 OBD, 86 injuries A 175 fallers, 367 falls, 13.8 falls per 1,000 OBD, 82 injuries Increased falls p=0.015 Multiple fallers p=0.06
Savage & Matheis-Kraft 2001	Uncontrolled before-and-after	Two psychogeriatric wards in a psychiatric hospital in Canada	23 patients for a four month before and four month after period	Individualised multifactorial	76	c. 250	11/31	-	B 9 fallers/11 falls A 1 faller/1 fall Fischer's exact p=<0.01
Tideiksaar et al. 1993	RCT	Geriatric assessment unit within an acute hospital in the USA	70 *'patients demonstrating poor bed mobility'* drawn from 295 admissions over nine months	A pressure sensitive bed alarm	84	-	-	5/20	I 1 bed fall, 4 other falls C 4 bed falls, 8 other falls Fischer's exact NS

Reference	Study design	Setting	Participants	Intervention	Participants' mean age (years)	Mean length of stay (days)	Quality score in Oliver et al. 2007	Quality criteria met in Coussement et al. 2008	Results I = Intervention (RCT/cohort) C = Control (RCT/cohort) B =Before A =After NS = not significant (no p value given) SNT = significance not tested
Uden et al. 1999	Uncontrolled before-and-after	A geriatric department in an acute hospital in Sweden	47 randomly selected patients from the year before intervention, all 332 admitted patients in the intervention year	Individualised multifactorial	75	50	-	-	B 17% (8/47) were fallers no fractures A 22% (151/332) were fallers two fractures SNT

As Table 2a shows, prior to 2004 there was very little published evidence on falls prevention in hospital settings, with only fourteen studies located by the five reviews, even though some of these reviews (especially Oliver et al. 2008) had very broad inclusion criteria. To summarise (Table 2b below) there were eight uncontrolled before-and-after studies of individualised multifactorial interventions (Barry et al. 2001, Brandis 1999, Grenier-Sennelier et al. 2002, Kilpack et al. 1991, Mitchell & Jones 1996, Oliver et al. 2002, Savage & Matheis-Kraft 2001, Uden et al. 1999). There were also three randomised controlled studies (Donald et al. 2000, Mayo et al. 1994, Tideiksaar et al. 1993) of single or dual interventions, and three uncontrolled before-and-after studies of single interventions (Boswell et al. 2001, Haumschild et al. 2003, O'Connell et al. 2001).

TABLE 2b: Summary of falls prevention studies published 1990-2003

	RCT	**Cluster RCT**	**Uncontrolled before-and-after**	**Totals**
Individualised multifactorial			8	**8**
Dual interventions	1		1	**2**
Single interventions	2		2	**4**
Totals	**3**	**0**	**11**	**14**

These studies will be discussed in more depth later in the context of later studies of similar interventions, but will be explored initially now in terms of their quality and any significant findings.

All the uncontrolled before-and-after studies of individualised multifactorial interventions had weak quality scores (13 points or less out of a possible 31 points using Downs & Black 1998[xxxix]) and three (Brandis 1999, Kilpack et al. 1991, Oliver et al. 2002) had very weak quality scores (five out of a possible 31 points using Downs & Black (1998).

Of three RCTs (Donald et al. 2000, Mayo et al. 1994, Tideiksaar et al. 1993), all of single or dual interventions, only Mayo et al. (1994) had a good quality score (25 points out of a

[xxxix] Downs & Black (1998) is a well-established checklist designed to assess the quality of both randomised and non-randomised studies of healthcare interventions, with components encompassing bias, confounding, power and external validity.

possible 31 points using Downs & Black 1998) in a study of the effect of applying wristbands to patients at risk of falling. The remaining two RCTs of additional physiotherapy with or without carpeted flooring (Donald et al. 2000), and bed alarms (Tideiksaar et al. 1993) enrolled only small numbers of participants (54 and 70 participants respectively) providing very few falls for analysis (eleven and five falls respectively) and were therefore very unlikely to be sufficiently powered to detect significant effects. In addition to their low power, these two studies appear to have had additional problems with design and analysis, which will be discussed later in Chapter 2.6. None of these three RCTs had significant findings.

There were two further uncontrolled before-and-after studies of single interventions. Boswell et al. (2001) in a study of paid companions in an acute hospital noted a marginal increase in falls. Haumschild et al. (2003) in a study of medication review has brief and unclear outcome data but a significant reduction in either falls or fallers is identified ($p<0.05$).

Of the eight uncontrolled before-and-after studies of individualised multifactorial interventions, only one was clearly intended as a research study at the outset (Savage & Matheis-Kraft 2001). This was a very small study (with 23 participants). The authors noted that many participants were lost to an *'influenza outbreak"* (p. 52) and it appears the 'statistically significant' reduction in fallers between before and after periods of the study (nine fallers before to one faller after p=<0.01) may reflect a marked reduction in participants rather than the success of their intervention (which consisted mainly of nurse education in falls prevention and the introduction of commercially marketed body restraint devices). The remaining seven before-and-after studies of multifactorial interventions (Barry et al. 2001, Brandis 1999, Grenier-Sennelier et al. 2002, Kilpack et al. 1991, Mitchell & Jones 1996, Oliver et al. 2002, Uden et al. 1999) described the outcome of local service improvement that may not have been prospectively planned as a research study.

None of these studies found a significant decrease in falls rates or fallers and three studies (Grenier-Sennelier et al. 2002, Oliver et al. 2002, Uden et al. 1999) identified an increase in falls rate which the authors speculate is due to under-reporting of falls in the 'before' phase of the study. Although Grenier-Sennelier et al. (2002) reported a significant ($p=0.03$) reduction in multiple fallers between a selected year pre-intervention and selected year post-intervention, this seems unlikely to be attributable to the intervention given significant year-to-year reductions recorded prior to the period when the intervention commenced.

Only Barry et al. (2001) (N=c.450) found any significant reduction in the proportion of injurious falls and the number of fractures.

Apart from Kilpack et al. (1991) and Uden et al. (1999) none of the studies articulate the rationale for the components they chose. Two of these studies (Kilpack et al. 1991, O'Connell et al. 2001) were in themselves intended as pilots for a wider whole hospital intervention, but the remaining studies appear to have been applied on a whole-hospital or whole-department basis without a pilot phase.

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Taken together, the studies of hospital falls prevention published prior to 2004 and examined above were limited in quality and quantity and provided little data to inform clinical practice. Mayo et al.'s (1993) study provided good evidence that application of wristbands to identify patients at high risk of falling was unlikely to be effective, and Oliver et al.'s (2002) study suggested that introducing a falls risk prediction tool without engaging nursing and medical staff on the need to carry out additional assessment and interventions will not reduce - and may even increase - the occurrence of falls. The significant reduction in fallers reported by Savage & Matheis-Kraft (2001) may not stand up to detailed scrutiny and would in any case have little relevance to UK hospitals where commercially marketed body restraint devices are not acceptable practice. The only positive results were the significant reductions in injury and fracture reported by Barry et al. (2001) after the introduction of individualised multifactorial interventions by a multidisciplinary team, but these have to be considered in the context of the low quality score of the study (10 points out of a possible 31 points using Downs & Black 1998) and the possibility that these reductions are attributable to confounding changes in the patient population rather than the intervention itself.

2.3 PLANNING OUR RCT

As described in the Introduction p. 2-3, our RCT was planned to respond to a need to 'do something' about falls within the elderly services directorate in York Hospitals NHS trust despite a limited evidence base on the effectiveness of interventions in hospitals. The directorate comprised three acute wards, two rehabilitation wards, two specialist wards and two community hospitals, with each pair or trio of units having near identical environments, admission criteria and staffing establishments. This created an ideal situation for a randomised paired cluster design and we received ethics committee approval to undertake this.

Designing the content of the intervention was more problematic given the limited evidence base from which we could draw. At a planning stage, we considered numerical risk assessment tools but found they identified more than two thirds of our inpatient population as 'high risk' (as might be expected in a needs-based elderly services unit with admission criteria of multi-pathology and an average inpatient age of around 82 years) whilst falls also occurred in those patients scored as low risk. Review of admission data suggested around 20% of our patients either had been admitted as a direct consequence of a fall or repeated falls, or had recent falls noted in their admission documentation. Apart from the high predictive value of a recent fall as an indicator of the likelihood of future falls (Oliver 2008), focusing on this group (and on any patients who fell whilst in our care) appeared to be ethically the highest priority. We based our interventions around what was known about risk factors for falling, particularly in hospital environments (Oliver et al. 2000) but selected only those which were plausibly causative risk factors for falls (rather than correlation effects) and potentially modifiable within our hospital environment and existing staff resources. We also tailored these interventions in the light of clinical experience. For example, whilst a component on reducing culprit medication was drawn from the literature, an associated warning on not discontinuing benzodiazepines abruptly in habituated patients was drawn from clinical experience, and whilst delirium as a risk factor was drawn from the literature, our focus on testing for urinary tract infections was drawn from our clinical experience of these being a frequent underlying cause of confusion and impaired mobility in our patient population.

We also drew from improvement methodology (Woodward 2008) which suggests that 'piggy-backing' new interventions onto established practice will increase the likelihood of successful implementation. In our directorate, core care plans were already in place for a range of clinical conditions, so a similar format was adopted for falls prevention. Because we had limited resources for staff training we aimed to make the falls prevention core care plan[xl] as self-explanatory as possible and assumed limited knowledge on the part of users (for example, we gave the names of the most commonly prescribed culprit medications rather than assumed all staff would know Haloperidol was an antipsychotic and therefore a culprit medication). Although the required interventions on modifiable risk factors clearly required input from across the multidisciplinary team, we drew on an understanding of human error (Reason 1990) which suggests that making actions 'everyone's responsibility'

[xl] The care plan can be seen on pages 42-43 of *Slips trips and falls in hospital* in Appendix A.

can in reality equate to making them ‘nobody’s responsibility’. Because of this, the core care plan format gave a clear responsibility to the nursing staff to trigger the actions of other members of the MDT, but made this as administratively simple as possible (for example, they had pre-printed stickers to request medical and medication review which were placed in the patient’s medical notes where they would be visible when carrying out the next medical round, and similar stickers for physiotherapists’ ward diaries). Finally, we prepared a constantly replenished stock of slippers in a range of sizes.

Our RCT of falls prevention in hospital inpatients ‘Using targeted risk factor reduction to prevent falls in older in-patients: a randomised controlled study’ (Healey et al. 2004) can be found in Appendix A.

2.4 STRENGTHS AND LIMITATIONS OF OUR STUDY

2.4.1 Strengths of our study

Our study was the first randomised controlled study of individualised multifactorial interventions which took place in an acute hospital setting, and the first to indicate a significant reduction in falls (rate ratio intervention to control 0.58 95%CI 0.49-0.70 $p<0.001$). This had great clinical importance given the near complete vacuum of evidence on falls prevention strategies in hospital settings prior to 2004 (as described above in Chapter 2.2.7).

Whilst a cluster randomised design would for many research questions be considered inferior to an individually randomised design, in the case of hospital falls prevention (Oliver 2004) and for complex interventions (MRC 2008) a cluster RCT design is suggested as an appropriate approach (as discussed above in chapter 2.2.5). Our quality score of 19/31 (Downs & Black 1998) was the third highest of the ten multifactorial hospital studies included in Oliver et al.’s (2007) systematic review.

A further important strength was the multidisciplinary nature of both the interventions and of the researchers (comprising a nurse manager, registrar, matron, consultant geriatrician and physiotherapist). The potential for replicating the intervention elsewhere was high, as the paper described the individual care plan components (Healey et al. 2004 Table 1 p. 391) and how they had been introduced, and it had not involved additional staff or new resources beyond those feasible to purchase within normal budgets.

The environment of the study was in itself a strength, since each pair of wards randomised to intervention or control were nearly identical in terms of physical layout and staff establishment. A further strength was comparison of patient characteristics in terms of age, gender, length of stay and main admission diagnosis between clusters during the intervention, which allows assessment of how well cluster randomisation created comparable groups, in line with the recommendation by ProFaNE (Lamb et al. 2005). We also described baseline falls and injury rates in each cluster prior to randomisation, and analysed these for statistically significant differences, which is an important source of information on whether there were any inherent differences at cluster rather than patient level (e.g. the effect of differences in environment, clinical practice, or reporting culture). Subsequent cluster randomised studies, despite recruiting pairs of wards with much greater apparent differences than in our RCT, have either not described pre-intervention falls rates (Stenvall et al. 2007), or have described rates which appear to differ but have not tested these for statistical significance (Cumming et al. 2008, Koh et al. 2009).

Because an incident reporting system was well established in the study wards, data collection was in effect blinded; the trust's risk management department supplied outcome data without any knowledge of which wards were intervention or control. We provided a detailed description not only of outcome data in terms of numbers of falls and injuries and rates of falls and injurious falls, but also provided the exact denominator data in terms of occupied OBDs and admission numbers, in line with the recommendation by ProFaNE (Lamb et al. 2005). Our description of both the components of the intervention and how they were implemented would comply with the subsequent MRC (2008) recommendations on complex interventions.

As discussed in Chapter 2.2.6, the statistical analysis of falls prevention studies presents challenges. With the help of the two lecturers in biostatistics acknowledged in our paper, we had designed a study with adequate power to detect a clinically significant reduction in rate of falls (Healey et al. 2004 p. 392) and selected rate ratio as the methodology to analyse the results; a methodology that recent comparative analysis (Haines & Hill in press) suggests may be the most clinically relevant and the least likely to produce Type 1 or Type 2 errors. As discussed earlier in chapter 2.2.6, like some other falls prevention studies and systematic reviews, we were technically incorrect in using the term relative risk to describe a rate ratio, but our study explicitly clarified what methodology our terminology was describing in both text and tables (Healey et al. p. 393, Table 4, and Table 5).

2.4.2 Limitations of our study

Due to the very large size required to detect changes in injury discussed above in Chapter 2.2.5, our study was underpowered to detect changes in the rate of injurious falls. Whilst this also applies to almost all subsequently published studies (see Chapter 2.6.2), it is less than ideal, because despite the psychological harm than can result even from a non-injurious fall (Oliver 2008), injurious falls are likely to have the greatest impact on mortality and morbidity (Nadkarni et al. 2005). Additionally, our overall power calculations could be criticised for failure to adjust for the effects of clustering, given individuals in the same cluster tend to have more similarities than individuals selected randomly from the whole population (the intracluster correlation coefficient) and therefore higher numbers of participants and/or clusters may be required to detect statistically significant effects (Campbell et al. 2004). This is a failing shared by many other cluster trials in general (Guittet et al. 2005) and by the other cluster randomised trials of falls prevention in hospitals (Cumming et al. 2008, Koh et al. 2009) that will be discussed later in Chapter 2.6.2.

Despite the existence of a standard definition of fall through the trust's incident reporting system and annual updates for staff on how to report, our study would be open to criticism through our failure to quote the definition in our paper or educate staff in the application of the definition before commencing the intervention. This may not, however, have been a problematic limitation given the findings of a subsequent study which indicated that providing a definition of a fall and education in its use made little or no difference to whether staff would recognise and report falls (Haines et al. 2009).

Our reliance on reported falls as an outcome measure was in itself a weakness, although one shared by almost all other reported studies of hospital falls prevention.[xli] As discussed in Chapter 1.4.2, in hospital settings, identification of falls from case note review or through

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[xli] Of the 40 studies that will be discussed within Chapter 2, only two used a data source in addition to reported falls; Cumming et al. (2008) questioned ward nurses and checked case notes and Van der Helm et al. (2006) supplemented reported falls with questioning of ward nurses.

questioning patients may be more incomplete sources than incident reporting systems, but data collection which uses all three sources to identify as many falls as possible would be preferred (Hill et al. 2010). However, daily questioning of patients and review of case notes was beyond the resource we had available for our RCT. The limitations of using reported falls may have been ameliorated by the very active reporting culture in the trust. The trust featured in the top 10% of trusts in England and Wales in terms of activity-adjusted reporting rate of all types of patient safety incident from inception of the NRLS to date (e.g. NPSA 2005, NPSA 2008, NPSA 2009)).

As discussed in Chapter 2.2.5, the MRC (2007) guidance on complex interventions suggests studies should attempt to separate failure of implementation from failure of implemented interventions to take effect. In common with most prior and subsequent trials of individualised multifactorial interventions (see Chapter 2.6.2) we did not have formal mechanisms to assess compliance with the intervention, although as the authors of our RCT were all clinically or managerially active in both control and intervention wards we had informal confirmation that the interventions were in widespread use. We also noticed the kinds of local adaptations to protocol implementation that the MRC (2007) guidance suggests should be seen as helpful. For example, one ward added a white board by their sluice to indicate what patients needed ward testing of urine, and lying and standing blood pressure checks were added as requests on routine observation charts.

The MRC (2007) guidance also emphasises the value of collecting process measures that can provide information on plausible clinical mechanisms underlying the observed outcomes. Such measures could have been built into our RCT. For example, knowing how often urine testing led to the identification and treatment of a urinary tract intervention would have been helpful in assessing if that component of our intervention was likely to have contributed to the reductions in falls, as would have point surveys of patient footwear or bedrail use. Unfortunately, as clinicians combining conduct of the RCT with our clinical and managerial roles, we did not have the time and resource to collect such measures (although none of the individualised multifactorial studies published to date, even those with dedicated funding, appear to have done so either).

Despite randomisation, some differences at the patient level were identified between control and intervention groups in our RCT. Whilst diagnostic group, age and gender mix were similar, the intervention group patients had a slightly longer length of stay (21 days v. 18 days) This longer length of stay would have been expected to increase the number of falls reported in the intervention group (as on average the patients would have three extra days on which any falls occurring would be included in outcome data, and a longer length of stay might indicate a group with greater co-morbidity and therefore vulnerability to falls) and therefore would be unlikely to produce a Type 1 error even if analysis of whole numbers of falls had been included in our study. Our chosen method of comparing rates of falls per 1,000 OBDs would however ensure the differences in length of stay were adjusted for in analysis. The intervention group also had lower turnover (749 new admissions v. 905 new admissions). As we discussed in our paper, if one theorises that falls are more likely to occur soon after admission (something for which no definitive evidence could be identified from the literature (Mahoney 1999)) the higher turnover in the control wards might be expected to increase the rate of falls. Identifying any differences between intervention and control in terms of numbers of patients who experienced one or more falls, and analysing days between admission and first fall would have been helpful in assessing if and how the differences in turnover affected our study. However, because of the difficulties of extracting named patient data from the local incident reporting system we did not obtain data on number of fallers, and we did not have the resources to collect data through case note review for each fall to identify days since admission. Despite these drawbacks, our collection of data on falls and injuries prior to randomisation helped us demonstrate our positive results were more plausibly related to our intervention than to any confounding differences between intervention and control groups. We found that not only was the rate ratio of falls significantly lower in intervention wards versus control wards post-intervention (0.58 95%CI 0.49-0.70 p<0.001), but the intervention wards also saw a significant reduction in rate ratio of falls between before and after periods (0.789 95% CI 0.65-0.95 p=0.02) whilst control wards saw a non-significant increase (1.12 95% CI 0.96 - 1.31 p=0.17).

Additionally, our finding that the rate ratio of falls was lower in intervention versus control wards prior to randomisation (0.83 95% CI 0.70-0.98 p=0.03) was potentially a confounding factor. Given the similarities in patient characteristics and environment, the most likely explanation for any differences would lie with staff behaviour, either in terms of clinical practice that reduced the occurrence of falls, or a reporting culture that meant falls were less likely to be reported. Neither of these would be likely to lead to a Type I error, as the former would have made demonstrating the effect of the intervention more difficult (since intervention ward patients would already be receiving slightly more effective falls prevention than controls) whilst the latter would be expected to result in potential for a

Type II error as any falls related intervention would tend to reduce under-reporting (Oliver et al. 2002, Barker et al. 2009).

In addition our study compared the ratio of rate changes, comparing the rate ratio between intervention and control in the before period with the rate ratio between intervention and control in the after period. This is not a typical methodology used in falls prevention studies (primarily because, as discussed in Chapter 2.4.1, other cluster randomised studies did not always collect or compare data from before the period before randomisation). This ratio of rate changes suggested a lower although still significant effect (0.71 95% CI 0.55-0.90 p=0.006) than the more conventional intervention to control rate ratio (0.59 95% CI 0.49-0.70 p<0.001). Interestingly, Haines and Hill (2004) suggested in a letter responding to the publication of our RCT that the outcome they believed most relevant was the before-and-after comparison of the intervention wards. Whilst this is a debatable approach – in effect discarding the data from control wards to make the study a before-and-after study – even analysed in this way our results were significant (0.79 95% CI 0.65-0.95 p=0.02).

A further limitation was appropriate adjustment for clustering in analysis. This again is a common limitation shared by cluster trials in general - Isaakidis & Ioannidis (2003) found the intracluster correlation coefficient was reported in only one out of a sample of 51 cluster RCTs - and by the other cluster randomised trials of falls prevention in hospitals (Cumming et al. 2008, Koh et al. 2009) that will be discussed later in Chapter 2.6.2.

2.5 EVIDENCE PUBLISHED SUBSEQUENT TO OUR RCT

From 2004 (when our RCT of falls prevention was published) onwards, further studies of falls prevention in hospitals have been published in peer reviewed journals. I will describe studies published from 2004 to 2009 below in Table 2c. Inclusion criteria were as for Table 2a above and included an additional updated search specific to hospital settings that I carried out to inform this doctoral statement and as the basis for a paper in Clinics in Geriatric Medicine which I co-authored (Oliver, Healey & Haines in press) (see Appendix G).

TABLE 2c: Design and results of falls prevention studies in hospitals 2004 - 2009

Reference	Study design	Setting	Participants	Intervention	Participants' mean age (years)	Mean length of stay (days)	Results I = Intervention (RCT/cohort) C = Control (RCT/cohort) B =Before A =After NS = not significant (no p value given) SNT = significance not tested	Comment
Barker et al. 2009	Uncontrolled before-and-after	Small acute hospital in Australia	271,095 patients admitted over three years before, and six years after intervention	Individualised multifactorial	47	3	Results presented as GAM plots with fall rate rises month to month prior to intervention and fluctuations after it. No significant changes in falls rates between before and after periods. Injury rates fell between a selected month pre-intervention and a selected month post-intervention $P < 0.001$. A subset of high risk wards showed a similar pattern for injury rates.	Had different months been selected for the injury rate comparison, very different results would have been obtained as injury rates before intervention ranged from around 0.3 to around 3.0, and after intervention from around 0.1 to around 2.5. However, whole year injury rates and numbers of injuries suggest a steady downward trend, although SNT.
Barreca et al. 2004	RCT	Stroke rehabilitation ward in Canada	48 medically stable stroke patients with modest impairment	Exercise (3 x 45 minutes additional group exercise weekly)	68	80	4 fallers in control group 3 fallers in intervention group $P=0.70$ (2 tailed Mann-Whitney U-test)	

Reference	Study design	Setting	Participants	Intervention	Participants' mean age (years)	Mean length of stay (days)	Results I = Intervention (RCT/cohort) C = Control (RCT/cohort) B =Before A =After NS = not significant (no p value given) SNT = significance not tested	Comment
Barrett et al. 2004	Uncontrolled before-and-after	Acute hospital in the UK	All patients admitted during a one year before and four year after study period	Yellow wristband and patient leaflet	-	-	B 2,271 falls per year, 710 injurious falls, of which fractures 28 A 2157-2470 falls per year, 519-725 injurious falls of which 14-21 fractures Reduction in number of injurious falls said to be significant at $p< 0.05$	The reduction in injurious falls was based on comparing 710 injurious falls in the pre-intervention year (1998) with 605 injurious falls in 2000 (second year post-intervention). Comparisons with other 'after' years would not have yielded the same results e.g. numbers of injurious falls in 1999 (first year post-intervention) were higher than in 1998 (725 v. 710)
Capan & Lynch 2007	Uncontrolled before-and-after	Small acute hospital in the USA	Admissions during one year (?) before period and eighteen month (?) after period	Individualised multifactorial	-	-	B (2003) 4.5 falls per 1,000 OBDs B or A? (2004) 3.9 falls per 1,000 OBDs B or A? (2005) 3.5 falls per 1,000 OBDs A (first six months of 2006) 2.4 falls per 1,000 OBDs SNT	The dates when either the one-ward pilot or the whole hospital implementation began are unclear, although the first year (2003) is clearly before the pilot and the last six months (2006) is clearly after for the whole hospital
Cumming et al. 2008	Cluster RCT	24 acute and rehabilitation elderly care wards in 12 Australian hospitals	3999 patients admitted during the three month study period on each ward	Individualised multifactorial	79	12	I 8.25 falls per 1,000 OBD C 7.62 falls per 1,000 OBD Unadjusted incidence rate ratio 1.02 (95% CI 0.70 to 1.49) P=0.92 Various adjusted rates and subgroup rates analysed and also non significant	Differences between patient characteristics in I & C described and appear similar although SNT

Reference	Study design	Setting	Participants	Intervention	Participants' mean age (years)	Mean length of stay (days)	Results I = Intervention (RCT/cohort) C = Control (RCT/cohort) B =Before A =After NS = not significant (no p value given) SNT = significance not tested	Comment
Donoghue et al. 2005	Uncontrolled before-and-after	One elderly care ward in an Australian acute hospital	Admissions during an eighteen month before and eighteen month after period	Volunteer observers (twelve hours per weekday) in one bay in one ward	-	-	B 65 falls, 16.4 falls per 1,000 OBDs (selected quarter) or 15.6 falls per 1,000 OBDs (unspecified period) A 29 falls, 8.4 falls per 1,000 OBDs (selected quarter) or 8.8 falls per 1,000 OBDs (unspecified period) Odds ratio 0.56 (95%CI 0.45-0.68 44% reduction in rate said to be significant at $p<0.000$ using *"Fisher's exact Chi squared test"* [sic] 51% reduction in selected quarter SNT. No falls occurred in observation bay whilst volunteers present	Probably not odds ratio but a rate ratio for the unspecified period (8.8 falls per 1,000 OBDs v. 15.6 falls per 1,000 OBDs = rate ratio of 0.56). Apparent considerable selection of 'worst' before periods and 'best' after periods as for six months before intervention and for a year after intervention the month-by month rates actually appear very similar, fluctuating between 5 and 15 falls per 1,000 OBDs. Additionally the two months when falls were highest in the after period are discarded from analysis because they coincided with a holiday period when it was difficult to recruit volunteers.

Reference	Study design	Setting	Participants	Intervention	Participants' mean age (years)	Mean length of stay (days)	Results I = Intervention (RCT/cohort) C = Control (RCT/cohort) B =Before A =After NS = not significant (no p value given) SNT = significance not tested	Comment
Fonda et al. 2006	Uncontrolled before-and-after	Four elderly acute and rehabilitation wards in an Australian acute hospital	All admitted patients (1905 year one, 2056 year three) over one year before, two years after	Individualised multifactorial	82	19	B 465 falls 27 serious injuries 12.5 falls per 1,000 OBD I Year 1 489 falls 17 serious injuries 11.3 falls per 1,000 OBD I Year 2 413 falls 7 serious injuries 10.1 falls per 1,000 OBD Percentage reduction in falls rate B to Year 2 19.2% (95%CI 16.7% to 21.7%) P=0.001 (chi-squared) Percentage reduction in injury rate B to Year 2 76.8% (95%CI 74.1% to 79.5%) P<0.001 (chi-squared)	Mean LOS had decreased by two days and unit had increased from 96 beds to 120 beds. Quality score in Oliver et al. 2007 24/31
Giles et al. 2006	Uncontrolled before-and-after	One medical wards and one dementia ward in an Australian acute hospital	'High-risk patients' allocated to observation bays	Volunteer observers (eight hours each weekday) in one bay in each of two wards	-	-	B 70 falls 14.5 falls per 1,00 OBDs A 82 falls 15.5 falls per 1,00 OBDs Rate ratio 1.07 (95%CI 0.77-1.49) *"no falls occurred when the volunteers were present"*	

Reference	Study design	Setting	Participants	Intervention	Participants' mean age (years)	Mean length of stay (days)	Results I = Intervention (RCT/cohort) C = Control (RCT/cohort) B =Before A =After NS = not significant (no p value given) SNT = significance not tested	Comment
Haines et al. 2004	RCT	Three subacute wards within an Australian rehabilitation and elderly care hospital	626 patients consenting to randomisation drawn from 1040 consecutive admissions	Standardised multiple	80	32	I 105 falls in 54 fallers C 149 falls in 71 fallers Relative risk 0.78 (95%CI 0.56-1.06) Nelson-Aalen cumulative hazard estimate diverged at day 45. Log rank test (P=0.004) and Peto extension (P=0.045) showed fewer falls in I	Note that two subgroup analyses of those receiving education and exercise were also published (Haines et al. 2006 and 2007) which both identified significant results by log rank test (p=0.007 and p=0.003 respectively). Quality score 24/31 in Oliver et al. (2007) and 14/20 in Coussement et al. (2008)
Jarvis et al. 2007	RCT	Rehabilitation ward in the UK	29 female patients excluding those with stroke or cognitive impairment	Ten physiotherapy sessions per week v. 3 sessions for controls	-	-	Relative risk of being a faller 0.46 (95%CI 0.15-1.44)	No abstract or full paper obtainable; data extracted from Cameron et al. 2010
Koh et al. 2009	Cluster RCT	Two acute hospitals in Singapore	All admissions during one year before and six months after	Individualised multifactorial	-	-	Falls rates differed between control and intervention pre-intervention (0.6 v. 1.4 falls per 1,000 OBD) and there were no significant changes (P value not given) post-intervention (0.6 v. 1.1 falls per 1,000 OBD)	

Reference	Study design	Setting	Participants	Intervention	Participants' mean age (years)	Mean length of stay (days)	Results I = Intervention (RCT/cohort) C = Control (RCT/cohort) B =Before A =After NS = not significant (no p value given) SNT = significance not tested	Comment
Krauss et al. 2008	Before-and-after study plus contemporaneous control	General medical wards in an acute academic hospital with control of all other wards	All admissions during nine month before and nine month after period (N not given)	Individualised multifactorial	-	-	I B 6.64 per 1,000 OBD I A 5.09 per 1,000 OBDS(P= 0.15) C B 7.37 per 1,000 OBD C A 6.24 per 1,000 OBDS(P= 0.41) No significant differences in injury rates (P=0.53) I A 48 fallers, 57 falls C A 70 fallers, 78 falls Fallers and falls before not described	The authors also select a five month post-intervention period for sub-analysis and in that period note the rate on intervention wards (3.81) was significantly lower (P=0.43) than the nine months pre-intervention rate (6.64) but such unplanned sub-analysis is likely to lead to Type 1 errors.
Kwok et al. 2006	RCT	Two stroke rehabilitation wards in a convalescent hospital in Hong Kong	180 consecutively admitted *"patients perceived to be at risk of falls"* individually randomised to enter the control or intervention ward	Bed and chair movement alarms	76	21	55.6% (50/90) of the intervention group accepted bed/chair alarms Four falls in intervention group (three whilst sensor in use) and three falls in control group. SNT	Note high concurrent use of trunk and chair restraints in both intervention and control at 79.4% (143/180)
Mador et al. 2004	RCT	Two acute academic hospitals in Australia	71 older patients with confusion and behavioural disturbance	Individualised advice from a nurse specialist on non-pharmacological behavioural management	82	9	I 10 fallers C 4 fallers p= 0.083	

Reference	Study design	Setting	Participants	Intervention	Participants' mean age (years)	Mean length of stay (days)	Results I = Intervention (RCT/cohort) C = Control (RCT/cohort) B =Before A =After NS = not significant (no p value given) SNT = significance not tested	Comment
Meade et al. 2006	Controlled before-and-after	27 wards in 14 hospitals in the USA	All inpatients during a month before and four week after study period	Selected wards requested to carry out hourly comfort rounds or two-hourly comfort rounds	-	-	C B 18 falls C A 17 falls NS Hourly rounds B 25 falls A 12 falls (p=0.01) Two hourly rounds B 19 falls A 13 falls NS	19 out of 46 units originally recruited were excluded from analysis for failing to collect 'reliable' data. The before period appeared to be a calendar month and the after period four weeks.
Murphy et al. 2008	Uncontrolled before-and-after	Medical wards in an acute academic hospital in the USA	All admissions during twelve months before and twelve months post first intervention , three months before and three months after second intervention	Phase one = orange wristbands and room labels Phase two = hourly comfort rounds	-	-	Before wristbands 5-6 falls per 1,000 OBDs After wristbands 5-8 falls per 1,000 OBDs Before hourly rounds 10 falls, 4 falls per 1,000 OBDs After hourly rounds 14 falls, 5 falls per 1,000 OBDs SNT	All results taken from Figure 1 which has a wide scale (so can only be interpreted without decimal places) and presents rates per quarter. The authors describe a 'dramatic decrease' in falls once the hourly rounds were introduced but they state hourly rounds were introduced from January 2007(p. 37) onwards. The 'dramatic decrease' actually occurred three months prior to this (34 falls in the third quarter of 2006 and 10 falls in the last quarter of 2006) and rose slightly after hourly rounds began.

Reference	Study design	Setting	Participants	Intervention	Participants' mean age (years)	Mean length of stay (days)	Results I = Intervention (RCT/cohort) C = Control (RCT/cohort) B =Before A =After NS = not significant (no p value given) SNT = significance not tested	Comment
Peterson et al. 2005	Interrupted time-series	An acute hospital in the USA	3718 patients aged over 65 years prescribed psychotropic medications over a 24 week period	Alerts in computerised prescribing system prompting lower dosing for older patients, avoidance of anti-psychotics, and time-limited rather than 'as required' prescriptions	75	4	B 60 falls, 13 injurious falls, 6.4 falls per 1,000 OBD A 24 falls, 5 injurious falls, 2.8 falls per 1,000 OBD Logistic regression indicated odds ratio of falls 0.50 (95% CI 0.30-0.82 p=0.001) Reduction in injurious falls rate p=0.09	

Reference	Study design	Setting	Participants	Intervention	Participants' mean age (years)	Mean length of stay (days)	Results I = Intervention (RCT/cohort) C = Control (RCT/cohort) B =Before A =After NS = not significant (no p value given) SNT = significance not tested	Comment
Sahota et al 2009	Uncontrolled before-and-after study	An orthogeriatric rehabilitation ward in the UK	209 patients over twelve months before and 153 patients over twelve months after	Bed and chair alarms as standard for all patients	-	-	After adjustments for age, odds ratio of being a faller 0.55, (95% CI 0.32, 0.94) Falls per patient including multiple falls decreased from 0.38 to 0.33 Based on mean falls per patient excluding and including multiple falls, 29 fallers experiencing 79 falls before and 14 fallers experiencing 51 falls after. This would suggest the unadjusted odds ratio would be 0.62 (B 29 fallers v. 180 non-fallers, A 14 v. 139). Relative risk of being a faller would be 0.66 (B 29/209 v. A 14/153).	Only brief results are given as this was a research letter describing a pilot study. The study may have been confounded by much lower occupancy in the after period (209 v. 153 patients in respective years, but LOS said to have not changed significantly). The presentation of results adjusted for age would also suggest confounding differences in age between before and after phases.

Reference	Study design	Setting	Participants	Intervention	Participants' mean age (years)	Mean length of stay (days)	Results I = Intervention (RCT/cohort) C = Control (RCT/cohort) B =Before A =After NS = not significant (no p value given) SNT = significance not tested	Comment
Schwendimann et al. 2006a	Uncontrolled before-and-after	Internal medicine, geriatric and surgical wards in a 300 bed Swiss acute hospital	34,972 admissions over an 18 month before and 42 month after period	Individualised multifactorial	67	12	Falls rates are presented graphically and a non-significant reduction from 9.1 falls per 1,000 OBDs in early 1999 to 8.6 in late 2003 is noted (P=0.086). Proportions of major injuries appear to increase significantly (P=0.014) whilst overall proportions of injury show no significant change (P=0.169 chi-squared) Significant changes in mean age, gender ratio and LOS between before and after periods (all p< 0.001)	The analysis is carried out by comparison of each calendar year (including a calendar year which encompassed six months before intervention and six months after intervention). Quality score 9/20 in Coussement et al. (2008)
Schwendimann et al. 2006b	Cohort study	Two internal medicine wards within a Swiss acute hospital	409 (198 intervention, 211 control) consecutively admitted patients over a four month period	Individualised multifactorial	71	12	C 25 fallers, 51 falls, 15.7 falls per 1,000 OBDs I 25 fallers, 31 falls, 11.5 falls per 1,000 OBDs Only significant finding fewer multiple fallers in intervention (5 v.14) P=0.009 chi-squared) Demographic differences between groups NS	Although published after Schwendimann et al. (2006a) this study took place in 1999 and appears to have been a pilot study for it

Reference	Study design	Setting	Participants	Intervention	Participants' mean age (years)	Mean length of stay (days)	Results I = Intervention (RCT/cohort) C = Control (RCT/cohort) B =Before A =After NS = not significant (no p value given) SNT = significance not tested	Comment
Stenvall et al. 2007	RCT	Ortho-geriatric ward (intervention) and orthopaedic ward and geriatric ward (control) in a Swedish acute hospital	199 consecutively admitted patients with femoral neck fracture consenting to randomisation and without complex needs	Individualised multifactorial	82	35	I 18 falls, 3 injurious falls, no fractures, 6.29 falls per 1,000 OBDS C 60 falls, 15 injurious falls, 4 fractures, 16.28 falls per 1,000 OBD Incidence rate ratio 0.38 (95% CI 0.20-0.76) after adjustments Kaplan-Meier survival to first fall significant (log rank 0.008) C had significantly higher levels of depression and anti-depressant use pre-randomisation (P= 0.031, P= 0.009) and a significantly longer LOS (38 v. 28 days P= 0.028)	This study was also published as Lundstrom et al. (2007) with an emphasis on effects on delirium
Van der Helm et al. 2006	Uncontrolled before-and-after	One internal medicine ward and one neurology ward within an acute hospital in the Netherlands	All admitted patients (2670) during a six month before and eighteen month after period	Individualised multifactorial	-	10	Internal medicine B 9 falls per 1,000 OBD A 8 falls per 1,000 OBD Neurology B 16 falls per 1,000 OBD A 16 falls per 1,000 OBD SNT	Note that the authors presented initial analysis of the same study in an earlier paper (Semin-Goossens et al. 2003).

Reference	Study design	Setting	Participants	Intervention	Participants' mean age (years)	Mean length of stay (days)	Results I = Intervention (RCT/cohort) C = Control (RCT/cohort) B =Before A =After NS = not significant (no p value given) SNT = significance not tested	Comment
Vassallo et al. 2004	Cohort study	Three rehabilitation wards within a UK rehabilitation hospital	825 patients (the first 275 patients to be admitted to each of the two control and one intervention wards)	Individualised multifactorial	82	24	C 111/550 fallers 170 falls, 45 injurious falls, 11.5 falls per 1,000 OBDS(170 falls in 14,791 OBD) I 39/275 fallers, 72 falls 12.3 falls per 1,000 OBDS(72 falls in 5,855 OBD) Difference in falls and OBDs said to be significant at P=0.045 using Mann-Whitney	Although the authors refer to the study as quasi-randomised and Oliver et al. (2007) refer to it as a cluster RCT it appears the intervention ward was selected as the ward where the researchers worked, and the quasi-randomisation relates only to the fact that patients would be allocated from a waiting list to whichever ward was the first to have an empty bed. Quality score 10/31 in Oliver et al. (2007) and 11/20 in Coussement et al. (2008)
Von Reteln-Kruse & Krause 2007	Uncontrolled before-and-after	Elderly acute and rehabilitation wards in an acute hospital in Germany	4,272 patients admitted in a 23 month before period, 2,982 admitted in a 16 month after period	Individualised multifactorial	80	20	B 893 falls 611fallers 129 injurious falls 10 fractures 10.0 falls per 1,000 OBD A 468 falls 330 fallers 129 injurious falls 9 fractures 8.2 falls per 1,000 OBDS Incidence rate ratio 0.82 (95% CI 0.73-0.92) Injury rate ratio 0.84 (95% CI 0.67-1.04)	A separate publication (von Reteln-Kruse & Krause 2004) describes a review of reported falls from January 2000 to December 2002 and suggests that the proportion of fallers had been reducing substantially year-on-year even before the intervention was introduced.

Reference	Study design	Setting	Participants	Intervention	Participants' mean age (years)	Mean length of stay (days)	Results I = Intervention (RCT/cohort) C = Control (RCT/cohort) B =Before A =After NS = not significant (no p value given) SNT = significance not tested	Comment
Williams et al. 2007	Uncontrolled before-and-after	Three general medicine and one geriatric assessment ward in an acute hospital in Australia	1357 patients admitted over six months and compared with the same calendar months in the previous year	Individualised multifactorial	79	8	B 119 falls ?9.5 falls per 1,000 OBD A 127 falls 8 falls per 1,000 OBD	Falls per 1,000 OBDs are converted to the % of days on which a fall occurred i.e. 8 falls per 1,000 OBDs = 0.8% of days had a fall occur on them after and '0.95%' before. They then calculate 95% CIs for the 0.15% difference as 0.14 -0.16% P<0.001.However, there were more falls in the post-intervention period and both the figure of 0.8 and 0.95 appear rounded.

As Table 2c indicates, there has been a substantial increase in the evidence base for falls prevention in hospital since the publication of our RCT, with 26 studies identified in the seven years between 2004 and 2009. To summarise (Table 2d) thirteen were studies of individualised multifactorial interventions (including one individually randomised RCT (Stenvall et al. 2007) and two cluster randomised RCTs (Cumming et al. 2008, Koh et al. 2009)). There was also one RCT of standardised multiple interventions (exercise, patient education, and hip protectors) (Haines et al. 2004). Twelve were single or dual intervention studies, of which five were RCTs (Barreca et al. 2004, Burleigh et al. 2007, Jarvis et al. 2007, Kwok et al. 2006, Mador et al. 2004).

TABLE 2d: Summary of falls prevention studies published 2004 - 2009

	RCT	**Cluster RCT**	**Interrupted time-series**	**Controlled before-and-after**	**Uncontrolled before-and-after**	**Cohort**	**Totals**
Individualised multifactorial	1	2		1	7	2	**13**
Standardised multifactorial	1						**1**
Dual interventions					2		**2**
Single interventions	5		1	1	3		**10**
Totals	**7**	**2**	**1**	**2**	**12**	**2**	**26**

Of the 25 studies, only four had been quality scored by previously published systematic reviews (mainly because most had been published subsequent to these). Fonda et al. (2006) and Haines et al. (2004) were given good scores of 24/31 (Downs & Black 1998 used by Oliver et al. 2007) whilst Schwendimann et al. (2006a) scored 11/20 in Coussement et al.’s (2008) quality criteria list. Vassallo et al. (2004) was given a weak score of 10/31 (Downs & Black 1998) by Oliver et al. (2007) but a more positive one of 11/20 quality criteria met in Coussement et al. (2008). Both of the cohort studies of individualised multifactorial interventions (Schwendimann et al. 2006b, Vassallo et al. 2004) appeared prospectively planned as research studies, as did five of the nine before-and-after studies of individualised multifactorial interventions (Krauss et al. 2008, Meade et al. 2006, Schwendimann et al. 2006a, Van der Helm et al. 2006, Von Reteln-Kruse & Krause 2007), whilst the remainder (Barker et al. 2009, Fonda et al. 2006, Capan & Lynch

2007, Williams et al. 2007) appeared to be local service improvement projects that had been retrospectively analysed.

These studies' findings will be discussed by intervention type below; pre-2004 studies discussed earlier in Chapter 2.2.7 will also be included in the discussion where appropriate.

2.6 COMMONALITIES, DIFFERENCES AND CLINICAL IMPLICATIONS

Because our RCT was an individualised multifactorial intervention, the single intervention studies outlined in Tables 2a and 2c above offer relatively little opportunity to compare and contrast approaches. I will therefore discuss these studies only briefly, to summarise if they offer effective alternatives to an individualised multifactorial approach. I will then move on to a more in-depth discussion of commonalities and differences between our RCT and other studies of individualised multifactorial interventions. Throughout this discussion I will draw out the implications for clinical practice in terms of the overall balance of evidence for single, dual, and multifactorial interventions, and for their individual components and how they are implemented.

2.6.1 Single interventions

2.6.1.1 Paid or volunteer observers

We know that most falls in hospital are unwitnessed, and it makes intuitive sense that timely assistance might reduce the risk of a fall occurring. Three studies described the use of observers who would alert nursing staff if a patient showed risky behaviour. Two of these (Donoghue 2005, Giles et al. 2006) allocated a volunteer observer for one or two bays that selected high-risk patients were allocated to. One of these studies (Giles et al. 2006) found a non-significant increase in falls overall, although no falls occurred whilst patients were being directly observed by volunteers. However, this may have been a chance finding given the small proportion of patients receiving observation and small proportion of time when volunteers were present. The comment of some staff involved that the volunteers called them too frequently might suggest that although patients in the observation bay benefited, this may have been at the cost of staff time and assistance provided to other patients. A second Australian study (Donoghue 2005) used volunteers for twelve hours each weekday for four patients in an observation bay on one ward. Whilst the study's results appear promising, the rate ratio of 0.56 (95% CI 0.45-0.68) appears based on selection of 'worst' quarter in the before period and 'best' quarter in the after period; month-by-month rates before and after intervention fall within a similar range. Although the ward struggled to recruit volunteers, especially during holiday periods, no falls were reported in the observation room whilst volunteers were present, and patients appeared to enjoy the extra social contact. Boswell et al. (2001) in a study of paid companions in an acute hospital noted a marginal increase in falls expressed as a rate per eight-hour shift. The extent to which sitters were used, and the patients to whom they were allocated, are not well described but one-to-one observation is implied. Whilst a paid role appeared to eliminate the recruitment difficulties and allowed observation to take place in unsocial hours, it is feasible that as this was low-paid casual employment not requiring healthcare experience or qualifications, the observers' motivation was lower than in the volunteer studies.

These studies suggest there may be potential in the approach of volunteer observers but further research is needed, and recruiting enough volunteers to work in more than one or two rooms per hospital or to work outside office hours may prove almost impossible.

2.6.1.2 Movement alarms

Tideiksaar et al. (1993) in a small rehabilitation hospital RCT (N=70) found no statistically significant changes after their introduction of a pressure sensitive alarm to alert staff when the patient moved out of their bed. Kwok et al. (2006) in an RCT of stroke rehabilitation patients (N=180) provided bed and chair movement alarms; they were used for 56% of the intervention group but no significant changes in falls were found. Sahota et al. (2009) in a research letter reported on the pilot phase of a before-and-after study (N=362) using movement sensors on beds and chairs linked to a central pager for all patients on an orthogeriatric rehabilitation ward. Preliminary results suggested a significant reduction in fallers and a non-significant reduction in falls, but a substantial reduction in bed occupancy in the after period may have confounded the findings, and a larger randomised trail is now underway. In addition, Shorr et al. (2010) in conference abstracts have described the preliminary results of a large cluster randomised study of bed and chair alarms on acute wards in the USA. Whilst full results await peer review, these early findings suggest that despite an alarm usage rate of 64 per 1,000 OBDs on the intervention wards versus 2 per 1,000 OBDs on the control wards, there were no significant differences in falls rates or relative risk of falling.

The apparent contradiction between these studies' results is clinically plausible given the real life scenario of fixed numbers of staff available; where movement alarms generate extra calls to staff for some patients, there is inevitably the potential for an increase in response times to other patients in the same unit without an alarm. Universal allocation of movement alarms, as in Sahota et al. (2009), may overcome this, but would only be appropriate for very dependent patient populations unable to mobilise safely without supervision. Even for these settings, there is not yet sufficient evidence to recommend their use.

2.6.1.3 Medication review

Only two hospital studies of medication review as a single intervention were identified. Peterson et al. (2005) in a large and well designed time-interrupted series (N=3718) introduced alerts within a computer based prescribing system. The alerts advised doctors on the risks of falls and special considerations for patients over 75 years if they attempted to prescribe psychotropic or sedative medications. Prescribed doses and dosing errors fell significantly and falls rates for patients in the intervention periods were significantly lower (p=0.001). Haumschild et al. (2003) in a study of medication review initiated by a consultant pharmacist in a rehabilitation hospital achieved marked reductions in prescriptions of psychoactive medication (18.2% reduction), sedatives and hypnotics (13.9%), cardiovascular medication (10.7%) and analgesics (6.3%). The intervention and the changes in prescribing patterns are well-described but the falls outcome data are brief and unclear; there were either 30 falls or 30 fallers in a random sample of 200 patients from the before period, and either 16 falls or 16 fallers in a random sample of 200 patients from the after period (p=0.05).

These studies suggest medication review, even in isolation from other interventions, is likely to reduce falls in hospital patients, and its importance as a component in studies of multifactorial interventions (including our RCT) and will be discussed further in Chapter 2.6.2 below.

2.6.1.4 Exercise

Donald et al. (2000) in their small RCT (N=48) and Barreca et al. (2004) in their small RCT (N=52) provided additional chair-based exercise for rehabilitation patients and both had null results. The Cochrane review (Cameron et al. 20100 also refers to a small (N=29) exercise RCT by Jarvis et al. (2007) with no significant effect on falls, but no abstract or full paper could be obtained. Further studies were unlikely to have been missed, as no additional studies from hospital settings were identified in the recent major systematic review on exercise interventions and falls by Sherrington et al. (2008).

However, although Haines et al.'s (2004) larger RCT (N=626) is technically a standardised multiple intervention (of exercise, patient education, and hip protectors) it might be better considered as an exercise intervention, because subgroup analysis suggested exercise was the effective component (p=0.003)[xlii] (Haines et al. 2007) and an element of patient education is normally a standard part of exercise programmes focused on the prevention of falls (Sherrington et al. 2008). Haines et al.'s (2004) study involved an intensive exercise intervention focused on strength and balance training in a rehabilitation setting with mean lengths of stay in excess of a month, and it identified significant reductions in falls (p=0.045), especially after 45 days, and a non-significant reductions in fallers.

These studies suggest that exercise may be an effective falls prevention intervention in hospital settings but, as in community settings (Sherrington et al. 2008), it would need to be intensive, focused on improving strength and balance, and sustained over weeks, making it impractical in any but slow-stream rehabilitation settings.

2.6.1.5 Calcium and Vitamin D

Burleigh et al (2007) published the only RCT to date of Vitamin D supplementation in hospital inpatients (N=225) and found no overall effect on falls or fractures. The null result is not unsurprising as the effects of Vitamin D would not be expected to become apparent in the short duration of most hospital admissions. Therefore whilst the identification of osteoporosis and Vitamin D deficiency during a hospital admission can ensure appropriate patients are commenced on biphosphonates and calcium plus Vitamin D to prevent further injuries post discharge, this is unlikely to deliver benefit whilst they are inpatients. No multifactorial interventions in hospitals included Vitamin D supplementation.

[xlii] Hip fractures were unchanged despite the hip protector intervention and would in any case only be expected to impact on fractures not falls.

2.6.1.6 Alert wristbands

Four studies described the introduction of alert wristbands applied to 'high risk' patients, in some cases accompanied by bedside alert signs. The best designed of these studies (Mayo et al. 1994) provided evidence that simply 'labelling' selected patients as being at high risk of falling through a coloured wristband was ineffective, with a non-significant increase in falls noted in the intervention group (rate ratio 1.34 (95% CI 0.76-2.38)). A similar before-and after study (O'Connell et al. 2001) saw a non-significant increase in falls rate after giving patients alert wristbands and bedside signs on the basis of high Morse (1997) scores. Barrett et al. (2004) in a research letter reported on a dual intervention using alert wristbands and a patient leaflet. Falls increased non-significantly and although the authors suggest that a significant reduction in the number of injurious falls occurred ($p < 0.05$), this appears based on selective comparison of a 'good' after year with the year before intervention; the number of injurious falls actually increased in some of the four years described post-intervention. The first phase of Murphy et al.'s (2008) study involved the introduction of alert wristbands and bedside alert signs; quarterly falls rates fluctuated in the following year but did not decrease.

These findings are not surprising given the high proportion of unwitnessed falls (Healey & Scobie for NPSA 2007a). Additionally, even if a patient was in sight of staff, wristbands are not necessarily visible under clothing or nightwear. Perhaps more importantly, none of the studies are clear on what staff behaviour the alert wristbands were intended to trigger, other than vague references to increased vigilance. It would certainly be inappropriate to use them to trigger actions such as not allowing patients to walk alone, since in all these studies a high proportion of patients were identified as high risk (e.g. 75% in O'Connell et al. 2001). The patients with alert wristbands would therefore almost certainly have included some patients who could and should be aiming for independence prior to their discharge home. The same lack of clarity on what staff behaviour was required would apply to alert signs at the bedside; information that a patient is at risk of falls may be of relatively little practical use in contrast to bedside information on whether the patient can safely mobilise with or without assistance from staff.

2.6.1.7 Comfort rounds

Murphy et al. (2008) state that the falls rate showed a *"dramatic decrease"* (p. 38) from 34 falls per quarter to ten per quarter when, in the second phase of their falls prevention initiative, they introduced a practice of 'mandatory comfort rounds' where every patient was asked every hour if they had any pain, toileting needs, or other needs. However, their paper identifies the hourly comfort round initiative as having begun *after* the quarter in which the number of falls dropped to ten, so this appears unlikely to have been related to the initiative. Meade et al. (2006) also describe a significant decrease in falls (p=0.01) on units selected to carry out hourly rounds to check on patients needs, whilst no significant changes occurred on control wards or wards selected to carry out two-hourly rounds to check on patients needs. However, the wards selected for hourly comfort rounds appear to have had a higher rate of falls in the month prior to intervention, so the reduction during intervention may solely have been regression to the mean. Additionally, no adjustment is made for occupancy, and before and after periods appear unequal. The study is also flawed by the failure of over a third of recruited units to provide data and by the very short time period involved (four weeks of intervention). Other studies not eligible for inclusion in the tables above through failure to provide outcome data in terms of falls numbers or rates (Bakarich et al. 1997) or awaiting publication in a peer-review journal (Williams et al. in press) suggest sustained compliance with hourly comfort rounds is very difficult to achieve.

Although comfort rounds make intuitive sense (and were welcomed by patients, except where staff took the 'mandatory' nature of the hourly comfort rounds to heart and woke them to ask if they needed anything), better-designed studies with longer follow-up periods would be needed before their impact on falls could be properly assessed.

2.6.1.8 Other single interventions

One small (N=71) RCT (Mador et al. 2004) involved a clinical nurse specialist providing advice on non-pharmacological methods of managing confused and agitated patients in an acute hospital. No reduction in psychotropic medication prescribed resulted and numbers of falls were unchanged. This may have been because the management techniques recommended by the specialist (e.g. music and diversional therapy including dolls) appeared drawn from care home settings rather than including interventions likely to be effective for delirium related to acute illness (BGS 2006).

Whilst Donald et al. (2000) concluded that there was a higher relative risk of falls in patients randomised to bed areas with carpet (ten falls) rather than vinyl (one fall) that was 'statistically significant' (p=0.05), this claim appeared to arise from the authors' misinterpretation of their confidence intervals - the authors appear to assume that their results were significant because their 95% confidence intervals did not cross zero, as would be the case for nominal data, but for relative risk the null hypothesis is represented by a value of one and their very wide 95% confidence intervals (0.95-73) crossed this value. In any case a reduced risk of falling on vinyl would be irrelevant in most hospital settings which will already be floored with vinyl. However, hospital flooring is an area of current research. Observational studies in hospitals (Healey 1994, Minns et al. 2004) and care homes (Simpson et al. 2004) suggested the standard hospital flooring of vinyl on concrete without underlay is likely to be associated with higher injury rates than almost any other type of flooring. Hospital studies are currently underway (Drahota et al. 2007, University of Portsmouth 2009) to assess the effect on injuries in falls from impact-cushioning underlay beneath vinyl, but results are not expected until 2011.

2.6 2 Individualised multifactorial interventions

In addition to the eight before-and after studies of individualised multifactorial interventions published before 2004, thirteen further studies of individualised multifactorial interventions were published between 2004 and 2009 and are described above in Table 2c. These included one individually randomised RCT (Stenvall et al. 2007), two cluster randomised RCTs (Cumming et al. 2008, Koh et al. 2009), seven uncontrolled before-and-after studies (Barker et al. 2009, Fonda et al. 2006, Capan & Lynch 2007, Schwendimann et al. 2006a, Van der Helm et al. 2006, Von Reteln-Kruse & Krause 2007, Williams et al. 2007), one controlled before-and-after study (Krauss et al. 2008) and two cohort studies (Schwendimann et al. 2006b, Vassallo et al. 2004). I will first summarise the key aspects of design and results for all these studies, before moving on to compare and contrast the components of the better designed studies.

2.6.2.1 Design and key results: RCTs of individualised multifactorial interventions 2004-2009

Stenvell et al. (2007) individually randomised 199 patients admitted with fractured neck of femur to either receive postoperative care on a specialist orthogeriatric ward or on standard orthopaedic wards. The individualised multifactorial intervention was in effect everything the orthogeriatric ward offered over and above the orthopaedic ward, including a larger and more diverse multi-professional team who had all had training in falls prevention, more single rooms, post operative protocols that included extensive screening for causes of delirium, earlier mobilisation, and early discharge. The study found significant reductions in falls (rate ratio 0.38 95% CI 0.20-0.70) and non-significant reductions in injuries and fractures. Whilst their findings were confounded by a significantly longer length of stay in the control group (38 days v. 28 days p=0.028) a significantly longer survival time to first fall in the intervention group (log rank 0.0008) suggests the reduction in falls was more plausibly attributable to the intervention than to the curtailed length of stay (which may in itself have been attributable to less harm from falls or to more active discharge planning). Given the study population limited to admissions with a specific diagnosis, results may not be generalisable to the wider hospital inpatient population.

Cumming et al.'s (2008) cluster RCT was large (N=3,999) and well-designed, but the actual interventions intended to prevent falls are not well described, and appear mainly to have been decided on an ad-hoc basis by the visiting nurse and physiotherapist rather than being defined in advance of the study. For example, the nurse intervention is said to have included *"liaising with other staff about possible changes to drugs"* and *"modifications to the bedside environment"* whilst the physiotherapist *"supervised patients doing exercises"* and *"educated staff…on the need for supervision"* (p. 2). No significant changes in falls or fallers were identified.

Koh et al.'s (2009) cluster RCT is arguably a contemporaneous cohort study, since the 'clusters' were two unmatched hospitals in the same city but with very different falls rates pre-intervention (0.6 and 1.4 falls per 1,000 OBDs). No significant changes in falls rates were identified post-intervention.

2.6.2.2 Design and key results: before-and-after studies of individualised multifactorial interventions 2004-2009

The eight before-and-after studies ranged from those describing short periods post-intervention (e.g. six months in Williams et al. 2007) to as much as six years post-intervention (Barker et al. 2009). Most involved more than a thousand admissions and one included 271,095 patients (Barker et al. 2009). Results and analysis ranged from brief summary findings (e.g. Capan & Lynch 2007) to extensive and complex statistical modelling (e.g. Barker et al. 2009).

Five of the studies (Capan & Lynch 2007, Krauss et al. 2008, Schwendimann et al. 2006a, Schwendimann et al. 2006b, Van der Helm et al. 2006) found no significant results in terms of falls rates, fallers, or injuries. Barker et al. (2009) saw no significant changes in falls rates between before and after periods, and their claim for a statistically significant reduction in injury rates of $p<0.001$ is based on a very selective subgroup analysis (see Table 2a). However, their year-on-year reductions in numbers of injurious falls suggest at least a trend towards a lower injurious falls rate is likely, although, as a steady decrease over six years, it is not convincingly linked to the timing of their introduction of the intervention.

Only Fonda et al. (2006) and Von Reteln-Kruse & Krause (2007) describe significant reductions in falls rates and injury rates. For Fonda et al. (2006) the timing of the year-on-year rate changes are convincingly linked to an extensive and well-described individualised multifactorial intervention. For Von Reteln-Kruse & Krause (2007), the link between their multifactorial intervention and the changes in rates are less convincing, since an earlier observational study (Von Reteln-Kruse & Krause 2004) suggested a similar pattern of year-on-year reductions had been apparent in the years prior to the intervention, perhaps because of secular trends in the vulnerability of the hospital population.

2.6.2.3 Design and key results: Cohort studies of individualised multifactorial interventions 2004-2009

The two cohort studies (Schwendimann et al. 2006b, Vassallo et al. 2004) both make a good case for their contemporaneous cohort being similar to their intervention unit in terms of patient demographics and service provision. Schwendimann et al.'s (2006b) pilot study was small (N=409), and the only significant finding was fewer multiple fallers ($p=0.009$) with no significant changes in fallers or falls rates. Vassallo et al. (2004) recruited 825 patients and there appear to be some issues with presentation and interpretation of results by the original authors. Difference in falls and OBDs said to be significant at $P=0.045$ using Mann-Whitney, but this appears to be comparison of raw data without adjustment for the control group being twice the size of the intervention group. In the text the authors interpret this as indicating the falls rate was significantly worse in intervention, but based on the more conventional incidence rate ratio and 95% CIs in Oliver et al.'s (2007) and Coussement et al.'s (2008) reviews, the increase in falls rate was non-significant, and the relative risk of being a faller may have been lower in the intervention group 0.70 (95% CI 0.50-0.98) although confounded by a significantly shorter length of stay ($p<0.001$). Later meta-analysis (Coussement et al. 2008, Oliver et al. 2007) also suggests there may have been a borderline significant reduction in fallers (0.70 95% CI 0.50-0.98) although this would not be clinically significant given fall rates increased non-significantly.

2.6.2.4 Components of individualised multifactorial intervention studies

These studies of individualised multifactorial interventions (and the pre-2004 studies discussed earlier) included very different combinations of components. Although this heterogeneity between studies is a barrier to meta-analysis (Haines & Hill in press), it can provide some helpful information on what characteristics are more likely to be seen in a successful study. To help facilitate identification of these successful characteristics and whether these show commonalities or differences with components included in our RCT, I have described in Table 2e the key components included in each study.

Given the difficulties in designing falls prevention studies in the hospital setting, in this chapter I will limit discussion of commonalities and differences to those studies which are either RCTS or, if cohort or before-and-after studies, clearly described at least a nine month intervention period. This is because (as discussed in Chapter 2.2.5) shorter periods of data collection in non-randomised studies risk producing Type II errors through inadequate power, and Type I errors through confounding the impact of the intervention with seasonal variations or a Hawthorne effect. Given changes over time in healthcare practice, demographic changes in the proportion of older people, and changes in hospital activity, I will limit discussion to those studies that have been published in the fifteen years between 1995 and 2009, since older studies would have limited relevance to current inpatient populations. Therefore of the 21 studies of individualised multifactorial interventions discussed so far (eight prior to 2004 and thirteen from 2004-2009), fifteen studies that either had a randomised design or sustained implementation period will be compared and contrasted with our RCT (Healey et al. 2004).

TABLE 2e: Components of sustained multi-factorial falls prevention studies in hospitals 1995 – 2009

KEY:
✓ = intervention included this component
(✓) = component planned but not implemented
🡇 = intervention discouraged use of this component
🡅 = intervention encouraged use of this component

Reference	Environment modified	Alert wristband	Bedside risk sign	Hip protectors	Staff education	Patient education	Bedrail review	Vest/belt/cuff restraint	Footwear	Toileting schedules	Exercise	Movement alarms	Medication review	Urine screening	Post-fall review	Other interventions	Total interventions	Statistically significant reductions in falls or injuries? (see Tables 2a & 2c for detail)
Barry et al. 2001	✓	-	-	✓	✓	-	-	-	-	-	-	-	✓	-	✓		5	Yes injuries
Fonda et al. 2006	✓	✓	-	-	-	-	-	🡇	✓	✓	-	✓	✓	-	✓	Ultralow beds, volunteer observers	10	Yes falls Yes injuries
Healey et al. 2004	-	-	-	-	-	✓	✓	-	✓	✓	-	-	✓	✓	✓	Vision testing, lying and standing blood pressure	9	Yes falls
Stenvall et al. 2007	-	-	-	-	✓	-	-	-	-	-	-	-	-	✓	✓	Additional therapy and nurse staffing Routine dietary protein supplementation Protocol driven delirium screening Early mobilisation	8	Yes falls
Barker et al. 2009	-	-	✓	-	-	-	-	-	-	✓	-	✓	-	-	-	Ultralow beds	4	Possibly injuries

Reference	Environment modified	Alert wristband	Bedside risk sign	Hip protectors	Staff education	Patient education	Bedrail review	Vest/belt/cuff restraint	Footwear	Toileting schedules	Exercise	Movement alarms	Medication review	Urine screening	Post-fall review	Other interventions	Total interventions	Statistically significant reductions in falls or injuries? (see Tables 2a & 2c for detail)
Brandis 1999	✓	✓	✓	✓	-	-	-	-	-	-	-	-	-	-	-	Falls history and continence assessment added to standard admission documentation	5	No
Cumming et al. 2008	-	-	-	-	✓	✓	✓	-	-	-	✓	✓	?	-	-		5	No
Grenier-Sennelier et al. 2002	-	-	-	-	-	✓	-	✓	✓	-	-	-	✓	-	✓	Improved assessment of mobility and self-efficacy	5	No
Koh et al. 2009	-	✓	✓	-	✓	-	-	-	-	-	-	-	-	-	-	'Stand by me' notices to prompt staff to wait outside toilets ready to assist. Mobility level signs at bedside	5	No
Krauss et al. 2008	-	✓	✓	-	✓	✓	-	-	-	-	-	✓	(✓)	-	-		5	No
Oliver et al. 2002	-	-	-	-	-	-	-	-	-	-	-	-	?	-	-	Nursing and medical checklist, content unclear and compliance poor	3	No
Schwendimann et al. 2006a	-	-	✓	✓	-	✓	↓	-	-	✓	-	-	✓	-	✓		7	No
Uden et al. 1999	-	-	-	-	-	✓	↑	-	✓	-	-	✓	-	-	-	Carer education	4	No
Van der Helm et al. 2006	(✓)	-	-	-	-	-	↑	↑	-	-	-	-	-	-	-		3	No
Vassallo et al. 2004	-	✓	-	-	-	✓	✓	-	✓	-	-	-	✓	-	-	Medical review	5	Possibly fallers

As Table 2e demonstrates, the components included within the multifactorial interventions differed widely. This variation is even greater than the table suggests, as the level and intensity of superficially similar interventions also differed. For example, the staff education element ranged from four days of training for all staff groups (Stenvall et al. 2007) to ad-hoc bedside sessions for nurses (Cumming et al. 2008). Some interventions were applied in opposing directions; for example, Fonda et al. (2006) discouraged the use of vest and belt restraint devices whilst Van der Helm (2006) encouraged their use.

To further facilitate comparison between the studies that achieved significant reductions in falls or injuries (Barry et al. 2001, Fonda et al. 2006, Healey et al. 2004, Stenvall et al. 2007, Von Reteln-Kruse & Krause 2007) and the eleven studies that did not identify significant reductions in falls or injuries, Figure 2a below summarises the components listed above in Table 2e and other aspects of design listed below in Table 2f.

FIGURE 2a: Comparison of components and approaches between the studies which identified significant reductions in falls and/or injuries and those that did not

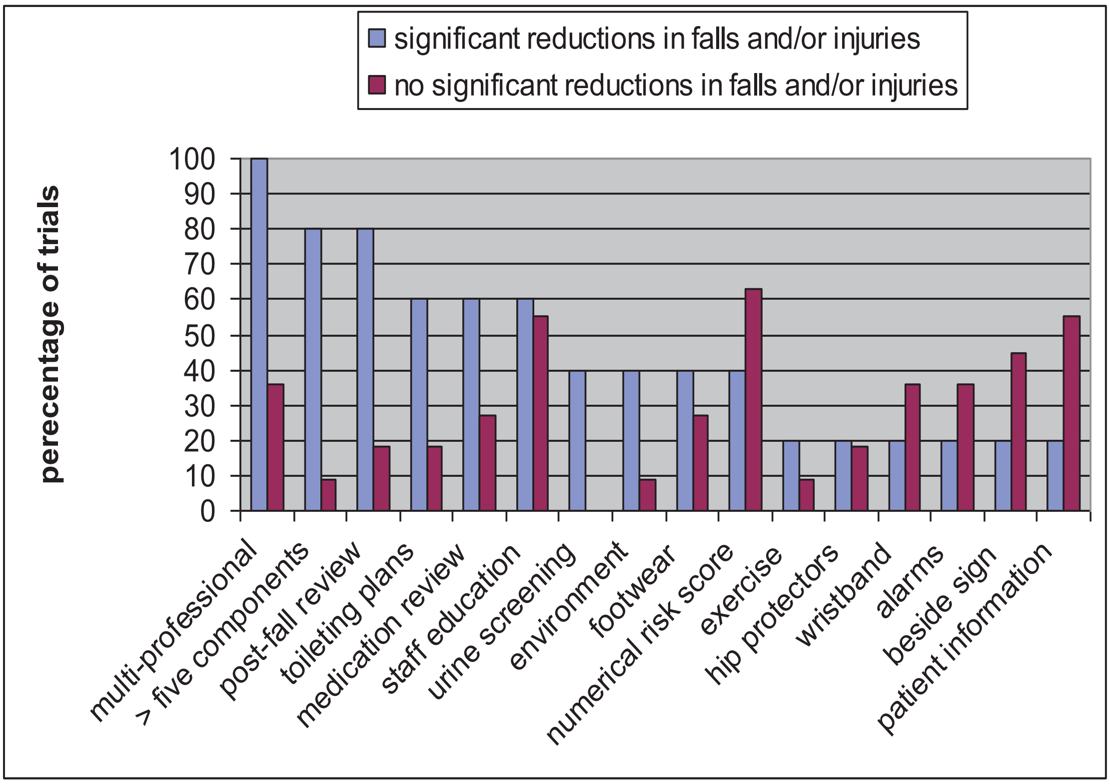

Figure 2a needs to be interpreted with caution, as the sample is small – just five studies seeing significant reductions in falls or injuries, and eleven without significant changes. However, it suggests that the components most commonly provided in successful interventions include post fall reviews, medication reviews, and staff education. But in terms of *differences* between components provided within successful and unsuccessful interventions, a slightly different pattern emerges. The components that were more likely to be seen in successful rather than unsuccessful interventions were post fall reviews (80% v.18%), medication reviews (60% v. 27%), urine screening (40% v. 0%), toileting plans (60% v. 18%), environmental improvements (40% v. 9%) and footwear review (40% v. 27%). Our RCT included all of these with the exception of environmental improvements.

The success of a post-fall review component is plausible given the proportion of multiple fallers seen in hospital settings (Mahoney 1998). Although a post-fall review cannot expect to change the number of fallers, identifying individual risk factors which could be modified could prevent second and subsequent falls, thereby reducing the falls rate. Commentators (Oliver et al. 2007, Oliver 2008) have suggested that the general pattern seen on meta-analysis of a significant pooled reduction in falls rates but not fallers may not solely reflect insufficient power, but could indicate that falls prevention interventions are generally reducing repeat falls rather than first falls. A post-fall review also arguably concentrates staff time and effort on the patients at very highest risk (since a previous fall is the strongest predictor of future falls (Oliver et al. 2006)). For our RCT, post-fall reviews were a key component, and our interventions were targeted primarily at those patients with a recent history of falling.

Medication review also has a plausible mechanism given the correlation between culprit medications (especially psychotropic medications) and falls (Oliver 2008). Medication review as a single intervention has been shown to significantly reduce falls in acute hospital settings (Haumschild et al. 2003, Peterson et al. 2005). Medication review was included as a component in three of the successful falls prevention interventions including our RCT (Barry et al. 2001, Fonda et al. 2006, Healey et al. 2004). Our RCT focused on psychotropic medication (anti-psychotics, sedatives, and anti-depressants) which was also the approach taken by Peterson et al. (2005) and the type of medication most often reduced by Haumschild et al.’s (2003) intervention. Early conference presentations (Close 2009) of a large before-and-after study in an Australian acute hospital also indicate falls rate reductions after an intervention to reduce prescribing of sedative medication.

Urine testing was included in our RCT and in Stenvell et al.'s (2007) RCT and has a plausible mechanism for falls prevention because of the high prevalence of urinary tract infections in hospital inpatients (Scottish Intercollegiate Guidelines Network (SIGN) 2006) and the association of urinary tract infections with delirium (Young and Inouye 2007, British Geriatrics Society 2006). The core care plan in our RCT included a note to junior medical staff that although they had been taught that asymptomatic bacteriurea should not be treated (SIGN 2006) increased confusion or reduced mobility should be considered as symptoms and therefore a reason to treat. Urinary tract infections are also associated with frequency and urgency of micturition, which is likely to increase the risk of falling (Oliver 2008). Anticipating individual patient's toilet needs by establishing a tailored routine of offering to help them to the toilet was also a component of our RCT and of two other successful interventions (Fonda et al. 2006, Von Reteln-Kruse & Krause 2007).

Environmental modifications were included as components in two of the successful interventions (Barry et al. 2001, Fonda et al. 2006) and involved fitting of non-slip flooring, polish-free cleaning, longer call bells, fitted sheets, safer commodes, night lights, chairs of more varied heights, extra handrails, and ultra-low beds.[xliii] These all had plausible theoretical mechanisms and had been drawn directly from the circumstances of falls reported within the hospitals pre-intervention. In contrast, an unsuccessful intervention (Van der Helm et al. 2006) noted that although some significant trip hazards were identified early in the intervention (trailing cables and a threshold between bays and toilets) management would not release funding to address them, which may have demoralised the nursing staff and reduced their motivation in relation to other aspects of the intervention. This would tend to suggest that whilst all the environmental modifications undertaken by Barry et al. (2001) and Fonda et al. (2006) have plausible direct mechanisms for reducing falls or injury, they may also have had an indirect benefit in terms of making ward staff believe that management were committed to falls prevention.

The components that were more likely to be provided in *unsuccessful* interventions were patient information (55% v. 20%), bedside signs (45% v. 20%), alert wristbands (36% v. 20%), exercise (9% v. 0%) and movement alarms (36% v. 20%). Finding that patient information is a component of unsuccessful interventions is not surprising given there is no evidence of effectiveness in community settings (Gillespie et al. 2009) and many hospital

[xliii] Standard hospital beds in England and Wales can usually be lowered so the mattress top is within 30-48cm above the floor. Ultra-low beds can lower flush to the floor, with the mattress top only around 20cm above floor level.

inpatients will be too ill or confused to read or retain information (although providing clear information to patients remains important in terms of patient involvement irrespective of effectiveness). The inclusion of bedside signs and alert wristbands as a component of unsuccessful multifactorial interventions is also consistent with the unsuccessful single or dual intervention studies that used this approach (Barrett et al. 2004, Mayo et al. 1994, Murphy et al. 2008, O'Connell et al. 2001). The evidence from single intervention studies of movement alarms discussed above (Kwok et al. 2006, Sahota et al. 2009, Shorr et al. 2010, Tideiksaar et al. 1993) is not consistent, and this inconclusive pattern is reflected by their inclusion as components in both successful and unsuccessful multifactorial interventions.

The proportion of studies with staff education as a component was similar (55% of unsuccessful interventions and 60% of successful interventions) but the intensity of the education appeared greater in successful interventions (e.g. Stenvall at al. 2007). Hip protectors were used in 20% of successful interventions and 18% of unsuccessful interventions, but none demonstrated a change in hip fracture rates.[xliv]

Of the components applied in opposing directions, it is notable that Fonda et al.'s (2006) study which discouraged the use of vest and belt restraints saw a significant reduction in falls, whilst Van der Helm et al. (2006) which encouraged their use did not. It appeared that studies with a requirement of either routine bedrail removal (Schwendimann et al. 2006a) or routine bedrail use (Uden et al. 1999, Van der Helm et al. 2006) were equally unsuccessful. Our RCT encouraged a review of risk versus benefit which, based on the evidence on bedrails that will be discussed later in Chapter 3, is likely to be a more appropriate approach.

It may also be notable that the number of components in successful multifactorial interventions appeared higher (80% had six or more components compared to only 9% of the unsuccessful interventions). Our own RCT had nine interventions (see Appendix A) which was a higher number than any other study with the exception of Fonda et al. (2006). Higher numbers of interventions may plausibly be required given the complex range of risk factors present in hospital patients (Oliver et al. 2006). Depth and intensity of components also appeared to be greater in the successful interventions (e.g. the intensive staff training

[xliv] Barry et al. (2001) only described total fractures, not solely hip fracture.

described by Stenvall et al. (2007), and the wide-ranging improvements to the environment made by Fonda et al. (2006)).

2.6.2.5 Other aspects of design

As discussed in Chapter 2.2.5, MRC (2009) guidance suggests that for complex interventions a careful description of the intervention components is vital for replication. Although it may be a publication rather than design effect (since authors may not feel it necessary to describe in any detail interventions that were not successful) all five of the successful interventions, including our RCT, described the components of their intervention in some detail, whilst only two of the eleven unsuccessful interventions (Schwendimann et al. 2006a, Vassallo et al. 2004) did so.

MRC (2009) guidance also suggests process measures are important to shed light on whether components failed to produce effects because they were not actually implemented, or whether they were consistently implemented but proved ineffective. Other than Oliver et al. (2002) (who noted poor levels of compliance with initial assessment and nursing and medical review), Koh et al. (2009) (who noted exemplary compliance with written assessment formats) and Schwendimann et al. 2006a (who noted poor levels of compliance with hip protectors), none of these trials collected process measures.

Qualitative data (e.g. interviews with staff or patients) would also be a useful source, although the unsuccessful studies tended to speculate on barriers to successful implementation e.g. *"it remains unclear if this can be explained by lack of commitment…insufficient knowledge…or communication skills"* (Schwendimann et al. 2006a p.75) and successful studies tended to speculate on reasons for success e.g. *"we attribute the success of our project to looking at aspects of the total system…interventions were identified, owned and adhered to by the staff themselves"* (Fonda et al. 2006 p. 381).

Additionally, for complex interventions a formal pilot stage would normally be preferred (MRC 2009). Only one of the studies (Schwendimann et al. 2006a) describes a formal pilot stage later described in a separate paper (Schwendimann et al. 2006b).

2.6.2.6 Application and costs of individualised multifactorial intervention studies

In addition to *what* interventions are applied, who they are applied to and who they are applied by may also be important. Differences in targeting of patients, involvement of different professional groups and the respective roles of ward and research staff, are described in Table 2f below. Costs of applying the interventions are also pragmatically banded.

TABLE 2f: Application of sustained multi-factorial falls prevention studies in hospitals 1995 - 2009

KEY:
UN = not described in original paper
Cost estimates:
Low = some equipment costs (e.g. hip protectors, slippers, alarms) for a limited proportion of patients or very minor environmental modifications
Moderate = more extensive environmental modifications and furniture purchase,
High = additional professional staff applying intervention up to 1.5 WTE per ward
Very high = additional professional staff applying intervention over 1.5 WTE per ward

Reference	Mean age	Mean length of stay	Cost estimates	Use of risk score	Assessment carried out by	Intervention carried out by	Professionals involved	Statistically significant reductions in falls or injuries? (see Tables 2a & 2c for detail)
Barry et al. 2001	>80	> month	Moderate	No	Ward staff	Ward staff	Multi-professional	Yes injuries
Fonda et al. 2006	>80	< month	Moderate	Local	Ward staff	Ward staff	Multi-professional	Yes falls Yes injuries
Healey et al. 2004	>80	< month	Low	No	Ward staff	Ward staff	Multi-professional	Yes falls
Stenvall et al. 2007	>80	> month	Very high	No	Research and ward staff	Research and ward staff	Multi-professional	Yes falls
Von Reteln-Kruse & Krause 2007	>80	< month	Low	STRATIFY	Ward staff	Ward staff	Multi-professional	Yes falls
Barker et al. 2009	<70	< week	Low	STRATIFY	Ward staff	Ward staff	Multi-professional	Possibly injuries
Brandis 1999	<70	UN	Low	No	Ward staff	Ward staff	Nursing only	No
Cumming et al. 2008	70-79	< month	High	No	Research staff	Ward staff	Nursing and Physiotherapy	No
Grenier-Sennelier et al. 2002	70-79	> month	Low	Local	Ward staff	Ward staff	Nursing only	No
Koh et al. 2009	UN	UN	Low	Local	Ward staff	Ward staff	Nursing only	No
Krauss et al. 2008	<70	UN	Low	No	Ward staff	Ward staff	Nursing only	No
Oliver et al. 2002	>80	UN	Low	STRATIFY	Ward staff	Ward staff	Multi-professional	No
Schwendimann et al. 2006a	<70	< month	Moderate	Local	Ward staff	Ward staff	Multi-professional	No

Reference	Mean age	Mean length of stay	Cost estimates	Use of risk score	Assessment carried out by	Intervention carried out by	Professionals involved	Statistically significant reductions in falls or injuries? (see Tables 2a & 2c for detail)
Uden et al. 1999	70-79	> month	Low	No	Ward staff	Ward staff	Nursing only	No
Van der Helm et al. 2006	>80	< month	Low	Local	Ward staff	Ward staff	Nursing only	No
Vassallo et al. 2004	>80	< month	Low	Downton	Ward staff	Ward staff	Multi-professional	Possibly fallers

Table 2f suggests that it is difficult to demonstrate success in a younger hospital population with a shorter length of stay. All the successful studies were applied to a patient group with a mean age of 80 years or more and a mean length of stay of 19 days or more, including our RCT where mean length of stay in the intervention group was 21 days and the mean age was 81 years. Cumming et al. (2008) suggest their patients' *median* length of stay of seven days was the reason their study was unsuccessful (although this suggestion is less convincing given the *mean* length of stay in the rehabilitation wards they included was 17 days). However, patients' age and length of stay are almost certainly interlinked; age over 80 years is clearly associated with higher falls rates in hospital patients (Healey et al. 2008a), and increased age will generally be associated with more complex illness and longer lengths of stay (Hospital Episode Statistics 2007). Therefore, in terms of research design, it is probably easier to design studies with adequate power in older patient groups due to their higher rate of falls, but fortunately this is also the population for whom falls are likely to have the most serious consequences and therefore where evidence of effective falls prevention strategies has the most clinical value.

In addition, studies differed in whether their multifactorial intervention was further targeted to a subset of patients. A range of approaches were used. In two of the successful studies (Barry et al. 2001, Stenvall et al. 2007) the intervention was applied to all patients from admission onwards. This was also the approach used by Cumming et al. (2008) but without success. This apparent contradiction might relate to the very different populations in these studies; applying a multifactorial intervention to all of a very vulnerable group, such as patients admitted with a fractured neck of femur in Stenvall et al. (2007) appears clinically appropriate, and given the prolonged length of stay (a mean of around 200 days) and low turnover of Barry et al.'s (2001) patients, applying it to all patients was manageable. However, doing the same in a general elderly care setting (as in Cumming et al. (2008)) may divert too much of a limited staff resource to patients who were never likely to fall. Our own RCT sought to focus resources on the most vulnerable patients by applying the intervention to those who had fallen before or after admission or come near to falling, although the expectation was that staff knowledge and practice triggered by the core care plan was likely to extend beyond this group to their patients in general.

Given the discussion above in Chapter 2.2.3 about the validity and utility of falls risk prediction tools, whether they were used to target interventions in successful falls prevention studies is of particular interest. As shown above in Table 2f, a risk prediction tool was used in only two of the five successful studies (Fonda et al. 2006, Von Reteln-

Kruse & Krausse 2007) with the former using a locally devised unvalidated risk prediction tool and the latter a modified version of STRATIFY (Oliver et al. 1997). However, in Fonda et al. (2006) almost all the components of the multifactorial intervention were made available to all patients (e.g. environmental improvements) or on the basis of need (e.g. early assistance with eating for dependant patients). In the latter (Von Reteln-Kruse & Krausse 2007) the risk prediction tool was combined with a list of suggested interventions which appear to have been provided where appropriate regardless of risk score (e.g. footwear, bedside commode). The unsuccessful studies also present a mixed picture, with five using locally devised risk prediction tools, two using validated risk prediction tools, and four not using any risk prediction tool. It therefore appears that the use of a risk prediction tool is not an essential part of a successful falls prevention intervention, but the success of the two studies (Fonda et al. 2006, Von Reteln-Kruse & Krausse 2007) that used a locally devised risk prediction tool that had never been validated or a tool whose total predictive value is known to be weak (STRATIFY as reviewed by Haines et al. 2007) would tend to support Oliver's (2008) suggestion that their value lies more in raising staff awareness than in their intended purpose of predicting which patients are most likely to fall.

In terms of staff groups involved in applying the interventions, the differences between successful and unsuccessful studies appear unambiguous. Having multi-professional involvement appears essential; no studies which focused solely on changing nursing practice succeeded in reducing falls or injuries, and all the successful studies, including our RCT, reported the involvement of at least nursing, medical and therapy staff (see Table 2f above). This is congruent with the apparent importance of medication review and post-fall reviews as a component of successful multifactorial interventions. It also echoes the findings of Cameron et al.'s (2010) systematic review of falls prevention in care homes, which found that multidisciplinary interventions in care homes may be effective in reducing falls and femoral fractures but that nurse-only interventions were not. It also appears an approach of visiting specialists carrying out assessments, with most interventions left to ward staff to implement (as in Cumming et al. 2008), is unlikely to prove effective, perhaps because of the dynamics of ownership and the relative workload involved.

Costs of the studies are pragmatically banded in Table 2f above. A detailed economic analysis is not possible due to lack of detail provided, but it is likely improvements to the environment and furniture, as in Fonda et al. (2006), would find it easier to demonstrate a cost benefit because the initial costs of the improvements could be balanced with benefit to patients over years to come. When extra staff are an integral part of the intervention (rather than used solely to collect data for analysis) this may be more difficult, but even a high cost intervention such as the extra nursing, therapy, and dietetic staff in Stenvell et al. (2007) may be able to demonstrate a cost benefit when not only falls and injury prevention but the substantially reduced length of stay they observed is taken into account. Cummings et al.'s (2008) study suggests that high cost interventions do not, however, guarantee success, perhaps particularly if the resource is focused on assessment rather than intervention. Perhaps more importantly for generalisation to a health economy always under financial pressure, Barry et al. (2001), Fonda et al. (2006), and our RCT (Healey et al. 2004) indicate that interventions with only low or moderate costs can be successful.

2.7 CONCLUSIONS OF SYSTEMATIC REVIEWS

There have been five recent systematic reviews focusing on the prevention of falls and falls injuries in hospitals, two that looked only at hospital studies (Coussement et al. 2008, Stern & Jayasekara 2009) and three that reviewed studies from hospital and long term care facilities (Cameron et al. 2010, Oliver et al. 2007, Robertson & Campbell 2008). All the studies included in any of these reviews have been included in Tables 2a and 2c above, and now I will discuss the inclusion strategy, analysis, and conclusions of each of these systematic reviews.

Oliver et al. (2007) did not restrict their search to RCTs but also included studies of non-randomised design where the data allowed comparison of falls or fracture rate ratio or relative risk of being a faller. Their search covered any studies published by January 2005 and adjusted for clustering. Eleven studies of multifactorial interventions[xlv] in hospital were included (including our RCT) with a pooled effect of an 18% reduction on falls rates on meta-analysis that just reached statistical significance (combined rate ratio 0.82 95% CI 0.68 to 0.997). No significant effects on fracture rate ratio (0.59 95% CI 0.22-1.58) or relative risk of being a faller (0.95 95% CI 0.71-1.27) were identified. Although the review included three studies of single or dual interventions in hospitals, there was no consistent evidence for any of the interventions included (bedrail removal, medication review, exercise and flooring materials). The fact that meta-analysis included some studies which were not RCTs attracted critical comment (Cameron and Kurle 2007) despite Oliver et al.

[xlv] Mayo et al. (1994) appears to have been misclassified as a multifactorial intervention rather than a single intervention, but given its increase in falls post-intervention and small size (N=134) removing it from analysis is likely to only marginally increase the pooled reduction.

(2007) making the case for including these because of the difficulties in performing RCTs of falls prevention in hospitals (See Chapter 2.2.5).

Coussement et al. (2008) included studies published by June 2006, and their inclusion criteria, as in Oliver et al. (2007), allowed the inclusion of studies with parallel or historical controls. However, most of the before-and-after studies identified by Oliver et al. (2007) were not included, perhaps because of a slightly different search strategy. They identified one additional study to Oliver et al. (2007) due to their later cut-off date (Schwendimann et al. 2006a) and one older small RCT (Tideiksaar et al. 1993) not included by Oliver et al. (2007). In total they included eight studies. Four were studies of single or dual interventions, with no significant effects noted except in Bischoff et al.'s Vitamin D study (2003), where patients had a length of stay of several years and which therefore might be better considered as a care home study. Four were studies of multifactorial interventions, including our RCT (Healey et al. 2004). Despite pooling only four studies, rather than the eleven pooled by Oliver et al. (2007), Coussement et al. (2008) identified the same rate ratio of 0.82, although the confidence intervals (95% CI 0.65-1.03) indicated this was not statistically significant. The pooled effect on relative risk of being a faller was also non-significant (0.87 95% CI 0.70-1.08).

Robertson & Campbell (2008) included only RCTs in their systematic review, with the cut-off date for inclusion unclear but apparently extended at least until 2008 given the dates of included studies. They identified five RCTs of single or dual interventions and three of multifactorial interventions, including our RCT (Haines et al. 2004, Healey et al. 2004, Stenvall et al. 2007). They pooled only Haines et al. (2004) and our RCT (Healey et al. 2004) for meta-analysis[xlvi] and found a significant pooled rate ratio[xlvii] of 0.69 (95% CI 0.54-0.88).

Stern & Jayasekara (2009) in a literature review completed for the Joanna Briggs Institute in Australia included five RCTs and two sub-group analyses of RCTs, including four RCTs of multifactorial interventions (Cumming et al. 2008, Haines et al. 2004, Healey et al. 2004,

[xlvi] They state *"For the trials in a hospital setting, data were not available or interventions were too dissimilar for pooling, except for two trials testing a multifactorial intervention"* (p. 40). On these grounds, their exclusion of Stenvall et al. (2007) is rather puzzling as it had well-described data and, as an individualised multifactorial intervention in an acute/rehabilitation setting focused on patients with a history of falling, it had more similarities with our RCT than Haines et al.'s (2004) standardised intervention focused on exercise in a rehabilitation hospital.

[xlvii] Although Figure 6 (p. 39) is entitled relative risk it is clearly rate ratio of falls from the data included.

Stenvall et al. 2007). Although the stated intention was to describe RCTs in acute hospitals, three of the studies included were from sub-acute hospitals. The findings of their meta-analysis are only available to subscribers, but they concluded that there is some evidence to support the use of multifactorial interventions.

The nature of the updated Cochrane Review (Cameron et al. 2010) means that this was limited to controlled studies. Eleven hospital-based studies were included. For multifactorial interventions, they pooled four RCTs including our RCT (Cumming et al. 2008, Haines et al. 2004, Healey et al. 2004, Stenvall et al. 2007) for meta-analysis, and demonstrated a significant reduction in falls rate ratio (0.69, 95% CI 0.49, 0.96) and also for relative risk of being a faller (0.73, 95% CI 0.56-0.96), although they conclude that these interventions may only be effective for patients with longer lengths of stay. This conclusion appears to relate mainly to Cumming et al.'s (2008) null result, which as discussed above could be explained by the lack of medical involvement, the unclear nature of the interventions, and the use of visiting specialists, rather than solely by their patients' length of stay. For exercise the Cochrane Review pooled Barreca et al. (2000), Donald et al. (2004) and Jarvis et al. (2007) and conclude that exercise may be effective in hospital (relative risk of being a faller 0.44, 95% CI 0.20-0.97) but attach a cautionary note given the small pooled size of the studies (N=131) and poor quality of Donald et al. (2004). There was no clear evidence around any other single intervention. The categorisation of Haines et al. (2004) as a multifactorial intervention rather than an exercise intervention is probably key to their findings; had this been categorised as an exercise intervention (as discussed in Chapter 2.6.1.4) the pooled rate ratio for multifactorial interventions may have been less significant and the effect of supervised exercise may have appeared more significant.

To summarise, despite their differing inclusion criteria and the addition of more recently published studies in the latest reviews, these four systematic reviews are surprisingly consistent in their findings, all suggesting that in acute hospitals no single interventions are fully supported by current evidence, and that multifactorial interventions may reduce falls by 18% to 31%. However, their differences in inclusion criteria, and the addition of further studies as they are published, appears to modify pooled 95% confidence intervals for falls rate ratios in multifactorial studies marginally to either side of the borderline of statistical significance. The importance of our RCT in the field of hospital falls prevention is emphasised by its inclusion in meta-analysis in all these reviews.

2.8 DIRECTIONS FOR FUTURE RESEARCH

The number of research studies of hospital falls prevention published to date is small, and although the evidence for individualised multifactorial interventions is promising, it is not yet compelling. The priority for future research appears to be high quality and adequately powered studies of individualised multifactorial interventions (rather than small studies unlikely to be powered to detect significant effects, or before-and-after studies that make no attempt to assess for potentially confounding changes in their inpatient population). In line with the MRC (2008) recommendations on complex interventions (discussed earlier in Chapter 2.2.5), these studies should be designed to collect process measures that would help to shed light on the components actually delivered in the clinical setting and their plausible clinical mechanisms. For example, the impact of components aimed at reducing delirium should be assessed through collecting information on levels of confusion and agitation, in addition to outcome data on falls. Measures to assess any adverse effects of falls prevention, particularly an overly risk-averse approach that restricts independence and dignity, are also critical. If studies apply high-intensity interventions which involve the appointment of additional staff, inbuilt modelling of cost benefit is essential to make the economic case for their wider implementation.

Future falls prevention studies should also aim to respond to Pope and Mays' (2009) appeal for quantitative studies to truly integrate qualitative elements. Understanding the perceptions of staff and patients – through meaningful in-depth interviews or focus groups rather than brief or superficial discussions - could assist with effective design of both the intervention and the implementation strategy. Ethnographic observation could explore any cultural or practical issues that might explain success or failure of implementation. Appropriate analysis and integration of the quantitative and qualitative findings may be useful to explain otherwise inexplicable results (for example, interviews with staff and patients may have identified a plausible explanation for the significant reduction in upper limb fractures seen in Kannus et al.'s (2000) hip protector trial).

Some single interventions merit further investigation. The most promising is medication review, especially reviews focused on psychotropic medication. The research questions include identifying the optimum methodology of implementing medication review, such as the respective roles of prompts in computerised prescribing systems, pharmacist advice, and the education of nurse and medical prescribers. Special observation and companionship, whether in small groups or as one-to-one observation, and whether carried out by volunteers or paid staff, is also an area meriting further research. For slower stream rehabilitation settings, research to replicate and refine the exercise intervention successfully trialled by Haines et al. (2004) would be of value.

Of the technological innovations, further studies of movement alarms are needed to shed light on the contradictory results of earlier studies, and the effect of ultralow beds needs to be explored. More research is required to assess what general environmental improvements are beneficial, and a particularly valuable approach would be studies designed to assess which environmental improvements would secure the most cost benefit, so limited funds can be directed to where they will have the greatest effect. Studies of lower impact flooring also merit research.

Some interventions are not priorities for research. Further research into alert wristbands or bedside alert signs is unlikely to overturn the consistently null results from previous studies. Given the challenges of research in hospital inpatients, hip protector studies in this setting could not be justified unless convincing evidence of effectiveness emerged from care home or community settings.

Some modifiable risk factors have high prevalence in hospital inpatients but have rarely been addressed by single or multifactorial interventions. These include delirium, often superimposed on poorly recognised and managed dementia (British Geriatrics Society (BGS) 2006). Delirium and dementia impact not only on risk of falls, but on morbidity and mortality. Because of this, they may be best researched in studies where interventions aim to improve their prevention, detection, treatment, and management, with primary outcome measures related to morbidity, mortality, and reduced distress, and with falls as a secondary outcome measure.

Perhaps the most important area for future research, given the levels of fractures and death from falls sustained in community settings (Gillespie et al. 2009), is research that encompasses the patient journey from hospital to community. Potential areas for research include interventions to detect conditions such as impaired vision, osteoporosis, and Vitamin D deficiency during hospital admissions and to initiate investigations and treatment that may result in reduced risk of falls after discharge home. Because stays on rehabilitation wards are rarely long enough for an effective falls prevention exercise programme, integrated exercise programmes initiated during an inpatient stay and continued after discharge also merit research.

Additionally, research is needed into how successful interventions can best be implemented and sustained. Qualitative investigation of leadership, teamwork, patient perspective, staff involvement, and managerial support may be fruitful areas for exploration.

2.9 CONCLUSION

Designing research on falls prevention in hospitals is challenging but important, since research on falls prevention in the community and in care homes cannot be directly generalised to hospitals. Prior to our RCT, most research effort had been focused on devising numerical tools that might predict the hospital patients most likely to fall, and only 14 falls prevention studies had been published prior to 2004, many of which were small and of poor quality. None of these studies described convincing and significant reduction in falls rates, and only one study (Barry et al. 2001) described a significant reduction in injuries and fractures.

The interventions in our RCT were based on known risk factors for falling in hospital environments, and also drew on clinical experience and improvement methodology. As the first RCT of multifactorial interventions in an acute hospital environment, the significant reduction we identified in falls rate in the intervention units was of great clinical importance. Strengths of our study included its cluster randomised design, its size, the multidisciplinary nature of the intervention, the similarity of control and intervention wards in terms of environment, staffing, and patient characteristics, and the presentation and analysis of outcome data. Areas where intervention and control groups differed, including length of stay and falls rates, were appropriately described and discussed. Limitations (that our study shared with almost all prior and subsequent hospital falls prevention studies) included inadequate power to detect changes in injury rates and reliance on falls reported by staff. Our RCT would have been strengthened if we had also had capacity to collect data on compliance with the individual components, to analyse at the level of fallers and time to first fall, and to collect qualitative data on any problems staff experienced in implementation.

From 2004 to 2009, 24 further studies of hospital falls prevention were published. Despite promising results from some studies of exercise in rehabilitation settings and of medication review, no convincing evidence was identified for any single intervention. In addition to our

RCT, four other studies of multifactorial interventions described significant reductions in falls rates or injuries. Examination of the components of successful and unsuccessful studies suggest that our RCT included most of the components seen more frequently in successful studies, including post-fall reviews, medication review, screening for urinary tract infection, toileting plans and footwear provision. Our approach of interventions applied by ward-based multidisciplinary teams was also the approach seen most frequently in successful studies. Our RCT was included in all subsequent systematic reviews and contributed to meta-analysis indicating multifactorial interventions can successfully prevent falls in hospital inpatients, but further research is required to identify the most effective combination of components and how these can best be implemented and sustained.

CHAPTER THREE: A SYSTEMATIC REVIEW OF BEDRAILS

3.1 INTRODUCTION

In this chapter I will focus on our paper 'The effect of bedrails on falls and injury: a systematic review of clinical studies' (Healey et al. 2008b). As outlined in earlier chapters, the key focus of my doctoral statement is on falls prevention in hospital settings, and therefore evidence from care homes or the community will be examined only where it is reasonable to expect it to be generalisable to hospital settings. Because the mechanism of falls from bed and the consequences of falls from bed would be expected to be similar wherever a patient is located, any such studies carried out outside hospital settings will be included in this discussion.

After briefly describing and defining bedrails and exploring the issue of whether bedrails are restraint devices, I will describe how patterns of bedrail use in healthcare settings have changed across the 20th century, including contrasting practice between UK and international healthcare systems. The influence on bedrail use of changes in legislation and litigation, of changes in ward layouts, and of changes in designs of hospital beds and mattresses will also be discussed, as will the divergence between international and UK nursing practice.

The relevance and importance of bedrail use in the context of hospital falls prevention will be outlined in terms of the evidence of harm associated with both falls from bed and with bedrail entrapment or bedrail failure. Patients' and relatives' views on bedrails will also be explored.

I will then discuss key findings from researchers prior to our systematic literature review, including systematic reviews of restraint devices which encompassed bedrails, and earlier semi-systematic or descriptive literature reviews of the effect of bedrails, and examine why these came to different conclusions to our review. To create an overview of the strongly negative approach to bedrails in the literature prior to the publication of our systematic literature review, I will also examine opinion-based publications on bedrails, as these demonstrate attitudes that are relevant to the discussion on interpretation of the evidence.

Having created a picture of the evidence and opinions present in the literature prior to the publication of our systematic literature review, I will briefly describe why the review was undertaken as part of a national project on bedrail safety. I will then go on to discuss the strengths and weaknesses of our systematic literature review.

I will then, most importantly, undertake a discussion of the commonalities and differences between the evidence presented prior to our systematic literature review, and the evidence within it. This will include detailed examination of why the opinions previously expressed in the literature had become so detached from the actual evidence, drawing on a range of potential explanations.

I will also examine direct responses to our systematic literature review in the form of journal letters, and summarise key findings from research published subsequently. Finally, I will indicate what our systematic literature review has added to the understanding of the issue, including the implications for clinical practice. I will close this chapter with suggested directions for future research.

3.2 BEDRAILS: TERMINOLOGY AND DEFINITIONS

Bedrails (also referred to as side rails, cotsides, or safety rails) are marketed as safety devices to reduce patients' risk of slipping, sliding, rolling or falling from bed (MHRA 2006). Whilst some patients may use bedrails to assist themselves in changing their own position or as a convenient hanging point for personal items (Gallinagh et al. 2002a) they are not designed for this purpose (MHRA 2006). There are several different designs used in healthcare settings, with varied heights and lengths. Designs include vertical and horizontal metal rails. Gaps between the rails are usually left open but sometimes filled with plastic shields, Perspex sheets, or elastic mesh, or covered with fabric or plastic padding (MHRA 2006). They may consist of one rail chapter attached to each side of the bed (bilateral or traditional bedrails) or consist of two separate chapters on each side of the bed (spilt-sided bedrails) (MHRA 2006). They come as standard attachments on some beds or as optional fixtures on others (see Figure 3a below).

FIGURE 3a: Some variations in bedrail design

Perhaps because of the ubiquitous nature of bedrail use, and their continued use in domestic furniture as well as in healthcare settings, there appears to be no standard definition of the term ‘bedrail’. For the purpose of this doctoral statement, bedrails are defined as temporary or permanent attachments to the side of beds in adult healthcare settings which rise higher than the surface of the mattress and extend for between a quarter and all of the length of the bed sides but do not completely surround the bed. This definition excludes ‘grab rails’ which are handholds extending for only about one-tenth of the length of the bed sides, and USA ‘total enclosure’ equipment that completely surrounds the foot, head and sides of the bed (see Figure 3b below).

The use of restraint in healthcare settings is controversial, and many papers on bedrails have automatically categorised bedrails as restraint. Restraint may be defined as *“the intentional restriction of a person’s voluntary movement or behaviour”* (Australian Council for Safety and Quality in Healthcare (ACSQH) 2005 p. 37) or *“stopping them from doing something they appear to want to do”* (Royal College of Nursing, 2008 p. 2). Using these definitions, bedrails used to stop a patient purposefully leaving their bed would be restraint, but used to prevent an accidental fall from bed, they may not be. Whether bedrails constitute restraint is further confused by differences in terminology between countries. In the UK the usual form used is the verb, for example *“we restrained the patient”* and the term encompasses physically holding an agitated or violent patient, or the use of sedating medication, as well as the use of equipment to control voluntary movement or behaviour (Royal College of Nursing, 2008). In the USA, restraint is usually used as a noun to describe a device marketed to restrain a patient, for example *“the patient is in a restraint”* and in some states legislation specifies that bilateral bedrails are a restraint (Brush & Capezuti, 2002). This automatic definition can distance the terminology of restraint from the ethics associated with restraint use as, by such definitions, bilateral bedrails supplied even to an unconscious patient would be defined as restraint, whilst pushing one side of a bed against the wall and raising a bedrail on the other side to stop an active patient who wants to get out of bed from doing so may not be defined as restraint.

USA terminology potentially creates additional confusion, as the tendency is to use the term 'restraints' not only to describe bedrails but to describe a range of devices marketed to restrain patients in beds or chairs, including vests, belts, cuffs, and harnesses (see Figure 3b). The use of these devices in some healthcare settings outside the UK is routine (Brush & Capezuti 2002, Evans et al. 2003, Hoffman et al. 2003, Retsas 1997, Retsas & Crabbe 1997, Retsas 1998, Tinetti et al. 1995).

FIGURE 3b: Vest, belt, cuff and harness restraint devices and 'total enclosure' bed equipment

All images taken from www.posey.com accessed 18/2/10

For clarity, this doctoral statement will use the term restraint to refer to the action of intentionally restricting *"a person's voluntary movement or behaviour"* (ACSQH 2005, Healey & Stephenson for NPSA 2007b, Royal College of Nursing 2008) and use the term 'restraint devices' when referring to vest, belt, cuff, harness and chair devices used to control patients' behaviour.

3.3 BEDRAILS: THE HISTORICAL CONTEXT

An appreciation of the historical patterns of bedrail use in healthcare settings across the 20th century is important to the understanding of current practice. The historical context is also important to understand contrasting practice between UK and international healthcare systems.

3.3.1 The emergence of bedrail use in hospital settings

Domestic beds with bedrails rising higher than the mattress surface have survived from the medieval period (Wright 2004) although the rails were intended as much to stop bed coverings as bed occupants from falling to the floor. High sided wooden 'cribs' were used for adults in 18th century asylums (Wright 2004). Photographic archives suggest 'cot beds' – iron bedsteads where the rail was an integral part of the bed - were used in 19th century hospitals and workhouse infirmaries in the UK (Higgs 2007). A historical analysis of bedrail use (Brush & Capezuti 2001) based on sources such as hospital equipment catalogues, suggests that bedrails as a separate detachable piece of equipment only became available in the USA in the 1930s. Litigation cases related to fatalities from failure to use bedrails (implying their use had become considered the norm) were recorded in the USA in 1940 (Potter et al. v. Dr WH Groves cited in Brush & Capezuti 2001) and in 1941 (Pennington v. Morningside Hospital cited in Brush & Capezuti 2001).

It is unclear when bedrails as a separate detachable piece of equipment came into use in the UK, but it is likely to have been at a similar time as their emergence in the USA. No formal surveys of levels of bedrail use could be located before the late 20th century, although Brush & Capezuti (2001) suggest that by the 1950s their use in all patients over the age of 65 years in the USA was standard, and some hospitals required bedrails fitted to every bed. Raising bedrails for all older patients in USA hospitals continued to be described as standard practice well into the 1980s (e.g. Catchen 1983, Rubenstein et al. 1983). In the UK anecdotal descriptions of levels of bedrail use can be identified from the

1980s; a commentary from *The Lancet* suggested that *"in Britain…cotsides are rarely and selectively used"* (anon, 1984, p. 383). This description appears contradicted by articles from nursing publications of the same era (e.g. Watson & Brunton 1990) which described raised bedrails on every bed of elderly care wards in a UK setting. Formal studies describing levels of bedrail use in care homes and hospitals in the UK and internationally appeared from the 1990s onwards, and will be explored in more detail later in chapter 4.2.

3.3.2 The influence of restraint devices on bedrail use

Although, as described earlier in Chapter 3.2, the use of vest, belt, cuff and harness devices marketed for the purpose of restraining patients in beds or chairs is commonplace in healthcare settings in most countries in the developed world, it is not part of healthcare practice in the UK. This has been demonstrated through observational surveys (O'Keeffe et al. 1996, Healey et al. 2009) and through UK nursing guidance (RCN 2008). The MHRA monitors the quality and safety of medical devices but has never had an application to approve any harness, vest or belt restraint devices in the UK (personal correspondence). The MHRA has not actively banned such devices, simply not needed to assess their quality and safety as they were not being manufactured in the UK or imported for sale in the UK (personal correspondence). The reasons for the difference in practice between the UK and most other developed countries are unknown; it appears to arise from nursing culture, custom and practice (O'Connor 1998) rather than official guidance, since the earlier editions of RCN guidance on restraint (RCN 1996, RCN 1999, RCN 2001) barely mention such devices.

The UK's apparent freedom from purpose-made vest, belt or harness restraint devices would not, however, exclude the use of restraint devices improvised from bandages or belts. In addition, the MHRA would not be in a position to monitor individually imported restraint devices if ordered via international websites. Chairs currently marketed in the UK as providing positional support or with fixed lap trays could also be misused as restraint. 'Buxton chairs'[xlviii] were undoubtedly widely used to restrain patients in UK settings in the

[xlviii] 'Buxton chairs' were wheeled armchairs with lap-trays which could be screwed into place across the chair's arms. They also had a tilt mechanism that allowed the whole chair to be tipped into a 45 degree reclining position.

1970s and 1980s, and 'cocoons'[xlix] were used at least occasionally in the late 1980s (Miller, 1989). However, despite the possibility of improvised restraint in the UK, the absence of any commercial market for restraint devices in the UK tends to suggest a much less restrictive and less risk-averse culture of care. This difference in culture might also extend to practice with bedrails.

3.3.3 The influence of changes in legislation and litigation on bedrail use

In the USA, legislation and litigation is considered to have been a key influence on bedrail use (Brush & Capezuti 2001). An early report on hospital insurance claims (Ludham 1957 cited in Brush & Capezuti 2001) noted claims awarded increased tenfold in falls that had occurred in the absence of bedrails, and urged hospitals to adopt policies of standard bedrail use for older or confused patients. Individual claims for injury after falling from beds without bedrails had a high profile in nursing publications in the USA throughout the 1970s, 1980s and 1990s (Brush & Capezuti 2001). During the1990s reports of deaths from bedrail entrapment also appeared (e.g. Miles 1996, Parker and Miles 1997, Todd et al. 1997). From 1987 onwards national legislation in the USA led to individual states developing licensing requirements on bedrail use for hospitals and nursing homes, generally requiring evidence of assessment of need and a written order from a physician for bilateral bedrail use (Braun & Capezuti 2000).

There are, however, marked differences in both the frequency of litigation and the financial consequences between the USA and the UK (Kessler, 2006). A review of almost eleven years of NHS Litigation Authority (NHSLA) data (Oliver & Healey 2006, Oliver et al. 2008) identified 108 claims relating to falls from bed, 70 of which were successful, and all of which were settled out of court. Thirty of the successful claims cited the failure to raise bedrails as the key element of the negligence claim, and resulted in damages and costs averaging around £14,000 per claim. Only three related to falls over bedrails, and these resulted in damages and costs averaging around £1,500 per claim.[l] Given the low numbers of claims, the low costs of claims, and the low public profile of the cases (not published in detail until 2008) they appear to have had little impact on practice in the UK.

[xlix] 'Cocoons' consisted of a duvet cover which could be zipped to a mattress cover, securing the patient rather tightly between their covers and their mattress. They were marketed as more ethical and dignified alternative to bedrails (Miller, 1989).

[l] The ratio of tenfold higher payouts for falls from bed without bedrails reported in the USA in 1950s (Ludham 1957 cited in Brush & Capezuti 2001) appeared replicated in the UK almost five decades later.

The first formal warning in the UK of the entrapment risk presented by bedrails (Department of Health 1994) predated the first formal warning in the USA (Food and Drug Administration 1995) and eight further alerts were issued in the UK at almost annual intervals between 1997 and 2004 by the Medical Devices Agency (MDA) and their successor organisation, the Medicines and Healthcare products Regulatory Agency (MHRA). Each alert (MDA 1997, MDA 1999, MDA 2000, MDA 2001, MDA 2002, MHRA 2004a, MHRA 2004b) related to different aspects of the risks of bedrail entrapment, such as inspecting for defective bedrails, removing two-bar bedrails, and checking the bedrail/mattress gap. There was no UK legislation equivalent to the USA federal inspection and licensing requirements on bedrails described above, but an increasing emphasis on clinical risk and clinical governance over the 1990s (Towse & Danson 1999), and the series of MDA/MHRA alerts led some hospital trusts to develop local policies on bedrail use. However, a survey of NHS organisations in London during 2001 indicated only 5% had any policy or protocol on bedrail use (Hughes 2002).

3.3.4 The influence of hospital ward, bed, and mattress design on bedrail use

The standard hospital ward design in the early 20th century was the 'Nightingale ward'[li] (Sloan-Devlin & Arneill 2003) which, although providing very little privacy, enabled high levels of observation, perhaps ensuring nursing staff were less anxious about falls occurring whilst a patient was unobserved. By 2001, 694 such wards were still in use across the NHS, with 165 remaining in 2006 despite political commitments to abolish them (Hansard 2007). However, moves to improve privacy and infection control led to the majority of UK wards being built in designs combining some single rooms with bays for four to six patients. Unlike the USA, where such designs were often accompanied by CCTV and decentralised nursing stations (Sloan-Devlin & Arneill 2003), UK designs tended to offer a single nursing station, with direct observation of only a minority of patients possible from it. In 2001 Department of Health guidance (NHS Estates 2001) required new hospital builds to aim for 50% single rooms. By 2006, 27.9% of beds across the NHS in England and Wales were in single rooms (Hansard 2007) and by 2009 the building of 100% single room hospitals had commenced in Glasgow, Gwent, and Maidstone (Public Health Journal, 2009).

[li] A 'Nightingale ward' consisted of two rows of beds arranged in straight lines facing each other, usually with between ten and fifteen beds in each row. All these beds would be visible from any point of the ward except when curtains or screens provided temporary privacy for washing, etc.

Over the 20th century, hospital bed design also evolved in ways which may have affected the likelihood of bedrail use. Around the early 20th century, domestic beds were normally about 50cm high (Mitchell et al 1998), but to reduce back strain to nurses carrying out patient care, the norm for hospital beds by the 1930s was about 70cm high (Brush & Capezuti 2001) with portable steps often needed for a patient to get out of or enter their bed. The greater potential for harm from falls from these higher beds may have provided the stimulus for the increasing use of bedrails which historically coincided with it (Brush & Capezuti 2001).

By the 1950s hospital beds with permanently attached bedrails could be purchased (Brush & Capezuti 2001) which may have made the routine use of bedrails more likely, but around the same period beds which could be adjusted in height to accommodate both patients' and nurses' needs also began to be marketed (Brush & Capezuti 2001). However, initial designs involved cumbersome cranking mechanisms, and easily adjustable beds with foot pumps became commonplace in UK hospitals only by the 1970s, with fixed height beds eliminated almost completely from general hospitals only as late as the 1990s (Mitchell et al. 1998). This increasing access to beds that could be returned to a fairly low height may have contributed to a less prescriptive attitude to bedrail use.

However, the design of beds began to diverge between the UK and the USA, perhaps due to the influence of the King's Fund bed specification in the UK (Mitchell et al 1998) and to different dominant hospital bed manufacturers. Whilst the lowest setting for adjustable beds in the USA tended to be around 46cm (Brush & Capezuti 2001) in the UK it was around 32cm (Mitchell et al. 1998).

By the late 1990s the concept of an ideal hospital bed had been abandoned (Mitchell et al 1998) with an acceptance that a range of bed types would be required for patients with differing needs. Electrical profiling beds that could be adjusted into sitting positions came into increasing use in acute hospitals in the UK over the 1990s, and around 80% of these were supplied with integral bedrails, usually of a two-piece split sided design which allowed the upper bedrail to rise with the bedbase when the patient was sitting up in bed (personal correspondence with manufacturers). Commentators speculated routine use might be encouraged by the permanent attachment of the bedrail (Gallinagh 2002a), but the split sides also introduced a new option of partial bedrail use rather than a simple choice between bedrails or no bedrails.

Concurrently, specialist mattresses which could increase the mattress height and reduce the surface stability came into use in the UK. Small-celled ripple mattress overlays and water-filled mattresses used in the 1960s were superseded by large-celled ripple mattresses, which may have been more effective (Bliss et al. 1967) but increased the height of the patient from the floor, which, together with the surface instability inherent in the alternating movement of the air-filled cells, meant bedrail use was a standard requirement. However, the use of such mattresses was limited due to their vulnerability to puncture and to mechanical breakdown. The use of alternating pressure mattresses and mattress overlays did not become widespread until improvements in design led to more reliable models becoming available in the UK from the late 1980s and early 1990's (Cullum et al. 2004). Because these designs had pressure-sensitive as well as alternating pressure functions (so they would deflate below the point where the patient's weight was concentrated, potentially precipitating any patient positioned off-centre out of bed) and could add extra height, bedrail use was usually a standard requirement. Indeed, alternating pressure overlays used on top of standard foam mattresses could create a mattress surface almost higher than the top of a standard UK bedrail, and higher bedrails appeared on the market as a consequence of this (MDA 2002).

Finally, towards the mid 1990s 'ultra low' beds, which could be lowered almost flush with the floor, became available in care home settings (Capezuti et al. 1999). 'Ultra low' beds with designs feasible for use in acute general hospital settings became available on the UK market in 2002 (personal correspondence with manufacturers).

In conclusion, changes in hospital ward layouts, bed design, mattress design, litigation and legislation may all have had an impact on bedrail use in the past, and future changes in these may continue to influence bedrail use. However, the impact of these factors varied considerably between the UK and other countries, meaning great care must be taking when applying international literature to a UK setting.

3.4 HARM FROM FALLS FROM BED AND HARM FROM BEDRAIL USE

<u>3.4.1 Evidence of harm from falls from bed</u>

In Chapter 1 I examined the evidence on numbers of falls in hospitals and their consequences. But how many falls in hospital are falls from bed?

The high proportion of falls that are unwitnessed (Healey & Scobie for NPSA 2007a), and patterns of care where hospital patients spend the majority of their time near their beds, make it difficult to conclusively distinguish between falls whilst walking or standing next to the bed and falls from bed. Sutton et al. (1995) and Morse (1996) estimate approximately one quarter of all falls in hospital or care home settings are from bed. Healey & Scobie for NPSA (2007a) estimated that of falls reported to the NPSA from hospitals in England and Wales during 2005/06, around 20% were falls from bed, leading to an estimate of around 43,600 (95% CI 33,205 - 56,348) falls from bed. However, this was almost certainly an underestimate given under-reporting of falls (see Chapter 1.4.2), the number of falls reports which are too brief to identify any circumstances of the fall (Healey & Scobie for NPSA 2007a), and increases in reporting as the NPSA's Reporting and Learning System matured (NPSA 2009).

Within the overall numbers of falls from bed described by Healey & Scobie for NPSA (2007a), 31.1% caused at least low harm (defined as needing first-aid level treatment) and 3.6% caused moderate harm (defined as needing an extended hospital stay for treatment). Evidence of the most serious harm was also identified through scrutiny of additional keyword samples. These indicated around 90 fractured necks of femur (95% CI 58-139) and two subdural haematomas had occurred in falls from bed. All reports of deaths in falls were reviewed, and eleven deaths were from falls from bed. However, given the nature of incident reporting systems, which tend to report the patients' condition shortly after the fall occurred, and the high mortality known to occur subsequent to hip fractures (Center et al. 1999), the reported number of deaths is likely to be an underestimate.

Three published papers provide some information on the proportion of falls occurring from bed, although definitions differ. Tan et al. (2005) identifies 38.2% (102/255) of all reported falls in an Irish acute hospital as falls whilst 'transferring to and from bed.' Van Leeuwen et al. (2001) identify 32.5% (136/419) of all reported falls in an Australian small specialist hospital as 'falls from bed'. Hanger et al. identified that 74.7% (592/792) of all reported falls in a New Zealand rehabilitation hospital were 'in the bedroom', and 52.8% (418/792) were 'around the bed'.

3.4.2 Evidence of harm from bedrail entrapment or bedrail failure

Direct harm from bedrails can be caused by contact injuries (body parts striking the bedrail), bedrail failure (falls to the floor when the bedrail breaks or becomes detached from the bed) or from bedrail entrapment (Hignett & Griffiths 2005). Bedrail entrapment occurs when body parts are trapped between components of the bedrail, or between the bedrail and the bed frame or mattress (MHRA 2006). Entrapments of limbs can cause injury through bruising or scraping as the patient attempts to extricate themselves, or through compromise of the circulation (MHRA 2006). The mechanism of fatal entrapments can involve direct asphyxiation through compression of the neck, through the face being held against the mattress and blocking the patient's airway, or through postural asphyxiation from compression of the chest (Parker & Miles 1997).

Our systematic literature review identified twelve studies (DiNunno et al. 2003, Everitt & Bridel-Nixon 1997, Gray & Gaskell 1990, Healey & Scobie for NPSA 2007a, Hignett & Griffiths 2005, Miles 1996, Miles 2002, Miles & Parker 1998, Parker & Miles 1997, Rubin et al. 1993, Todd et al. 1997, USA Food and Drug Administration 1999) that described direct injury from bedrails or injury in falls after bedrail failure, ranging from fatal entrapment to minor injuries. Most of these studies combined review of incidents in patients' own homes, nursing homes, and hospitals in the USA, and four of these (Hignett & Griffiths 2005, Miles 2002, Todd et al. 1997, USA Food and Drug Administration 1999) were overlapping studies drawing on different years of the same data collection. Most of these studies were poor at differentiating injury from bedrail failure from contact injuries and from injuries sustained through bedrail entrapment, but together these studies suggested around 20 deaths from bedrail failure or bedrail entrapment are reported each year in the USA.

Of these studies, only two were from the UK. Everitt & Bridel-Nixon's (1997) study identified eight direct injuries from bedrails in one year in an English teaching hospital, but their severity was not described. The NPSA analysis (Healey & Scobie for NPSA 2007a) used a random sample of 500 reports to estimate that around 1,250 direct injuries from striking limbs on bedrails or trapping limbs within bedrails were reported from England and Wales during 2005/06, predominantly involving minor injuries. However, even minor injuries to lower limbs can heal poorly in older patients and lead to long term ulceration (Coleridge-Smith 2006).

No papers on fatal bedrail entrapment in UK settings appear to have been published, but, over the seven years 2000–2006, the Medicines and Healthcare products Regulatory Agency (MHRA) received 252 reports of injuries or near misses involving bedrails (personal correspondence). These included 18 reports of deaths related to bedrail entrapment or bedrail failure in nursing or residential homes or the patient's own home (personal correspondence) and three reports of bedrail entrapment deaths in hospitals (Healey & Stephenson for NPSA 2007b). The Health and Safety Executive (whose data may overlap with the MHRA data) had six reports of injury from bedrail entrapment in hospitals over a three year period, including two upper arm fractures and a shoulder dislocation (Healey & Scobie for NPSA 2007a).

3.4.3 The balance of risks

Taking reported incidents in hospitals in England and Wales (the only setting for which data on falls and data on direct injury from bedrails are collected nationally) discussed above (Healey & Scobie for NPSA 2007a), and acknowledging the limitations of data derived from voluntary incident reporting (Sari et al. 2007), falls from bed appear to be to be responsible for more than one hundred injuries to every one injury caused by bedrail entrapment.[lii] At the level of fatalities, around twenty deaths from falls from bed are reported to every one death caused by bedrail entrapment,[liii] although given mortality subsequent to fractured neck of femur sustained in falls from bed (Center et al. 1999), the true ratio of fatalities from falls from bed to fatalities from bedrail entrapment may be considerably higher.

However, as will be outlined later in the discussion of our systematic literature review, this is not an either/or issue; fatal bedrail entrapment is not an inherent risk of bedrail use, but arises from poorly designed bedrails, incompatible combinations of beds, bedrails and mattresses, poor maintenance, and incorrect fitting of bedrails (USA FDA 2006, MHRA 2006).

[lii] Over twelve months of 2005/06, 35.3% of 43,600 falls from bed resulted in injury, and around 1,250 direct injuries from bedrails were reported (Healey & Scobie for NPSA 2007a).

[liii] Over twelve months of 2005/06, eleven deaths in from falls from bed (NPSA 2007a) in hospitals were reported, with three reported in seven years from fatal entrapment in hospitals (Healey & Stephenson for NPSA 2007b).

3.4.4 Patients' and relatives' perspectives on bedrail use

Many authors (e.g. Jehan 1999, O'Keeffe 2004, O'Keeffe 2009, Talerico & Capezuti 2001, van Leeuwen et al. 2001) suggest that bedrails cause psychological harm or distress to patients through feelings of entrapment or infantilisation, or to their relatives through creating a barrier to contact. These include telling anecdotes such as O'Keeffe's (2004) comment that *"it is not uncommon to see the sad and ludicrous situation of families trying to interact with dying patients through bedrails"* (p. 343). However, published research into patients' or their relatives' views on bedrails is limited to a handful of studies from UK settings, perhaps because outside the UK research has been predominantly focused on patients' perceptions of the vest, belt, cuff, harness and chair restraint devices used in most other countries (Mion et al. 1996).

Our systematic literature review identified only three studies that included patients' views on bedrails, two including relatives' views, and one including staff views. The largest of these studies (N=200) was a questionnaire based study described across two papers (Vassallo 2004, Vassallo 2005). The study explored the acceptability of a range of falls prevention measures and was carried out with a convenience sample of patients, relatives and staff in an English district general hospital. Bedrails, even in the context of *"using bedrails to make it more difficult for a patient to get out of bed"* (Vassallo 2005 p. 69)) were thought acceptable by 89.5% (51/57) of inpatients surveyed. Relatives' views of bedrails were very similar to patients' views, with 90.7% (39/43) stating bedrails used in this way were acceptable. Only 64% (64/100) of staff thought bedrails used in this way were acceptable, which was significantly lower than relatives or patients (p=0.001).

This study also provided useful data on the relative acceptability of bedrail use compared to other falls prevention measures. Combining results from patients, relatives, and staff (N=200) bedrails were seen as acceptable by more respondents (77%) than a discreet falls risk symbol by the head of the bed (75%), lap belts (65%), furniture used to block patients' movement (63%), mattresses on the floor (41%), reclining chairs (39%), tranquilisers (9%), and direct binding (5%). Bedrails used in this way were seen as less acceptable than bed/chair alarms (80%), wristbands denoting falls risk (95%), and moving the patient to a bed more easily observed by nursing staff (95%).

A small qualitative study (N=17) on a rehabilitation ward in Northern Ireland interviewed a convenience sample of patients with either bedrails raised or screw-on tables on their chairs (Gallinagh et al. 2001a). The study does not specifically separate bedrail data, but quotations from patients are attributed to each device. The study suggested most patients with bedrails were positive *"I feel safer with them up, I'm used to them now"* (p. 855) or indifferent about them *"The side rails don't hinder me from getting out. I'm not able to get up anyway!"* (p. 856). However, one patient was distressed by their bedrails *"I cannot get out of bed with them and they prevent me doing things I want"* (p. 855) although the attached commentary implied this was a patient unable to mobilise independently following a stroke.

In an interlinked study, where a convenience sample of nine relatives of patients were interviewed (Gallinagh et al. 2001b), they were found to *"place value on the perceived safety function of bedrails"* (p. 391) generally in relation to prevention of falls from bed. They could identify possible risks associated with bedrails if prompted, for example *"There's a million to one chance that somebody would try to get their head through the rails"* (p. 396) and although none of the nine relatives felt able to suggest any alternative to bedrails, three relatives made suggestions for improved bedrail design.

In a separate small (N=21) qualitative study (Healey for NPSA 2007c) carried out in England, two focus groups were held to explore patients' views on bedrails. One focus group was held with a convenience sample of former stroke patients at a day centre for Caribbean elders. The second focus group was held with a convenience sample of patients at a day hospital for older people with mental health needs. Whilst no questions were predetermined, any comment made by one member of the focus group was explored with the rest of the participants. Most of the participants in the first group and some of the participants in the second group had personally experienced bedrail use in recent hospital admissions. None had been given bedrails against their wishes. The participants considered that bedrails were a practical and temporary safety measure for preventing falls from bed and did not impact on their independence and dignity. They expected to be involved in decisions about using bedrails if they were well enough, but wanted staff to do whatever would be safest if they were too ill to decide. They considered the term *'cotside'* was demeaning.

Additionally, some bedrail reduction studies (Hoffmann et al. 2003, Si et al. 1999) found patients reluctant to stop using bedrails, suggesting these patients had positive rather than negative perceptions about bedrails. Ralphs-Thibodeu et al. (2006) had to abandon their planned bedrail reduction study when a proportion of patients who had initially agreed to participate changed their mind once they were randomised to bedrail removal (and vice versa).

For context it is important to consider that, as discussed earlier in Chapter 1.2.1, falls – or even the fear of falling – can also involve considerable psychological distress (Jorstad et al. 2005, Zijlstra et al. 2007).

3.5 THE LITERATURE ON THE EFFECTS OF BEDRAILS PRIOR TO 2008

3.5.1 General literature reviews including the effect of bedrails

Some reviews of the wider literature on institutional falls or restraints (ACSQH 2005, Capezuti 2004, Evans et al. 2002, Evans et al. 2003, Oliver et al. 2007, Registered Nurses' Association of Ontario 2004) have included search terms related to bedrails or identified some studies on bedrails.

Evans et al.'s (2002) systematic review focused on restraint reduction programmes and included the terms bedrail, cotside and siderail in their search strategy (but not the terms 'bed rail' or 'side rail' written as two separate words) . By 2001, three of the five bedrail reduction studies identified in our systematic literature review had been published, and Evans et al. (2002) identified two of these (Hanger et al. 1999, Si et al. 1999). However, they were grouped for analysis with 14 other studies relating to reductions in the use of vest, belt, cuff, harness and chair restraint devices. These studies were combined in results and discussion, leading to an overall conclusion that education and access to expert clinical advisors can reduce the use of restraint devices, and that in care home settings *"this reduction was not accompanied by an increase in the number of residents falling"* (p. 624) with insufficient studies to comment on the effect of restraint reduction in hospital settings.

Evans et al.'s (2003) systematic review drew on the same search strategy, but included studies on direct injury from physical restraint devices in addition to the studies on physical restraint removal examined in Evans et al. (2002). Of the six case reports or case series of direct harm from bedrails identified by our systematic literature review and published by 2001, Evan et al.'s (2003) review identified two (Parker & Miles 1997, Rubin et al. 1993). Their review also included nine additional studies related to direct or indirect harm from vest, belt, cuff, harness, and chair restraint devices. Again, analysis and discussion was generalised across bedrails and physical restraint devices, and the authors concluded *“physical restraint may increase the risk of death, falls, serious injury and increased duration of hospitalisation”* (p. 274).

Capezuti’s (2004) paper focused on the use of restraint devices in patients with dementia in care home or hospital settings, and did not call itself a literature review, but stated its aim as presenting *“the current state of the science related to restrictive device use amongst the cognitively impaired”* (p. 625) and used an academic style, with 160 references. The paper included bedrail studies within the wider literature on vest, belt, cuff, harness, and chair restraint devices. Sixteen of the 24 studies identified in our systematic literature review had been published by 2003, and the paper cited five of these. Three were studies of direct injury from bedrails (Miles 2002, Parker & Miles 1997, Todd et al. 1997) and two were bedrail reduction studies (Hanger et al. 1999, Si et al. 1999). Only Hanger et al. (1999) and Si et al. (1999) were individually discussed, and Si et al.’s (1999) results were incorrectly described as showing no significant increases in falls rates[liv] and as showing a reduction in injuries after siderail removal.[lv] The paper concluded that *“numerous studies have demonstrated the negative effects of….side rails and their ineffectiveness in reducing falls…The findings from several empirically based studies of ….side rail reduction demonstrate these devices can be removed without negative consequences”* (p. 625).

The guideline of the Registered Nurses’ Association of Ontario (2004) on *Prevention of falls and falls injuries in older adults* stated that their recommendations were based on a systematic literature review, although search terms and methodology were not defined. Although 16 of the 24 studies identified in our systematic literature review had been published by 2003, the guideline referenced only one retrospective cohort study (Capezuti et al. 2002) and on the basis of that study having identified no significant difference in falls rates with or without bedrails, recommended *“Nurses should not use side rails for the prevention of falls or recurrent falls for clients receiving care in health care facilities…………”* (p. 31).

[liv] The increase in falls rates after bedrail reduction was not tested for significance, although the increase in multiple fallers and the increase in falls rate for a sub-group of patients with a history of stroke were significant.

[lv] The number of injuries before (two minor injuries) and after bedrail removal (one minor and one serious injury) were unchanged.

Oliver et al.'s (2007) systematic literature review on the prevention of falls and injuries in hospitals and care homes included no bedrail specific search terms, but included restraint and 'protective devices' as search terms. It identified one bedrail reduction study (Hanger et al. 1999). Their review standardised studies' results in terms of rate ratio of falls, and noted that the increased rate ratio of falls in Hanger et al. (1999) after bedrail reduction was statistically significant at 1.16 (95% CI 1.01-1.34). However, for analysis and discussion they grouped this study with four other studies related to reductions in the use of vest, belt, cuff, harness and chair restraint devices, and concluded that overall there is no evidence of significant effects on falls from restraint reduction programmes.

The Australian Council for Safety and Quality in Healthcare's (2005) guideline *Preventing falls and harm from falls in older people* stated their recommendations were based on a literature review, although they note this was a *"peer review rather than a systematic process"* (p. xvii). It recommended that *"restraint should be considered as the last option for people who are at risk of falling"* and through accompanying examples and case studies indicated that bedrails were considered to be restraint. Although 17 of the 24 studies identified in our systematic literature review had been published by 2004, none of these were directly cited, with the only citations relevant to bedrail use an opinion piece on bedrails (Oliver 2002) and Evans et al.'s (2003) systematic literature review on restraints which, as discussed above, referenced four bedrail studies.

3.5.2 Reviews or overviews specific to the effect of bedrails

Although no fully systematic reviews specific to the effect of bedrails had been published prior to our systematic review, there had been a number of scholarly reviews or overviews of the literature on bedrails which merit discussion.

Capezuti's (2000) paper *Preventing falls and injuries whilst reducing siderail use* is headed as a 'review' but makes no description of any systematic search process and, despite a title focused on bedrail use, draws heavily on studies of vest, belt, cuff, harness, and chair restraint devices. Of the ten bedrail studies identified by our systematic literature review and published by 1999, Capezuti's (2000) review cites two (Parker & Miles 1997, Todd et al. 1997). Her review also appeared to identify two studies relevant to bedrails but not identified by our systematic review, but on examination these appear to be references to conference sessions that gave early findings from Capezuti et al. (2002) rather than papers. It concluded there should be a comprehensive assessment process before deciding on bedrail use, and more use of alternatives to side rails including *"half- or quarter-length rails, body-length pillows and bedside mats"* but noted *"further research is needed to determine the efficacy of these"* (p. 62).

Gallinagh et al.'s (2002a) overview of bedrail use is the closest that could be found to a systematic literature review specific to bedrails, as it used a systematic search strategy. However, the findings were descriptive and combined advice from the authors and the recommendations of published guidelines as well as empirical evidence. By 2001, when Gallinagh et al.'s (2002a) paper was under preparation, eleven of the 24 studies examined in our systematic literature review had been published. Gallinagh et al.'s (2002a) search strategy used only the terms side rails or cotsides (omitting the terms bedrails and safety rails) but despite this identified six of the eleven studies published by that date, including one case report of injury from lowered bedrails (Gray & Gaskell 1990) three case series of direct injury from bedrails (Parker & Miles 1997, Rubin et al. 1993, Todd et al. 1997) and two bedrail reduction studies (Hanger et al. 1999, Si et al. 1999). Only these latter two studies are examined in detail, and Gallinagh et al. (2002a) provided clear summaries of their findings, along with comment on their methodological limitations. However, the conclusions of the original authors that bedrail reduction will result in no increase in falls and a significant reduction in serious injuries (Hanger et al. 1999), and that side rails do not enhance safety and can be removed without increases in serious injury (Si et al. 1999), appeared to be accepted without a critical examination of the data actually reported in these studies. The overall recommendations were appropriately non-didactic, given the gaps in the evidence the review identified, and suggested *"an individualised systematic approach in the decision making process"* for bedrail use and that *"only when side rails pose fewer hazards than other considered interventions should their use be sanctioned"* (p. 303).

Oliver's (2002) paper was designed as an opinion piece primarily focused on the ethics and legality of bedrail use, but included a chapter providing an overview of research evidence. However, other than Hanger et al. (1999), Parker & Miles (1997), and a secondary reference to Todd et al. (1997), the references used in this chapter were to studies which involved the reduction of vest, belt, cuff, harness, and chair restraint devices or were references to the effects of chemical restraint. The key messages were the need for better research into falls prevention in hospitals and the need to balance safety with autonomy and rehabilitation, but in relation to bedrails the paper suggested *"……the balance of evidence is against the use of bedrails"* (p. 416) and that bedrails should only be used after *"….all reasonable alternatives …have been explored"* (p. 417). Unlike all other papers described in this and the preceding chapter, this paper gave a clear message that bedrail entrapment could be avoided by *"safe design, maintenance, and application"* (p. 417) and directed readers to UK and USA sources that gave details of how to ensure this.

Taken together, all these general or bedrail specific reviews or overviews were limited either through omitting synonyms for bedrails, through failure to separate published evidence from published opinion, or through an uncritical repetition of previous researchers' conclusions or recommendations, rather than review of their actual findings. In addition, the reviews that grouped bedrail studies with the more numerous studies of vest, belt, cuff, harness, and chair restraint devices drew generalised conclusions that may not be relevant to the specific effects of bedrails.

3.5.3 Opinion pieces and editorials

Whilst examining the literature in the context of the background to our systematic review it would normally be inappropriate to comment on opinions, rather than evidence. However, it is impossible to read the body of published literature on bedrails, primarily opinion pieces and editorials, without being struck by an overwhelmingly negative emphasis. There appear to be three main arguments used against bedrails. They are described as ineffective in preventing falls e.g. *"The lack of benefit of bedrails has long been recognised"* (O'Keeffe et al. 1996) or as increasing the risk of falls and injury e.g. *"Bedrails increase the height from which a patient can fall and hence the risk of serious injury"* (O'Keeffe 2004 p. 343). They are also described as inherently dangerous through direct injury e.g. *"a killer"* (Frengley & Mion 1998).

Another key argument appears to be that their use is morally impermissible. Statements to the effect that bedrails are "*dangerous and possibly unethical"* (Marcy-Edwards 2005) cause *"humiliation"* (Noone & Fleming 1998) and constitute *"a type of physical abuse"* (Jehan 1998) are commonplace. Bedrail use has been described as *"absurd and distasteful"* and equated to *"the use of fetters in schizophrenia"* (*The Lancet* 1989). One article entitled 'The dark side of nursing' very clearly links bedrail use with stereotyping and irrational prejudice on the part of the nurse *"do you more freely use bedrails for clients who are…homosexual, have AIDS, are prisoners…?"* (Corley & Goren 1998).

Although many papers on bedrails begin with a statement that they are challenging the accepted view that bedrails increase safety (e.g. Capezuti 2004, Evans et al. 2002, Frengley & Mion 1998) it could be argued that the view that bedrails are ineffective, harmful, dangerous and morally impermissible has for some years, if not decades, been the prevailing orthodoxy in the literature. The negative literature is not limited to UK, USA and Australian settings, with similar views apparent in publications from European settings e.g. *"the purpose of this study was to address one component of the complex topic 'elder abuse'……the most commonly used devices …. were bedrails…."* (Bredthauer et al. 2005).

The authors of such papers are clearly motivated by a genuine, and often passionately held, belief that bedrail use is harmful. For example O'Keeffe's (2004) commentary in *The Lancet* states that *"the evidence that is available does not show benefits from bedrails, let alone sufficient benefit to offset the disadvantages, particularly that they can cause a particularly horrifying, painful, and humiliating death"* (p. 344). However, such statements render objective analysis of the evidence difficult, and this complicates the existing clinical challenge staff face in balancing patient safety with the promotion of independence and rehabilitation (ACSQH 2005, Oliver et al. 2007, Healey & Scobie for NPSA 2007a).

3.5.4 Safer designs and dimensions

In addition to the literature published in journals outlined above, there have been a series of reports focused on the mechanisms of bedrail entrapment published by safety agencies in the USA and the UK. These have been based on investigation of incidents of bedrail entrapment, in combination with anthropometric data.

The most comprehensive format of dimensional guidance was produced by the USA Food and Drug Administration (USA FDA, 2006) and replaced earlier less specific guidance. The 2006 USA FDA guidance is entitled *Guidance for industry and USA FDA staff*, but within the document it advised hospitals and care homes to use it to check their existing bedrail stock. The bibliography of the guidance suggests it was based on methods used to draw up standards for playground design and domestic bunk bed design, where parallels with bedrail entrapment may exist.

Based on entrapment incidents reported to the USA FDA,[lvi] the guidance identified six entrapment zones related to bedrail design (within the rail, under the rail, between the rail and the mattress, below the end of the rail, between split bedrails, and between the headboard and end of the rail). To avoid entrapment in these zones, minimum and maximum dimensions are advised. For example, to avoid entrapment of the head within rails, inter-rail gaps should be less than 120mm apart. The figure was identified through establishing that all reported cases of head entrapment had occurred between rails that were more than 120mm apart, and that, based on anthropometric data, ear-to-ear head breadth in adults exceeds 120mm to the 99th percentile. A similar process is used to recommend that open gaps between the rail end and the bed-head should be less than 60mm or greater than 318mm to avoid neck and chest entrapment.

However, the guidance recommends a complex testing procedure involving a cone and cylinder tool whose dimensions represent a small adult head and small adult neck. The tool also incorporates a spring scale and a spirit level and the instructions for its use cover 17 pages of the guidance. The advantage of the cone and cylinder technique is that it can assess dimensions which exist when a mattress is compressed, as it would be by a patient's weight. The disadvantage is its complexity, which whilst feasible for a manufacturer testing a single new design, appears impractical for healthcare staff seeking to assess the safety of all existing equipment.

In the UK, reports from safety agencies were initially also fairly generalised warnings based on reports of entrapments (Department of Health 1994, MDA 1997, MDA 1999, MDA 2000) without specific dimensional guidance. A more extensive Device Bulletin (MDA 2001) complied and expanded on this earlier guidance, providing pragmatic checklists advising healthcare staff how to compare the individual patient's head, neck and body size with the dimensions of their bedrails and mattress. They also provided a very detailed evaluation of the dimensions of all bedrails approved for use as medical devices in the UK (MDA 2002). In 2004 the MHRA issued advice specifying a 12cm maximum between-rail gap (MHRA 2004a) and on ensuring replacement mattresses matched or exceeded the size of original mattresses to avoid bedrail/mattress gaps where postural asphyxiation could occur (MHRA 2004b). In 2006 an updated and expanded Device Bulletin (MHRA

[lvi] Many of these incidents were also described in journal articles within our systematic review, including Todd et al. (1997) Hignett & Griffiths (2005) and Miles (2002). Parker and Miles (1997) had previously identified three of the entrapment zones later specified in USA FDA (2006).

2006) adopted the neck and chest dimensions specified in the USA FDA (2006) guidance, with the latter rounded from 318mm to 32cm.

Because the majority of reports of bedrail entrapment in the UK had occurred in care home settings, the MHRA advice appears tailored to be practical in this environment, with simple dimensional checklists that could be completed with a ruler and hand compression of mattress edges. Where inter-rail or under-rail gaps did not meet dimensional standards, bedrails needed to be removed and disposed of. For traditional detachable bedrails, safe dimensions between the rail end and the bed-head could be achieved by educating healthcare staff on correct techniques for attaching bedrails, whilst for mattress/bedrail gaps the mattress would need replacing with a mattress of appropriate size.

Both the MHRA (2006) advice and the USA FDA (2006) advice also emphasised the importance of good maintenance of bedrails and of ensuring staff were correctly trained in their fitting. The rationale was that poorly maintained or incorrectly fitted bedrails had been implicated in most reports of death or injury after falls to the floor related to bedrail failure.

Advice issued in other countries (e.g. South Australian Department of Health 2007) also adopted the USA FDA (2006) dimensions. Therefore there was a high degree of international consensus on bedrail dimensions that would be expected to eliminate fatal entrapments, although differences remained in the techniques recommended to check these dimensions.

3.6 DEVELOPING A SYSTEMATIC LITERATURE REVIEW ON BEDRAILS

3.6.1 A national bedrail safety project

The National Patient Safety Agency and its role was described earlier in Chapter 1.3.1. Topics for specific NPSA projects were selected through a prioritisation process which weighted the evidence of harm against the likelihood of identifying a successful improvement strategy, based on clinical concerns, patient perspectives, and published literature as well as incidents reported to the NRLS. In late 2005 I was allocated to lead a project on ‘elder restraint’ that had been funded primarily because of concerns expressed by specialist nurses, and with a budget of £5,000.

The NPSA had a flexible approach to project development, with the one core ingredient being an external reference group including patient and carer representatives, clinical experts, and key partner organisations such as the Royal Colleges relevant to the specific patient safety topic. It was also at this time a small agency with around 100 centrally based employees, the majority of whom were engaged in developing and maintaining reporting to the NRLS, plus thirty Patient Safety Managers working regionally. This meant the agency had relatively little access to staff with research skills, and formal literature reviews were not a standard part of its project development, although projects would undertake some form of literature scanning, and usually draw on any relevant key papers.

3.6.2 The need for a systematic literature review

Through early meetings of the expert reference group for our elder restraint project, and through our analysis of incidents reported to the NRLS (Healey & Scobie for NPSA 2007a, Healey et al. 2008a) described in Chapter One, it became evident there were two areas where the NPSA might best add value. These were supporting other organisations that already provided advice on restraint in older people to update and improve their guidance, and exploring whether advice from the NPSA could secure improvements to patient safety in the area of bedrails. My achievements in respect of the first objective will be described in more detail later in Chapter Five, but in brief I became lead author of new restraint guidance published by the Royal College of Nursing (RCN 2007).

On the topic of bedrails, it became clear from external reference group discussions and early reading of the literature that the most fundamental problem was a considerable confusion on whether the evidence suggested harm or benefit from bedrails, and, without resolving this, it would prove impossible to move forwards and identify appropriate recommendations to improve patient safety. This led me to undertake a systematic review of the literature on bedrails, primarily intended for a readership of frontline nurses to support an NPSA ‘Safer Practice Notice’ on bedrail safety (Healey & Stephenson for NPSA 2007b) which will be described in more detail in Chapter Five. Therefore, whilst methodologically sound, this version of the literature review also needed to be in an easy-to-read style, and was published in that format (Healey for NPSA 2007d). Thereafter I undertook additional work with the support of my co-authors updating and refining search strategies, quality assessing included studies, and rewriting the systematic review in a style appropriate to a scientific journal. This was published in 2008 (Healey et al. 2008b).

‘The effect of bedrails on falls and injury: a systematic review of clinical studies’ (Healey et al. 2008b) can be found in Appendix A.

3.7 STRENGTHS AND LIMITATIONS OF OUR SYSTEMATIC LITERATURE REVIEW

3.7.1 Strengths of our systematic literature review

Our literature review is the first truly systematic review focused on the effects of bedrails. It remains the most comprehensive systematic review and synthesis of published evidence of the effect of bedrails on falls and injury to date. By extending its focus beyond RCTs and the few studies where standardised outcomes can be calculated, to include observational or quasi-experimental studies, it provided an inclusive analysis which allowed users to see the range and the limitations of evidence often used by those advocating strongly against bedrail use. However, through formal quality scoring and critical comment it also acknowledged the limitations of the studies with weaker methodologies.

Its search strategy included all possible variant terms and spellings used to describe bedrail use, which avoided missing important papers and also reduced national selection bias.[lvii] The review process used to identify the 24 empirical studies was both comprehensive (involving the review of 472 abstracts after duplicates had been identified) and conscientious (all studies on body restraint reduction were examined in their full version to ascertain if they included bedrails in their definition of restraint and held separate bedrail data). Whilst any literature review is reliant on published studies and could not therefore completely overcome publication bias, the systematic search strategy used in our review ensured that studies which were less well known and not commonly cited were included where appropriate; we identified more than twice as many studies as any earlier review. Our focus on both the effect of bedrails on falls from bed and on direct injury from bedrails enabled us to discuss the balance of risks rather than considering the evidence of harm from bedrail entrapment in isolation from evidence on the harm sustained in falls from bed.

[lvii] Side rails, for example, appears a more commonly used term in the USA and Canada, whilst bedrails is the term most commonly used in the UK and New Zealand.

Another strength was the careful extraction of the studies' context, methods, and results into standardised tables. Whilst this is of course a key component of any literature review, the less academic of the included studies had brief and often scattered presentation of data within discussion chapters rather than in clear results chapters (e.g. Si et al. 1999, Hoffmann et al. 2003). Standardisation of the studies' results into falls per thousand occupied bed days was also a vital element to enable an appropriate overview of their findings. This was often a complex process, as some papers presented rates such as falls per resident per month, or falls rates had to be retrospectively calculated from injury rates and the proportion of injurious falls (e.g. Capezuti et al. 2007).

A further strength was the detailed discussion, which explored not only the actual findings, but also the ethical implications of bedrail use, why the attitudes in the literature to bedrails appeared to have become so divorced from the actual evidence, and the dichotomy apparent between the views of staff and of patients and their relatives. Whilst acknowledging the limitations of the evidence base, our systematic review's conclusion gave clear directions for clinical practice in areas supported by the evidence. These included the inappropriateness of bedrail use for certain patient groups, the need for safely designed, correctly fitted and well-maintained bedrail stock, the risks of programmes aimed at across-the-board reductions in bedrail use, and the adoption of a broad approach to reducing a wide range of individual and environmental falls risk factors, rather than an isolated focus on preventing falls from bed.

A further strength was the inclusion of a discussion of the ethical and design challenges involved in any future RCT of bedrail use, and the identification of several additional bedrail-related issues where quantitative and qualitative research is required.

3.7.2 Limitations of our systematic literature review

We identified no RCTs so the level of evidence is less strong than in a traditional Cochrane review (Oxford Centre for Evidence Based Medicine 2001). Even the eight better designed studies (Brown 1997, Capezuti et al. 2002, Capezuti et al. 2007, Hanger et al. 1999, Hoffmann et al. 2003, Krauss et al. 2005, Kron et al. 2003, Si et al. 1999) met only between four and eight quality criteria out of a maximum of ten. There may be many factors influencing the lack of high quality studies, including the nature of bedrail use as a 'low-tech' intervention already routinely embedded in practice, and the fact that both bedrail use and bedrail removal can be seen as interventions. The high prevalence of frailty and cognitive impairment in potential study populations also creates challenges for informed consent to individually randomised studies (Connelly 2001, Mayer 2004, Olgilvie et al. 2004).

Meta-analysis was not attempted as a recent meta-analysis on falls prevention in institutions identified very few papers where standardised outcome data could be extracted (Oliver et al. 2007). The most likely source for any attempt at meta-analysis would be the five before and after studies of bedrail reduction (Brown 1997, Capezuti et al. 2007, Hanger et al. 1999, Hoffmann et al. 2003, Si et al. 1999) but their heterogeneity (in terms of settings, patient groups, levels of bedrail reduction and alternatives to bedrails put in place) would have made meta-analysis inappropriate even if standardised outcome data had been extractable. No additional tests of statistical significance were carried out, but tests of statistical significance within original papers were supplemented by abstracting the findings of a previously published meta-analysis (Oliver et al. 2007). This was helpful in indentifying where the original researchers had incorrectly calculated statistical significance (e.g. Oliver et al. 2007 on Hanger et al. 1999).

Additionally, most studies were based on reports from frontline staff, a method limited by incomplete data and under-reporting, as discussed earlier in Chapter 1.4.2. However, it can be argued that the role of systematic reviews *"is not to let the desire for 'best' evidence stand in the way of using the best available evidence"* (Olgilvie et al. 2005).

3.8 DISCUSSION OF COMMONALITIES AND DIFFERENCES

3.8.1 Introduction

Despite the weak methodological quality of many of the studies, the evidence presented in our systematic literature review did not support the prevailing orthodoxy that bedrails increase the likelihood of falls and injury or that bedrails result in an inherent risk of fatal entrapment, as described in the prior publications outlined in Chapter 3.5. So why the current negative view of bedrail use?

To try and understand the gap between the orthodoxy and our findings, I will discuss the commonalities and differences between the evidence presented prior to our systematic literature review, and the evidence within it. This will include a description of how some individual studies included in our systematic literature review drew conclusions that appear at odds with their data, and will incorporate discussion of the systematic reviews of restraint devices and semi-systematic literature reviews or overviews on bedrails outlined earlier in Chapters 3.5.1 and 3.5.2.

This overall discussion of commonalities and differences will include detailed exploration of why the opinions previously expressed in the literature had become so detached from the evidence. This will draw on a range of potential explanations.

3.8.2 Healthcare staff's values and decision making frameworks

There can be little doubt that, in the past, routine and inappropriate bedrail use *did* occur (Watson & Brunton 1990, Brush & Capezuti 2002, Gallinagh et al. 2002a, Evans et al. 2003). It may be that challenging the traditional routine use of bedrails has resulted in the adoption of an opposing view, where not using bedrails at all represents up-to-date and enlightened practice.

Traditionally, nursing and medical practice was considered to have progressed from a paternalistic style, where staff made decisions on patients' behalf, to one where patients' autonomy and individuality was respected. Commentators equate the routine use of bedrails with a paternalistic approach (e.g. Corley & Goren 1998, Marcy-Edwards 2005, Oliver 2002) but only one of the five bedrail reduction studies appeared to have obtained patient consent (Capezuti et al. 2007) and in some of the bedrail reduction studies patients' autonomy and individuality was not respected if they wished to keep bedrails. For example, in Hoffman et al.'s (2003) study, staff who were advocating for patients who wanted to keep their own bedrails raised were viewed as *"particularly problematic"* (p. 41). Si et al. (1999) described a bedrail reduction process that is clearly standardised (bedrails removed on all existing residents and not permitted for any new residents) and allowed no element of patient choice. These studies may be influenced by Rubenstein et al. (1983) who argued that if an RCT of bedrail reduction was carried out *"the patient's informed consent may be legally and ethically unnecessary"* (p. 276). Together these suggest paternalistic attitudes were not confined to the traditional routine use of bedrails, but also affected bedrail reduction programmes.

Our systematic literature review differed from the earlier papers on bedrails by seeking to avoid a paternalistic approach, instead extending the discussion chapter to include legal and ethical frameworks encompassing the rights of patients with capacity to make their own decisions about bedrail use.

3.8.3 The original authors' interpretation of their studies' results

Some bedrail studies included in our systematic literature review drew conclusions that appear at odds with their data. Whilst it was not appropriate to explore this in our systematic literature review, where the emphasis had to be on the included studies' actual results and their statistical significance, these dichotomies between results and conclusions are relevant to a discussion of how our systematic literature review differed from earlier publications. For example, Brown (1997) who saw highly significant increases in falls rates overall, and in a subset of visually impaired residents, concluded that in bedrail reduction programmes *"the increase in non-serious falls should be anticipated and not considered rationale for maintaining side rails"* (p.1) Brown's study contains extensive statistical analysis, and it therefore seems unlikely the author was unaware that her small study[lviii] was underpowered to detect any corresponding increase in serious injuries.

Equally, Si et al. (1999), who saw multiple fallers and falls in a subset of patients with stroke increase significantly, and numbers of falls from bed almost double, with no serious injuries before bedrail reduction and one serious (possibly fatal) subdural haematoma after bedrail reduction, concluded *"the vast majority of patients did well without bedrails, and serious injuries did not increase"* (p. 615). This study presented the results in a table where the increase in falls was unclear without additional calculations, and emphasised the reduction in single fallers as a positive outcome (although this was achieved through an increase in patients who fell twice or more rather than once). The authors appeared to be working to a hypothesis that the results of bedrail removal programmes should duplicate the results of programmes removing vest, belt, cuff, harness, and chair restraint devices: *"These results are similar to our earlier restraint minimisation project, where we found serious injuries did not increase…"* (p. 614).

Hanger et al.'s (1999) paper also drew a strong anti-bedrails conclusion *"….our study [showed] no change in total fall rate, and a beneficial reduction in serious injuries"* (p. 530) and stated that the continuation of bedrail use *"must be seriously questioned"* (p. 531).

[lviii] The study included a total of 16 falls prior to bedrail reduction, and 35 falls after.

There is, however, less dichotomy here, as through an error in statistical testing[lix] the authors believed the increased rate of falls after bedrail reduction *was not* statistically significant, although later analysis (Oliver et al. 2007) indicated it *was* statistically significant. However, their conclusion that 'serious' injuries declined does not reflect their findings that serious injuries as conventionally defined (fractures and lacerations needing suture) increased non-significantly, and the only actual decrease was in the number of neurological observations recorded. It appeared the authors used the nurses' decision to take neurological observations (however normal the observations actually were) as a proxy indicator of serious injury.[lx] Hanger et al. (1999) apparently approached their study with the conviction that bedrail reduction would show benefits, referring in their introduction to *"….a distinct lack of evidence they work….our previous work has suggested bedrails are at best a nuisance…We hypothesised that bedrails are not effective at preventing falls and may themselves cause serious injury"* (p. 529).

Capezuti et al.'s (2007) study included complex statistical analysis. Rather than any actual dichotomy between findings and conclusion, the issue here was which of their statistically significant findings were emphasised. Beneath the academic presentational style of the paper was a clinically pragmatic study, taking a group of elderly nursing home residents with bilateral bedrail use and, through advice from a clinical nurse specialist, selecting the more mobile and more independent residents for bedrail reduction or removal (creating statistically significant differences in independence and mobility between the two groups). This selection process also meant the groups were significantly different in falls rates pre-intervention, with the residents selected for bedrail reduction more than three times as likely to fall. In the 'after' year of the study, falls in both groups reduce by similar amounts – 46% in the residents selected for bedrail reduction, and 38% in the residents selected for bedrail continuation. The reduction in falls in both intervention and control groups could be attributed to a 'Hawthorne effect' of the researchers' presence, or because the individually tracked residents moved into end-of-life stages when they were no longer able to move enough to risk falling. However, the authors' key emphasis is on their finding that the 46% reduction (from a threefold higher baseline) is statistically significant, whilst the 38% reduction is not statistically significant: *"For the group that reduced restrictive side rail use*

[lix] The authors treat the numerator of a rate as though it were a whole number.

[lx] The low level of neurological observations noted across the twelve months of the study (792 falls were reported but neurological observations were recorded only 39 times) may not have been clinically appropriate (NICE 2007).

there was a significantly reduced falls rate, whereas the group that continued restrictive side rail use did not demonstrate a significantly reduced falls rate" (p. 334). The alternative explanation for this finding is that the continue bedrails group, with far fewer falls at baseline[lxi] was underpowered to detect statistical significance even when falls fell by substantial percentages, but no mention of this is made in their discussion. Their conclusion is, however, a balanced reflection of their results, that the *"routine use [of bedrails] is not supported"* (p. 334).

It is possible to speculate that the before and after studies which viewed bedrail elimination as a desirable goal at the design stage (Brown 1997, Hanger et al. 1999, Si et al. 1999, Hoffmann et al. 2003) were more likely to see significant increases in falls than the study using balanced assessments of individual patients (Capezuti et al. 2007). Hoffman et al.'s (2003) study (in which the researchers were highly committed to the value of bedrail reduction, but falls did not increase significantly) would appear to contradict that assumption, but the paper contains clear indications that the frontline staff in the units that participated in the study did not share the researchers' conviction, and were prone to restore bedrail use whenever they were unobserved.

It may also be relevant to note that the two bedrail reduction studies that did not see significant increases in falls or multiple fallers (Hoffmann et al. 2003, Capezuti et al. 2007) were focused on reducing full bedrail use. In these studies, the intervention group still retained varying degrees of partial bedrail use, including use of one to three spilt sides in Capezuti et al. (2007) and use of full-length bedrails on one side (including with the opposite side of the bed placed against the wall) in Hoffmann et al. (2003). In contrast, the intervention in the three bedrail reduction studies that did see significant increases in falls or multiple fallers (Brown 1997, Hanger et al. 1999, Si et al. 1999) lowered all four segments of split rails (Brown 1997, Si et al. 1999) or detached and removed traditional bilateral bedrails (Hanger et al. 1999).

Two studies where a very severe injury occurred in a fall from bed also provide contrasting interpretations of their findings. In Van Leeuwen et al.'s (2001) retrospective survey a fatal fall occurred with bedrails raised, and was used to make the case that bedrail use should be eliminated, whilst in Si et al.'s (1999) study a subdural haematoma from a fall after

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[lxi] There were 56 falls in the continue bedrails group pre-intervention and 188 falls in the bedrail reduction group pre-intervention.

bedrail removal (the authors leave it unclear whether the patient recovered or died) was dismissed as statistically non-significant.

Adjustments for differences between cohorts are also an interesting area of analysis and interpretation. Capezuti et al.'s (2002) retrospective observational study found patients with bilateral bedrails were significantly less likely to fall (odds ratio 0.56 95% CI 0.33-0.94) and non-significantly less likely to experience multiple falls (0.58 95% 0.27-1.23) than patients with partial or no bedrails. The bilateral bedrail patients were also significantly more likely to have impaired mobility, greater dependence, greater cognitive impairment, and greater 'behavioural disturbance' all of which might reasonably be anticipated to increase the likelihood of falls (Oliver et al. 2004). However, after *"necessary adjustments for these clinical characteristics"* (p. 93) the authors present adjusted odds ratios suggesting patients with bilateral bedrails are non-significantly *more* likely to fall (adjusted odds ratio 1.13 95% CI 0.45-2.03) and to be multiple fallers (adjusted odds ratio 1.25 95% CI 0.33-4.67).

Therefore a key difference between our systematic literature review and most of the earlier literature was our careful extraction of included studies' results, and our formation of conclusions that were reflective of the empirical evidence (whilst acknowledging its limitations).

<u>3.8.4 The subsumption of bedrails into the restraint devices literature</u>

As outlined above in Chapter 3.5.1, some systematic reviews subsumed a small number of bedrail studies into the wider body of literature on the effect of vest, belt, cuff, harness and chair restraint devices. These reviews came to conclusions which, whilst including bedrails in their definitions for inclusion, were primarily drawn from studies which did not include bedrails, despite the inaccuracy inherent in assuming the effects of studies of one device can be directly applied to the studies of another. In addition, perhaps bedrails became 'guilty by association' due to the papers that grouped them with vest, belt, cuff, harness and chair restraint devices, as the use of these other devices is associated with considerable distress and harm (Capezuti 2004, Evans et al. 2002, Evans et al. 2003, Gastmans & Milisen 2006).

This effect of combined conclusions covering both bedrails and physical restraint devices is also seen in one paper included in our systematic review (Tan et al. 2005). The study found that the rate of falls with bedrails raised appeared non-significantly lower and the rate of injuries from falls with bedrails raised was non-significantly higher; severity of injury related to falls with bedrails raised is not described. However, the results and discussion subsume these findings into the overall fall and injury rates including those from lap-table chairs (which do show significantly higher injury rates) to conclude *“Much of the concern regarding use of bedrails and other restraints has focused on the risk of asphyxial death [but our study found that] a more common consequence is the increased severity of injury in restrained patients who fall”* (Tan et al. 2005 p. 30-31).

As discussed earlier in Chapter 3.5.3, opinion pieces on bedrails frequently referenced studies of vest, belt, cuff, harness and chair restraint devices as though they were applicable to bedrails. Perhaps this was because of the relative dearth of bedrail literature that could be cited, but in some cases this may have been due to genuine misunderstandings, particularly from UK authors unaware of the use of these restraint devices in other countries. Studies of vest, belt, cuff, harness and chair restraint devices do not always describe or define the restraint devices they were studying, perhaps because their use was so ubiquitous in the setting where the research was based that the authors felt no need to do so. Capezuti et al.’s (1999) study entitled ‘Outcomes of nighttime physical restraint removal for severely impaired nursing home residents’ appeared to create particular confusion, although it related solely to vest, harness and cuff devices used in bed at night.

Therefore a key difference between our systematic literature review and most of the earlier literature was that it created a clear separation between studies of the effects of bedrails and studies of vest, belt, cuff, harness and chair restraint devices.

3.8.5 Patient advocacy

Criticism of bedrails may relate to an assumption that patients dislike bedrails, but as discussed earlier in Chapter 3.4.4, the limited literature suggests most patients do not have negative views about bedrails, whilst the opinions of staff were much less positive in the studies that included them (Vassallo 2004, Vassallo 2005). Advocating for patients is part of good clinical practice, but the assumption in the literature prior to our systematic review that patients disliked bedrails may have been based on staff projecting their own opinions, rather than based on asking patients for their views. Our review differed in discussing the available evidence on patients' views on bedrails, rather than making assumptions that their beliefs on bedrails could be equated with staff or relatives' opinions.

3.8.6 Beliefs and practice towards the evidence base for interventions

Evidence based practice requires critical appraisal, rather than partial citation. Despite the dictum that *"absence of evidence is not the same as evidence of absence of effect"* (Mayer 2004) commentators have stated that bedrails should not be used to prevent falls from bed because no RCTs have been carried out (Marcy-Edwards 2005, O'Keeffe 2004). Smith & Pell (2006) in their systematic review of the effect of parachutes on injury in falls from height used humour to make a serious point that a lack of RCTs is not always a good reason to change practice.

Other commentators (e.g. Jehan 1999, Hoffmann et al. 2003, Noone & Fleming 1998) have stated that bedrails should not be used to prevent falls from bed on the basis of no significant findings in inadequately powered arms of studies, particularly analysis of serious injury such as fracture, despite all the bedrail reduction studies being underpowered to detect significant changes in the very small proportion of falls which result in serious injury.[lxii]

Perhaps because of the relative paucity of the evidence base and difficulty in accessing some papers, citations of citations are common, with content or context lost in repetition; this may have influenced the view that bedrail use increases the risk of falls and injury. Examples of this are shown in Box 3a.

[lxii] Combining before and after stages of the bedrail reduction studies, Brown (1997) recorded no serious injury in 51 falls, Hanger et al. (1999) recorded six fractures in 792 falls, Si et al. (1999) recorded one sub-dural haematoma and no fractures in 50 falls, Hoffman et al. (2003) recorded three hip fractures in 268 falls, and Capezuti et al. (2007) recorded 14 'serious injuries' (defined as lacerations requiring suturing, fractures, dislocations, or sub-dural haematomas) in 495 falls.

BOX 3a: Examples of citation errors and lost context

"90% of falls occur with the bedrails raised" continues to be cited (e.g. Hignett & Masud 2006, Oliver 2002) based on 10 reported falls in Bates et al. (1995) or 16 reported falls in Rubenstein et al. (1983) even though the latter data were collected three decades ago in a hospital in the USA where *"bedrails were used for all patients aged 65 years or over and most patients between ages 60 and 65"* (Rubenstein et al. 1983 p. 272).

An ambiguous sentence in the abstract of Van Leeuwen et al. (2001) *"Patients in a 'non rational' state at the time of falling were significantly more likely to have fallen with the bedrails elevated (chi 2 = 19.463, p < 0.001)"* is frequently cited as showing confused patients are significantly more likely to fall if bedrails were raised (e.g. Prevention of Falls Network Europe (ProFaNE) 2008) although scrutiny of the full paper indicates sentence order has been accidentally reversed in the abstract and these statistics actually referred to fallers being significantly more likely to be confused.

Hanger's (1999) study is frequently cited as having shown a significant decrease in serious injury after bedrail reduction (e.g. Talerico et al. 2001, Gallinagh et al. 2002a, O'Keeffe 2004) with readers of the citations unlikely to appreciate the detail that serious injuries as conventionally defined (fractures and lacerations needing suture) increased non-significantly, and the only actual decrease was in occasions when nurses decided to record neurological observations.

Some citation errors have no obvious explanation (e.g. Capezuti's (2004) description of Si et al. (1999) as showing *"fewer injuries in those without side rails"* p. 636) but have gone on to be cited by others (e.g. Hughes 2008, Shanahan & Evans 2009).

Studies that indicated patients provided with bedrails were older, less mobile, more cognitively impaired, and more likely to be incontinent than patients who were not provided with bedrails (Brandeis et al. 1997, Capezuti et al. 2002, Irving 2004, Mildner et al. 2003, O'Keeffe et al. 1996, Tutuarima et al. 2003) have been cited as evidence that bedrails *cause* incontinence, confusion, or reduced mobility (Gallinagh et al. 2002a, Govier & Kingdom 2000, Tan et al. 2005, Talerico & Capezuti 2001). This appears to arise from mistaking correlation for causation. The correlation is more likely to arise because these factors are significant indicators of falls risk (Oliver et al. 2004) and a perceived risk of falls is nurses' main rationale for providing bedrails (Healey et al. 2009, Hignett et al. 2005, Gallinagh et al. 2002a, Minnick et al. 2008, Noone & Fleming 1998, O'Keeffe et al. 1996, Shanahan & Evans 2009).

It is also notable that introducing 'evidence based' practice is a key argument that commentators calling for the abolition of bedrail use draw on (e.g. Hoffmann et al. 2004, Marcy-Edwards 2005, Talerico & Capezuti 2001). However, the appeal for clinical staff to be more evidence based in their practice seems to be used most in informal papers that only make incomplete references to the actual published evidence on bedrails (e.g. Jehan 1999, Marcy-Edwards 2005, Rollins 2007).

Our systematic literature review differed from these earlier approaches by seeking to identify and include all relevant studies, and by carefully extracting, standardising, and presenting the findings based on the full original papers.

3.8.7 Publication bias

There is potential for publication bias given the previous orthodoxy that bedrail use was harmful. Brown's (1997) bedrail reduction study, which found significant increases in falls, and highly significant increases in subgroups of patients with visual impairment, achieved publication only as an abstract and doctoral thesis.

Dunbar & Neufeld presented a series of conference abstracts (Neufeld & Dunbar 1999a, Neufeld & Dunbar 1999b, Dunbar & Neufeld 1999) based on retrospective analysis of incident reports (N=300) over one year in a chain of nursing homes in the USA and on a questionnaire of residents, their families and staff (N=259) The conference abstracts indicated that, although residents with and without full bedrails were very similar in measures of dependency, residents with full bedrails had around 50% fewer falls from bed. The questionnaire indicated that *"residents and families are much more likely than staff to view their bedrails as necessary and favourable"* (Dunbar & Neufeld1999 p. 500). There are many reasons why conference abstracts do not get developed into full papers, including poor design or description that fails to pass peer review, but this seems unlikely given both authors remained active in nursing research and successfully published other papers. The possibility that study findings apparently contradicting the prevailing orthodoxy may be less likely to be put forward for publication, or less likely to be accepted for publication, must therefore be considered.

In publication of the case studies and case series of bedrail injury and entrapment (DiNunno et al. 2003, Everitt & Bridel-Nixon 1997, Gray & Gaskell 1990, Healey & Scobie for NPSA 2007a, Hignett & Griffiths 2005, Miles 1996, Miles & Parker 1998, Miles 2002, Parker & Miles 1997, Rubin et al. 1993, Todd et al. 1997, USA Food and Drug Administration 2006), death or injury from bedrails may have been considered rare enough to merit writing up as a case study, whilst death or serious injury in a fall from bed may have been seen as too well known an issue. The overlapping nature of some of these studies, which all drew on historic data in the same database (Hignett & Griffiths 2005, Miles 2002, Todd et al. 1997, USA Food and Drug Administration 2006), may also have created an impression that extremely high numbers of patients were being harmed. In the UK, the MHRA's remit, which was limited to the safety of medications and medical equipment, made it inevitable that they could only issue warnings on direct harm from bedrails (Department of Health 1994, MDA 1997, MDA 1999, MDA 2000, MDA 2001, MDA 2002, MHRA 2004a, MHRA 2004b, MHRA 2006) without mention of potential for harm from falls from bed.

3.8.8 Perceptions of risk

It is a facet of human behaviour that we tend to give more attention to unusual risks than to commonplace ones, which we mentally 'sanitise' as a defence against constant anxiety (Reason 1990) – for example, worrying more about being bitten by a poisonous snake on holiday than dying of heart disease at home, although the latter is much more likely to occur. We also tend to rate disproportionately highly risks that we feel are outside our personal control (Reason 1990) – for example, fearing being a passenger in a plane more than driving our own car, although statistically the latter is much more likely to be fatal. It may be that for healthcare staff, particularly nurses, bedrail entrapment was perceived as a higher risk through its very unusualness, whilst the risk of harm in falls from bed became 'sanitised' through its relatively everyday nature. As outlined above in Chapters 3.5.1 – 3.5.3, much of the literature on bedrails (with notable exceptions including Parker & Miles 1997, Miles & Parker 1998 and Hignett & Griffiths 2005) referred to bedrail entrapment deaths as an apparently random and inevitable consequence of bedrail use, rather than explaining how bedrail entrapment could be avoided. This perceived lack of control may have led healthcare staff to rate the risk of bedrail entrapment disproportionately highly.

Our systematic literature review differed from earlier publications by including a specific chapter on how bedrail entrapment occurred (Healey et al. 2008b Figure 2 p. 375). This described how such risks could be avoided through organisational leadership to remove outdated equipment, and assessment by frontline staff of the risks specific to individual patients, based on the guidance issued by the MHRA (2206) and USA FDA (2006) discussed earlier in Chapter 3.5.4. This was summarised in our key point that *"Fatalities from bedrail entrapment are not an inherent risk of bedrail use but usually relate to outmoded design, incorrect assembly, and incompatible combinations of equipment"* (Healey et al. 2008b p. 377).

3.8.9 Changes in the acuity of patients, and in bed and mattress design

As explored above in Chapter 3.1, the context in which care was carried out changed dramatically over the 20th century, and has continued to do so in the 21st century. Reductions in hospital length of stay and moves to day case surgery are noted year-on-year in the UK (Hospital Episode Statistics 2008), leading to an inpatient population much more likely to be acutely ill and bedfast or hoist dependent, and therefore less likely to have bedrails contraindicated on the grounds that they impede their independence. However, much of the literature on bedrails predating our systematic literature review was written either at a time where far more patients were independent (and therefore far lower proportions of bedrail use were appropriate) or was written more recently, but appeared to consider that the inpatient population was still primarily mobile and independent (e.g. Talerico & Capezuti 2001, Marcy-Edwards 2005, Rollins 2006). By contrast, our systematic literature review emphasised that there can be no such thing as a 'correct' level of bedrail use, as this will be dependent on the needs and wishes of individual patients.

Access to profiling beds and alternating pressure mattresses has transformed the comfort of many inpatients, but also creates potential postural instability. Because of a study (Miles 2002) that described entrapment between pressure relieving mattresses and bedrails, such mattresses were often described as contraindications for bedrails in the literature (e.g. Marcy-Edwards 2005, Rollins 2006), even though manufacturers of such mattresses often recommended bedrail use to protect against their inherent surface instability. Our systematic literature review was able to clarify that the mattresses in the case series were predominantly of a type almost unknown in the UK[lxiii] and to emphasise the need to ensure any replacement mattress, pressure relieving or not, was an appropriate size for the bedbase to avoid entrapment gaps.

3.9 EVIDENCE PUBLISHED SUBSEQUENT TO 2008

In this chapter I will examine direct responses to our systematic literature review in the form of journal letters (O'Keeffe 2009, Hanger 2009) and summarise key findings from other research published subsequent to the search undertaken for our literature review.

3.9.1 Direct responses to our literature review

Two letters to the editor responding to our systematic literature review were published in *Age and Ageing*; these are provided in Appendix J.

The first was from O'Keeffe (2009) whose research (Tan et al. 2005) and opinion pieces (O'Keeffe et al. 1996, O'Keeffe 2004) on bedrails were discussed earlier in Chapters 3.3.3 and 3.5.3. O'Keeffe's (2009) letter made several points, beginning by stating that Tan et al. (2005)[lxiv] had shown injury was more likely in falls from beds with bedrails. It went on to describe the scenario of a mobile patient who wanted to urgently use the toilet being trapped and distressed by their bedrails, then climbing over them and falling from a greater height. After points on probable under-reporting of bedrail entrapment deaths, and advice on the cone and cylinder testing method for entrapment gaps described earlier in Chapter 3.5.4, O'Keeffe concluded that avoiding bedrails for any patient who could conceivably manoeuvre themselves into a dangerous position would be an easier solution than carrying out such testing.

[lxiii] The mattresses implicated in most asphyxial deaths were air fluidised bed replacements and 'high air loss' mattresses. These devices have a constant loss of air through a permeable surface replaced by a constant air input from a pump. They are around twice the height of conventional alternating pressure mattress replacements currently in use in the UK and create a considerably more unstable surface. The constant replacement of air can result in the mattress being rapidly inflated around a patient who has fallen off one side of the surfaces, pressing them against their bedrail and creating a postural asphyxia.

[lxiv] Tan et al. (2005) was a retrospective survey of falls of which O'Keeffe was sixth named co-author, and which was included in our systematic review.

In our concurrently published reply (Healey & Oliver 2009) (Appendix J) we aimed to convey the respect we had for O'Keeffe's previous publications on bedrail safety. In relation to O'Keeffe's point that every possible effort should be made to avoid bedrail entrapment, we noted that these were views we shared and had expressed within our systematic review. We corrected points of fact, including providing the non-significant p value for Tan et al. (2005) from Table 4 of our literature review, to confirm that none of the single hospital retrospective surveys included in our review had statistically significant findings. We also summarised the data on deaths and fractures in falls from bed with and without bedrails in Healey & Scobie for NPSA (2007a) to put O'Keeffe's selective citations on subdural haematomas in falls from bed from Healey & Scobie for NPSA (2007a) into context, and pointed out that far from advocating bedrail use in the scenario O'Keeffe described, our literature review made it clear that using bedrails for patients who could be mobile without them, or who were at risk of climbing over them, was never justified.

The second letter (Hanger 2009) was primarily drawing the readers' attention to a study the author had carried out indicating bedrails in the down position, but still attached to the bed, could slow down patients' movement from sitting to standing (Ball et al. 1997). Although Hanger et al.'s (1999) bedrail reduction study had concluded that the *"continued use [of bedrails] in older patients must be seriously questioned"* (p. 529) the letter opened with the comment *"Healey et al. are to be congratulated for their review of the use of bedrails. I agree with their balanced conclusion that healthcare organisations should be encouraged to reduce inappropriate bedrail use, rather than a universal reduction".* The letter raised no objections to our clarification that the increase in falls initially reported as statically non-significant in Hanger et al. (1999) actually was statistically significant, or our clarification that the apparent decrease in 'serious' injuries was not a decrease in serious injuries as conventionally defined, but a decrease in occasions when neurological observations were recorded.

Given the examples from the earlier literature on bedrails discussed in Chapter 3.5.3, where not only is bedrail use viewed as morally and ethically bad practice, but also clinical staff using bedrails are viewed as old-fashioned, paternalistic, not evidence based, or even discriminatory, the mainly constructive response to our systematic literature review may help set the tone for a less emotive and less polarised debate in the future.

3.9.2 Subsequently published literature

Rerunning the search strategy used in our systematic literature review up to 31/12/2009, nine further studies related to bedrails' effects on falls and injury published subsequent to our literature review's search were identified.

Bowers et al.'s (2008) report in a nursing journal on an ergonomic study using crash test dummies dropped head-first or feet-first from heights of 97.5cm (to represent a fall over a bedrail) and 33.5cm (to represent a fall from bed without a bedrail) with and without a impact-absorbing mat by the beside. Perhaps unsurprisingly, the authors found that falls from greater height were associated with greater impact (p=0.05), falls onto vinyl on concrete were associate with greater impact than falls onto impact-absorbing mats (p=0.001), and head-first falls were associated with greater risk of impact to the head than feet-first falls (p=0.0001). They note that their calculated risk of serious head injury in 40% of head-first falls from bed and 25% of feet-first falls from bed does not appear to match reported injury rates from falls from bed. They also acknowledge that the mechanism of a fall over bedrails may differ from the direct drop used in their study, but perplexingly note that they could not include bedrails as *"they may only be used if prescribed by an attending physician"* (p.258) although it seems highly unlikely any such restriction applies to crash test dummies. Although they note *"results of this study do not directly answer the question of whether bedrails increase the risk of injury in falls from bed"* they state that avoiding bedrails, placing beds at the lowest possible height, and using crash mats at the bedside represents *"assurance that the highest quality care is being provided"* (p. 258).

Diccini et al. (2008) reported on a small prospective observational study of 97 patients undergoing neurological surgery. Of eight fallers, two had bedrails raised and six had no bedrails raised, but no context of overall bedrail use is provided.

Fonad et al. (2008a) and (2008b) combined an annual one day survey of the residents of 21 units within nursing homes in Sweden - collecting data such as the Berg Balance Scale (Berg et al. 1989), and bedrail, wheelchair and anti-depressant use - to inform a model identifying correlation between these factors and reported falls at unit, rather than individual resident, level. Their first paper (Fonad et al. 2008a) analysed data from all 21 units and identified that at unit level bedrail use correlated significantly with patients with balance problems as assessed by the Berg Balance Scale (Pearson's correlation 0.446 p<0.01) but not with actual falls. Whilst the paper stated in its conclusion that bedrail use was associated with a lower risk of falls *"…bedrails did not eliminate falls but our results support the hypothesis that they might be protective when used selectively…"* (p. 127) this finding does not appear from its results chapter to be statistically significant (regression coefficient 0.540 p=0.25) and appears to be the authors' interpretation of their finding that patients given bedrails could be considered more vulnerable to falls (due to the correlation of bedrails with poorer Berg Balance scores) but bedrails did not correlate with actual falls.

Whilst Fonad et al.'s second paper (2008b) described a sub-analysis of Fonad et al. (2008a) that divided the 21 units into those caring for dementia patients and those caring for patients with predominantly physical illnesses, it included an additional 308 reported falls in analysis without any explanation of their source. In these separate groups, a significant negative correlation (regression coefficient -2.829 p=0.011) was found between bedrail use and falls in dementia units (i.e. dementia units reporting higher bedrail use tended to have fewer reported falls) and a significant positive correlation (regression coefficient 1.304 p=0.001) was found in units for physically ill older people (i.e. units caring for physically ill older people reporting higher bedrail use tended to also have more reported falls). In their discussion the authors emphasise the statistical significance of the correlations rather than the direction, and so do not explore potential reasons for the observed differences. The most plausible is that some dementia units cared predominantly for patients still 'wandering' for whom bedrails were likely to be inappropriate however frequently they fell, whilst some dementia units cared for patients who were almost immobile in late-stage dementia and therefore might report both higher bedrail use and fewer falls (since their patients were no longer mobilising at all). The additional negative correlation Fonad et al. (2008b) found between wheelchair use and falls in dementia units (regression coefficient -3.765 p=0.002) would tend to support this hypothesis. For the units caring for physically ill older people, the positive correlation between bedrail use and reported falls may be explained by differences in their resident populations, such as the proportion of residents with unsafe mobility (the strong correlations between bedrail use and impaired mobility at the individual patient level will be discussed later in Chapter 4.7.3.) However, since the authors collected no data on dependency or mobility this cannot be confirmed.

Hamers et al. (2008) assessed through questionnaire the attitudes of samples of nursing staff in three European countries to a range of 'restraint measures' including vest, belt and cuff devices, locked doors, and movement alarms. They found staff rated bilateral and unilateral bedrails as amongst the least restrictive of restraint measures (only movement alarms were rated as less restrictive) and the same ranking applied to how uncomfortable staff felt about using them; they indicated no discomfort in using unilateral bedrails and only mild discomfort in using bilateral bedrails. There were no significant differences between nurses in Germany, Holland or Switzerland. These results are consistent with the findings of Vassollo et al.'s study (2004, 2005) of staff perspectives in the UK discussed above in Chapter 3.4.4.

Miles (2009) (whose earlier work on deaths related to bedrail entrapment is discussed above in Chapter 3.5.4) published a further analysis of post-mortem reports, describing what findings pathologists could expect to see at autopsy following a death related to bedrail entrapment.

Agnshivala & Wenchen (2008) in study predominantly focused on correlations between medication types and falls examined a database where details of 11,940 residents of nursing homes in the USA were recorded. The found that use of bedrails appeared to be associated with a lower risk of reported falls at the individual patient level (odds ratio 0.714 $p<0.001$).

Ng et al. (2008) combined a systematic review of the literature with a retrospective survey of reported falls in two hospitals in Singapore. Whilst their search strategy included all possible variant terms for bedrails, it also required inclusion of the term fall or falls, and was limited only to papers with abstracts accessible in the PUBMED database. They identified five of the 24 studies identified by our systematic literature review. They then excluded two (Hanger et al. 1999 and Hoffmann et al. 1999) on the grounds of poor quality, leaving only three studies (Capezuti et al. 2002, Krauss et al. 2005, Capezuti et al. 2007). The background described within the paper indicated the use of full bedrails was almost standard practice in Singapore, including for ambulant patients, and the authors were seeking to make the case for routine practice to be changed to raising only two or three of the four split bedrail chapters; the potential effects of removing bedrails completely are not discussed. They concluded that partial bedrail use (up to three chapters raised out of four-piece split-sided bedrail designs) was as effective as fully raised bedrails for falls prevention. In my personal correspondence with the authors, they indicated that nursing practice in Singapore is very rules-driven, and the concept of individual decision making on bedrails was thought unlikely to succeed. The paper also compared injury rates between patients in two local hospitals who fell from bed with full bedrails raised, or who fell from bed with part of their bedrails raised. It is unclear if they excluded data on falls from beds without any raised bedrails, or had no such data to include due to the high levels of bedrail use. The injury rate from the two hospitals combined suggested fewer injuries in falls from bed with full bedrails raised (32.1% injurious falls (36/112)) than with partial bedrails (40.7% injurious falls (11/27)). Of injuries with full bedrails raised, four were noted as 'severe', whilst with partial bedrails raised none were noted as 'severe'. No tests of statistical significance were made.

Oliver et al. (2008) expanded on the review of eleven years of litigation data from NHS organisations in England that was included in our systematic review in the form of an earlier and briefer paper (Oliver & Healey 2006). This paper was described earlier in Chapter 3.3.4 as part of the discussion of the influence of litigation on clinical practice, but in summary noted only three of the total of 108 claims related to falls from bed over an eleven year period described raised bedrails.

Overall, whilst the studies published since our systematic literature review are few in number, they suggest some degree of change in the presentation and interpretation of results. Excluding the two studies I co-authored (Oliver and Healey 2006, Healey & Scobie for NPSA 2007a) only one of the 24 studies included in our systematic review (Krauss et al. 2005) mentioned any potentially beneficial effects of bedrails in their abstract or conclusions, whilst two studies were neutral (Kron et al. 2003, Everitt & Bridel-Nixon 1997). The remaining 19 studies noted only potentially negative effects, although in some cases (as discussed in Chapter 3.8.3) these did not always appear to be justified by their actual findings.

Of the nine studies published since our literature review, three mentioned potentially beneficial effects of bedrails in their abstract or conclusions (Fonad et al. 2008a, Agnshivala & Wenchen 2008, Oliver et al. 2008) and although Ng et al. (2008) presented negative conclusions on full bedrail use, they did so in context of encouraging partial bedrail use. Therefore, whilst it is impossible to confirm this until further time has passed, our literature review may have created a tipping point where studies noting possibly beneficial effects of bedrails, as well as their disadvantages, are no longer seen as unacceptable. However, Ng et al.'s (2008) study is also an important reminder that, whilst our systematic literature review identified the risks of moving from a policy of routine bedrail use to the opposite extreme of a policy of bedrail elimination, routine bedrail use continues to be a challenge in some international healthcare settings.

3.10 IMPLICATIONS FOR CLINICAL PRACTICE

Despite the limitations of the literature available for inclusion in our review, and the care we took to only draw conclusions that could be justified either by this limited evidence or by legal and ethical frameworks, our systematic literature review was able to provide a clear and clinically-focused conclusion. This included an emphasis that neither a policy of routine bedrail use nor a policy of bedrail elimination could be justified by the evidence. We were able to highlight patient groups that may benefit from bedrail use, as well as those for whom bedrail use would clearly be inappropriate. We were also able to emphasise that bedrail entrapment was not a random or inevitable risk, but could be avoided through the use of safely designed, correctly fitted and well maintained bedrails.

These points had already been made in the UK setting, based on our systematic literature review but prior to its publication, with an NPSA Safer Practice Notice *Using bedrails safely and effectively* (Healey & Stephenson for NPSA 2007b) that was issued directly to all hospitals in England and Wales and to hospitals and care homes in Northern Ireland. However, national advice does not have the same academic credibility as a systematic literature review published in a peer reviewed journal. Therefore our review was core to establishing that these recommendations were empirically based, rather than simply good practice advice. Safety Notices and Alerts also tend to have a limited circulation in trusts in the UK, primarily within clinical governance, risk management, and nursing leadership. Our choice to submit our systematic literature review to *Age and Ageing* was key to ensuring it reached the majority of practicing geriatricians in the UK as well as international audiences.

Our review's contribution to clinical understanding may also have been enhanced by the authorship. The majority of papers published prior to our systematic literature review were authored either by doctors or by nurses, rather than co-authors including both a nurse and a doctor. Most of the bedrail opinion-pieces from the UK were written by doctors (e.g. *The Lancet* 1984, Oliver 2002, O'Keeffe 2004) although in UK settings decision making on bedrails is almost always undertaken by nurses (Healey et al. 2009). Also, the clinical experience of the authors meant we could draw conclusions and key points from the empirical evidence that were practical and relevant to clinical practice.

Additionally, both the second author and I had a history of research and publication in the field of hospital falls prevention which helped to ensure our clinical recommendations on bedrails were appropriately placed within the wider clinical context of strategies to reduce falls in hospital patients, unlike much of the earlier literature where the role of bedrails in falls from bed is treated in isolation from wider falls prevention interventions. My experience as lead author of Royal College of Nursing guidance on restraint (RCN 2008) also allowed me to ensure the discussion in our systematic literature review was appropriately placed within the context of wider legal and ethical issues of restraint.

Further, changes in clinical understanding and practice are not influenced solely by evidence, but by the beliefs and values of individuals and the social influences of the teams or groups they work within (Kitson et al. 1998). Our systematic review, in exploring the dichotomy between the evidence and opinion in the previously published literature and discussing its possible causes, prompted its readers to reconsider the basis for their own opinions and beliefs.

Because of the close links of our systematic literature review with NPSA Safer Practice Notice *Using bedrails safely and effectively* (Healey & Stephenson for NPSA 2007b), including its publication in an early form (Healey for NPSA 2007d) to support the Safer Practice Notice, it is difficult to discuss its impact on clinical practice in isolation. Chapter Five of this doctoral statement will therefore explore in detail the evidence of impact for all my interlinked publications.

3.11 DIRECTIONS FOR FUTURE RESEARCH

In our systematic review, we highlight key areas for future research on bedrail use. The most important issue is whether an RCT of bedrail use is feasible, given how embedded the intervention is in practice, and given the evidence we identified in our systematic literature review that both routine bedrail use and routine bedrail elimination are likely to be harmful. In our review we stated that *“Whilst an RCT of bedrail use would present design challenges and for ethical reasons could randomise only individuals without absolute contraindications or indications for bedrail use, the bedrail controversy is unlikely to be fully resolved until such a trial is carried out”* (Healey et al, 2008 p. 377). Such a trial would face the normal challenges of all hospital falls prevention trials discussed earlier in Chapter 2.2.5. These include the need for patients to be recruited early in their admission, and strategies for recruitment of patients unable to give informed consent through illness, unconsciousness, or cognitive impairment. Additionally, any such RCT would probably be highly dependent on how well decisions on elimination of patients with absolute contraindications or indications for bedrail use were made, with randomisation only ethically justifiable for patients without these.

Additionally, such trials would face the dilemma that patient choice is a legitimate reason for allocation or non-allocation of bedrails in clinical practice, but not in individually randomised trials. The element of patient choice could potentially be addressed by using a preference based trial (Torgerson & Sibbald 1998). In cases where patients' preference for a particular treatment is elicited prior to randomisation, but all participants are still randomised, the results are as valid as any conventional RCT, but can also provide useful additional information on the effect of preferences on outcomes of the treatment received (Donovan et al. 2002, Adamson et al. 2005) . However, Ralphs-Thibedeau et al. (2006) had to abandon a planned RCT of bedrail reduction after 33% (20/60) of residents withdrew their consent when their randomisation did not match their preference. This suggests that a more complex preference based trial design might be required (Torgerson & Sibbald 1998) with two non-randomised groups (patients whose preference for raised bedrails or no bedrails is so strong they will not consent to randomisation) in addition to two conventionally randomised groups. Whilst any comparison between the groups exercising choice would be invalid due to potential confounders introduced by their self-selection, exploring these groups' outcomes as an observational study could add useful context to the randomised arm, potentially including whether the results seen in the randomised arm could be generalised to patients unwilling to be randomised.

It may be more feasible to conduct a cluster randomised trial comparing the effect on falls and injury rates of interventions directed at promoting individualised decision making on bedrails, with control wards continuing 'normal practice'. The use of randomisation by cluster overcomes the challenges of patient recruitment and self-selection described above, but creates new challenges in terms of design and analysis techniques in order to avoid false positives (Donner & Klar 2000). Cluster randomised studies need to be larger than individualised randomised studies to achieve the same power (Donner & Klar 2000) but the increased costs inherent in a larger study can potentially be offset by the reduced cost of individual recruitment and consent.

The nature of the intervention used to encourage appropriate use of bedrails in any cluster randomised trial may also benefit from further research. In studies aimed at reducing the use of vest, belt, harness, cuff and chair restraint devices, a variety of interventions were used, including staff education, patient and family education, policy change, and resident or visiting expert advisors (Evans et al. 2002). A range of locally developed tools intended to prompt individualised decisions on bedrail use are in use in healthcare settings (Healey for NPSA 2007c) but their relative utility and effectiveness is unknown.

It is difficult to construct a clinical rationale for partial bedrail use, since partial bedrails are unlikely to successfully prevent a vulnerable patient falling from their bed, whilst if the patient is not vulnerable to falling from bed, they would provide no benefit. However, partial bedrail use is being used in many settings apparently as a compromise between full bedrail use and no bedrail use (e.g. Capezuti et al. 2002, Krauss et al. 2005, Capezuti et al. 2007, Ng et al. 2008). Therefore in our review we also suggested trials randomising to an additional arm of partial bedrails may also be useful.

Our review suggested that *"In addition to effects on falls and injury, any other potential harms or benefits of bedrail use merit investigation"* (p. 377). Because of the potential for bedrails to restrict independence, useful measures are likely to include mobility and dependency scores, continence status, length of hospital stay, and discharge destination.

As discussed in Chapter 3.2, there are many varieties of bedrails available, in a range of sizes and materials. Our review therefore suggested the effect of differing bedrail designs merits further research. Aspects to explore would include the influence of different designs on contact or limb entrapment injury, and their acceptability from the patient's perspective.

Our review proposes that *"Given the emotive nature of the bedrail debate, qualitative exploration of the views of patients and staff may also be helpful"* (Healey et al. 2008b p. 377). This would need to include exploration of any variations between different social or cultural groups. Vassollo et al.'s (2004, 2005) approach of comparing and contrasting the views of patients, relatives, and staff merits replication, but the evidence on patients' perspectives is very limited and must be considered a priority for future research.

3.12 CONCLUSION

Because both falls from bed and direct injury from bedrails can lead to harm at all levels, from psychological distress and minor injuries to fatalities, the examination of bedrail use is an area of key importance in preventing harm to hospital patients from falls. But prior to our systematic literature review the evidence on the effect of bedrails was scattered and unclear, with papers containing empirical evidence hard to locate within the many opinion based papers expressing strongly negative perspectives of bedrail use. No truly systematic literature reviews specific to bedrail use existed, and semi-systematic reviews or overviews of the literature were weak or outdated.

Our systematic literature review sought to address this empirical vacuum through providing a comprehensive and contemporaneous picture of the evidence base in order to inform a more balanced and rational debate on bedrail use, to influence clinical practice, and to provide an evidence base for local and national policies or clinical protocols on bedrail use. Our systematic literature review was the most comprehensive systematic review and synthesis of published evidence of the effect of bedrails on falls and injury published to date, with strengths including an inclusive and comprehensive search strategy that identified more than twice as many studies as any earlier review, data standardisation, and critical comment. Our inclusion of both falls from bed and direct injury from bedrails enabled us to make recommendations that were balanced and acknowledged both these risks. Our inclusion criteria acknowledged the limitations of non RCT studies through carrying out formal quality assessment of their design, but did not reject reasonably well designed studies that could provide useful information.

A further strength of our systematic literature review was the detailed discussion, which encompassed the ethical implications of bedrail use, patients' perspectives, and why the attitudes in the literature to bedrails appeared to have become so divorced from the actual evidence. Whilst acknowledging the limitations of the evidence base, our systematic review's conclusion gave very clear directions for clinical practice in areas the evidence could support, including the inappropriateness of bedrail use for certain patient groups, the need for safely designed, correctly fitted and well maintained bedrails, the risks of programmes aimed at across-the-board reductions in bedrail use, and the need for a broad approach to reducing individual falls risk factors rather than simply aiming to prevent falls from bed.

Our systematic literature review differed from the majority of the earlier literature by drawing on legal and ethical frameworks to emphasise the rights of patients with capacity to make their own decisions about bedrail use, rather than the paternalistic decision making demonstrated in some bedrail reduction studies. Most importantly, it included a specific chapter on how bedrail entrapment occurred and how it could be avoided.

Overall, the mainly constructive response to our systematic literature review may have created a tipping point where studies noting possibly beneficial effects of bedrails, as well as their disadvantages, are no longer viewed as heresy, and has set the tone for a less emotive and less polarised debate.

CHAPTER FOUR: AN OVERNIGHT SURVEY OF BEDRAIL USE

4.1 INTRODUCTION

In this chapter of my doctoral statement I will focus on our overnight survey of bedrail use in England and Wales (Healey et al. 2009). Our systematic literature review found that neither routine bedrail use nor total bedrail elimination was appropriate, that bedrails were likely to be unsuitable for some groups of patients, and that bedrails should not be used with the intention of restricting patients' voluntary behaviour. Therefore, understanding current levels of bedrail use, the characteristics of patients using them and nurses' rationale for their use are very important elements in ensuring bedrail use is as safe and effective as possible.

I will begin by discussing studies published prior to our overnight survey, including all identified studies on the prevalence of bedrail use in hospitals, with a particular focus on studies from UK hospitals. I will then examine in detail those prevalence studies that also included examination of any patient variables or other variables influencing bedrail use, or described rationales given by nurses for bedrail use.

Having created a picture of the evidence published prior to our overnight survey, I will briefly describe why the overnight survey was undertaken as part of a national project on bedrail safety. I will then go on to discuss the strengths and weaknesses of our overnight survey.

I will then, most importantly, discuss the commonalities and differences between the evidence presented prior to our overnight survey, and the evidence within it. Key to this discussion will be the incorporation of key patient and equipment variables, and the effect of techniques used to analyse the data. Commonalities and differences between nurses' rationale for bedrail use found in our own study and nurses' rationale in previously published studies will also be discussed.

I will then summarise key findings from research published subsequent to our overnight survey. Finally, I will indicate what our overnight survey has added to the understanding of the issue, including the implications for clinical practice and directions for future research.

4.2 PREVALENCE STUDIES OF BEDRAIL USE IN HOSPITALS

4.2.1 Introduction

In Chapter 3.3.3 the early history of bedrail use was examined. This chapter will not revisit these early and limited data on bedrail use, but will examine only empirical studies published prior to our overnight survey. To do this I will use studies designed to collect bedrail prevalence, and also any other types of studies which provided incidental data on bedrail use. Whilst all the studies I will describe included some data on the prevalence of bedrails, only some included data on variables associated with bedrail use, or on nurses' rationale for bedrail use. For clarity, these aspects of the studies will be discussed separately, beginning with an overview of prevalence outside and inside the UK, before exploring patient and environmental variables related to bedrail use, and nurses' rationale.

4.2.2 Prevalence studies of bedrails in care homes

As outlined in earlier chapters, the key focus of my doctoral statement is on falls prevention in hospital settings. The inclusion of care home studies in Chapter Three of this doctoral statement is justified because the mechanism of falls from bed and the consequences of falls from bed would be expected to be similar whether a patient was located in a care home or a hospital. However, there are many reasons why levels of use of bedrails in care home settings would be expected to differ from hospital settings. These include the older average age of care home residents, a longer length of stay, and residents' chronic rather than acute illness. Additionally, care home residents, unlike hospital patients, would not be undergoing procedures carried out under anaesthetic or sedation.

Therefore I will not examine levels of bedrail use in care homes in detail, but note that there appear to be wide variations in bedrail prevalence between individual care homes. From 9% to 71% of residents are reported to have their bedrails raised in care home settings in Australia and the USA (Tinetti et al. 1995, Retsas 1997, Retsas & Crabbe 1997, Retsas 1998, Retsas & Crabbe 1998, Evans et al. 2003, Hoffman et al. 2003). Levels of bedrail use even differ greatly between similar care homes located near each other (Capezuit et al. 2002, Capezuti et al. 2007) and may change markedly in the same care home over time. For example, Si et al. (1999) note that after a change in protocol, bedrail use in a single care home changed from over 90% to around 15% over a six month period.

4.2.3 Prevalence studies of bedrails in hospitals outside the UK

Few studies of bedrail prevalence in hospitals outside the UK appear to have been published prior to our overnight survey. Perhaps the widespread use of vest, belt, cuff, harness, and chair restraint devices in most healthcare settings outside the UK (described earlier in Chapter 3.3.2) has diverted research efforts to measuring the prevalence of these devices instead.

As shown in Table 4a below, nine studies providing data on bedrail prevalence in hospitals outside the UK were located.

TABLE 4a: Prevalence studies of bedrail use in hospitals

Reference	Study type	Setting, subjects & process	Prevalence findings	Patient variables	Nurses' rationale
Capezuti et al. 2000	Prevalence study (number of data collection points unknown) only available through secondary references[lxv]	Large acute teaching hospital in the USA during 1994 - 1997 patient/bed numbers not provided *"Night-time"* observation of beds with all four split bedrail chapters raised	30% fully raised bedrails on medical and surgical wards 67% fully raised bedrails in critical care units	-	-
Hanger et al. 1999	Two point prevalence carried out during the before and after stages of a bedrail reduction study	Small rehabilitation hospital (135 beds) in New Zealand Daytime observation of beds with *"bedrails attached physically to a bed"*	29.6% (40/135) of beds with bedrails attached at point one, 11.5% (18/135) of bedrails attached at point two (six months later).	-	-
Noone & Fleming 1998	Two point prevalence study	Small general hospital (132 patients) in Ireland One observation for raised bedrails in *"daytime"* and one *"during the night"*	16% (21/132) of patients had raised bedrails at night 9% (12/132) in daytime Patients on care of the elderly wards are said to be *"significantly less likely"* to have bedrails raised but no p value is given	-	N=21 76.2% (16/21) to prevent falls 9.5% (2/21) patient request

[lxv] These data were taken from Capezuti 2004 and Brush & Capezuti 2001 where it is referenced to 'Capezuti et al. Side rail use in a large urban medical centre *The Gerontologist* 40:1 p. 117'. However, this reference is actually to an announcement of a symposium that includes this only as the title of the presentation, and does not include any of the findings – these are only described in the later papers by the same author , with Capezuti et al. 2000 cited as the source.

Reference	Study type	Setting, subjects & process	Prevalence findings	Patient variables	Nurses' rationale
Tan et al. 2005	Two point prevalence study conducted as context for a retrospective survey of reported falls	Patients aged over 18 years in a large acute teaching hospital in Ireland with 730 beds Two observations in one day between 14.00-17.00 and 23.00-02.00	22.4% had *"bedrails raised on at least one assessment"* but this figure is said to be based on 98 out of 642 patients (actually = 15.3%)	-	-
Minnick et al. 2008	18 point prevalence study within a study encompassing restraint devices (separately published as Minnick et al. 2007)	Partially randomised sample of 40 hospitals with at least 100 beds each (totalling 434 wards or units) drawn from three states in the USA selected for convenience Obstetric and rehabilitation wards were excluded and paediatric units were included. Observed or reported bedrail use between 05.00 and 07.00 defined as *"full side rail use (without any other restraints)"* 18 sets of observations each on around 8000-9000 patients resulting in 155,412 observation points	11.0% had *"full side rail use (without any other restraints)"* but this figure is said to be based on 12,489 out of 155,412 (actually = 8.0%) 55.0% in adult ICUs 20.9% in paediatric ICUs 10.2% on medical wards 12.6% on neurology wards 13.9% on surgical wards 6.5% on orthopaedic wards 7.2% on cardiac wards 7.2% on paediatric wards No data is provided on overall variations in bedrail use between the 40 hospitals, but variations between similar units in a sub-sample of 18 hospitals are noted e.g. rates from 1% to 92% in individual medical units	Descriptive results: 65.6% of patients with raised bedrails aged over 65 & 47.8% of patients overall aged over 65 45.8% of patients with raised bedrails male & 46.3% of patients overall male 9.2% of ventilated patients had raised bedrails & 6.1% of patients overall were ventilated	N=?12,489 Multiple rationales permitted 46.9% to prevent falls 24.1% confusion 9.2% patient or family request 4.7% to prevent therapy disruption 3.8% to prevent wandering 3.5% raised in error 23.9% remaining 'other' reasons[lxvi]

[lxvi] The study initially presents 30.9% other reasons, and then breaks these down into percentages of 'other'. These have been recalculated for this table as a percentage of the total for clarity e.g. of all 'other reasons' (which were 30.9% of all reasons), 29.9% were patient or family request = 9.2% of all reasons were patient or family request. However, overall totals in the original paper total 116.1% which is said to be *"due to multiple reasons"* (p. 43).

Reference	Study type	Setting, subjects & process	Prevalence findings	Patient variables	Nurses' rationale
Bredthauer et al. 2005	Multiple point prevalence within a study encompassing restraint devices and chemical restraint (abstract only in English)	122 consecutively admitted patients on a psychogeriatric unit within an acute psychiatric hospital in Germany Daily observation (any use within previous 24 hours implied)	30% (37/122) had bedrails raised 48% (29/60) of *"patients with severe cognitive impairments"* had bedrails raised	-	-
Irving 2004	Single point prevalence within a study encompassing restraint devices and chemical restraint	Nine wards (256 patients) within an acute teaching hospital in Australia (450 beds) Observation *"during one day"* of bedrails that *"constituted restraint"* (criteria not provided)	8.6% (22/256) had bedrails that *"constituted restraint"* in daytime	-	-
Kwok et al. 2006	Multiple point prevalence study of bedrail use as an outcome measure in an RCT of movement alarms	*"patients considered to be at risk of falls"* on two rehabilitation wards (27 beds x 2) in Hong Kong Bilateral bedrail use observed six days per week for 10 months (any use within previous 24 hours implied)	76% (137/180) of *"patients considered to be at risk of falls"* had bilateral bedrails raised	-	-

Reference	Study type	Setting, subjects & process	Prevalence findings	Patient variables	Nurses' rationale
Tutuarima et al. 2003	Twelve point prevalence study within a study encompassing restraint devices	208 consecutively admitted patients on two wards (internal medicine 145 patients and neurology ward treating primarily stroke 63 patients) observed daily during one month during 2001. Observations made between 07.00 and 08.00 on three weekdays Concurrent use of body restraints	34% (71/208) of patients had side-rails raised on at least one observation On the medical ward, 23% (34/145) had side-rails raised on at least one observation On the neurology/stroke ward, 59% (37/63) had side-rails raised on at least one observation	Odds ratios (95% CI) using multivariable logistic regression: Gender NS Neurology ward 3.7 (1.4-10.1) Age>80 years 12.2 (2.9-51) Stroke 6.5 (1.8-24) Disorientation to time place or person recorded in nursing records 9.0 (2.7-29) Restlessness or agitation (undefined) 68 (7.8-596)	-
O'Keeffe et al. 1996	Single point prevalence study	688 patients in a large acute teaching hospital in England: 668 patients observed ITU and observation wards excluded Observed bedrail use between 00:00 and 06:30	8.4% (64/668) had bedrails raised 11% on medical wards 7% on surgical wards 4% on elderly medicine wards (significantly less likely in step wise logistic regression analysis OR=0.1 95% CI 0.03-0.4).	Odds ratio (95% CI) using step wise logistic regression analysis: Fall during the current hospital admission NS Cognitive impairment[lxvii] without agitation NS Gender NS Cognitive impairment plus agitation[lxviii] 10.7 (4.4-26.8) Age>70 years 9.4 (3.7-23.6) Major hemiplegic stroke 4.8 (2.1-11)	N=56 92.8% (52/56) to prevent falls 5.4% (3/56) patient request 1.8% (1/56) to prevent wandering

[lxvii] Defined as any mention *"in the medical or nursing notes as 'confused' or any similar term"*
[lxviii] Defined as any item from the Cohen-Mansfield inventory, or removal of treatment devices, within the day preceding the survey

Reference	Study type	Setting, subjects & process	Prevalence findings	Patient variables	Nurses' rationale
Gallinagh et al. 2002b	Twelve point prevalence within a study also examining the use of chair restraint	Convenience sample: four rehabilitation wards across two hospitals in Northern Ireland: 102 patients Observations made around 10.00, 14.00, 18.00, and 22.00 on three consecutive days	50% (150/306) bilateral raised bedrails at 22.00 13% (39/306) partially raised bedrails at 22.00 23% (71/306) bilateral raised bedrails at 10.00 7% (21/306) partially raised bedrails at 10.00 28% (85/306) bilateral raised bedrails at 14.00 9% (27/306) partially raised bedrails at 14.00 28% (85/306) bilateral raised bedrails at 18.00 8% (25/306) partially raised bedrails at 18.00	Statistical comparison between bedrails raised & no bedrails groups:[lxix] Age in whole years NS Gender NS Other prior diagnoses NS History of stroke $p<0.05$	N=51 88% (45/51)[lxx] to *"promote positional support"* Of patients with raised bedrails, 41% had a history of a fall within the last month v. 61% of those without, 69.9% were described as 'very dependent'[lxxi] by their nurses, v. 6.1% of those without ,18.5% were prescribed benzodiazepines, v. 35.7% of those without
Govier & Kingdom 2000	Two point prevalence study conducted as context for a retrospective survey of reported falls	206 beds in eight elderly care, neurology, neurosurgery, trauma and orthopaedic wards across one district general hospitals in England Observations made *"by day"* and *"by night"* Bilateral and partial bedrails included	40% (83/206) had complete or partial bedrails raised at one or both of the observation points	-	-

[lxix] This study did not separate variables associated with bedrail use from variables associated with the use of restraining chairs, but 91.4% of observations in the study related to bedrails, and only 8.6% to restraining chairs, and it is implied that the patients in restraining chairs by day had raised bedrails at night

[lxx] Note that Table 5 (p.152) in Gallinagh et al. (2002) although headed *'nurses' rationale for bedrail use'* actually describes patient variables measured through case note review e.g. history of falls within the past month. The text below separately describes *'reasons cited by nurses'*. Unlike patient variables, nurses' rationale are reported separately for bedrails (i.e. the figure above does not include rationale for use of restraint chairs).

[lxxi] Defined as a *"tick chart"* with options of *"independent/minimal independence/moderate independence/very dependent"*

Reference	**Study type**	**Setting, subjects & process**	**Prevalence findings**	**Patient variables**	**Nurses' rationale**
Hignett et al. 2005	Three point prevalence study published as a book chapter	295 beds on twelve medical and rehabilitation wards in one acute hospital in England Observations made between 10.00-13.00, 16.00-1.00 and 22.00-01.30	18% (54/295) raised bedrails in the morning 22% (64/295) early evening 46% (135/295) overnight Risk assessments documented for 71% (180/253) of patients with raised bedrails	-	N=135 42% to prevent falls 22% patient or relative request 6% unconsciousness 4% to prevent wandering 2% because of confusion 1% restraint 23% other
Mildner et al. 2003	Single point prevalence study published as a letter to the editor	Acute elderly, medical and surgical wards and rehabilitation wards in two large acute teaching hospitals and three district general hospitals in England: 1109 beds observed ITU, obstetrics, paediatrics, orthopaedics and specialist wards excluded. Time of observation not described	61.3% on rehabilitation wards 76% on acute elderly 36.6% on acute medical wards 14.5% on acute surgical wards Overall prevalence higher in the teaching hospitals (36.8%) than the district general hospitals (29.6%) but *"no statistical differences"* between similar wards at either site	-	-
Raw & Stacy 2004	Single point prevalence study published as a letter to the editor	Acute integrated elderly & medical wards, surgical wards, and rehabilitation wards in one district general hospitals in England: 587 beds observed ITU, obstetrics, paediatrics, orthopaedics and specialist wards excluded. Time of observation not described	28.1% (165/587) had bedrails raised 23.6% on integrated elderly & medical wards 47.7% on rehabilitation wards	-	-

The nine studies from outside the UK cover a range of countries, including Ireland (Noone & Fleming 1998, Tan et al. 2005), the USA (Capezuti et al. 2000, Minnick et al. 2008), Australia (Irving 2004), New Zealand (Hanger et al. 1999), the Netherlands (Tutuarima et al. 2003), Germany (Bredthauer et al. 2005), and Hong Kong (Kwok et al. 2006).

However, in five of the studies data collection on bedrails was a secondary part of a study carried out with different aims (see Table 4a). These studies provided data limited to the overall number or percentage of bedrails in use (Irving 2004, Bredthauer et al. 2005, Tan et al. 2005, Kwok et al. 2006) or bedrails available for use (Hanger et al. 1999). All but Kwok et al. (2006) were limited further by a lack of clarity on whether the totals they provided included partially raised bedrails,[lxxii] and only Tan et al. (2005) observed bedrail use at night. The remaining studies collected data by day (Hanger et al. 1999, Irving 2004) or observed bedrail use by day in combination with questioning staff on bedrail use during the previous night (Bredthauer et al. 2005, Kwok et al. 2006). A further study (Capezuti et al. 2000) provided only very brief summary data through secondary references to a conference presentation. The two studies based in acute general hospitals described 30% of patients with fully raised bedrails at night (Capezuti et al. 2000) and 22.4% of patients with bedrails raised either by day and/or by night (Tan et al. 2005). The other four studies were limited to a small range of wards or specialist units, and described rates of 11.5% to 29.6% of beds with bedrails attached (Hanger et al. 1999), 8.6% of patients with 'bedrails that constituted restraint' (Irving 2004), 30% of patients with raised bedrails (Bredthauer et al. 2005), and 76% of 'patients considered to be at risk of falls' with bilateral bedrails raised (Kwok et al. 2006).

Only three were studies whose main purpose was to collect data on the use of bedrails (Noone & Fleming 1998, Tutuarima et al. 2003, Minnick et al. 2008). Noone & Fleming (1998) described a single point prevalence study in a small acute hospital in Ireland (132 patients), with a night-time prevalence of 16% of bedrails raised and a day-time prevalence rate of 9%. It is unclear if partially raised bedrails were included in these figures. Patients on care of the elderly wards are said to be 'significantly less likely' to have bedrails raised but no p value is given, and the sample size may have been too small to detect significant differences.

[lxxii] Partial bedrail use would include one side of bilateral bedrails raised, or between one and three chapters of split bedrails raised. Full bedrails would include both sides of bilateral bedrails raised, or all four chapters of split-sided bedrails raised.

Tutuarima et al. (2003) used a sample of 208 patients consecutively admitted to one neurology ward and one internal medicine ward in the Netherlands. The study observed patients on three weekday mornings between 07:00 and 08:00 for four weeks, and identified that over the two wards 34% of patients had raised bedrails on at least one observation. It is unclear if partially raised bedrails were included in these figures. On the neurology ward, 59% had bedrails raised on at least one observation, with 23% on the internal medicine ward. The specialist nature of the wards, and the observation of bedrail use by day, may limit the relevance of the study to other times and settings.

Minnick et al. (2008) described a very wide scale multi-point bedrail prevalence study carried out over 40 acute hospitals in the USA, each with at least 100 beds. The bedrail prevalence study was a secondary part of a study on vest, belt, cuff, harness, and chair restraint devices that was published separately (Minnick et al. 2007). The purpose of the survey was to establish a benchmark level of bedrail use that *"managers and other quality management personnel"* (p. 37) should use to set targets for reducing their local use of bedrails.

The method used was self-collection of data by the individual hospitals. In a context where state legislation may automatically define bilateral bedrails as restraint devices (Brush & Capezuti 2002), and regulatory organisations can serve 'deficiency notices'[lxxiii] on healthcare institutions for excess use of bedrails (Brush & Capezuti 2002, Minnick et al. 2007), self-collection of data by participating hospitals could potentially be subject to bias. Data were collected during between 05:00 and 07:00 on 18 days within one month per hospital. The early morning hours used for data collection would be likely to be reasonably representative of night time bedrail use. Paediatric patients were included but rehabilitation patients were excluded; no rationale is given for this.

Although the hospitals are only briefly described as 'randomly selected' in Minnick et al. (2008) the fuller description of methodology in Minnick et al. (2007) described difficulties with randomisation. Three states were selected on the basis of geographical convenience to the researchers and all hospitals within the three states were entered to randomisation,

[lxxiii] In the USA 'deficiency notices' appear to be issued by various bodies which exist as part of different states' legislature, and appear akin to improvement notices issued in the UK by bodies such as the Health and Safety Executive or the Care Quality Commission. Failure to comply can result in loss of registration, and the 'deficiency notices' are in the public domain.

but the number of hospitals declining to participate probably skewed the sample. Whilst 27 out of 40 (67.5%) of the initial randomised sample agreed to participate, it took 39 further random selections to recruit twelve further hospitals, and one additional hospital was selected on the basis of convenience.

Although the repeated surveys in multiple hospitals generated 155,412 patient days of data, these do not all appear to have been used for analysis. The authors stated they used data ‘representing’ the full data set, but not how the subset of data was obtained. They also stated that a subset of 18 hospitals was used for some aspects of analysis, but not how these hospitals were selected. The methodology also explicitly excluded data where patients had both bedrails and restraint devices in use, and so described bedrail use only in patients without these devices.

The study described an overall rate of full bedrail use in the absence of restraint devices as 11.0%. However, the numerical data supplied on bedrail use (12,489 observations out of 155,142 observations) would suggest a rate of 8.0%. Average rates of use are also described for several specialities, including 55.0% reported on adult ICUs, 10.2% on medical wards, 12.6% on neurology wards, 13.9% on surgical wards, and 7.2% on cardiac wards.

With the exception of Noone & Fleming (1998) and Hanger et al. (1999), all of the nine international studies described above took place in countries where vest, belt, cuff, and harness devices are also used on patients in bed. The interaction between these restraint devices and bedrail use is unclear. Some of these restraint devices, particularly cuff restraints, may require raised bedrails, as these may be used to anchor the cuff device. Tinetti et al. (1995) suggested restraint devices tend to be associated with raised bedrails under the ‘belt and braces’ principle, although Capezuti et al.’s (1999) study found that a reduction in the use of restraint devices in bed led to an increase in the use of bedrails. Regardless of whether the use of restraint devices tends to increase or decrease bedrail use, the results of bedrail prevalence studies in countries that use restraint devices should be applied with caution to countries that do not.

4.2.4 Prevalence studies of bedrails in UK hospitals

As outlined in Table 4a above, prior to our overnight prevalence study only one whole hospital prevalence study of bedrail use in the U.K had been published (O’Keeffe et al.

1996) with five additional studies limited to selected wards or departments within a single hospital (Govier & Kingdom 2000, Raw & Stacy 2004, Hignett et al. 2005) or more than one hospital (Gallinagh et al. 2002b, Mildner et al. 2003). Of these five part-hospital studies, only one is a full paper in a peer-reviewed journal (Gallinagh et al. 2002b).

One study (Govier & Kingdom 2000) only briefly described bedrail prevalence in 206 beds within elderly care, neurology and orthopaedic wards in a district general hospital in England, as context in a retrospective survey of falls. One observation was made by day and one at night (the exact times are not described) and 40% of patients are described as having partial or full bedrails raised on one or both observations.

Two studies of bedrail prevalence (Mildner et al. 2003, Raw & Stacy 2004) were described only in brief non-peer reviewed journal letters that were written primarily as responses to an earlier editorial on bedrail use (Oliver, 2002). Neither letter described whether patients were surveyed by day or night, nor whether or not partial bedrails were included. Mildner et al. (2003) described surveying acute medical, surgical, geriatric or rehabilitation wards across a local cluster of two large teaching hospitals and three district general hospitals in England. However, the small number of beds surveyed (1,109) in comparison to the size and number of the hospitals suggests either partial sampling and/or the exclusion of any sub-speciality wards within medicine and surgery. The letter described a prevalence of 76% on acute elderly medicine wards, with 61.3% on rehabilitation wards, 36.6% on acute medical wards, and 14.5% on acute surgical wards, leading to a combined average prevalence of 32.4%. Raw & Stacy's (2004) letter described a survey of single district general hospital in England intended to replicate Mildner et al. (2003) in terms of wards included. However, they surveyed 587 beds, which in the context of a single hospital suggests less sampling occurred or fewer wards were excluded. They described a prevalence of 47.7% on rehabilitation wards, 36.6% on acute medical wards, and 14.5% on acute surgical wards, leading to a combined average prevalence of 28.1%.

Hignett et al. (2005) described their bedrail prevalence study in a book chapter. The study observed 295 beds in a medical and rehabilitation department within an acute general hospital in England. They found that 46% of patients had bedrails raised at night; it is unclear if partially raised bedrails were included. Bedrail prevalence in the morning and early evening was also described, but these data used total beds as the denominator, and without any data on the proportion of patients out of bed cannot be meaningfully interpreted.

The only detailed UK study of bedrail prevalence that was not limited to specific wards or specialities (O'Keeffe et al. 1996) observed 668 patients in an acute general hospital in England at night. An overall prevalence of 8.4% of raised bedrails was identified, but it is unclear if partially raised bedrails were included. In contrast to Mildner et al. (2003) and Raw & Stacy (2004), where the highest prevalence of raised bedrails was found on elderly medicine and rehabilitation wards, O'Keeffe et al. (1996) found 11% on medical wards, 7% on surgical wards, and 4% on elderly medicine wards (with bedrail use significantly less likely on elderly medicine wards in stepwise logistic regression analysis OR=0.1 95% CI 0.03-0.4).

Gallinagh et al. (2002b) observed bedrail use at 22:00 over three successive days on 102 patients on older people's wards in two hospitals in Northern Ireland. A prevalence of 50% fully raised bedrails plus 13% partially raised bedrails was recorded. The observation time of 22:00 would be likely to be reasonably representative of night time bedrail use. Bedrail prevalence at 10:00, 14:00 and 18:00 was also described, but again these data used total beds as the denominator.

4.2.5 Variations in bedrail use between hospitals

Minnick et al. (2008) is the only study from outside the UK where prevalence was collected at more than one hospital. Whilst no data were provided on overall variations in bedrail use between the 40 hospitals, the authors noted variations between similar units, including a range from 1% to 92% between individual medical wards, 1% to 87% between neurological ICUs, and 1% to 43% between cardiac units. Because any patients with both bedrails and restraint devices were excluded from analysis, it impossible to say whether the lower ends of the ranges actually described low levels of bedrail use or high levels of use of restraint devices.

Two of the UK studies described above were carried out over more than one hospital. Gallinagh et al. (2002b) presented no data on any similarities or differences between the elderly care wards of the two hospitals. Mildner et al. (2003) noted the overall bedrail prevalence was higher in the two teaching hospitals included in the study (36.8%) than in the three district general hospitals (29.6%) but that *"…there were no statistical differences between similar wards at either site"* (p. 555).

4.3 VARIABLES INFLUENCING BEDRAIL USE

4.3.1 Introduction and methodologies

In addition to collecting data on the levels of bedrail use, four of the studies above included data on a range of patient variables. One study (Gallinagh et al. 2002b) also included data on environmental factors and staffing factors. The variables collected in studies published prior to our overnight survey are shown above in Table 4a.

As Table 4a shows, the number and scale of studies collecting a range of variables was limited, with only one whole hospital study (O'Keeffe et al. 1996), one study based on two hospital wards (Tutuarima et al. 2004), and one study based on five wards across two hospitals (Gallinagh et al. 2002b). In addition, the only multi-hospital study (Minnick et al. 2008) collected a small number of patient variables (age, gender, and whether the patient was currently being ventilated).

As well as the small number of studies, there are also limitations in the design of some of the studies. Gallinagh et al. (2002b) did not separate variables associated with bedrail use from variables associated with the use of restraining chairs, although only bedrail use was noted during night-time observation, and the paper implies that the patients restrained in chairs by day also had raised bedrails at night. Because of the predominance of bedrail use (91.4% of observations in the study related to bedrails, and only 8.6% to restraining chairs) this study has been included for discussion, but the lack of separation between patients with raised bedrails and patients in restraining chairs means its results must be treated with caution.

Additionally, even similar variables are defined in different terms in individual studies, for example definitions of stroke that differ between three studies (O'Keeffe et al. 1996, Gallinagh et al. 2002b, Tutuarima et al. 2003), and definitions of a history of falls that differed between two of the studies (O'Keeffe et al. 1996, Gallinagh et al. 2002b). Other variables were vaguely defined, for example O'Keeffe et al.'s (1996) definition of *"a diagnosis of cognitive impairment"* as any verbal or written mention of the word *"'confused' or any similar term"* (p. 1086). Some are not defined at all (e.g. Tutuarima et al. (2003) assume the term *"restless or agitated"* to be self explanatory). The rationale for the choice of variables was not clear in any of the studies except Gallinagh et al. (2002b) who stated they were derived from studies of restraint devices in the USA referenced to Magee et al. (1993) and *"adapted for use in British settings"* (p. 149).

None of these studies applied formal assessments such as cognitive testing. Data collection in Minnick et al. (2008) was observation of bedrail use by hospital staff plus questioning of ward nurses. Data sources in O'Keeffe et al. (1996), Gallinagh et al. (2002b) and Tutuarima et al. (2004) were a mix of case note review, questioning of ward nurses, and observation by researchers. Where case note review was used, all records made during the current admission were used in two studies (O'Keeffe 1996, Tutuarima et al. 2003) whilst the past month of nursing records was used in one study (Gallinagh et al. 2002b). For variables like identifying a prior diagnosis of stroke these time periods could be too short. Conversely, in the context of current bedrail use, they could be too lengthy for variables likely to fluctuate during a hospital admission. O'Keeffe et al. (1996) partially overcame this by limiting their identification of one variable (agitation) to the previous 24 hours.

In addition to the limitations on variables collected, there are limitations in the analyses conducted. Minnick et al. (2008) provided only descriptive data, with no tests of statistical significance. Gallinagh et al. (2002b) did not use logistic regression, and tested only some variables for statistical significance, with others described as percentages. O'Keeffe et al. (1996) apparently used stepwise logistic regression analysis for only some of the collected variables, although it is possible the logistic model was applied to all variables but only the significant findings were described. Confusion and agitation were not used as separate variables, but combined before analysis to create two new variables of confusion with or without agitation.[lxxiv] Only Tutuarima et al. (2004) applied multi-variable logistical regression to all collected variables. The smaller studies (Gallinagh et al. 2002b, Tutuarima et al. 2004) may not have been adequately powered to detect statistical significance for all variables included, and findings from the specialist wards used in these studies may not be generalisable to other clinical areas.

4.3.2 Patient variables

The findings of bedrail prevalence studies on variables between patients with or without raised bedrails are described above in Table 4a.

[lxxiv] It is implied but not explicit that there were no patients with agitation but without confusion.

As Table 4a shows, the only patient factor consistently collected and statistically significant in all of the studies that tested for statistical significance (O'Keeffe et al. 1996, Gallinagh et al. 2002b, Tutuarima et al. 2003) was a history of stroke. Given the difficulty in maintaining a stable position experienced by patients with hemiplegia, this is not a surprising finding. Using logistic regression, the odds ratio of bedrail use was significantly higher in patients with disorientation in one study (Tutuarima et al. 2003) and in patients with 'agitation' in two studies (O'Keeffe et al. 1996, Tutuarima et al. 2003). However, the definitions used by these studies for agitation were wide. O'Keeffe et al. (1996) used the Cohen-Mansfield inventory (Cohen-Mansfield et al. 1989) which includes items such as scratching and complaining, and both O'Keeffe et al. (1996) and Tutuarima et al. (2003) included 'restlessness' within their definition of agitation. It is therefore possible that this variable included patients unable to find a comfortable position to sleep in, as well as patients with an agitated delirium or confusion. Whilst the odds ratio of bedrail use was found to be significantly higher in older people in two studies using logistic regression (O'Keeffe et al. 1996, Tutuarima et al. 2003) neither of these studies collected data on patient mobility. Whilst age was found to be non-significant by Gallinagh et al. (2002b) this study took place on care of the elderly wards, with no younger patients included.

Patient variables that were found not to be significantly associated with bedrail use included diagnostic group (Gallinagh et al. 2002b), history of falls (O'Keeffe et al. 1996), cognitive impairment without agitation (O'Keeffe et al. 1996) and gender (O'Keeffe et al. 1996, Gallinagh et al. 2002b).

In addition to data tested for statistical significance, Gallinagh et al.'s (2002b) study also presented some descriptive data. Of patients with raised bedrails, 41% had a history of a fall within the last month, whilst 61% of those without raised bedrails had a history of a fall within the last month. Of patients with raised bedrails, 69.9% were described as 'very dependent' by their nurses, compared to 6.1% of patients without raised bedrails. Of patients with raised bedrails, 18.5% were prescribed benzodiazepines, whilst 35.7% of patients without raised bedrails were prescribed benzodiazepines.

Minnick et al.'s (2008) study only provided descriptive data. It noted that patients were male in 45.8% of observations of raised bedrails and males occupied 46.3% of beds, suggesting no gender effect. Of patients with raised bedrails, 9.2% were ventilated, and overall 6.1% of patients were ventilated, suggesting being ventilated may make bedrail use more likely. Although uncontrolled for any other variables, patients were aged over 65 years in 65.6% of observations of raised bedrails whilst patients aged over 65 years occupied only 47.8% of beds.

Therefore, prior to our overnight survey, data were very limited on patient variables affecting bedrail use, with one large scale study (Minnick et al. 2008) providing only descriptive analysis of a small number of variables, and two studies that were confined to one or two specialist departments rather than a whole hospital (Gallinagh et al. 2002b, Tutuarima et al. 2003). The single whole hospital study to use logistic regression (O'Keeffe et al. 1996) was based on data collected at least thirteen years ago.

4.3.3 Environmental factors

Of the studies described above, only one (Gallinagh et al. 2002b) examined additional factors such as visibility of beds, staffing levels and skill mix. The authors hypothesised that nurses would be less likely to use bedrails where the bed is visible from the nursing station, but found this to have no statistically significant effect on the likelihood of bedrail use. At each of the bedrail observation points of 10.00, 14.00, 18.00, and 22.00 data were collected on numbers of staff present on the ward, and whether they were qualified nurses, healthcare assistants or student nurses. However, the authors note that *"staffing levels are confounded with the effect of time of day and these two effects could not be untangled in this study"* (p. 153).

4.3.4 Policy factors

Several of the studies described above made reference to whether or not formal policies on bedrail use existed in the hospitals studied. Mildner et al. (2003) noted that although *"two of the [five] hospitals surveyed had formal written policy for using bedrails, this did not appear to reduce the extent of their use"* (p. 555). Minnick et al. (2008) noted that 15 of the 40 hospitals studied had no policy on bedrail use. O'Keeffe et al. (1996) noted there was no formal policy on bedrail use in place, and that *"there was no documentation of bedrail use in the medical notes for any patient"* (p. 1087). Hignett et al. (2005) studied departments within a hospital where a bedrail policy including a risk matrix was in place, and found 71% of patients with raised bedrails had a risk assessment documented.

4.4 NURSES' REPORTED RATIONALE FOR BEDRAIL USE

4.4.1 Introduction and methodologies

Five of the bedrail prevalence studies described above in Table 4a also asked nurses why they had used bedrails. None of the studies asked nurses for their rationale if bedrails were not raised. The studies' methodologies for questioning nurses were not clearly defined but usually appeared to have included choice from a list of pre-set categories, with a free text option if the response did not meet any predefined category. Choice of more than one category was allowed in one study (Minnick et al. 2008). The origin of the pre-set categories was not described in any of these studies. Only one study (Gallinagh et al. 2002b) appeared to have piloted the methodology and refined their categories in response to the pilot study's findings. This lack of piloting resulted in one study (Minnick et al. 2008) collecting a high level of responses of 'other' (30.9%) that were grouped into new categories at the point of data analysis. Thematic sorting of free text responses into categories can also lead to issues of reliability, but no description of any tests of inter-rater reliability were included in the paper.

4.4.2 Findings on nurses' reported rationale for bedrail use

As shown in Table 4a, falls prevention was the most common rationale given by nurses for raising bedrails in all five of the studies. Findings ranged from 42% (Hignett et al. 2005), 46.9% (Minnick et al. 2008), 76.2% (Noone & Fleming 1998), 88%[lxxv] (Gallinagh et al. 2002b) to 92.8% (O'Keeffe et al. 1996) of patients whose bedrails were raised. O'Keeffe et al. (1996) commented that this may be inappropriate given that they found no significant differences in history of falls between patients with or without raised bedrails. However, the lack of a history of a fall may not mean a consideration of falls prevention is inappropriate, as there are many other factors that affect falls risk (Oliver et al. 2004).

In two of the studies (O'Keeffe et al. 1996, Noone & Fleming 1998) patient preference was the next most likely reason for raised bedrails, although because of the dominance of falls prevention as a rationale the percentages are small (5.4% and 9.5% respectively). Two studies (Hignett et al. 2004, Minnick et al. 2008) combine patient and relative choice in the

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[lxxv] The actual rationale given in the paper is *'to promote positional support'* but the associated discussion in the paper suggests this is the authors' rephrasing of bedside nurses' description of using bedrails to prevent the patient falling out of bed.

same category, with these reported as nurses' rationale in 22% and 9.2% of cases respectively. In UK settings, current legislation (Mental Capacity Act 2005) would expect relatives' views to be considered where patients lacked capacity, but not to absolutely determine bedrail use, which should be decided by healthcare staff using the 'best interests' principle. Whilst Hignett et al.'s (2004) study predated the Mental Capacity Act (2005) its basic principles were already established in common law. Their findings might superficially suggest that relatives exert a greater influence than expected by legislation. However, the nurses' rationale was collected in brief bedside discussions that were unlikely to have captured the subtleties of whether a request initiated by relatives had or had not been recognised as being in the best interests of a patient who lacked capacity.

The legal situation in studies carried out in non-UK settings may be very different. In the USA, some relatives have a formal role as proxy decision makers (Brush & Capezuti 2002). This may explain why Minnick et al.'s (2008) original list of preset categories for nurses' rationale did not include patient choice, whilst relatives' choice may be legally justified in certain circumstances in the USA.

Patient confusion or cognitive impairment was recorded as the nurses' rationale for bedrail use in 24.1% of patients with raised bedrails in USA hospitals by Minnick et al. (2008). This is in contrast to the other four studies of nurses' rationale that were carried out in the UK or Ireland (O'Keeffe et al. 1996, Noone & Fleming 1998, Gallinagh et al. 2002b, Hignett et al. 2004). Patient confusion was not given as a nurses' rationale for bedrail use in three of these studies (O'Keeffe et al. 1996, Noone & Fleming 1998, Gallinagh et al. 2002b), and was recorded as the nurses' rationale for bedrail use in only 4% of patients with raised bedrails by Hignett et al. (2004). The high rate of patient confusion or cognitive impairment recorded as the nurses' rationale for bedrail use by Minnick et al. (2008) may therefore be specific to a USA setting, and may potentially relate to the use of restraint devices in combination with raised bedrails. The inclusion of *'to avoid therapy disruption'* as a rationale in 4.7% of cases of bedrail use within this study would tend to suggest there was some confusion between rationale for bedrails and rationale for restraint devices. Therapy disruption was explained as the patient dislodging their IV lines, catheters, or monitoring equipment and it seems unlikely that raising bedrails would have any effect on this.

Prevention of wandering would be an inappropriate use of bedrails as restraint (NPSA 2007b) and probably an ineffective one, since a patient capable of wandering is unlikely to be kept in bed by bedrails for long (Healey for NPSA 2007c). Prevention of wandering was given as nurses' rationale in 1.8% of patients with raised bedrails by O'Keeffe et al. (1996), 3.8% by Minnick et al. (2008) and 4% by Hignett et al. (2004).

Unconsciousness was the nurses' rationale in 6% of cases of raised bedrails by Hignett et al. (2004) although not mentioned as a rationale in the other four studies. Not all unconscious patients are immobile; they could have involuntary movements from muscle spasm, rigor, epilepsy, or other reasons. They might also be on alternating pressure mattresses that create postural instability. Therefore this may be an appropriate rationale for bedrail use, and bedrails used on unconscious patients would not fit the definition of restraint as *"the intentional restriction of a person's voluntary movement or behaviour"* (ACSQH 2005 p. 37).

As outlined in Chapter 3.2, some patients may use bedrails to assist themselves in changing their own position (Gallinagh et al. 2002a), although bedrails are not designed for this purpose (MHRA 2006). Bedrails used as a mobility aid was given as the nurses' rationale in 9.5% of cases by Noone & Fleming (1998), although not mentioned as a rationale in the other four studies.

In summary, prior to our overnight survey data were very limited on nurses' rationale for bedrail use in UK settings, with only one UK study extending to all types of wards (O'Keeffe et al. 1996). The only large scale study of nurses' rationale for bedrail use (Minnick et al. 2008) may not have been generalisable to UK settings because of differences in legislation and regulation in the USA, and the concurrent use of vest, belt, cuff, and harness restraint devices.

4.5 PLANNING AN OVERNIGHT SURVEY ON BEDRAIL USE

In Chapter 3.6, the background to the NPSA undertaking a bedrail safety project was outlined. For any safety improvement project it is important to understand how current practice compares with recommended practice. However, as outlined in Chapters 4.1 to 4.4 above, there was very little information available from published studies. Our overnight survey of bedrail use (Healey et al. 2009) was therefore planned to create a representative and contemporary picture of bedrail use in hospitals in England and Wales.

This chapter will not describe the detailed methodology of our overnight survey, as this is well described in the published study. The data collected in our overnight survey was informed by the data collected in the studies discussed above in Chapters 4.2 to 4.4, but supplemented by the findings of the literature review described in Chapter Three, and the analysis of reported incidents described in Chapter One. Study design was also influenced by resource considerations. Because of the potential for bedrails to be used to restrain patients, data collection included whether the patient was capable of mobilising without help from staff. Because bedrail use would be recommended by the manufacturers of some alternating pressure mattresses or electric beds, collecting data on mattress and bed type was also considered important. We carried out piloting in a single hospital to test the feasibility of data collection and calculate the number of staff that would be required to collect data.

Random selection of NHS organisations providing acute general hospital care was stratified to organisational size and between England and Wales. For randomisation to be successfully representative, agreement to participate from all randomised organisations was highly desirable. At the planning stage we sought to enhance recruitment through several measures, including formal and informal contact with randomly selected organisations. These efforts at the planning stage may have influenced high levels of recruitment, as all of the eight organisations selected agreed to participate, although one was unable to agree a survey date within the timescales of the study.

Our overnight survey of bedrail use 'Bedrail use in English and Welsh hospitals' (Healey et al. 2009) can be found in Appendix A.

4.6 STRENGTHS AND WEAKNESSES OF OUR SURVEY OF BEDRAIL USE

4.6.1 Strengths of our overnight survey of bedrail use

The key strength of our overnight survey of bedrail use was that it was the first multi-hospital study to use logistic regression to identify which patient variables are independently associated with bedrail use. Studies that do not use logistic regression can be confounded by naturally occurring associations between patient variables. For example, without logistic regression it is impossible to determine if Minnick et al.'s (2008) finding that ventilated patients were more likely to have bedrails raised indicates ventilation directly influences bedrail use. Ventilated patients will tend to be either unconscious or sedated, so the apparent influence of ventilation may simply be an association with one of these variables. Our overnight survey used logistic regression based on forward selection, with all two-way combinations of variables tested for interaction effects. The final model could then be tested using the independent variables which were statistically significant. We also incorporated a test of goodness-of-fit, which acts as a further check on the accuracy of the model (Lemeshow 1982) with a result of p=0.94, suggesting good explanatory power.

Perhaps even more importantly, our overnight survey was the first study in which data on patients' ability to mobilise was included in the analysis. The greatly increased odds ratio of bedrail use in immobile patients found in our study would suggest that the results of earlier studies using logistic regression (O'Keeffe et al. 1996, Tutuarima et al. 2003) must be interpreted with great caution since they did not collect data on this important variable. Our study was also the largest UK study in terms of the number of patients for whom variables were collected (1092 patients compared with 668 patients in O'Keeffe et al. 1996 and 102 patients in Gallinagh et al. (2002b)). The only study internationally that may have exceeded this number (Minnick et al. 2008) collected only limited variables of age, gender and ventilatory status.

Another important strength was that our overnight survey collected data on equipment factors influencing bedrail use. These data had never been collected before. It was also the first study not only to ask nurses for their rationale for using bedrails, but also to ask them for their rationale for *not* using bedrails, and the first study to separate rationales for partial bedrail use from rationales for full bedrail use. Our overnight survey was the largest UK study to collect data on nurses' rationale for bedrail use, collecting data for 383 patients with bedrails raised, compared to data for 56 patients in O'Keeffe et al. (1996) and 51 patients in Gallinagh et al. (2002b).

As it included seven organisations providing care from twelve hospitals, our overnight survey was the largest UK bedrail prevalence study in terms of numbers of organisations and hospitals. The next largest UK bedrail prevalence survey (Milner et al. 2003) included only selected wards from five organisations providing care from five hospitals. In our overnight survey, all data were collected overnight, unlike some earlier studies which relied on observing bedrail use in the late evening (Gallinagh et al. 2002b) or early morning (Tutuarima et al. 2004, Minnick et al. 2008).

Internationally, our study was the first bedrail prevalence study to randomly select from a national sample of all organisations, with earlier studies partially randomising from within geographical locations selected on the basis of convenience (Minnick et al. 2008) or directly selecting the participating hospital (O'Keeffe et al. 1996, Noone & Fleming 1998, Hanger et al. 1999, Capezuti et al. 2000, Tutuarima et al. 2003, Irving 2004, Raw & Stacy 2004, Hignett et al. 2005) or hospitals (Gallinagh et al. 2002b, Milner et al. 2003) on the basis of convenience. Our overnight survey was the first since O'Keeffe et al. (1996) to collect data across all types of wards, and the first study to analyse variations in bedrail use between each individual organisation using logistic regression.

4.6.2 Limitations of our overnight survey of bedrail use

Although our study was small in the context of 167 organisations providing acute hospital care in England and Wales, it was the largest UK bedrail prevalence study in terms of number of organisations included, and our sample size was adequately powered to detect statistically significant results for most variables examined. For pragmatic reasons, patient sampling within each organisation was not individually randomised, but based on a purposive sample of every third bed. Any non-random selection can potentially introduce bias, but the likelihood of these patients differing markedly from the patients in each neighbouring bed appeared low. Also, any randomised organisations refusing to participate can skew the representativeness of the organisational sample, since organisations refusing to participate in service evaluation may have different characteristics than organisations who welcome it. Seven of the eight organisations we randomly selected participated in our overnight survey. However, because the eighth organisation was willing to participate but was excluded due to the time constraints of the improvement project, this is less likely to have skewed the sample than an organisation declining to participate.

The resource constraints of our study meant that patients' medical histories, including of hemiplegic stroke, were not collected. All the studies that collected data on history of stroke (O'Keeffe et al. 1996, Gallinagh et al. 2002b, Tutuarima et al. 2003) found this to be a statistically significant factor. Had we collected these data, we may have been able to establish whether history of stroke is a significant variable for bedrail use, or whether the earlier studies found stroke to be significant only because it was associated with impaired mobility.

The method used to collect data on patients' mobility and confusion or unconsciousness was an interview with their nurses, which is unlikely always to be an accurate portrayal of their true mobility or level of cognitive impairment. However, like earlier researchers (O'Keeffe et al. 1996, Gallinagh et al. 2002b), we would maintain that, in the context of decision making on bedrail use, nurses' subjective perception of mobility and confusion is a more appropriate measure than objective measures of ability to mobilise or cognitive impairment. Unlike earlier studies we were careful to refer throughout to 'nurses' descriptions of mobility' and 'nurses' descriptions of confusion', rather than refer to these variables as though they were objectively measured. Whilst questioning nurses was the only practical methodology for determining their rationale for actions, the responses given may be influenced by the interaction with the researcher. For questionnaires administered face-to-face without anonymity, it could be theorised that respondents may change their responses in line with their expectations of what the researcher would like to hear. However, a systematic review (McColl et al. 2001) suggested questionnaires administered on paper or face-to-face did not differ significantly in terms of quality of response, and anonymity or lack of it did not appear to influence participation levels.

Data were collected by single observers, but the simple observations of how many bedrails were raised, whether mattresses were standard or alternating pressure, and whether beds were standard hospital beds or were electrical profiling beds raised no issues of inter-rater reliability in the pilot stage of our study. The inter-rater reliability of observation of how many bedrails were raised was also found to be 100% in Gallinagh et al. (2002b).

Given the emotive debate on bedrail use outlined in Chapter 3.5.4, any bedrail survey may be particularly vulnerable to a Hawthorne effect. If frontline staff intentionally amend their normal practice when they know they are being surveyed, they are more likely to sustain this for a single point prevalence study like ours than in studies which repeatedly measured prevalence over several points such as Gallinagh et al. (2002b) and Minnick et al. (2008). However, the amount of time that had to be spent by our observers on each ward and department to explain why we were there suggested that organisations had not forewarned their staff that we would be carrying out the survey.

4.7 DISCUSSION OF THE COMMONALITIES AND DIFFERENCES

4.7.1 Introduction

In this chapter I will undertake a discussion of the commonalities and differences between the evidence presented prior to our overnight survey, and the evidence within it. This will include discussion on why earlier studies suggested that patient age was a significant variable for bedrail use, whilst our study indicated age did not have a significant influence on the likelihood of bedrail use. Other areas where commonalities and differences will be explored include the influence of local policy on bedrail use. Data unique to our study, including inter-organisation comparison, the effect of mattress and bed design on likelihood of bedrail use, and nurses' rationales for partial use of bedrails or non-use of bedrails, will also be explored.

4.7.2 Commonalities and differences: prevalence of bedrail use in hospitals

Levels of bedrail use were described in Chapter 4.2.3 and 4.2.4, with general acute hospital prevalence of full bedrails raised ranging from 11% (Minnick et al. 2008) to 30% (Capezuti et al. 2000) in the USA, and from 8.4% (O'Keeffe et al. 1996) to 36.8% (Mildner et al. 2003) in the UK. The overall prevalence of full bedrails raised found in our study was 25.7%, which fits within the range previously described. Interestingly, the levels of bedrail use found in each of the seven organisations that participated in our study also closely matches this range, from the lowest prevalence of 12.2% in organisation A, to the highest prevalence rate of 38.9% in organisation B.

The earlier UK studies described in Chapters 4.2.3 and 4.2.4 were separated in time, and gave an impression that levels of bedrail use were apparently increasing in the UK over time. Because our study was a contemporaneous survey of seven hospitals and found a similar degree of variation, it suggests that the variation noted between earlier studies may relate to practice in individual hospitals, rather than to a secular trend.

These earlier studies provided no opportunity to compare variations in bedrail prevalence between hospitals, other than the brief comparison of combined rates from two teaching hospitals with the combined rate from three district general hospitals provided by Mildner et al. (2003). In contrast, our overnight survey not only provided prevalence of bedrail use in each participating organisation, but through logistic regression confirmed that the observed differences in bedrail use between organisations could not be attributed to differences in patient variables or equipment availability.

4.7.3 Commonalities and differences: patient variables

The most marked difference between our overnight survey and previous studies was that we collected data on patients' ability to mobilise. In our overnight survey, this proved a very significant variable, with patients unable to mobilise at all more than sixty times as likely to have raised bedrails as patients who were independently mobile. The absence of any data collection on patients' ability to mobilise in earlier studies is surprising considering the potential effect of bedrails on restricting independence in patients who could mobilise alone. However, earlier studies collected some patient variables that might be expected to be associated with impaired mobility. O'Keeffe et al. (1996), Gallinagh et al. (2002b) and Tutuarima et al. (2003) found a history of stroke to be associated with a significantly increased likelihood of raised bedrails. Since many strokes resulting in acute hospital admission would involve some impairment to mobility, these studies' findings on stroke would therefore be consistent with our findings on mobility. Additionally, Gallinagh et al. (2002b) found a strong association of bedrail use with dependency; almost 70% of patients with bedrails raised were 'very dependent' whilst only 6% of those without bedrails were. Dependency is not a direct equivalent to immobility but overlap would be expected.

Our overnight survey's findings on mobility are particularly relevant to the debate on whether bedrails are being used as restraint. Where restraint is defined as *"the intentional restriction of a person's voluntary movement or behaviour"* (ACSQH 2005 p. 37), the use of bedrails on patients incapable of leaving their bed without help from nurses would not be considered restraint.

Both O'Keeffe et al. (1996) and Tutuarima et al. (2003) found the odds ratio of bedrail use to be significantly higher in older patients. Our study found age not to be significant in the analysis of effects (p=0.09) compared to very high significance levels for all other variables (p=<0.001). The omission of patient mobility as a variable in these studies is a plausible explanation; older patients are much more likely to have mobility problems than younger patients and therefore without the incorporation of mobility as a variable, age appeared directly, rather than indirectly, associated with bedrail use.

The findings of our overnight survey in relation to patient age were particularly important in the context of the debate on whether bedrail use is ageist, as outlined in Chapter 3.5.4. Many opinion pieces suggest that this is the case (e.g. Corley & Goren 1998, Jehan 1998, Bredthauer et al. 2005, Marcy-Edwards 2005) and some of the bedrail prevalence studies discussed above believed their results confirmed this. For example, Minnick et al. (2008), whose descriptive statistics indicate bedrails are more frequently used in patients over 65 years, state that *"age mattered most"* (p. 41). In contrast, the inclusion of mobility as a patient variable in our overnight survey, and the more robust analytical methodology we used, has produced evidence to suggest that nurses' decisions on bedrail use appeared not to be directly affected by patient age.

Our findings that patients described by their nurses as slightly or very confused were significantly more likely to have bedrails raised are very similar to previous studies, as cognitive impairment with agitation in O'Keeffe et al. (1996), and disorientation, restlessness and agitation in Tutuarima et al. (2003), were associated with a significantly increased odds ratio of bedrail use. These earlier studies tended to assume any use of bedrails in confused patients was inevitably inappropriate, for example *"Bedrails are particularly unsuitable for such patients"* (O'Keeffe et al. 1996 p. 1087). Our overnight survey differed from these earlier studies in also describing individual patient's combinations of variables, to distinguish between patients who were confused and mobile (and therefore likely to be at risk of climbing over the bedrails) and those who were confused but not capable of getting out of bed without assistance from nurses. We identified six patients with raised bedrails who were described by their nurses as both very confused and capable of mobilising (safely or unsafely) without help from nurses. For these patients, raised bedrails were almost certainly inappropriate, but the remainder of bedrail use in patients with confusion was in patients whose mobility appeared too limited to put them at risk of climbing over the bedrails. This focus on the appropriateness of bedrail use at the individual patient level contrasts with most of the earlier studies, where conclusions focus on the need to drive down overall bedrail use. For example, O'Keeffe et al. (1996) conclude that *"bedrail use [is not] rare enough"* (p. 1088), whilst Raw & Stacy (2004) state their aim is *"to drastically reduce the total bedrail usage"* (p. 641).

4.7.4 Commonalities and differences: equipment variables

In Chapter 3.3.5 the potential influence of increased use of alternating pressure mattresses, and electrical profiling beds on bedrail use was discussed. These types of equipment have real benefits for patients in terms of comfortable positioning and pressure relief (NICE 2005). However, no earlier studies had collected information on types of bed or mattress in relation to bedrail use. Our study found that both alternating pressure mattresses and electrical profiling beds were associated with a significantly increased odds ratio of bedrail use. Given the inherent instability of alternating pressure mattresses as a support surface, this is likely to reflect appropriate positional support. Electrical profiling beds can deliver a variety of patient positions, most of which would be inherently less stable than a supine position. Patients may also self-operate the controls to adjust their own position. Therefore the increased likelihood of raised bedrails in patients with electrical profiling beds is also likely to reflect appropriate positional support.

Earlier studies have frequently suggested that to avoid the risk of bedrails being raised inappropriately, bedrails should be physically removed from wards and access to them should be restricted. This is the approach used in Hanger et al.'s (1999) bedrail reduction study, and is proposed by several of the prevalence studies discussed above. For example, Raw & Stacey (2004) note *"we are considering centralising bedrail use, only allowing them for a few specific reasons and on a named-patient basis"* (p. 641). Because of this prior assumption that bedrails would be raised if they were left permanently attached to the bed, our overnight survey also collected data on whether beds had bedrails attached and available for use. We found that although 61.0% of beds had bedrails attached, they were partially or fully raised for only 34.6% of patients, with 25.3% of patients found to have bedrails attached to their beds but not raised at all. This tends to suggest that bedrails are not raised by staff simply because they are available.

4.7.5 Commonalities and differences: policy variables

Of the multi-site studies discussed above, Minnick et al. (2008) noted that 15 of the 40 hospitals studied had no policy on bedrail use but made no comment on whether levels of bedrail use differed between these two groups. Mildner et al. (2003) noted there appeared to be no differences in levels of bedrail use between hospitals with a policy on bedrail use and hospitals without one, but did not attempt to control for any differences in the patient population. Our overnight survey, like Mildner et al. (2003), found no association between levels of bedrail use and the existence of a local bedrail policy.

What was notable in several of the prevalence studies discussed above (O'Keeffe 1996, Mildner et al., 2003, Raw & Stacey 2004, Minnick et al. 2008) was an assumption that a policy on bedrail use should drive down the rate of bedrail use. This may arise from the orthodoxy that bedrails do more harm than good described in Chapter 3.5.4. In contrast, our overnight survey not only noted if there was a local policy in place, but whether these policies gave examples of harm caused by bedrails and/or whether they included any situations in which bedrail use was recommended. Of the three organisations with local policies, all included examples of harm caused by bedrails but only one included recommendations for when bedrail use might be appropriate. Interestingly, this policy was in place in one of the organisations that showed significantly lower levels of bedrail use.

4.7.6 Commonalities and differences: nurses' rationale for bedrail use

In all earlier studies that included nurses' rationale for bedrail use (O'Keeffe et al. 1996, Noone & Fleming 1998, Gallinagh et al. 2002b, Hignett et al. 2005, Minnick et al. 2008) prevention of falls was the most frequently reported rationale. Our study found the same, with this given as the reason for raised bedrails in 74.4% of cases. Other rationales we identified, including bedrails used to turn or roll, and patient or relative request for bedrails, were also in line with the findings of other UK studies (O'Keeffe et al. 1996, Gallinagh et al. 2002b, Hignett et al. 2005) or Irish studies (Noone & Fleming 1998). In contrast, Minnick et al. (2008) study in the USA found patient confusion was the nurses' rationale in almost a quarter of cases where bedrails were raised, whilst we found no evidence that confusion was a rationale given by nurses for bedrail use, in line with the findings of other UK and Irish studies (O'Keeffe et al. 1996, Gallinagh et al. 2002b, Hignett et al. 2005, Noone & Fleming 1998). Therefore our study added to an emerging pattern of nurses' rationale for bedrail use that appeared fairly consistent across the UK and Ireland, but with apparent differences to the USA, where confusion appears much more frequently given as a rationale for raising bedrails.

Additionally, our study collected data on nurses' rationale for when partial bedrails were raised. This has not been separately examined in any prior study, although some studies may have combined nurses' rationale for full bedrails raised with nurses' rationale for partial bedrails raised (Gallinagh et al. 2002b) and the description of the methodology in other studies (O'Keeffe et al. 1996, Noone & Fleming 1998) leaves it unclear whether their data on nurses' rationale included partial bedrail use or not.

Our overnight survey indicated that nurses' rationale for partial bedrail use differed substantially from their rationales for full bedrail use. The most frequently reported rationales were patients using partial bedrails to turn or roll (30.4%) patient request (23.5%) and other reasons including patient operated controls mounted in the bedrail (16.7%). Our findings underline the importance of separating full bedrail use from partial bedrail use, as for full bedrail use nurses' rationales appear closely related to bedrails' intended purpose of preventing falls from bed. In the case of partial bedrail use, the uses bedrails are put to appear almost incidental, with the bedrail simply providing a convenient leverage point or a convenient location to mount controls or call bells.

Our overnight survey was also the first to collect nurses' rationale for *not* raising bedrails. The omission of this data in any previous study may also be related to the orthodoxy that bedrails do more harm than good described in Chapter 3.5.4. If that was the belief of the researchers, any use of bedrails would be questioned, whilst non-use of bedrails would be accepted as good practice. We found that nurses' rationales for leaving bedrails down were also predominantly related to falls prevention; in 92.0% (N=645) of patients without raised bedrails, the nurses' rationale was that they were not needed as the patient was not at risk of falling.

4.8 RESEARCH PUBLISHED SUBSEQUENT TO OUR OVERNIGHT SURVEY

Only one study of hospital bedrail prevalence (Shanahan & Evans 2009) was identified subsequent to our overnight survey.[lxxvi] As will be described in more detail in Chapter 5, our overnight survey's methodology and data collection formats were made available on the NPSA website (Healey for NPSA 2007c) and NHS organisations in England and Wales were encouraged to carry out their own local surveys. Shanahan & Evans (2009) based their study on these materials, although with local adaptations, and incorporating checks on bedrail design recommended by the MHRA (2006). Their study is a single overnight point prevalence study across a single organisation with acute and rehabilitation hospitals on different sites. Their findings were descriptive, with no tests for statistical significance.

They found 36.5% of hospital beds (206/564) had full bedrails raised, with a further 17% (98/564) of beds with partial bedrail use. However, the findings they present in Table 1 (p. 233) suggest they included 84 empty beds in their denominator. If this is the case, their levels of full bedrail use would actually be 42.9% (206/480), and partial bedrail use 20.4%

[lxxvi] This study's publication date actually preceded our overnight survey's publication date by two months, but since it was directly based on the methodology of our study it is more appropriate and less confusing to describe it as a subsequent rather than preceding study.

(98/480). By either denominator, the levels of bedrail use observed in their study were similar to the organisations with the highest levels of bedrail use within our overnight survey. However, the authors stated that they provided more slow-stream rehabilitation and continuing care than was usual for NHS organisations, and there are indications they had a less mobile patient population, with 76.3% (366/480) of patients overall said to be unable to mobilise without help from nurses. Because of the effect of impaired mobility on the likelihood of bedrail use identified in our overnight survey, higher levels of bedrail use might be expected in their organisation.

Their findings on compliance with MHRA guidance on the safe fitting of bedrails initially appear alarming, with a suggestion that only 77% (448/581) of bedrails appeared compliant. However, it is evident they have used all beds as the denominator, whilst later in the paper they indicate 86 beds had no bedrails at all. The correct figure would be 448/495 (91%). They also note this was *"difficult to assess without disturbing patients"* (p. 235), which implies they visually estimated rather than measured bedrail dimensions. More importantly, they stated that all bedrail to headboard gaps were within recommended limits, and the concern for the 47 bedrails they did not consider compliant with MHRA guidance was the bedrail to footboard gap, which would constitute a risk of entrapment only if the patient was able to rotate their position so that their head was at the foot of the bed.

Shanahan & Evans (2009) findings on nurses' reported rationale for bedrail use differed markedly from the rationales seen in our overnight survey. *"To stop patients getting up because they are at risk of falling"* accounted for 25% (73/298) of responses (p. 234). Prevention of wandering was very rarely given as nurses' rationale in either our overnight survey or any of the other UK or Irish studies (O'Keeffe et al. 1996, Gallinagh et al. 2002b, Hignett et al. 2005, Noone & Fleming 1998). It is possible that nursing culture and beliefs were very different in the organisation that Shanahan & Evans (2009) surveyed than it was in the other UK organisations studied. However, it seems possible that the researchers' categorisation of responses into the umbrella term *"to stop patients getting up because they are at risk of falling"* might have incorporated rationales related to prevention of falls from bed, rather than falls after leaving bed, since it is difficult to reconcile the numbers of occasions where this was nurses' rationale (N=73) with the much lower number of patients with full bedrails raised said to be capable of mobilising at all without help from nurses (N= 23).

Shanahan & Evans (2009) do not appear to have collected any data on nurses' descriptions of whether patients were confused or not, but noted with concern that 'confused' accounted for 13% (39/298) of nurses' rationales (p. 234) for raising bedrails. Again, this could reflect different nursing culture and beliefs in the organisation surveyed. However, it is notable that confusion as a nurses' rationale for bedrail use only appeared in the two studies that allowed nurses to select multiple rationales (Minnick et al. 2008, Shanahan & Evans 2009). Therefore it is possible that nurses were describing the reason for their primary rationale (e.g. the patient is at risk of falling out of bed *because* he is confused) rather than describing confusion as a direct rationale for bedrail use.

Shanahan & Evans (2009) concluded that their study *"reflects concerns in the published literature that bedrails are sometimes used indiscriminately and excessively"* (p. 235). However, the changes in local policy subsequent to their survey that they described suggested that they were encouraging staff to consider the risks and benefits of bedrail use for individual patients, rather than seeking an overall reduction in levels of bedrail use.

Despite the lack of tests of statistical significance, and some apparent confusion in selecting denominators to calculate percentages for their descriptive findings, Shanahan & Evans' (2009) study demonstrates findings broadly in line with our overnight survey. It suggests that local organisations can replicate the data collection methods used in our overnight survey without outside support, and use their findings to inform improvements to local policy and practice.

4.9 IMPLICATIONS FOR CLINICAL PRACTICE

Our overnight survey had some positive implications for clinical practice. Although much of the earlier literature discussed in Chapter 3.5.4 asserted that bedrail use is routine or ritualistic, our overnight survey suggested that staff are making individualised decisions in response to different factors they observe in individual patients. Despite the arguments in the earlier literature that bedrails either fail to prevent falls or actively increase the risk of falling, we found that bedside nurses appear to believe bedrails can prevent falls from bed, with their rationales both for using bedrails and for not using bedrails dominated by consideration of whether the patient was at risk of falling. In this earlier literature, nurses were often criticised for continuing to use bedrails when the 'evidence' suggested their use should be abolished or drastically curtailed (e.g. Talerico & Capezuti 2001, Marcy-Edwards 2005). However, the beliefs of frontline nurses appear more in line with evidence described in our literature review than with the earlier negative literature. It is unlikely this concordance was related to them personally undertaking a critique and synthesis of the literature, as few frontline nurses would have the skills or resources to carry this out. Their continued belief that bedrails are effective for preventing falls might be explained by few frontline nurses having seen any of the negative literature on bedrails, but this seems unlikely given the number of articles published in journals with a high circulation amongst UK nurses (e.g. Everitt & Bridel-Nixon 1997, Govier & Kingdom 2000, Ali 2000, Rollins 2006, Goodman & Smith 2007). The most likely explanation appears to be that they rejected the case that bedrails were ineffective at preventing falls because it did not concur with their clinical experience of the effect of bedrails.

Our overnight survey was also reassuring in that only a very small proportion of patients (1%, 11/1092) had bedrails that were potentially restraining their independence. However, there is no room for complacency, as even a single case of inappropriate use of bedrails as restraint is one case too many. There were also a small proportion of patients (2.5%, 27/1092) who appeared likely to need bedrail use but who did not have raised bedrails. Taken together, these findings suggest that improvements to clinical practice need to focus both on avoiding bedrail use for patients in whom it would be inappropriate, and on encouraging bedrail use for patients where it is appropriate.

Our overnight survey indicated that staff understand patient choice as an important rationale in decisions to use bedrails, but the occasions when relatives' request was given as a rationale for bedrail use suggested staff may not always understand the appropriate decision making processes for patients without capacity. This may therefore be an important issue to include in local education.

Although our overnight survey identified significant variations between organisations in the odds ratio of full bedrails being used, the implications of these variations for clinical practice are unclear until further research can identify what underlies them. Because of the relatively small proportion of bedrail use that was apparently inappropriate, most of the variation between organisations must be occurring in patients who have neither absolute indications for bedrail use nor absolute contra-indications.

We found that some organisations with low levels of bedrail use had a high proportion of beds where bedrails were available but not used. This suggests the concept that bedrails must be removed from wards in order to drive down levels of bedrail use, as advocated by

Hanger et al. (1999) and Raw & Stacey (2004), is not valid (even if desirable, bearing in mind that the evidence discussed in Chapter 3 suggests that unselective reductions in bedrail use potentially increase falls). Increasing stocks of electrical profiling beds, most of which come supplied with permanently attached bedrails, may in any case make removal of bedrails from wards an impractical strategy.

Because our survey found little difference between organisations with high or low odds ratio of bedrail use in terms of whether they had a local policy on bedrail use, any efforts to change practice may need to extend beyond developing written policy to interventions with a direct influence on frontline staff. Some potential interventions are discussed further in Chapter Five, where the NPSA's bedrail safety project, including tools to support local improvements in practice, will be discussed.

4.10 DIRECTIONS FOR FUTURE RESEARCH

The key issue for future research identified by our overnight survey is the significant variation in the odds ratio of bedrail use observed between hospitals. Equipment used as an alternative to bedrail use, such as ultra-low beds does not provide an explanation, since only a tiny proportion of patients had such beds (four out of 1092 patients surveyed). It seems unlikely that any patient variable not included in our overnight survey can account for this variation, as the minor differences in service provision and local population between the seven organisations seem unlikely to have created inpatient populations sufficiently different from each other to explain the ten-fold difference in the odds ratio of bedrail use seen after adjusting for other patient and equipment variables.

Possible influences on bedrail use debated in the literature include litigation practice, staffing levels and proportion of registered nurses, visibility of patients from nurses' stations, access to expert advice, the beliefs and attitudes of patients, and the knowledge and beliefs of nurses (Brush & Capezuti 2002, RCN 2008, Healey et al. 2008b). Of these, it seems unlikely that litigation practice would differ between different hospitals in the UK, although nurses may potentially be influenced by recent or high-profile cases of litigation or coroners' inquests in their own organisation. Staffing levels and skill mix are a plausible factor, but would be complex to assess, as staff numbers and skills in relation to workload would be a more appropriate measure than raw numbers of registered and unregistered nurses. The layout of inpatient areas undoubtedly differs between individual hospitals, as discussed in Chapter 3.3.5, and so is a promising area for future research seeking to understand variations between organisations. The influences of ward layout may however be more complex than the line-of-sight considered by Gallinagh et al. (2002b).

Access to expert advice has been shown to influence levels of bedrail use in care home settings (Capezuti et al. 2007), although the effect appears to depend on the interaction between the expert advisor and local staff, since the impact was not uniform across different care homes within the study. As discussed in Chapter 4.4.2, O'Keeffe et al. (1996), in contrast to other UK studies, reported very low levels of bedrail use on elderly medicine wards. It is possible that local practice was strongly influenced by the lead author of the study, who was in a clinical leadership role in the elderly medicine department, and who has expressed strong opposition to the use of bedrails (e.g. O'Keeffe 2004, O'Keeffe 2009). If so, it would suggest future research would have to consider the influence not only of designated bedrail experts but of local leaders or role models.

The observed variation between organisations may also potentially create the basis for a correlation study comparing organisations' levels of bedrail use with the level of reported falls, but any such study would be complex due to the need to control for all the wide range of intrinsic and extrinsic factors affecting risk of falls (Oliver et al. 2004) and those affecting reporting culture (Hutchinson et al. 2007). However, given the challenges of conducting RCTs on bedrail use discussed earlier in Chapter 3.10.5, this may be a research approach that merits exploration.

Within our overnight survey, the nurses' strongest emphasis was on falls prevention as a rationale for bedrail use (and on low risk of falls as a rationale for non-use of bedrails). This suggests any future research on how nurses' beliefs and knowledge influence bedrail use should be embedded in an exploration of their beliefs and knowledge about the wider aspects of fall prevention.

4.11 CONCLUSION

Prior to our overnight survey, very few studies of bedrail use encompassing whole hospitals had been carried out internationally, and the only detailed whole hospital study that had been carried out in the UK (O'Keeffe et al. 1996) was more than a decade old. There was also very limited information on variations in bedrail use between hospitals, with one USA study suggesting marked variations between similar units, and one UK study suggesting little difference in levels of bedrail use between similar wards in neighbouring hospitals. Only five studies had collected data on patient variables associated with bedrail use or nurses' rationale for bedrail use, and only two of these studies analysed variables using logistic regression (O'Keeffe et al. 1996, Tutuarima et al. 2004).

Our overnight survey of seven randomly selected organisations providing healthcare in twelve hospitals was therefore largest detailed study of bedrail use published to date. The variables we included and our use of logistic regression meant that we could identify inability to mobilise independently as by far the most significant predictor of bedrail use; this variable had never previously been collected. Our findings on the association of confusion with bedrail use were congruent with earlier studies, whilst our findings on the influence of profiling beds and alternating pressure mattresses on bedrail use were plausible given their potential to create postural instability. Inclusion of mobility as a variable enabled us to identify that the association of bedrail use with older age found by prior studies was probably an artefact of the greater prevalence of mobility problems in old age, rather than ageist practice. Our review of variable combinations at the individual patient level allowed us to identify small sets of patients where bedrail use appeared inappropriate and could be constituting restraint, as well as patients who appeared likely to benefit from bedrails but did not have them. Limitations of our study included reliance on data that could be collected at the bedside, but data on the nurses' understanding of their patients' mobility and confusion was probably more relevant than objective measures of mobility and confusion in the context of understanding nurses' rationale for bedrail use.

Our overnight survey found that prevention of falls was nurses' dominant reason for full bedrail use, and this was congruent with previous studies. We were the first to collect data on rationale for partial bedrail use and found a very different set of rationales centred on incidental uses of the bedrail. We were also the first study to collect nurses' rationale for non-use of bedrails, and found that consideration of risk of falls was also dominant here, in that bedrails were not considered necessary if the nurses considered there was no risk of a fall.

The significant variations in levels of bedrail use between the seven organisations that we found could not be fully explained by access to bedrails or by local policies on bedrail use. This raises interesting questions for future research.

CHAPTER FIVE: INFLUENCING CLINICAL POLICY AND PRACTICE

5.1 INTRODUCTION

The proposed new Research Excellence Framework (REF) (Higher Education Funding Council for England (HEFCE) 2009) strongly emphasises the need for research to demonstrate social and economic impact; "*Reflecting its importance in policy terms, impact will be weighted more highly than environment, and will significantly influence the overall outcomes where strong impacts build on the submitted unit's excellent research"* (p.7). To be judged as excellent, a research unit will be required to demonstrate *"activity effectively building on [their research] to achieve impact"* and *"the effective sharing of its research findings with a range of audiences"* (p. 6).

The framework accepts that *"the process through which research leads to impact is non-linear, and there can be a number of intervening factors that influence the impact of research. Thus there are challenges in 'attributing' impacts to research activity"* (p.15). It therefore proposes the use of *"narrative evidence…. supported by appropriate indicators"* with *"third party corroboration of claims where appropriate"* (p. 15). For healthcare research, proposed key indicators of impact encompass improved patient care or health outcomes, including *"changes to clinical or healthcare training, practice or guidelines"* (p. 42). In this chapter of my doctoral statement I will therefore describe the impact of my research on clinical policy and practice in the field of hospital falls prevention and the safe and effective use of bedrails. I will use the methodology proposed in the REF of narrative evidence supported by appropriate indicators and corroborated by third parties.

First, I will briefly describe the facility of the National Patient Safety Agency (NPSA), to require action from organisations providing NHS-funded care in England and Wales. I will then show how the evidence from the research described in previous chapters was adapted and expanded into interlinked publications intended to inform and influence the practice of frontline staff. The first publication to be discussed will be *Slips trips and falls in hospital* (Healey & Scobie for NPSA 2007a) (see Appendix A). This presented the analysis of reported falls in hospital described earlier in Chapter 1, together with additional analysis, advice on improving the quality of reporting and learning from falls, a survey of local hospitals' risk assessment tools for falls, a summary of the evidence related to hospital falls prevention (including the Randomised Controlled Trial (RCT) (Healey et al. 2004) described in Chapter 2), and case studies from hospitals where this evidence had been put into clinical practice.

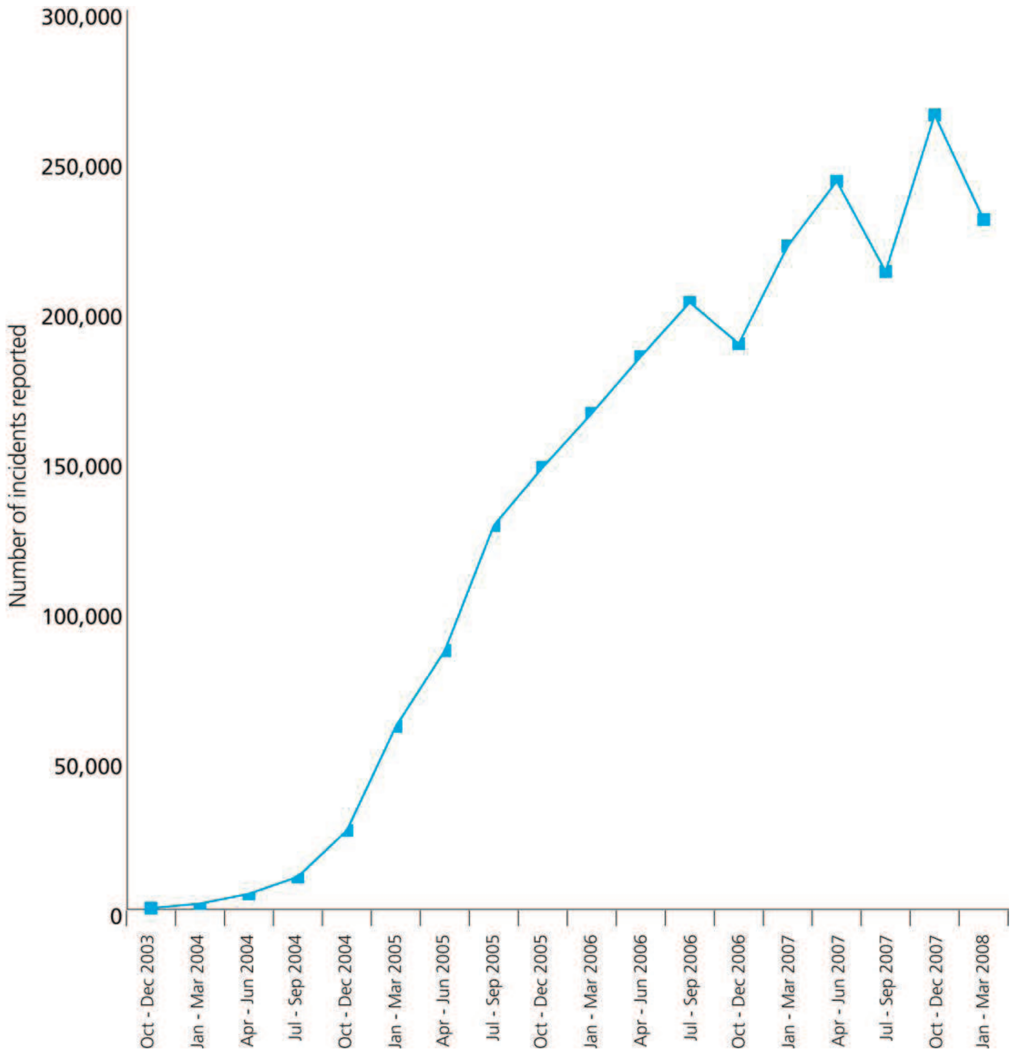
The second publication to be discussed will be *Using bedrails safely and effectively* (Healey & Stephenson for NPSA 2007b) (see Appendix A), which was a Safer Practice Notice requiring action from organisations providing NHS-funded care in England and Wales, disseminated via the Department of Health's Safety Alert Broadcast System (SABS). The findings from additional research undertaken to inform the Notice will be described, including a survey of hospitals' bedrail policies. I will also discuss a range of resources (Healey for NPSA 2007c) provided to support this Notice, including a model policy, audit tools, bedside decision-making aids, posters, educational materials, and a version of the systematic literature review described earlier in Chapter 4 adapted for easy reading by frontline staff (Healey for NPSA 2007d).

I will then describe the dissemination strategy for these publications, including official mechanisms and distribution through clinical and academic networks, conference presentations and additional journal articles (see Appendices C and D). Download numbers will be used to provide evidence of widespread dissemination. Most importantly, I will then provide evidence of impact on clinical practice of my peer reviewed publications and the linked NPSA publications. Because the REF suggests changes to guidelines are key indicators of impact, changes in hospitals' policies on falls prevention and bedrails will be examined in detail. For third party corroboration of impact I will outline independent evaluation data, compliance recorded on SABS, Healthcare Commission inspection reports, and the Royal College of Physicians' *National clinical audit of falls and bone health in older people*. I will also provide evidence of international influence and conclude by describing my ongoing work in the areas of hospital falls prevention and the safe and effective use of bedrails.

5.2 THE ORIGINS AND FUNCTIONS OF THE NATIONAL PATIENT SAFETY AGENCY (NPSA)

As briefly outlined in earlier chapters, the NPSA was founded in 2001 in response to *An organisation with a memory* (Department of Health, 2000) which set out aspirations for a national reporting system to inform national learning and action to improve patient safety. The design and content of the National Reporting and Learning System (NRLS) was described in detail in Chapter 1.3.2. There were early technical challenges to establishing such a reporting system, including the need for vendors of local risk management system software to redesign their products to permit uploading to a national system. During 2004 only minimal numbers of NHS organisations were connected and regularly reporting to the NRLS, with a steady increase in connections over the following year (see Figure 5a). By the end of 2005, all NHS organisations had reported at least one incident, and around 50% of acute organisations were reporting at least 100 incidents monthly (NPSA 2006).

FIGURE 5a: Reporting from England and Wales to the NRLS October 2003 – March 2008



(NPSA 2008 p.7)

Because of this relatively long period between the establishment of the NPSA in 2001 and the connection of the majority of NHS organisations to the NRLS in 2005, the NPSA's safety improvement work had up to that date been primarily reliant on addressing patient safety issues derived from professional opinion, rather than driven by reported incidents. During the period before the NRLS was fully established, the NPSA had two main types of publication (NPSA 2003). It produced general patient safety improvement tools focused on improving the culture of reporting and learning, including Root Cause Analysis techniques. It also produced Safety Alerts or Notices that required action on specific patient safety issues by a specified date, usually backed up by piloted packages of resources which, dependent on the topic, might include business cases, model policies, and training materials. Examples of Safety Alerts and Notices included restricting access to stocks of concentrated potassium chloride (NPSA 2002), rationalising provision of infusion devices (NPSA 2004a), and standardising the crash call number used in NHS organisations (NPSA 2004b).

NPSA Safety Alerts and Notices were distributed in England through SABS, with equivalent processes in Wales. These systems were hosted by the Department of Health and the Welsh Assembly Government and were the formal distribution route, not only for NPSA alerts but also for alerts on medication and equipment issued by other organisations, including the Medicines and Healthcare products Regulatory Agency (MHRA). By 2005 these Alerts and Notices were beginning to use NRLS data, usually in the context of emphasising the importance of the patient safety issue by referring to the numbers of related reports received. However, the majority of NRLS data were not analysed or published.

Additionally, as discussed in Chapter 1, all reporting systems, whether voluntary or mandatory, are inevitably an incomplete source of data (Sari et al. 2007). In recognition of this, the NPSA sought to create a Patient Safety Observatory (PSO) with access to multiple sources of data on patient safety. This included agreements to access data from sources such as the NHS Litigation Authority (NHSLA) and the Health and Safety Executive (HSE) (Scobie et al. 2006).

Therefore a new type of publication was needed to make use of the majority of NRLS data that was unrelated to specific Alerts or Notices, and to make use of the data obtained from

PSO sources. A PSO Report format was developed to meet this need; an overview of reports from all care settings was published as *Building a memory* (NPSA 2005) and an overview of incidents in mental health services was published as *Safety in mind* (NPSA 2006). These initial PSO Reports were almost exclusively based on quantitative analysis of incident and harm categories, although free text descriptions of individual incidents were used to provide examples. This meant that, in effect, the NPSA had one product (Alerts and Notices) that provided solutions for a very limited range of specific types of patient safety incident, and one product (PSO reports) that highlighted the most frequently reported patient safety issues, but initially with limited content on how to improve patient safety, and usually no supporting resources.

It was in this context that I began to develop the concept of a PSO report that would encompass the strengths of both products. This PSO report was titled *Slips trips and falls in hospital* and was planned as a simultaneous and complementary publication to a Safer Practice Notice requiring specific actions related to patient safety and bedrails.

5.3 *'SLIPS, TRIPS AND FALLS IN HOSPITAL'*

<u>5.3.1 Aims</u>

In most NHS organisations, although falls prevention might be a considerable concern to individual clinical staff, the issue appeared to be given relatively low priority at Board level. By outlining the scale and consequences of falls, we hoped to drive falls prevention higher on their agenda.

The relative dearth of research on falls prevention in inpatient settings had led NICE to confine their falls prevention guidance (NICE 2004) to care homes and community settings. There was therefore a vacuum in terms of any national resource or direction on falls prevention in hospitals, leading to a variety of approaches in individual organisations. However, by the point in time when the concept of a PSO report on falls was being developed, there was not a complete evidence vacuum, as some RCTs had been completed (including our cluster RCT described in Chapter 2) and a systematic review (later published as Oliver et al. 2007) was at an advanced stage. Therefore, whilst the NPSA had neither the resources nor the remit to undertake the development of the type of evidence-based guidelines produced by NICE, it could signpost this more recent evidence. This opened up the possibility of a PSO report that not only outlined the scale and nature of harm from inpatient falls, but also directed organisations to the appropriate evidence to guide action to prevent them.

These aims were summarised in the foreword to the published report as *“This report looks to improve understanding of the scale and impact of falls within the NHS, and should energise staff, from the frontline to NHS chief executives, to renew efforts to prevent falls by directing them to some of the excellent resources on falls prevention which are available”* (Healey & Scobie for NPSA 2007a p. 3).

There was, in addition, an implicit aim of demonstrating the value of data collected via the NRLS through extracting additional learning from the free text narrative of individual reports. Because of the uniqueness of the NRLS, there was no model to draw upon of how this should be undertaken. Additionally, the NPSA’s internal organisation structure had led primarily to the recruitment of either data analysts firmly embedded in a quantitative tradition, or clinical experts without experience of data analysis who tended to use reported incidents as isolated case examples. I sought to make greater use of the free text both in quantitative terms (for example, key word searches followed by sample review to estimate numbers of particular types of injuries as described in Chapter 1.4.1) and through the identification of themes repeated across samples of incidents (as described in Chapter 5.3.2 below). In the course of this, I developed methods that remain in constant use in the NPSA today (NPSA 2008, NPSA 2009).

5.3.2 Analysis of NRLS data related to falls

Much of the analysis of NRLS data included in *Slips trips and falls in hospital* has already been outlined in Chapter 1, which described how this analysis was devised and published as Healey et al. (2008). This publication included the numbers of patients who fell, harm from falls by severity grading and specific injury type (including fractured neck of femur), activity-adjusted comparisons of fallers by age and gender, benchmark rates in acute, mental health, and community hospital settings, and the pattern of falls by time of day. For *Slips trips and falls in hospital* these data were presented in the clinical context of how NHS organisations could target falls prevention efforts to the patient groups and times of day when most patients fell.

In addition to the data presented in Healey et al. (2008), *Slips trips and falls in hospital* described further analysis of NRLS data, particularly drawing on the free text reports of falls. Categorisation of free text has limitations, including reliance on a subset of reports where sufficient detail of the circumstances of falls were provided, the relatively small proportion of reports that it is practical to review and categorise in comparison to the full dataset, and the potential for errors in interpretation and categorisation. Whilst recognising these limitations, we undertook categorisation of a random sample of 600 incident reports and were able to identify proportions of reports describing contributory environmental factors related to flooring, footwear, and medical equipment (Healey & Scobie for NPSA 2007a p. 22-23) and the circumstances of falls in terms of patient activity and staff witnesses (Healey & Scobie for NPSA 2007a p. 26-28). Additionally, free text analysis was embedded in the chapters on evidence for falls prevention (Healey & Scobie for NPSA 2007a p. 36-55) to provide both positive examples of where the evidence had been put into practice, and cautionary examples of where this had not happened. The identification of themes repeated across a series of incident reports was used to demonstrate issues with risk prediction tools for falls being used inappropriately (Healey & Scobie for NPSA 2007a p. 36-37), and failures in aftercare and detection of injury following a fall (Healey & Scobie for NPSA 2007a p. 56-57).

5.3.3 Improving the quality of reporting and analysis

The purpose of reporting falls, whether locally or nationally, is to use the reports for learning, both through prioritising efforts to the patients, places and times most affected by falls, and through systematically identifying individual and environmental factors that can be modified either for the individual patient or for future patients. The analysis of NRLS data described above was challenging due to the variable quality of many reports of falls, but equally importantly this variable quality of reporting could prevent any meaningful learning being extracted locally. Discussion with patient safety networks suggested the existence of a negative cycle where, if reports from frontline staff were of poor quality, no analysis beyond crude numbers of falls was attempted by organisations' risk teams, and therefore frontline staff, believing their reports were only required to count numbers of falls, saw no reason to improve the quality of reporting. *Slips trips and falls in hospital* attempted to break this negative cycle by providing examples of information that should be collected and, more importantly, explaining how the information could be used for learning (Healey & Scobie for NPSA 2007a p. 30). This approach was emphasised by a case study from an NHS organisation that had improved the quality of their reports and applied the learning to service improvement (Healey & Scobie for NPSA 2007a p. 31).

5.3.4 Analysis of other sources of incident data on falls

Slips trips and falls in hospital was the first NPSA publication to draw on data obtained through the Patient Safety Observatory. The HSE collects limited data on falls occurring in specific circumstances, with complex reporting rules (HSE 2006) that can be summarised as requiring reporting for significant or fatal injuries involving an environmental hazard. The complexity of the reporting rules and the need for submission of duplicate reports to a separate reporting system means data were even more likely to be incomplete than the NRLS, but it proved possible to extract headline data on numbers of reported serious falls and fatalities in hospital patients (Healey & Scobie for NPSA 2007a p. 17) that were congruent with the NRLS data.

The NHSLA database was designed primarily to track the status of claims in terms of resolution, costs and damages paid, but again it proved possible to extract headline data on numbers of serious falls and fatalities (Healey & Scobie for NPSA 2007a p. 18) in hospital patients leading to litigation, and of the subsequent awards and costs.[lxxvii] Whilst litigation cases are inevitably unrepresentative of falls overall, they are in themselves an area of interest, particularly in the context of the cost burden to the NHS of avoidable lapses in falls prevention.

5.3.5 Summarising the evidence on falls prevention

As outlined above, the intention of *Slips trips and falls in hospital* was to summarise and signpost evidence on hospital falls prevention in a way that made it accessible to frontline staff. This was achieved through dividing falls prevention into topic areas including risk assessment, multifactorial interventions, patients' perspectives, the environment, wristbands, observation and actions after a fall (Healey & Scobie for NPSA 2007a p. 41-57). Each chapter gave a summary of the relevant evidence and provided links to systematic reviews, RCTs, and resources, where appropriate accompanied by a commentary from an expert in the field (e.g. Oliver's commentary on risk prediction tools p. 38). Also included were case studies of how organisations had implemented the evidence in their organisations, including a matron's perspective on our RCT described in Chapter 2 (Healey et al. 2009) and a sample care plan based on our RCT (Healey & Scobie for NPSA 2007a p. 42-43). Whilst simplifying the evidence base to make it accessible

[lxxvii] The analysis of NHSLA data was later expanded into publications (Oliver & Healey 2006, Oliver et al. 2008) described within the systematic literature review (Healey et al. 2008) in Chapter 3.

involves a risk of misinterpretation, our format mitigated against this as far as feasible by clear delineation between summarised evidence and the informal commentaries, and by providing weblinks to the source evidence.

5.3.6 Risk assessment tool survey

As outlined in Chapter 2.2.1 above, 'falls risk assessment' is used as an umbrella term used to describe both numerical tools intended to predict the likelihood of an individual person falling and assessment formats that would prompt staff to consider individual risk factors in order to formulate a plan of care or treatment. As explained above, analysis of NRLS data demonstrated a recurring theme of falls risk prediction tools for falls being used inappropriately (Healey & Scobie for NPSA 2007a p. 36-37). These included patients with repeated falls being treated as 'low risk' on the basis of their risk score, and reports that suggested calculation and recalculation of the score was used as a substitute for action to prevent falls. NRLS reports rarely referred to the name of the tool being used, so a survey was undertaken to establish which tools were in current use within inpatient falls prevention policies in NHS organisations in England and Wales.[lxxviii] The key findings from this policy survey were summarised in *Slips trips and falls in hospital* as:

"Around half [of the policies] appeared to be using falls risk scores that had not been validated. These appear to have been locally devised, or partly based on published tools but with local additions that would affect validity" (Healey & Scobie for NPSA 2007a p. 36). To help illustrate the variation and complexity within the locally devised numerical falls risk prediction tools, a photograph illustrating a selection of these was included in *Slips trips and falls in hospital* (Healey & Scobie for NPSA 2007a p. 36) and is reproduced in Figure 5b.

[lxxviii] The survey carried out in 2006 was an opportunity sample of policies volunteered though an email request to clinical governance leads via the NPSA's Patient Safety Manager networks. Although able to provide a useful snapshot to inform *Slips trips and falls in hospital*, as an unrepresentative sample it does not provide an appropriate baseline for assessing impact, and therefore in Chapter 5.6.2 a repeat survey based on a randomised sample of trusts was used to collect both policies current in 2009 and archived from 2006.

BOX 5a: a selection of inpatient risk scoring tools in use in 2006

5.3.7 Recommendations for action

Where evidence is weak or ambiguous, clinical staff and local policy makers may particularly value recommendations on best practice, but great care has to made to ensure recommendations are grounded in the evidence, and do not do more harm than good. This was a particular challenge in the area of falls risk prediction tools. Given the evidence and the findings of the policy survey, *Slips trips and falls in hospital* sought to strike a balance through a recommendation that *"if using a falls risk score, [organisations should] understand to what degree it under- or over-predicts the risk of patients falling"* (Healey & Scobie for NPSA 2007a p. 7). This was supported by an evidence summary, including the recommendation from a systematic review (Oliver et al. 2004) that even validated tools had poor total predictive value and therefore the focus of assessment should shift away from attempting to predict falls to identifying and treating those risk factors than can be modified. For organisations still keen to use a falls risk prediction tool, information was given on which tools had been validated outside the original study population, and how to use case note review and reported falls to judge how well their selected tool worked for their local inpatient population.

The five other recommendations in *Slips trips and falls in hospital* were also intended to ensure that the foundations of a sustainable falls prevention programme were in place, rather than to dictate its detail. They were directed at: improving the quality of falls reporting so that reports could be used for learning; improving the analysis of these reports at an organisational level; creating a truly multi-disciplinary falls prevention group; reviewing the evidence base of interventions in their local falls prevention policy; and providing guidance for staff to follow after a patient has fallen (Healey & Scobie for NPSA 2007a p. 7).

Slips trips and falls in hospital (Healey & Scobie for NPSA 2007a) can be found in Appendix A.

5.4 USING BEDRAILS SAFELY AND EFFECTIVELY

5.4.1 Background and aims

As explained in Chapter 3.6.1, the need for a Safer Practice Notice on the use of bedrails arose from an NPSA scoping project on 'elder restraint' that identified a lack of clarity on when and if bedrail use was acceptable and effective. This situation arose in part because of the series of MHRA alerts described earlier in Chapter 3.3.4 (MDA 1997, MDA 1999, MDA 2000, MDA 2001, MDA 2002, MHRA 2004a, MHRA 2004b) that related to different aspects of the risks of bedrail entrapment, but were solely related to the technical design of bedrails, rather than clinical decision-making on their use or the place of bedrails with a wider falls prevention agenda. A Safer Practice Notice *Using bedrails safely and effectively* (Healey & Stephenson for NPSA 2007b) requiring specific actions related to patient safety and bedrails was therefore planned as a simultaneous and complementary publication to *Slips trips and falls in hospital* (Healey & Scobie for NPSA 2007a).

5.4.2 Analysis of data related to bedrails

To inform any actions required within *Using bedrails safely and effectively,* I devised and undertook extensive additional analyses of the NRLS and other sources of incident data to identify harm in falls from bed or direct injury from bedrails. Methodology of the NRLS analysis, including keyword search terms, sampling, and the analytical process, can be found in an appendix to *Slips trips and falls in hospital* (Healey & Scobie for NPSA 2007a p. 66-67). The results of this analysis are described as headline findings in the NPSA Safer Practice Notice *Using bedrails safely and effectively* (Healey & Stephenson for NPSA 2007b) and in greater detail, including confidence intervals and tests of statistical significance, in the appendix to *Slips trips and falls in hospital* (Healey & Scobie for NPSA 2007a p. 66-67). We also provided an estimate of the contact and entrapment injuries from bedrails during a six month period (164 95% CI 120-196), and identification of subsets of falls from bed with and without bedrails with outcomes of fatalities, fractured neck of femur, subdural haematoma, and minor head injury. Significant differences were found in the proportion of no harm falls from bed (86/100 no harm with bedrails raised v. 69/100 no harm with bedrails down $p<0.05$) and in minor head injuries (3/100 minor head injuries with bedrails raised v. 21/100 minor head injuries with bedrails down $p<0.01$). Although all these data should be interpreted with great caution, because their source was a voluntary reporting system, and because some were based on subsets of reports that were detailed enough to determine bedrail status, they provided useful information to emphasise the scale of the problem of falls from bed, including an estimate of the number of reports of falls from bed (43,631 95% CI 33,205 to 56,348) and an estimate of fractured neck of femurs in falls from bed (89 95% CI 58-139).

It was also possible to extract useful data on the circumstances of falls from bed with and without bedrails from the NHSLA database (Healey & Scobie for NPSA 2007a p. 67).[lxxix] The HSE database also provided useful information on injuries from bedrail entrapment and where falls had resulted from bedrails becoming detached or broken (Healey & Scobie for NPSA 2007a p. 67).

5.4.3 Bedrails – Reviewing the evidence

As described in Chapter 3.6.2, it became clear from project group discussions and early reading of the literature that, without identifying, critiquing and synthesising the available evidence on the effect of bedrails, it would prove impossible to move forwards and identify appropriate recommendations to improve patient safety. This led me to undertake a systematic review of the literature on bedrails as described in Chapter 3, which was

[lxxix] The analysis of NHSLA data was later expanded into publications (Oliver & Healey 2006, Oliver et al. 2008) described within the systematic literature review (Healey et al. 2008) in Chapter 3.

published in 2008 (Healey et al. 2008b). An early version of this literature review (Healey for NPSA 2007d), primarily intended for a readership of frontline nurses, was published as part of the support material to *Using bedrails safely and effectively*. This version had to remain methodologically sound but also to be in an easy-to-read style, and sought to achieve this by approaching various aspects of the evidence (e.g. patients' perspectives, entrapment risks, and falls from bed) in separate chapters, each giving an overview of the evidence and key points for clinical practice, whilst relegating tables giving detail of the evidence to an appendix.

5.4.4 Survey of hospitals' bedrail policies

A survey of bedrail policies in place in NHS organisations was undertaken to inform the content of *Using bedrails safely and effectively* (Healey & Stephenson for NPSA 2007b).[lxxx] This survey indicated many current policies had missing or inappropriate content, for example:

- Policies that suggested fatal entrapment could be prevented only by avoiding bedrail use, rather than providing information on how the risks could be reduced
- Policies that prohibited bedrails for entire groups of patients, including in one policy prohibiting them for all patients with a history of falls
- Policies that gave incorrect advice that relatives could make decisions for adult patients
- Policies that required repeated bedside checks for aspects of bedrail design (e.g. internal gaps between bars) that could have been more effectively addressed by a single organisation-wide survey to identify and remove unsafe equipment
- Policies that suggested ineffective alternatives to bedrails such as 'tucking the sheets in'
- Policies citing research on studies of vest, belt, cuff and harness devices as though these were bedrail studies
- Policies that equated any use of bedrails with restraint, which in one policy was taken so far as to say the use of bedrails without written consent may amount to common assault punishable by a jail sentence of up to six months

[lxxx] The survey carried out in 2006 was an opportunity sample of policies volunteered though an email request to clinical governance leads via the NPSA's Patient Safety Manager networks. Although able to provide a useful snapshot to inform *Using bedrails safely and effectively*, as an unrepresentative sample it does not provide an appropriate baseline for assessing impact, and therefore in Chapter 5.6.2 a repeat survey based on a randomised sample of trusts was used to collect both policies current in 2009 and archived from 2006.

These findings were used to inform the model bedrail policy described below, and were summarised in the supporting resources (Healey for NPSA 2007c p. 4-5) provided with *Using bedrails safely and effectively* (Healey & Stephenson for NPSA 2007b).

5.4.5 Findings from an overnight survey of bedrail use

For any safety improvement project it is important to understand how current practice compares with recommended practice. However, as outlined in Chapters 4.1 to 4.4 above, there was very little current information available from published studies on bedrail use in the UK. For *Using bedrails safely and effectively,* the key aim of the overnight survey of bedrail use (Healey et al. 2009) described in Chapter 4 was to create a representative and contemporary picture of bedrail use in hospitals in England and Wales. We also sought to identify if bedrails were being used inappropriately. As described earlier in Chapter 4, the findings of our overnight survey indicated that at least a small proportion of patients had bedrails in use in circumstances where they appeared contra-indicated, or not in use where they were strongly indicated. This suggested that the Safer Practice Notice needed to address both overuse and underuse of bedrails.

5.4.6 Actions required on bedrails

The actions included in the Notice were derived from the analysis of data, the literature review, the policy survey, and the overnight survey of bedrail use described above. They required organisations providing NHS funded care to:

- Produce a policy on bedrails based on the draft policy provided, or ensure their policy on bedrails covers the key areas required within the Safer Practice Notice
- Ensure ongoing training programmes are in place for staff who make decisions about bedrails, purchase, store, attach or maintain bedrails, or care for patients using bedrails
- Develop an effective implementation plan to bring their new or revised policy on bedrails to the attention of all relevant staff
- Develop plans to audit and evaluate the impact of their new or revised policy on bedrails, including taking baseline measures before the implementation of their new or revised policy on bedrails, where appropriate

Using bedrails safely and effectively (Healey & Stephenson for NPSA 2007b) can be found in Appendix A.

5.4.7 Resources for reviewing or developing a bedrail policy:

In order to support implementation in individual organisations, I developed a range of resources that were made available via the NPSA website. A key component, given the problems with existing policies described above in Chapter 5.4.4, was creating a model policy (Healey for NPSA 2007c p. 12-23) that could be adapted for use in local organisations. The timescales and resources available to the project meant that developing and testing a bedside decision aid on bedrails was not feasible, but I produced composite models based on those tools already in use within organisations that had face validity (NPSA 2007c p. 24-35). This was less ideal than properly piloted and validated tools, but this was mitigated by providing accompanying advice on potential advantages and disadvantages of each tool, and case scenarios to support local piloting of the tools.

The methodology and data collection formats used for our overnight survey of bedrail use were made available as a resource on the NPSA website and NHS organisations in England and Wales were encouraged to carry out their own local surveys. As described in Chapter 4.8 above, Shanahan & Evans (2009) based their published survey of bedrail use on these materials.

To help convey key messages to frontline staff, I devised a series of posters and we commissioned cartoonists to illustrate these. Their aims were to convey the scale of harm from falls from bed, the situations in which bedrails would be considered restraint, and how to avoid bedrail entrapment (see Figure 5c). The posters could be ordered without charge by NHS organisations. To accompany these I developed a set of slides and case scenarios that could be used for local training or awareness sessions.

FIGURE 5c: sample of bedrail posters

The resource set also gave us a forum to publish some of the key findings from the survey of policies and practice described above, and to summarise the findings from focus groups held with patients.

Resources for reviewing or developing a bedrail policy can be found in Appendix A.

<u>5.4.8 Complementary work on restraint</u>

Given the varying definitions of restraint, and the confusion between studies of vest, belt, harness or cuff restraints and bedrails described in Chapter 3, it would have been almost impossible to give coherent advice on bedrail policy without reference to authoritative national guidance on restraint. Unfortunately, at the outset of the work described above, this did not exist. Royal College of Nursing guidance on restraint had been published and revised (RCN 1996, RCN 1999, RCN 2001, RCN 2003, RCN 2004); however, the guidance offered a range of definitions of restraint and debated (rather than clarified) the differences between them but, despite these ambiguities, placed bedrails first on the list of 'methods of restraint' (RCN 2004 p. 6). The emphasis was rightly on good practice that could avoid the need for restraint, but this emphasis left it unclear whether there were any situations in which restraint might be justified, and strong suggestions that it could not be: *"It should be obvious that restricting someone's movement against their wishes is entirely wrong in almost all circumstances …..restraint used by a healthcare professional on someone in their care is a potential abuse…."* (RCN 2004 p. 3). Some content was misleading, for example drawing a division between ‘holding still’ and restraint, with the latter implied to involve excessive and inappropriate force: *“Holding still is distinguished from restraint by the degree of force required…”* (RCN 2003 p. 4).

In the early part of the restraint project I identified incidents reported to the NRLS that suggested physical restraint in acute hospital situations could be very poorly managed, with clinical and security staff unsure of their respective roles, and that nursing staff were afraid to use restraint even in situations where a patient without capacity was in immediate danger. Together with our findings related to bedrails from reported incidents, policy, and practice, I approached the Royal College of Nursing. They had planned a revision of their restraint guidance because of the Mental Capacity Act (2005) but were persuaded by this evidence that a complete rewrite was needed, and I acted as the lead author for their revised guidance *‘Let’s talk about restraint’* (Healey et al. for RCN 2007) (see Appendix E). The guidance included case studies illustrating circumstances when the use of bedrails was not restraint, as well as an example of where use was inappropriate. I also influenced the NHS Counter Fraud and Security Service to include advice and case studies on detecting and treating medical causes of confused or aggressive behaviour in their guidance on management of violence and aggression in NHS settings (CFSMS 2008).

5.5 DISSEMINATION STRATEGY

5.5.1 Formal mechanisms

The main formal mechanism for the distribution of *Slips trips and falls in hospital* was via the Chief Executives’ Bulletin (which is a web-linked weekly email distributed by the Department of Health in England to all Chief Executives and Executive Directors plus any individuals who have registered to receive it) and via equivalent network communications in Wales. *Slips trips and falls in hospital* and *Using bedrails safely and effectively* (Healey & Stephenson for NPSA 2007b) were highlighted in the same edition of the Chief Executives’ Bulletin (Department of Health 2007). This communication included links to the NPSA website where they were available to download. Additionally hard copies of each were distributed to all Nurse Directors in NHS organisations in England and Wales during February 2007, with the remainder of a print run of 5,000 copies of each available free to order by NHS staff.

Using bedrails safely and effectively (Healey & Stephenson for NPSA 2007b) was a Safer Practice Notice requiring specific actions from organisations providing NHS-funded care, and was therefore distributed via SABS[lxxxi] in England and equivalent processes in Wales. These systems require NHS organisations to acknowledge receipt and to confirm when the required actions have been completed.[lxxxii] Failure to comply within specified timescales is monitored by Strategic Health Authorities, and by the Healthcare Commission (now the Care Quality Commission) and their Welsh equivalents.

Slips trips and falls in hospital (Healey & Scobie for NPSA 2007a) and *Using bedrails safely and effectively* (Healey & Stephenson for NPSA 2007b) and the range of supporting materials, including packs of posters, were also provided to Nurse Directors in NHS organisations in England and Wales during April 2007 as hard copies in a boxed 'toolkit' (see Figure 5d).

FIGURE 5d: Content of bedrails toolkit

[lxxxi] This system was replaced in 2008 by an upgraded system called the Central Alerting System (CAS).

[lxxxii] This compliance data will be used later to demonstrate the impact of my work on clinical policy and practice in Chapter 5.6.3.3.

5.5.2 Dissemination through other national organisations

Dissemination in England was supported by the Healthcare Commission's inclusion of compliance with *Slips trips and falls in hospital* in their *Inspection Guide 2007/08* (Healthcare Commission 2008). The Healthcare Commission (subsumed in 2009 into the Care Quality Commission) was at that time the regulatory organisation for all healthcare providers in England. They operated a system of annual quality assessments of NHS trusts based on self-assessment backed up by targeted inspection of 10% of trusts selected at random and 10% of trusts selected on the basis of intelligence (Healthcare Commission 2008). For the inspection round in 2008 their *Inspection Guidance 2007/08* (Healthcare Commission 2008) took a 'litmus test' approach, where inspectors would focus on a selected aspect of quality, and take compliance or non-compliance in the topic area as a proxy for compliance or non-compliance with the overall standard. For Core Standard 1a *"Healthcare organisations protect patients through systems that identify and learn from all patient safety incidents and other reportable incidents, and make improvements in practice based on local and national experience and information derived from the analysis of incidents"* (Healthcare Commission 2008 p. 9) the litmus test selected was compliance with the recommendations in *Slips trips and falls in hospital* (Healey & Scobie for NPSA 2007a). Extracted detail is shown below in Box 5a.

BOX 5a: Extracts from the Healthcare Commission's *Inspection Guidance 2007/08*

'Litmus test' for Core standard C1a

a) Information and recommendations from the NPSA's *Slips, Trips and Falls Report* (see point of information 11) should be taken into account to make improvements in:

- organisational practice, for the benefit of patients in general (see point of information … 12)
- interventions for individual patients who have experienced an in-patient fall

b) The healthcare organisation communicates learning from the local analysis of incidents and national reports from the NRLS to relevant staff across the organisation.

Points of information

11. The NPSA published the *Slips, trips and falls in hospital* report in February 2007. It presents a comprehensive national picture on in-patient falls and has recommendations for trusts. The report is based on research, evidence and information from over 200,000 falls that were reported to the NPSA's NRLS. Further details can be found on the NPSA's website.
12. Key elements of a policy based on NPSA's national analysis may include environmental and clinical falls prevention interventions, recognition of rehabilitation, independence and privacy needs, and where a numerical falls prediction score is used for in-patients, the organisation has tested whether it works locally to predict fallers.

Extracted from Healthcare Commission's *Inspection Guidance 2007/08* (2008a) p. 8-11

Whilst only 20% of trusts would be inspected, the trusts did not know at the time the *Inspection Guidance* was published whether they would become one of the 20%, and therefore the *Inspection Guidance* was disseminated to, and considered by, all trusts.

The Healthcare Commission provided further dissemination with *Safely does it* (Healthcare Commission 2009) which included, amongst other patient safety topics, the summary findings of *Slips trips and falls in hospital* and actions that a sample of trusts had taken in response to it.

The Royal College of Physician's National Clinical Audit of Falls and Bone Health in Older People also supported dissemination to almost all UK hospitals by including audit standards drawn from *Slips trips and falls in hospital* in the round of service audit carried out during 2008 (RCP 2009), including a specific standard that inpatient falls prevention policies should be based on it, and standards based on the recommendations within *Slips trips and falls in hospital* and *Using bedrails safely and effectively*. Detail is given in Box 5b below.

BOX 5b: Standards within the National Clinical Audit of Falls and Bone Health in Older People (organisational audit 2008)
5.3.1. Is there an in-patient or resident falls prevention/reduction policy? 5.3.2. Is the in-patient policy based on the National Patient Safety Agency *Slips, trips and falls in hospital* report? 5.3.3. Does the in-patient / resident falls policy include the use of bedrails? 5.3.5. Does the in-patient / resident falls policy include how to record, report and monitor falls? 5.3.6. Does the in-patient / resident falls policy include guidance on clinical actions to be taken after a patient or resident has fallen? 5.3.9. Does your care home or trust routinely review the overall pattern and trends for in-patient or resident falls? (RCP 2009)

These secondary routes of distribution also provide useful sources of evidence of impact that will be examined later in Chapter 5.6.3.

5.5.3 Other dissemination mechanisms

5.5.3.1 Dissemination through endorsements and media coverage

The launch of *Slips trips and falls in hospital* was supported by a media event and press release containing endorsements from organisations and individuals with an interest in falls prevention (see Box 5c).

BOX 5c: Endorsements for the launch of *Slips, trips and falls in hospital*

Pamela Holmes, Programme Manager, Healthy Ageing Programme, Help the Aged

"This is a welcome report which, for the first time, addresses the key issue of falls prevention in hospital and gives a clear picture of how to reduce the likelihood of falls happening. Falling is not an inevitable part of ageing but the risk increases as people get older. And the consequences can be devastating for an older person in terms of loss of mobility, confidence and independence. We hope that on the basis of these findings, NHS organisations will have better awareness of how to reduce the risk of falls without compromising patients' dignity and privacy."

Dr Finbarr C Martin, Chair of the British Geriatrics Society Chapter on Falls and Bone Health

"We welcome this comprehensive and careful report on the key issue of older people falling in hospitals. The NPSA has collected vital information from hospitals, researchers and clinicians. It does justice to the published evidence as well as other important sources of knowledge like incident reporting and locally evaluated initiatives. It sets out the complexity of factors involved and why there is no universal quick fix. The report avoids the pitfalls of over optimism and of putting institutional caution above individual autonomy. But the great variation in rates of falls around the NHS does suggest that we can and must do better. The report shows that success lies in clinical teams working together to put careful assessment of individual patients and targeting of good clinical practice at the centre of the strategy. We commend this report. It should prove a useful resource wherever hospitals are committed to devote sufficient effort and expertise to improve matters for the most vulnerable of patients."

Professor Ian Philp, National Director for Older People's Health, Department of Health

"The cost of falls to the NHS, both in financial and human terms, is enormous; I welcome the work that the NPSA is doing to improve understanding of the problem and to encourage the implementation of practical solutions."

Slips trips and falls in hospital was also covered in the news chapters of five clinical publications and in the general media including The Times, Radio 2, regional television and nine regional newspapers (see Appendix H). A commentary in the British Journal of Nursing (Hayes 2007) urged readers to look at the report and to bring their practice closer to the evidence base described within it.

5.5.3.2 Dissemination via supplementary articles in healthcare journals

To support dissemination of the NPSA publications and their associated journal articles, I produced a range of additional papers summarising their findings for differing audiences, including senior managers, frontline nurses, doctors, and clinical governance leads. The target journals were chosen for their wide readership by frontline staff and managers with an interest in falls prevention, and the topics were approached in styles appropriate for each audience. These nine papers and two letters to the editor are summarised in Table 5a and available in Appendix C.

TABLE 5a: Additional dissemination articles

Reference	Topic	Journal	Main readership	Circulation (per edition)
Healey 2010	'Nursing by numbers: we must use clinical judgement to assess risk' – a clinical practice comment referring to the requirement in NPSA 2007a to locally assess validity of risk prediction tools	*Nursing Times*	Senior and frontline nurses	30,000
Healey 2009a	'A safer night's sleep' – a commissioned overview of bedrail safety referencing NPSA 2007a and NPSA 2007b.	*Public Service Review*	Senior managers	5,000
Healey 2009b	'Decisions on bedrails must not be made through emotive arguments' – a clinical practice comment drawing on the findings of NPSA 2007b and Healey 2008b.	*Nursing Times*	Senior and frontline nurses	30,000
Healey & Oliver 2009	'Bedrails, falls and injury: evidence or opinion?' – a peer reviewed overview of the literature on bedrails based on Healey et al. 2008b, drawing on the findings of NPSA 2007a, NPSA 2007b and NPSA 2007c.	*Nursing Times*	Senior and frontline nurses	30,000
Oliver & Healey 2009	'Falls risk prediction tools for hospital inpatients: do they work?' – a peer reviewed overview of the role of numerical risk prediction tools within hospital falls prevention, referencing Healey et al. 2008b and NPSA 2007a.	*Nursing Times*	Senior and frontline nurses	30,000
Oliver & Healey 2008	'Interpreting the null result' – a letter to the editor in response to Cummings et al.'s (2008) conclusion that multi-faceted interventions do not work, drawing on the findings of Healey et al. 2004	*BMJ*	Doctors	120,000
Healey et al. 2007	'A national bedrail safety project' - a peer reviewed overview of the literature on and guidance on bedrails drawing on the findings of NPSA 2007b, NPSA 2007c and NPSA 2007d.	*Nursing Times*	Senior and frontline nurses	30,000
Healey & Scobie 2007	'Keeping a balance: preventing patient falls in hospital'– a commissioned overview of hospital falls prevention and bedrail safety drawing on the findings of NPSA 2007a & b.	*British Journal of Healthcare Management*	Senior managers	Not known
Healey & Oliver 2006	'Preventing falls and injury in hospitals: where are efforts best directed?' – early findings on national reports of falls signposting the future publication of NPSA 2007a and drawing on the findings of Healey et al. 2004	*Healthcare Risk Report*	Risk and clinical governance leads	2,000
Oliver & Healey 2006	'Preventing Falls and injury in hospitals: the evidence for intervention' - early findings on national reports of falls from bed signposting NPSA 2007b	*Healthcare Risk Report*	Risk and clinical governance leads	2,000
Healey 2006	'The best methods of preventing falls in hospitals' – a defence of the methodology	*Canadian*	Senior and frontline	Not known

	of Healey et al. 2004 in response to a letter to the editor suggesting RCTs which did not use a numerical risk prediction tool were "immoral and unethical".	*Journal of Nursing Research*	nurses	

5.5.3.3 Dissemination via conference presentations

I also presented to a wide range of conferences, including plenary sessions at three international conferences (Royal Society of Medicine 1st International Conference on Prevention of falls and injuries in hospitals and care homes, Royal Society of Medicine 2nd International Conference on Prevention of falls and injuries in hospitals and care homes, and the British Geriatrics Society 8th International Conference on Falls and Postural Stability). In addition I presented in plenary sessions at eleven national, and three regional conferences, and in five concurrent sessions or poster presentations at international, national or regional conferences. I also presented at around thirty local conferences and workshops. The key conferences are summarised in Appendix F.

5.5.3.4 Dissemination via websites

Additional routes of dissemination were via websites including the NPSA website, the British Geriatrics Society (BGS) website, the Safer Healthcare website (a patient safety website targeted at clinicians) and the Prevention of Falls Network Europe (ProFaNE) website. ProFaNE was established as a network for individuals active in research on falls prevention, but has broadened to include a wider community of frontline staff with an interest in falls prevention, and provides regular round-ups of new research and resources alongside active discussion boards. ProFaNE made a commentary on our systematic review of the bedrails literature the main feature in their July 2008 newsletter (ProFaNE 2008) and backed this up with a debate on their discussion board, including a mini-poll. Our overnight survey of bedrails was a feature item in their October 2009 newsletter (ProFaNE 2009). Evidence of downloads from these sites will be examined later in Chapter 5.6.4.

5.5.3.5 Strengths and weaknesses of our dissemination strategy

As described above, we were able to take advantage of a wide range of dissemination mechanisms, including formal NHS channels directed at Boards and risk managers, and journals read by a variety of clinical and managerial groups, including both academically credible journals and popular journals with a wide readership. This was supported with a number of conference presentations. By combining access to resources via websites with the distribution of hard copies we ensured our publications could reach those without easy access to the web. Dissemination was supported by convincing other organisations to include NPSA materials as audit or inspection standards, or to create links on their own websites, and by creating launch events which gained coverage in the popular media, including regional television and national newspapers. However, communication is a two-way process; information has to be understood and acted on rather than passively received. Therefore below I will examine evidence of whether this wide dissemination succeeded in influencing policy and practice.

5.6 EVIDENCE OF IMPACT ON CLINICAL POLICY

5.6.1 Introduction

As outlined in the introduction to this chapter, evidence of impact is a fundamental component of assessing the quality of research, despite the challenges involved in the attribution of impact to research activity. All the publications described in Chapters 1 to 4 were linked by the two NPSA publications described above, and therefore the assessment of their impact needs to be considered in the round. Their interlinking is extensive; the analysis of reported falls (Healey et al. 2008a) described in Chapter 1 comprised the core content of *Slips trips and falls in hospital*, but this also drew on the RCT described in Chapter 2, both as a case study and as a model care plan for taking action on modifiable risk factors. *Using bedrails safely and effectively* drew on our systematic review described in Chapter 3 and the overnight survey of bedrail use described in Chapter 4. *Slips trips and falls in hospital* and *Using bedrails safely and effectively* were simultaneous and complementary publications. In addition, the supplementary papers and conference presentations described above in Chapter 5.5.3.2 were also interlinked, often referencing more than one of these publications. Because of this, it is difficult to discuss the evidence of impact in isolation, and I will therefore describe their combined impact, whilst drawing out particular aspects of my work that may have been key influences.

5.6.2 Evidence of impact on organisations' falls prevention and bedrail policies

5.6.2.1 Introduction: policy review

A key recommendation in *Slips trips and falls in hospital* (NPSA 2007a) was for organisations to review their falls prevention policy in light of the evidence presented within it. *Using bedrails safely and effectively (*NPSA 2007a) also recommended that organisations develop a policy on bedrail use using the model policy provided, or review existing policy to ensure it included key points within it. Therefore, to illustrate the effect of our peer reviewed papers and interlinked NPSA publications on clinical policy and practice, I have undertaken a survey of bedrail and falls prevention policies in NHS organisations in England and Wales.

5.6.2.2 Aims: policy review

The aim was to compare policies in place during 2006 and during 2009 to identify any changes in their key content. The policy survey aimed to identify:

- The proportion of NHS organisations in England and Wales with a current falls policy referencing *Slips trips and falls in hospital* (Healey & Scobie for NPSA 2007a)
- Any changes in the key content of falls policies, including type of risk prediction tools or modifiable risk factor checklists used, if any, and advice on care after a fall
- The proportion of NHS organisations in England and Wales with a bedrail policy referencing *Using bedrails safely and effectively* (Healey & Stephenson for NPSA 2007a) and those using the model bedrail policy
- Any changes in the key content of bedrail policies, including appropriate advice on consent and capacity, specific advice on avoiding bedrail entrapment, and indications as well as contraindications for bedrail use

5.6.2.3 Methods

A baseline policy survey had been carried out prior to the NPSA publications, and this survey found gaps in existing policies (described earlier in Chapters 5.3.6. and Chapters 5.4.4). However, these policies had been collected primarily to inform recommendations rather than as a baseline for evaluation, and were therefore drawn from a local opportunity sample that was unlikely to be representative of policies across England and Wales. To provide a more representative baseline, 50 acute hospital trusts were selected by random number table from a list of all acute hospital trusts in England and Wales and requested via email to share any falls prevention and/or bedrail policies or procedures in place during October 2006 and any in place during October 2009. Because trusts are required to include the date of approval on all policies and to routinely archive older versions of policies in case of retrospective legal action (NHSLA 2008), policies active in 2006 were expected to be available on request. The Freedom of Information Act (2000) requires trusts to respond to information requests within specified timescales unless certain exemptions apply.

Requests were made during October 2009 and responses collated up to the end of December 2009. Key aspects of each policy received were then categorised using definitions provided in Appendix I.

5.6.2.4 Results: policy review

By the cut-off date of December 31st 2009, 37 (74%) of the 50 randomly selected trusts had responded. The key content of the policies they provided is summarised in Table 5b below.

TABLE 5b: Comparison of key content of falls prevention and bedrail policies in use in England and Wales during 2006 and 2009

KEY:
areas of notable change **shaded and bold**

	2006		2009	
Falls prevention policies:	*Number*	%	*Number*	%
Has an inpatient falls prevention policy	*24/37*	**65%**	*37/37*	**100%**
References *Slips trips and falls in hospital*	*N/A*	N/A	*18/37*	49%
Assessment tool prescribed by policy:				
• Direct to multifactorial checklist	*0/24*	0%	*3/37*	8%
• York RCT 'four questions'	*1/24*	4%	*6/37*	16%
• Numerical validated tool (Morse)	*4/24*	17%	*4/37*	11%
• Numerical validated tool (STRATIFY)	*5/24*	21%	*5/37*	14%
• Referenced numerical tool	*2/24*	8%	*8/37*	22%
• Locally devised numerical tool	*12/24*	**50%**	*7/37*	**19%**
• Unclear what tool in use if any	*0/24*	0%	*4/37*	11%
Gives advice on clinical checks after a fall	*7/37*	**19%**	*19/37*	**51%**
Uses the York RCT care plan	*1/37*	3%	*6/37*	16%
Bedrail policies:				
Has a bedrail policy	*18/37*	**49%**	*33/37*	**89%**
References NPSA Bedrail materials	*N/A*	N/A	*26/37*	70%
Uses the NPSA model bedrail policy	*N/A*	N/A	*19/37*	51%
Gives advice on capacity and consent:				
• Appropriate advice	*3/37*	**8%**	*23/37*	**62%**
• Incorrect advice	*3/37*	8%	*3/37*	8%
Gives indications for bedrail use	*12/37*	**32%**	*30/37*	**81%**
Advice on how to avoid bedrail entrapment:				
• Some	*11/37*	30%	*11/37*	30%
• Specific	*2/37*	**5%**	*17/37*	**46%**

5.6.2.5 Discussion

Table 5b demonstrates that one of the most notable changes appeared to be in the proportion of trusts with an inpatient falls prevention policy (rather than solely policies directed at environmental hazards which offered the same actions for patients, visitors and staff), which rose from 65% to 100%. More importantly, some of the key recommendations within *Slips, trips and falls in Hospitals* were reflected in policy changes:

- The use of unreferenced apparently 'home made' numerical risk prediction tools reduced from around 50% of policies in 2006 to around 19% of policies in 2009.
- The use of any kind of numerical risk prediction tools (local or validated) reduced from 96% of policies in 2006 to 66% by 2009.
- Advice on clinical checks after a fall was available in 19% of trusts in 2006, and this increased to 51% by 2009.
- 16% of the policies collected above included care plan formats directly based on the example from the York RCT (Healey et al. 2004) presented in *Slips trips and falls in hospital* (Healey & Scobie for NPSA 2007a p. 42-43). This may be an underestimate of its use in practice, as many policies did not include detail on their bedside documentation.

Influences on changes in policy are usually multiple and complex, and the recommendation within *Slips trips and falls in hospital* - that a risk prediction tool was not an essential part of a falls prevention policy, but that if used it must be a validated tool - is unlikely to have been the sole influence on these changes. Further academic reviews of risk assessment tools published between 2006 and 2009 (e.g. Haines et al. 2008, Oliver et al. 2009) may also have been an influence, as would Oliver's frequent conference platforms critiquing risk assessment tools (e.g. International Falls and Bone Health Conference 2009). However, respondents to the *Slips trips and falls in hospital* evaluation (see Chapter 5.6.3.1) suggested it had 'given them permission' to translate the academic evidence into practice. *Slips trips and falls in hospital* was directly referenced in 49% of these policies, suggesting it was a key influencing factor.

Table 5b also demonstrates that the proportion of trusts with a bedrail policy rose from 49% to 89%. More importantly, some of the key recommendations within *Using bedrails safely and effectively* were reflected in policy changes. These included appropriate advice on capacity and consent, which increased from 8% of bedrail policies in 2006 to 62% of bedrail policies in 2009, although this is likely also to have been influenced by the Mental Capacity Act (2005). Changes also occurred in the inclusion of indications for bedrail use, which rose from 32% to 81%.

The further MHRA guidance on avoiding bedrail entrapment issued in late 2006 (MHRA 2006) and early 2007 (MHRA 2007) was also likely to have been influential on changes in local bedrail policies between 2006 and 2009. However, it is notable that although MHRA guidance requiring action on specific dimensions (e.g. between rails gap of no more than 12cm) had been in place since 2004, by 2006 only 5% of local policies included any of these dimensions, whilst by 2009 46% of local policies included these (and all the trusts who had used the NPSA model policy as the basis for their local policy provided specific dimensions).

The policy survey was strengthened by the use of a randomly selected sample, but also had limitations. Thirteen trusts (26%) failed to respond within required timescales, and therefore the sample may not be fully representative. Complex topics like falls may be covered by multiple policies and protocols (for example, separate policies for environmental hazard assessment or additional protocols in departments or divisions) and there was no way of determining if trusts had sent all relevant documents, so the provided policies may actually under-represent true provision. Its findings therefore need to be triangulated with the other sources explored below.

5.6.3 Evidence of impact from independent sources

5.6.3.1 Commissioned independent evaluation

The NPSA commissioned an independent researcher to carry out an evaluation of *Slips trips and falls in hospital* and their findings (Wright, 2007) are described below in Box 5e below to provide third party corroboration of its impact.

BOX 5e: Evaluation of the third report of the Patient Safety Observatory: *Slips, trips and falls in hospital* drawn from Wright (2007)

All text below is direct quotations from Wright (2007) but to avoid confusion with quotes from participants within Wright (2007) quotation marks are not used; italic text in quotation marks indicates quotes by participants recorded by Wright (2007).

Thirty trusts or local health boards providing inpatient care were selected randomly across England and Wales and invited to participate in the evaluation. Of these, 25 agreed to take part. Short structured interviews were carried out with nurse directors/deputies and longer (in-depth) semi-structured interviews were conducted with the person in each organisation most involved in falls prevention. The interviews took place over June and July 2007, relatively soon after the publication of *Slips trips and falls in hospital* in February 2007.

The evaluation was designed to focus on the following areas:

- General usefulness
- Practical actions that had taken place in the organisation as a result of the report
- Helpfulness of specific content
- Comprehensiveness of content
- Format and style

The report appeared to be very positively received, with an overall rating 7.75 on a scale where 10 represented extremely useful and zero represented not useful at all, and very positive comments:

"It was a fantastically helpful document."

"It was like 'manna from heaven'."

"Speaking from my own perspective, I thought the report was absolutely brilliant. It was a really good resource. It's the only official report I've read cover to cover."

The mix of analysis, costs, evidence, good practice case studies and contacts, patient perspective, and resource links was also very positively received:

"The combination of analysis with evidence and case study was excellent. It was the first time in a long time that I had read something that showed a practical application of the evidence."

"It was great to see the numbers and costs of falls data. It was absolutely fascinating."

Suggestions for additional content included a model falls prevention policy and detailed patient case studies. Comments on readability, flow, and layout were positive. Length was commented on but generally felt to be justified by content. Although this was an early evaluation (brought forward to inform an internal NPSA review of products) almost all respondents identified changes in practice influenced by the report. Key areas were:

- Increasing the priority given to falls prevention at Board level
- Targeting and prioritising what needed to be done
- Validating where they were doing the right thing
- Changing assessment away from numerical scoring and towards risk reduction
- Updating falls prevention strategies
- Benchmarking their falls rates

The evaluation confirmed that some staff like a very tight focus on their own area of speciality; a participant working in primary care would have preferred a report on falls prevention in patients' own homes, and a participant working in mental health would have liked the findings from acute and community hospitals deleted to provide a version purely focused on mental health settings.

Overall, the report has been received favourably and is being used to validate existing work or develop and shape new work with practical activity taking place in a number of areas, particularly policy development and risk assessment. The report is seen as comprehensive and has helpfully brought together information about falls into one readable, logically laid out and clear document. The data within the report have proved useful for seeing what is happening nationally, and for providing the opportunity to compare performance against others and assess current practice against that recommended in the report. Views on the format and style of the report have been particularly positive, with many people liking the combination of data analysis, evidence base and practical examples, overall structure and presentation.
(Wright 2007 condensed from p. 1-15)

Whilst the independent evaluation had limitations, including the small sample size, the focus on staff with an interest in falls prevention, and its early timing before most trusts had been able to take implementation of its recommendations forward, it was able to provide a summary of the subjective views of NHS staff on its utility and likely impact.

5.6.3.2 The National Clinical Audit of Falls and Bone Health in Older People

The National Clinical Audit of Falls and Bone Health in Older People (RCP 2009) used data collected in 2008 and provided a useful third party corroboration of the impact of my interlinked publications. The audit indicated that 95% (173/183) acute hospital organisations within England, Scotland, Wales and Northern Ireland had an inpatient falls prevention policy, which is consistent with the 100% (37/37) of a random sample of trusts in England and Wales able to supply a copy of such a policy discussed above in Chapter 5.6.2.4. Of these 93% (160/173) said that their policy was based on *Slips trips and falls in* *hospital.*[lxxxiii] For Mental Health units the equivalent figure was 86% (38/46), whilst for Primary Care Organisations with inpatient services the figure was 71% (99/140).

The RCP (2009) audit also included a question on whether their falls prevention policy included a chapter on bedrail use (or was linked to a policy on bedrail use). Responses indicated that 92% (160/173) of acute hospitals, 76% (29/38) of mental health units were and 87% (85/98) of community hospitals had such a policy. Although as self-reported compliance should be treated with caution, this is consistent with the 87% (33/37) of acute hospitals able to provide a copy of such a policy discussed above in Chapter 5.6.2.4.

A further important recommendation within *Slips trips and falls in hospital* was for organisations to provide guidance on clinical actions to be taken after a patient had fallen. The RCP audit indicated that by 2008 this was included within 95% (164/173) of acute hospitals' falls prevention policies, 92% (35/38) of mental health units' policies, and 86% (85/99) of policies in primary care organisations providing inpatient care. This self-reported compliance is greater than the proportion of 51% that was found in the policy survey discussed above in Chapter 5.6.2.4. This dichotomy could be explained by the inherent unreliability of self-reporting, but it is also possible that brief guidance on clinical actions after a fall was issued separately to formal policy in some organisations.

5.6.3.3 Registration of compliance on SABS

Key evidence for substantial clinical impact of *Using bedrails safely and effectively* can be drawn from the SABS system described above in Chapter 5.5.1. This system provided a facility for organisations to declare when the required actions had been complied with. This feedback was monitored not only by the NPSA, but also by regulatory organisations such as the Healthcare Commission and performance management organisations such as the Strategic Health Authorities and Welsh Assembly Government. SABS indicated that, by 31st October 2009, 87% (236/272) of relevant trusts[lxxxiv] recorded that they had completed organisation wide action to improve bedrail safety. Because of the ambiguities within the SABS categories, most of the remaining 36 organisations may also have

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[lxxxiii] NPSA guidance was only issued to England and Wales, with no obligation for hospitals in Northern Ireland or Scotland to consider it, but the RCP audit included acute hospital organisations in Scotland and Northern Ireland in the totals above.

[lxxxiv] Relevant trusts were those providing adult inpatient beds in England, as SABS is used only in England (although the Notice was distributed in both England and Wales).

complied, as they were registered mainly as ‘action not required’ (16/36) (which could indicate they were satisfied their existing policy met the requirements of *Using bedrails safely and effectively* without the need for a new or revised policy) or as ‘action ongoing’ (18/36) (which is an option sometimes selected by trusts to emphasise the fact that policy implementation is an ongoing rather than one-off process).

As self-reported data, SABS compliance is unlikely to be a robust reflection of actual implementation, but the reported compliance level of 87% is consistent with the policy survey discussed above in Chapter 5.6.2.4, which indicated 89% of trusts had a bedrail policy in place, of which 70% included specific reference to *Using bedrails safely and effectively*.

5.6.3.4 Healthcare Commission inspections

As outlined above in Chapter 5.5.2, the Healthcare Commission included compliance with the recommendations of *Slips trips and falls in hospital* (Healey & Scobie for NPSA 2007a) in their *Inspection Guide 2007/08* (Healthcare Commission 2008a) as a ‘litmus test’ for inspectors to assess how well trusts were performing in Core standard 1a (reporting and learning).

Healthcare Commission publications do not separate the findings from inspected trusts from the findings from self-declaration, but overall 97% of trusts were compliant with Core Standard 1a (Healthcare Commission 2008b). This suggests that out of the 20% of trusts that underwent inspection, most must have been able to supply sufficient evidence to convince inspectors that they had implemented the recommendations in *Slips trips and falls in hospital*. For the minority of trusts that were found to be non-compliant, efforts to secure compliance would be expected as part of their post inspection action planning overseen by Strategic Health Authorities. An example of an action plan citing *Slips trips and falls in hospital* is shown in Box 5f.

BOX 5f: Example action plan from a PCT failing the Healthcare Commission's 'litmus text'
• Review NPSA's *Slips, trips and falls* report and agree any action required for in-patient services • Clarify and implement cascade system to ward level of incident analysis reports and national reports on in-patient falls from the NRLS (in-patient facilities only) to ensure all areas implement relevant action to improve service and safety • Audit service and practice changes in relation to falls in in-patient facilities across the PCT and evaluate to identify improvements Extract from Trust Board minutes at www.esdw.nhs.uk/EasySiteWeb/GatewayLink.aspx?alId=155899

5.6.4 Download numbers

In addition to 5,000 hard copies of *Slips trips and falls in hospital* that were distributed to NHS staff,[lxxxv] the report could also be downloaded from the NPSA website. Unfortunately, due to licensing issues for website activity monitoring software, no data are available for download numbers between the release of the report in February 2007 and October 2008. However, even 30 months after release, *Slips trips and falls in hospital* is still being downloaded over 400 times a month[lxxxvi] and *Using bedrails safely and effectively* around 150 times a month.[lxxxvii]

The British Geriatrics Society also posted *Slips trips and falls in hospital* on their website and found it was the most popular download during 2008 (see Table 5c).

[lxxxv] These were made available free to NHS staff via a publications ordering system, with a maximum of 20 copies per order, and stocks were exhausted by November 2007.

[lxxxvi] Based on 593 + 247 downloads between 29/8/09 and 27/10/09 (just under two months).

[lxxxvii] Based on 1580 downloads between 30/10/08 and 19/9/09 (just under eleven months).

TABLE 5c: Visits and downloads from British Geriatrics Society website		
Month[lxxxviii]	**Unique visits to BGS website**	**Relative popularity of *Slips trips and falls in hospital***
March 2007	16,409	4th most popular download
April 2007	17,500	3rd most popular download
January 2008	18,214	1st most popular download
Mar 2008	17,781	1st most popular download
Apr 2008	21,423	2nd most popular download
May 2008	20,926	1st most popular download
Sep 2008	15,812	2nd most popular download

Additionally, by 23rd January 2010, the ProFaNE links described above in Chapter 5.5.3.4 in the context of dissemination generated 4,975 views for the commentary on and abstract of our systematic review of bedrails and 3,364 views for the commentary on and abstract of our overnight survey of bedrail use.

5.6.5 Evidence of international impact

The evidence of impact within the academic literature, described above in Chapter 5.7, came from a range of countries, with inclusion in systematic reviews authored in Australia (Cameron et al. 2010) and Belgium (Coussement et al. 2008), with response letters coming from Australia (Haines & Hill 2005), New Zealand (Hanger 2009) and Ireland (O'Keeffe 2009). There is also evidence of our interlinked publications being influential on clinical decision making in other countries. For example, our systematic review on bedrails provoked debate from Australian contacts and within the European falls prevention network including the comment *"You can be sure that the ripple effects from your systematic literature review are being felt here in Australia with a number of hospital interest groups reassessing their stance on bed rails based on your results"* (ProFaNE 2009).

The interlinked publications also appear to have influenced official guidance internationally. '*Preventing Falls and Harm from Falls in Older People: Best Practice*

[lxxxviii] Only some months can be described since the BGS lost part of their records of website activity during a change of website provider. The months above represent all the data available from the BGS, not selected months.

Guidelines for Australian Hospitals' (Australian Commission on Safety and Quality in Health Care 2009) described the key content of our RCT (Healey et al. 2004) with particular emphasis on the elements of ward urinalysis and the bedside check for major visual problems, both of which the guidance recommends as interventions. Coussement et al. (2009) described the process of developing national falls prevention guidance for Belgium hospitals *"based on the best evidence currently available and on international guidelines such as …from the UK National Patient Safety Agency"* (p. 399). The South Australian Department of Health's alert *Safe use of hospital bed rails* issued in May 2007 appears to have been prompted by the release of the NPSA Safer Practice Notice (Healey & Stephenson for NPSA 2007b) in February 2007 and includes chapters from the NPSA material as appendices and, also in Australia, the Northern Territory Government's Department of Health and Families has adopted one of the bedside decision tools provided with *Using bedrails safely and effectively* for use in all their inpatient settings (personal correspondence).

5.7 EVIDENCE OF IMPACT WITHIN THE LITERATURE

The citation numbers for my key publications[lxxxix] by January 2010 are shown in Table 5d below:

TABLE 5d: Citations of our key journal articles at January 2010		
Publication	**Date of publication**	**Citation numbers**
'Using targeted risk factor reduction to prevent falls in older in-patients: a randomised controlled trial' (Healey et al. 2004)	July 2004	59
'The effect of bedrails on falls and injury: a systematic review of clinical studies' (Healey et al. 2008b)	July 2008	7
'Falls in English and Welsh hospitals; a national observational study based on retrospective analysis of 12 months of patient safety incident reports' (Healey et al. 2008a)	December 2008	5
'Bedrail Use in England and Wales' (Healey et al. 2009)	August 2009	1

Citation numbers are in part dependant on the time that has passed since the paper's publication, and given the timescales of production and publication for papers which might

lxxxix These figures were obtained by checking both Science and Social Science Citation Indexes and Google Scholar, and then deducting any citations counted on more than one database.

reference them, few citations of the papers published in 2008 and in 2009 would be expected as yet.

As outlined earlier in Chapter 2.7, our RCT of inpatient falls prevention (Healey et al. 2004) has been included in four systematic reviews of hospital or care home falls prevention. These are Oliver et al. (2007), Coussement et al. (2008), Robertson & Campbell (2008) and the Cochrane review by Cameron et al. (2009). Our systematic review of bedrails is included in the Database of Abstracts of Reviews of Effects (Centre for Reviews and Dissemination 2009).

Additionally, two of our papers were the topics of editorials in the journal edition where they were published; Healey et al. (2004) was the focus of an editorial by Oliver (2004) setting out the future research direction for hospital falls prevention, and Healey et al. (2008b) was also discussed in an accompanying editorial (Francis, 2008) (see Appendix J).

As described in earlier chapters, letters to the Editor by were also published in response to Healey et al. (2004) by Haines and Hill (2004) and in response to Healey et al. (2008a) by O'Keeffe (2008) and Hanger (2009).

5.8 CONCLUSION

As part of the assessment of the value of research, evidence of impact on policy and practice is very important (HEFCE 2009). Developing NPSA publications based on our published research ensured that the findings influenced not only clinicians but also managers and frontline staff providing clinical care. The style and language of the publications were adapted to the needs of diverse audiences, and based on careful exploration of the issues and challenges within hospitals and mental health units. We provided practical resources to help healthcare staff implement our recommendations, including model policies, educational materials, and posters. Our dissemination plan made good use not only of official distribution networks such as SABS and the Chief Executives' Bulletin, but also of the general media, healthcare journals, conferences, and websites. An early independent evaluation provided positive feedback on the utility and readability of *Slips trips and falls in hospital* from Nurse Directors and leads for falls prevention, and it remains a popular download from NPSA and BGS websites even three years after its publication.

In England and Wales, a review of a random sample of policies indicated substantial increases in the proportion of trusts with falls prevention policies focused on inpatients and with policies on bedrail use. Changes in their content were also noted, including marked reductions in those used ‘home-made’ numerical risk scores, and substantial increases in those giving appropriate advice on patient consent, how to avoid the risk of entrapment, and immediate aftercare following a fall. These findings were supported by inspection and audit data. The interlinked journal articles and NPSA publications appear to have influenced falls prevention guidance in Belgium and Australia, and bedrail guidance in Australia.

SUMMARY AND CONCLUSION

In this doctoral statement I have described my previous research work, and how it arose from the need for service improvement in areas where the empirical evidence was very limited or unclear. These challenges were linked to my clinical and managerial career, initially as a nurse specialist and directorate manager in an acute trust, and later through working for the National Patient Safety Agency (NPSA). Whilst my roles were always service based, I was fortunate to receive advice and guidance that amounted to an apprenticeship in research design, conduct, analysis and interpretation, latterly and most valuably under the supervision of Professor Richard Thomson in his roles with the NPSA and Newcastle University, and through collaboration with Professor David Oliver.

My role with the NPSA gave me access to a unique and evolving source of data, the National Reporting and Learning System (NRLS). This was the basis of the first publication explored above: 'Falls in English and Welsh hospitals: a national observational study based on retrospective analysis of 12 months of patient safety incident reports' (Healey et al. 2008a). Prior to this study, very few multi-organisation studies described the rate of falls or injuries across acute and rehabilitation hospitals, and none described rates of falls across typical mental health units. Our study drew from over 200,000 reported falls, which is a greater pool of data than any past or subsequent study has used, and is therefore the most extensive source of information on rates of falls and injury in acute and rehabilitation hospitals, and the only published source of falls rates across mental health units. Our analysis of levels of harm, including lacerations, fractured neck of femur, head injury, and fatalities related to falls, helped to emphasise the scale of harm to patients from hospital falls, to make the case for this area of patient safety receiving greater priority than perhaps had been the case in the past.

The size of our study also made it possible to identify and graphically illustrate the excess frequency of falls in the 'oldest old' aged over 85 years and in male patients. This had important clinical implications in terms of focusing falls prevention efforts to the patients most vulnerable to falling, and in casting further doubt on the utility of some falls risk prediction tools in use in UK settings that attribute highest levels of risk to female patients and patients aged less than 80 years. Our analysis of falls by time band, although limited by the potential for bias in reporting, allowed hospitals to compare and contrast their own peak periods for falls.

We acknowledged throughout the inherent flaws of any study drawn from reported incidents, using only methods of statistical analysis appropriate to observational data, and compensating for issues of inaccuracy of severity coding through scrutiny of samples of reports for specific injury types. We also made appropriate reference to the wider literature in terms of the high subsequent mortality and morbidity seen in the weeks and months following serious injury from falls in hospital patients.

I placed our observational study on reported falls in the context of the wider literature through a systematic search for studies that gave either rates of falls or proportions of falls resulting in injury, and I standardised their findings to facilitate comparison. This search identified over fifty studies, providing a much more robust basis for assessing variation within and between countries, and between specialist wards or care settings, than the handful of studies previously cited in the introductions of most academic papers on falls in hospitals. I was able to identify that our findings were mainly congruent with similar large and well-designed studies internationally, although differences in patient populations and service provision may also lead to some variation between countries.

Having established the scale of harm from falls in hospital, I described our RCT of falls prevention in hospital inpatients ‘Using targeted risk factor reduction to prevent falls in older in-patients: a randomised controlled study’ (Healey et al. 2004). As the first RCT of multifactorial interventions from an acute hospital setting published internationally, and as one of only a handful of RCTS of multifactorial interventions in hospitals published to date, it made an important contribution to the evidence base, reflected by its inclusion in all subsequent systematic reviews and meta-analyses of falls prevention in hospitals. The strengths of the study included its size and power, cluster matching for environment and patient and staff characteristics, design informed by clinical experience and improvement methodology, and the multidisciplinary nature of the intervention. The limitations of the study, including resource constraints that affected the extent of data collection, reliance on reported falls as an outcome measure, baseline differences in falls rates between intervention and control wards, and inadequate power to detect changes in injury rates, were also discussed.

The accompanying exploration of the literature was conscientious and extensive and provided an update of previously published systematic reviews that will be utilised in a commissioned overview of hospital falls prevention for *Clinics in Geriatric Medicine* (Oliver, Healey & Haines in press). This suggested there is very limited evidence for any single intervention, with the possible exception of exercise in rehabilitation settings and of medication review, whilst multifactorial interventions may reduce the risk of falls from 18% to 31%. Because multifactorial falls prevention is a complex intervention, my exploration of the literature covered those aspects emphasised by Medical Research Council guidance (MRC 2008) including the theoretical basis for interventions, implementation methodology, process measures to supplement outcome measures, and any explanatory qualitative findings. I provided a detailed breakdown of the components within successful and unsuccessful trials of multifactorial interventions, alongside a breakdown of their costs, the staff involved in applying the intervention, and the patient populations to which the interventions were applied. This allowed an in-depth discussion of commonalities and differences, and suggested that our RCT included many of the components most often seen in successful studies, including post-fall reviews, reviews of psychotropic medication, urine screening, toileting plans and footwear replacement. Our implementation approach of using multidisciplinary ward-based staff to apply interventions also featured in the majority of successful studies.

A substantial proportion of falls in hospital are direct falls from bed, and it was in that context that I went on to discuss 'The effect of bedrails on falls and injury: a systematic review of clinical studies' (Healey et al. 2008b). This was an extensive and comprehensive review of the literature on direct harm associated with bedrails and on the effect of bedrails on falls from bed. This was the first, and to date the only, truly systematic review of the literature focussed on bedrails and identified twice as many studies as any earlier semi-systematic reviews or overviews. By including both evidence of harm from falls from bed and evidence of direct harm from bedrail entrapment we were able to provide a balanced overview that acknowledged both these risks. Our review recognised the weak quality of many published studies through formal quality assessment, whilst not excluding those studies which, in a relative empirical vacuum, included some useful information to inform practice. Further strengths included our careful extraction and standardisation of outcome data.

The findings of our systematic review were placed in the context of the history of bedrail use, and I explored why attitudes to bedrails in the literature had become so divorced from the actual evidence, including areas such as nursing and medical values and belief systems, the subsumption of bedrails into the literature on vest, belt or cuff restraint devices, publication bias, and perceptions of risk. The perspectives of patients and carers and the legal and ethical frameworks for patients without capacity were also explored.

Our systematic review was able to identify clear directions for clinical practice in areas that the evidence could support. We were able to identify that evangelical attempts to eliminate or drastically curtail bedrail use were as inappropriate as routine use of bedrails, and that both approaches appeared to arise from paternalistic attitudes. We identified patient groups for whom bedrail use is not appropriate, but emphasised that for most patients the balance of risk and benefit needs to be assessed individually, and that patients with capacity have the right to make their own decisions. Importantly, we had a chapter on bedrail entrapment that explained this is not a random or inevitable consequence of bedrail use, but can be avoided by safely designed, correctly fitted, and well-maintained combinations of bed, bedrail and mattress.

I then described our overnight survey of ‘Bedrail use in English and Welsh hospitals’ (Healey et al. 2009). Prior to this survey, very few studies of bedrail use across whole hospitals had been published, and only five studies had collected data on variables associated with bedrail use, of which only two studies had used logistic regression. Our study was the largest detailed study of bedrail use published to date, and the first to collect equipment variables and nurses’ rationale for partial bedrail use and for not raising bedrails. Our inclusion of patient mobility as a variable enabled us to identify an inability to mobilise without help from staff as the strongest predictor of bedrail use, which had important implications for the ethical concerns of whether bedrails were being used to restrain patients and whether bedrail use was ‘ageist’. Analysis at the individual patient level allowed us to identify small subsets of patients whose raised bedrails were unlikely to be appropriate, as well as patients who were likely to benefit from bedrails but did not have them provided.

Our findings were placed in the wider context of earlier and subsequent surveys of bedrail use, which indicated significant variations between countries and between individual hospitals. Our survey identified a wide variation between hospitals once adjustments for patient and equipment factors had been made; this could not be easily explained by differences in policy or access to bedrails, and predominantly occurred in the ‘grey area’ where bedrails were neither strongly indicated nor contraindicated.

All our papers included suggestions for future research, and these were expanded on in my doctoral statement. Key areas identified were research into the extent of under-reporting and reporting bias in reports of falls made through local or national incident reporting systems, including variations between organisations. More detailed analysis, such as seeking to identify whether peak times for falls and linked to particular patient activities or staff routines, may enable better targeting of local falls prevention initiatives, alongside exploration of whether such ongoing analysis can create a positive feedback loop linking the quality of reporting with the quality of falls prevention initiatives.

The priority for future research into falls prevention in hospitals is for well designed and adequately powered studies of individualised multifactorial interventions which collect process measures to shed light on which components are delivered and effective in practice. Such studies should include assessment of any detrimental effects of the intervention, qualitative exploration of patient and staff perspectives, and cost-benefit analysis. Other important areas include medication review, prevention and early detection of delirium, the effects of new technology such as movement alarms and ultra-low beds, and research that encompasses falls and fracture prevention across the patient journey from acute care through rehabilitation to the community.

In the area of bedrails, the design of future research is challenging, and may need to encompass preference-based trial methodologies, or cluster randomised trials aimed at supporting frontline staff to make balanced recommendations on the risks and benefits of bedrails for individual patients. Again, such trials would need to include measures of any detrimental effects of the intervention, such as restrictions of independence, and incorporate in-depth exploration of patients' perspectives. The observed variation between hospitals in levels of bedrail use also merits exploration, and may potentially create the basis for a correlation study linking bedrail use with falls after adjustment for intrinsic and extrinsic risk factors. Given the typically complex combination of risk factors for falls seen in individual patients, and given only a minority of falls in hospital are falls from bed, it may be more appropriate to research bedrail use as one component within an individualised multifactorial intervention (as in our RCT) rather than in isolation. Given the direct harm that can result from bedrail entrapment or contact injury, research into designs that further reduce these risks is also critical.

Through three interlinked NPSA publications – *Slips trips and falls in hospital* (Healey & Scobie for NPSA 2007a) *Using bedrails safely and effectively* (Healey & Stephenson or

NPSA 2007b) and *Resources for reviewing or developing a bedrail policy* (Healey for NPSA 2007c) – we were able to bring together the evidence discussed above into guidance for the NHS, with style and language adapted to the needs of diverse clinical and managerial audiences, and supported by practical resources such as awareness-raising posters and model policy. Our dissemination strategy encompassed hard copy and electronic distribution, including through the Central Alerting System and Chief Executives' Bulletin in England and equivalent mechanisms in Wales. I also supported dissemination through an additional eleven journal papers or letters targeted to reach different healthcare audiences, and through plenary or concurrent presentations at over twenty international, national or regional conferences. This was supported by the inclusion of aspects of NPSA guidance as audit standards by the Healthcare Commission and the National Clinical Audit of Falls and Bone Health in Older People, and these audits identified high levels of self-reported compliance, as did associated Healthcare Commission inspections.

Further evidence of impact was obtained from a range of sources, including an early independent evaluation that provided positive feedback on *Slips trips and falls in hospital*, and download numbers from the NPSA and British Geriatric Society websites. Their impact on policies in NHS organisations was assessed through a review that indicated substantial increases in the proportion of trusts with falls prevention policies focused on inpatients and with policies on bedrail use, alongside reductions in those used 'home-made' numerical risk scores, and substantial increases in those giving appropriate advice on patient consent, how to avoid the risk of entrapment, and immediate aftercare following a fall. These findings were supported by inspection and audit data. The interlinked journal articles and NPSA publications also appear to have influenced falls prevention and bedrail guidance internationally.

I continue to be actively involved in falls prevention in hospitals, including through further journal publications, membership of steering groups for national, regional and local projects, and collaboration on research proposals. Through my role with NPSA I am currently actively supporting the use of the *'How to' guide for reducing harm from falls* (Patient Safety First 2009) in hospitals within England and Wales, and developing further resources to assist NHS staff in their local falls prevention programmes.

In summary, I have used my doctoral statement to demonstrate that my published papers amounted to a sustained level of recent research activity, including a large-scale analysis of over 200,000 reported falls, a cluster randomised trial of falls prevention, a systematic review of the literature on bedrails, and an analysis of patient and equipment factors associated with bedrail use. I have described how, for all these studies, I was instrumental in identifying the need to undertake research, and I took the lead role from the initial planning stages through to final preparation for publication, with invaluable support from my co-authors and supervisor. All these papers made an original contribution to the field of the prevention of falls in hospitals. Because of the interlinking of my research work with publications from the NPSA (Healey & Scobie for NPSA 2007a, Healey and Stephenson for NPSA 2007b, Healey for NPSA 2007c) which recommended or required action from the NHS, I have been able to demonstrate evidence of substantial impact on policy and clinical practice, that may in turn have led to reduced harm to patients in NHS funded care.

APPENDIX A: KEY PUBLICATIONS

I. Healey F, Scobie S, Oliver D, Pryce A, Thomson R, Glampson B. (2008) Falls in English and Welsh hospitals; a national observational study based on retrospective analysis of 12 months of patient safety incident reports. *Quality and Safety in Healthcare* 17:424-430

II. Healey F. Munro A. Cockram A Adams V. Heseltine D. (2004) Using targeted risk factor reduction to prevent falls in older in-patients: a randomised controlled trial *Age and Ageing* 33(4) 390-394

III. Healey F, Oliver D, Milne A. (2008) The effect of bedrails on falls and injury: a systematic review of clinical studies. *Age and Ageing* 37 (4) 368-78

IV. Healey F, Cronberg A. Oliver D (2009) Bedrail Use in England and Wales *Journal of the American Geriatric Society* 57(10):1887-91

V. Healey F and Scobie S for NPSA (2007) *Slips trips and falls in hospital*

VI. Healey F and Stevenson E for NPSA (2007) *Using bedrails safely and effectively*

VII. Healey F for NPSA (2007) *Resources to support the development of a bedrail* policy

APPENDIX B: CO-AUTHORSHIP DECLARATIONS

Submitted to the graduate office.

APPENDIX C: ADDITIONAL DISSEMINATION PUBLICATIONS

I Healey F (2010) Nursing by numbers: we must use clinical judgement to assess risk Nursing Times 106 14

II Healey F (2009b) A safer night's sleep *Public Service Review* Vol. 21 17 November 2009

III Healey F (2009a) Decisions on bedrails must not be made through emotive arguments *Nursing Times* 105:26 11

IV Healey F & Oliver D (2009b) Bedrails, falls and injury: evidence or opinion? A review of their use and effects *Nursing Times* 105:26 20-24

V Oliver D & Healey F (2009) Falls risk prediction tools for hospital inpatients: do they work? *Nursing Times* 105: 7, 18–21.

VI Oliver D & Healey F (2008) Interpreting the null result *BMJ* 19;336 (7649):847.

VII Healey F, Stevenson E and Oliver D (2007) A national bedrail safety project *Nursing Times* 103: 21: 30-33.

VIII Healey F & Scobie S (2007) Keeping a balance: preventing patient falls in hospital *British Journal of Healthcare Management* 1 March 2007

IX Healey F and Oliver D (2006) Preventing falls and injury in hospitals: where are efforts best directed? *Healthcare Risk Report* 12(7) 15-17

X Oliver D and Healey F (2006) Preventing Falls and injury in hospitals: the evidence for intervention *Healthcare Risk Report* 12(7) 12-14

XI Healey F (2006) The best methods of preventing falls in hospitals (Letter to the Editor) *Canadian Journal of Nursing* 38:3 3-4

APPENDIX D: EARLY PUBLICATIONS AND NON-FALL RELATED PUBLICATIONS

I. Healey F (1994) Does flooring type affect risk of injury in older inpatients? *Nursing Times* 90(27) 40-42. - *A retrospective analysis of reports of falls to determine whether injuries were more or less likely on carpeted or vinyl areas within wards*

II. Healey F (1996) Using incidence data to improve risk assessment *Journal of Tissue Viability* 6(1)3 - *An incidence study based on over 7000 admissions, describing a pressure ulcer incidence rate and also identifying that using Waterlow with a cut-off point of 15 optimised specificity and sensitivity.*

III. Healey F (1996) Waterlow revisited *Nursing Times* 1996 92(11) 82 - *As above, presented for a less specialised nursing audience.*

V. Healey F (1995) The reliability and utility of pressure sore grading scales *Journal of Tissue Viability* 5(4) 111 - *An inter-rater reliability and utility test with observations from 109 registered nurses of ten photographs of pressure ulcers*

VI. Healey F (1996) Classification of pressure sores *British Journal of Nursing* 5:9 567 - *As above, presented for a less specialised nursing audience.*

VII. Thomson R, Luettel D, Healey F, and Scobie S. 2007 *The fifth report from the patient safety observatory: safer care for the seriously ill patient* NPSA 2007

VIII. Luettel D, Beaumont K, Healey F. 2007 *Recognising and responding appropriately to early signs of deterioration in hospitalised patients* NPSA 2007

IX. Healey F, Sandars DS, Lamont T, et al. 2010 Early detection of complications after gastrostomy: summary of a safety report from the National Patient Safety Agency *BMJ* 2010 340: c2160

APPENDIX E: CO-PRODUCED GUIDANCE

I. Healey F & Paine T for the Royal College of Nursing *Let's talk about restraint: rights, risks and responsibility* Royal College of Nursing: London: 2008

II. Healey F, Clarke J, Oliver D et al. for Patient Safety First *The 'How-to' Guide to Reducing harm from falls* Patient Safety First: London 2009

APPENDIX F: CONFERENCE PRESENTATIONS

Date	Conference Title	Conference type	Presentation title	Presentation type
February 2010	Developing a positive approach to falls prevention in older people	National (England)	Bedrails, falls and injury	Plenary
November 2009	Developing a positive approach to falls prevention in older people	National (England)	Slips trips and falls in hospitals: new evidence, new learning	Plenary
October 2009	Action against Medical Accidents: Older People's Care - Turning Scandals into Successes	National (England)	Preventing Falls and Fractures in Hospital	Plenary
October 2009	The NW orthopaedic interface and falls group 12th meeting	Regional (NW England)	Managing inpatient falls: evidence and practice	Plenary
June 2009	[Tuscany Ministry of Health falls prevention conference]	Regional (Tuscany)	Patient falls: monitoring and prevention in the NHS	Plenary
April 2009	Developing a positive approach to falls prevention in older people	National (England)	Falls prevention in hospitals	Plenary
November 2008	Developing a positive approach to falls prevention in older people	National (England)	Recommendations from the NPSA to reduce the risk of falling	Plenary
June 2008	[Prague national convention of patient safety]	National (Czech Republic)	The NPSA approach	Plenary
March 2008	Developing a positive approach to falls prevention in older people	National (England)	Recommendations from the NPSA to reduce the risk of falling	Plenary
March 2008	Improving Patient Safety	Regional (East of England)	Falls prevention in hospitals	Concurrent

February 2008	Estates managers' annual meeting and learning event	National (England)	Slips trips and falls: what can estates managers do?	Plenary
January 2008	Older people on the ward	National (England)	Falls in hospitals	Plenary
November 2007	Royal College of Nursing: Respecting the difference (nursing older people)	National (UK)	*'I thought I'd never walk again'* – older people and falls prevention in hospitals	Concurrent
September 2007	Nursing older people	National (England)	Slips, trips, and falls in hospitals: lessons from the third report of the Patient Safety Observatory	Plenary
September 2007	British Geriatric Society: 8th International Conference on Falls and Postural Stability	International	National Patient Safety Agency Falls Report and Bedrails Notice	Plenary
2007	Patient Safety Research: shaping the European agenda	International	Slips, trips, and falls in Hospitals; learning from 200,000 reports to the National Patient Safety Agency	Poster
July 2007	Royal Society of Medicine: 2nd international conference on prevention of falls and injuries in hospitals and care homes	International	Reports of falls in hospitals	Plenary
June 2007	Falls and fracture prevention	National (Wales)	Preventing falls in hospitals	Plenary
November 2006	Risk 2006	National (UK)	Older people, falls and bedrails	Concurrent

October 2006	Powys local health board: prevention of falls and injuries in hospitals and care homes	Regional (South Wales)	Preventing falls in hospitals	Plenary
April 2006	Royal Society of Medicine: 1st international conference on prevention of falls and injuries in hospitals and care homes	International	A national reporting system: falls and bedrails	Plenary
Additionally around 30 presentations at local (single hospital) falls prevention events and workshops between 2007 and 2009				

APPENDIX G: LITERATURE SEARCH STRATEGIES AND INCLUSION CRITERIA

I. Search strategy and inclusion criteria for Tables 1a-1f

II. Search strategy and inclusion criteria for Tables 2a-2d

III. Hand search of risk management journals for falls rates

Appendix G (I): Search strategy and inclusion criteria for Tables 1a - 1f

The search was conducted once with the date range 1/1/1986 to 14/10/09 but separated into studies published before 31/12/06 and after 1/1/07 for presentation in the tables.

Included databases were Cinahl, Medline, BNI and Psycinfo.

Key phrases searched for within title or abstract were:

‘Falls per 1,000’ (including all variations of numeric and text presentation of 1,000, 1 000, 1000, one thousand, thousand)
‘Falls per 10,000’ (including all variations of numeric and text presentation of 10 000 as above)
‘Falls per person-year’ (with and without hyphen) AND [hospital OR hospitalised OR hospitalized OR patient OR inpatient]
‘Falls rate’ AND [hospital OR hospitalised OR hospitalized OR patient OR inpatient]

Inclusion criteria were studies that provided falls or injury rates expressed as a denominator of activity and where the setting of the fall (not merely the treatment for a fall) was a hospital, unless this was a ‘hospital’ providing long term care (defined as average length of stay one year or more).

Where studies identified in the search strategy used for studies of falls prevention in Section 2 (Appendix x) or in the systematic review of the effect of bedrails on falls and injury reported in Section 3 reported a falls or injury rate, or numbers of falls and OBDs from which a rate could be calculated, these were also included, unless they were based on selected subsets of hospital populations (e.g. Reuben et al. (1995) who studied only inpatients with certain risk factors).

Unless stated otherwise, studies included adult patients only.

Where ‘serious’ or ‘severe’ or ‘major’ injury were defined, definitions are provided in the footnotes; where these terms are not defined in the table, this is because they were not explicitly defined in original papers.

Rates were standardised to falls per 1,000 OBDs. Where this was a simple conversion from rates per 10,000 OBDs no calculations are provided, but more complex standardisations (e.g. from rates expressed as patient years) are shown in footnotes.

Appendix G (II): Search strategy and inclusion criteria for Tables 2a-2d

The search was conducted with the date range 1/1/2005 (the date where Oliver et al.'s (2007) systematic review ended) to 31/12/09.

Included databases were Cinahl, Medline, BNI and Psycinfo.

Key phrases searched for within title or abstract were any of the list below
'Falls prevention'
'prevention of falls'
'falls and injury'
Fallers
'accidental falls'
'Falls per'
'falls rate'
'falls incidence'

AND [hospital OR hospitalised OR hospitalized OR patient OR inpatient OR bed days OR beddays OR bed-days]

'Falls' alone could not be used as a search term due to its use in other medical contexts, e.g. falls in mortality rates.

Inclusion criteria were studies that described a falls prevention programme and where the setting of the fall was a hospital, unless this was a 'hospital' providing long term care (average length of stay one year or more), and where outcome data of falls rate, injury rate, or whole numbers of falls, fallers, or injuries were provided. For inclusion, the date of intervention commencement had to be described as did the nature of the intervention. Where the 'intervention' includes components that could be assumed to have been provided to controls (e.g. call bells left in reach), these are not described in the tables.

Where data (e.g. mean age of patients) is missing in tables, this is because it was not provided in the original papers.

Any studies related solely to the use or removal of body restraints (vest, belt, cuff or harness devices) were excluded since these are not relevant to UK hospital settings (see Section 3.3.2) whilst bedrail reduction studies (e.g. Hanger et al. 1999) are examined in depth together with other bedrail studies in Section 3.

Where studies identified in the search strategy used for studies of falls incidence in Tables 1a-1f (Appendix G.I) described a falls prevention programme, these were also included.

Appendix G (III): Hand search of risk management journals for falls rates

Health Care Risk Report was hand-searched from January 2008 to December 2009 (24 months and twenty editions).

Articles relevant to falls were:

- ‘Analysing falls management using failure modes and effect analysis’ Vol. 15 Issue 3 p. 17-19 – a methodology of learning from reported falls with no rates or numbers of falls described

- ‘Failure to move people safely’ Vol. 15 Issue 3 p. 8-9 – a description of two litigation cases related to a fall from a hoist

- ‘Failure to move patient safely’ Vol. 15 Issue 6 p. 9 – a description of a litigation case related to a fall from a hoist

- ‘Falls from unsafe windows’ Vol. 15 Issue 7 p. 8-9 – a description of two litigation cases

- ‘Beneath the radar: the hidden harm in healthcare for children’ Vol. 15 Issue 9 p. 10-11 – whole numbers of falls affecting children reported to the NRLS, no rate described

- ‘George Eliot’s patient safety story’ Vol.16 Issue 1 p. 15 – a general description of a falls prevention project with no rates or numbers of falls described

APPENDIX H: GENERAL MEDIA AND CLINICAL NEWS MEDIA COVERAGE

Media coverage	**Media type**	**Edition date**
British Medical Journal (BMJ) news section	Clinical media	3rd March 2007
British Medical Association (BMA) newsletter	Clinical media	March 2007
Nursing Times news section	Clinical media	27th February 2007
British Journal of Nursing commentary	Clinical media	12th July 2007
Pharmaceutical journal news section	Clinical media	March 2007
Hospital development news section	NHS management media	March 2007
The Times	National newspaper	6th March 2007
BBC1 'Look North'	Regional TV	27th February 2007
BBC Radio 2	National radio	27th February 2007
BBC Radio York	Regional radio	26th February 2007
Minster Radio	Regional radio	27th February 2007
Yorkshire Post	Regional newspaper	27th February 2007
The Press (Yorkshire)	Regional newspaper	27th February 2007
Manchester Evening News	Regional newspaper	27th February 2007
Western Mail	Regional newspaper	28th February 2007
Derby Evening Telegraph	Regional newspaper	28th February 2007
Scunthorpe Evening Telegraph	Regional newspaper	27th February 2007
Argus Lite (Brighton)	Regional newspaper	2nd March 2007
Derby Evening Telegraph	Regional newspaper	27th February 2007
Pontypridd and Llantrisant Observer	Regional newspaper	9th March 2007

APPENDIX I: POLICY REVIEW METHODOLOGY AND DEFINITIONS

Methodology detail

The policy requests were made to 50 trusts selected by random number table from an alphabetically ordered list of all acute trusts in England and Wales. Requests were made via each organisation Freedom of Information email address, obtained from their websites. Requests were sent 1-14 September 2009: replies received by 31 December 2009 were included in analysis.

Criteria used to categorise key policy content

QUESTION	CRITERIA
Falls prevention policies:	
Has an inpatient falls prevention policy?	Policies that were solely directed at the environment, cleaning, and staff footwear (traditional health and safety falls prevention policies) with no content specific to inpatients (i.e. inpatients were offered no greater falls prevention than visitors) were not counted
References *Slips trips and falls in hospital*?	Yes if referenced in text and/or as a footnote
Assessment tool used	Tools were categorised as validated for hospital use if they were Morse or STRATIFY and had no changes made to the scoring system.
Gives advice on clinical checks after a fall?	Yes if advice on checking for injury and observations to be taken post-fall (even if only for falls with head injury) included
Uses the York RCT care plan?	Yes if at least eight of the twelve actions replicated in identical or near-identical wording
Bedrail policies:	
References *Using bedrails safely and effectively*?	Yes if referenced in text and/or as a footnote

Uses the model bedrail policy in NPSA (2007b)?	Yes if at least two paragraphs identical to model policy
Gives appropriate advice on capacity and consent?	Yes if consent, capacity and best interests mentioned however briefly, and relatives not said to be able to give consent on adult patients' behalf
Gives indications (not just contra-indications) for bedrail use?	Yes if any indications at all included (even if only transporting on bed)
Gives advice on how to avoid bedrail entrapment?	Specific only if unsafe dimensions described in cm or mm.

APPENDIX J: RESPONSE LETTERS AND EDITORIALS

I. Oliver D. Prevention of falls in hospital inpatients: agendas for research and practice *Age and Ageing* 2004 33 p. 328–330

II. Haines, T. & Hill, K. 2005. Difficulties encountered in hospital falls prevention research. *Age and Ageing*, 34, (3) 311

III. Healey F. 2005 Reply *Age and Ageing*, 34, (3) 311-312

IV. Francis R.M. Editor’s view 2008 *Age and Ageing* 37 4 p.359

V. O’Keeffe S. The effect of bedrails on falls and injury *Age and Ageing* 2009 38 1 p. 129

VI. Healey F. & Oliver D. Reply *Age and Ageing* 2009 38 1 p. 130

VII. Hanger, H.C. 2009. The effect of bedrails on falls and injury. *Age Ageing*, 38, (3) 355

REFERENCES

Adamson SJ, Bland JM, Hay EM et al. 2008 Patients' preferences within randomised trials: systematic review and patient level meta-analysis BMJ. 2008 Oct 31;337:a1864

Adamson, S.J., Sellman, D.J., & Dore, G.M. 2005. Therapy preference and treatment outcome in clients with mild to moderate alcohol dependence. *Drug and Alcohol Review*, 24, (3) 209-216

Agashivala, N. & Wu, W.K. 2009. Effects of Potentially Inappropriate Psychoactive Medications on Falls in US Nursing Home Residents: Analysis of the 2004 National Nursing Home Survey Database. *Drugs & Aging*, 26, (10) 853-860

Aisen, M.L., Iverson, D., Schwalbe, C. et al. 1994. Falls on a neurorehabilitation unit: reassessment of a prevention program. *The Journal of the American Paraplegia Society*, 17, (4) 179

Ali G . 2000 Ensuring the safe use of cot sides in patient settings. *Professional Nurse* 2000;15:278–9

Altman, D.G. & Royston, P. 2000. What do we mean by validating a prognostic model? *Statistics in Medicine*, 19, (4) 453-473

American Geriatrics Society, British Geriatrics Society, and American Academy of Orthopaedic Surgeons Panel on Falls Prevention. 2001 Guideline for the prevention of falls in older persons. *J Am Geriatr Soc*. 2001 May; 49(5):664-72.

Aranaz-Andres, J.M., Aibar-Remon, C., Vitaller-Burillo et al. 2009. Impact and preventability of adverse events in Spanish public hospitals: results of the Spanish National Study of Adverse Events (ENEAS). *International Journal for Quality in Health Care* 21 6 408-414

Assmann, S.F., Pocock, S.J., Enos, L.E., & Kasten, L.E. 2000. Subgroup analysis and other (mis) uses of baseline data in clinical trials. *The Lancet*, 355, (9209) 1064-1069

Australian Commission for Safety and Quality in Healthcare 2009 *Preventing Falls and Harm From Falls in Older People: Best Practice Guidelines for Australian Hospitals* ACSQH 2009 http://www.health.gov.au/internet/safety/publishing.nsf/content/FallsGuidelines Accessed 24/4/10

Australian Council on Safety and Quality in Healthcare 2005 Preventing falls and harm from falls in older people; b*est practice guidelines for Australian hospitals and residential aged care facilities.* ACSQH http://www.health.gov.au/internet/safety/publishing.nsf/Content/2716397CDDE8A410CA257483000D8462/$File/falls.pdf Accessed 24/4/10

Bakarich, A., McMillan, V., & Prosser, R. 1997 The effect of a nursing intervention on the incidence of older patient falls. *The Australian journal of advanced nursing: a quarterly publication of the Royal Australian Nursing Federation*, 15, (1) 26

Baker, G.R., Norton, P.G., Flintoft, V. et al. 2004. The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada. *Canadian Medical Association Journal*, 170, (11) 1678-1686

Barker, A., Kamar, J., Morton, A., & Berlowitz, D. 2009. Bridging the gap between research and practice: review of a targeted hospital inpatient fall prevention programme. *Quality and Safety in Health Care*, 18, (6) 467-472

Barreca, S., Sigouin, C.S., Lambert, C., & Ansley, B. 2004. Effects of extra training on the ability of stroke survivors to perform an independent sit-to-stand: A randomized controlled trial. *Journal of Geriatric Physical Therapy*, 27, 59-64

Barrett, J.A., Bradshaw, M., Hutchinson, K. et al. 2004. Reduction of falls-related injuries using a hospital inpatient falls prevention program. *Journal of the American Geriatrics Society*, 52, (11) 1969-1971

Barry, E., Laffoy, M., Matthews, E., & Carey, D. 2001. Preventing accidental falls among older people in long stay units. *Irish Medical Journal*, 94, (6) 172-175

Bates D, Pruess K, Souney P, Platt R. Serious falls in hospitalised patients. Correlates and resource utilisation. *AmJ Med* 1995; 99; 137-43.

Bentzen, H., Bergland, A., & Forsqn, L. 2008. Risk of hip fractures in soft protected, hard protected, and unprotected falls. *Injury Prevention*, 14, (5) 306-310

Bischoff-Ferrari, H.A., Dawson-Hughes, B., Willett et al. 2004. Effect of vitamin D on falls: a meta-analysis. *JAMA*, 291, (16) 1999-2006

Blair, E. & Gruman, C. 2005. Falls in an Inpatient Geriatric Psychiatric Population. *Journal of the American Psychiatric Nurses Association*, 11, (6) 351-354

Bland, M. 2000. *An introduction to medical statistics* Oxford University Press Oxford.

Bliss, MR, McLaren, R & Exton-Smith, 1967 ‘Preventing pressure sores in hospital: controlled trial of a large-celled ripple mattress’ *BMJ*, vol. 1, pp. 394-397

Boonen, S., Vanderschueren, D., Haentjens, P., & Lips, P. 2006. Calcium and vitamin D in the prevention and treatment of osteoporosis-a clinical update. *Journal of internal medicine*, 259, (6) 539-552

Boswell, D.J., Ramsey, J., Smith, M.A., & Wagers, B. 2001. The cost-effectiveness of a patient-sitter program in an acute care hospital: a test of the impact of sitters on the incidence of falls and patient satisfaction. *Quality Management in Healthcare*, 10, (1) 10-16

Bowers, B., Lloyd, J., Lee, W., Powell-Cope, G., & Baptiste, A. 2008. Biomechanical evaluation of injury severity associated with patient falls from bed. *Rehabil.Nurs.*, 33, (6) 253-259

Bradley, G. & Wildman, K. 2002. Psychosocial predictors of emerging adults' risk and reckless behaviors. *Journal of Youth and Adolescence*, 31, (4) 253-265

Brady, R., Chester, F.R., Pierce, L.L., Salter, J.P., Schreck, S., & Radziewicz, R. 1993. Geriatric falls: prevention strategies for the staff. *Journal of Gerontological Nursing*, 19, (9) 26-32

Brandeis, G.H., Baumann, M.M., Hossain, M. et al. 1997. The prevalence of potentially remediable urinary incontinence in frail older people: a study using the Minimum Data Set. *J.Am.Geriatr.Soc.*, 45, (2) 179-184

Brandis, S. 1999. A collaborative occupational therapy and nursing approach to falls prevention in hospital inpatients. *Journal of quality in clinical practice*, 19, (4) 215-220

Bredthauer, D., Becker, C., Eichner, B., Koczy, P., & Nikolaus, T. 2005. Factors relating to the use of physical restraints in psychogeriatric care: a paradigm for elder abuse. *Zeitschrift fur Gerontologie und Geriatrie*, 38, (1) 10-18

Brennan TA, Leape LL, Laird NM et al. 1991 Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard medical practice study I. N Engl J Med 1991 Feb 7;324(6):370-6

Brennan, P. & Croft, P. 1994. Interpreting the results of observational research: chance is not such a fine thing. *British Medical Journal*, 309, (6956) 727-730

British Geriatrics Society 2006 *Guidelines for the diagnosis and management of delirium.* London. Accessed on 30/6/07 at http://www.bgs.org.uk/Publications/Clinical%20Guidelines/clinical_1-2_delirium.htm on 30/6/07

Brown EL *A study of a side rail reduction program in a long-term care facility: implications for a professional nursing staff* 1997 Columbia University Teachers' College

Brush, L & Capezuti, E 2001 'Historical analysis of siderail use in American hospitals', *Journal of Nursing Scholarship*, vol 33, no. 4, pp. 381-386.

Burleigh, E., McColl, J., & Potter, J. 2007. Does vitamin D stop inpatients falling? A randomised controlled trial. *Age and ageing*, 36, (5) 507-513

Cameron ID & Kurrle S 2007 Preventing falls in elderly people living in hospitals and care homes *BMJ* 334:53-54

Cameron ID, Murray GR, Gillespie LD et al. 2010 *Interventions for preventing falls in older people in nursing care facilities and hospitals.* Cochrane Database of Systematic Reviews 2010, Issue 1. Art.No.: CD005465. DOI: 10.1002/14651858.CD005465.pub2.

Cannard, G. 1996 Falling trend. *Nursing Times*, 92, (2) 36

Capan, K. & Lynch, B. 2007. A hospital fall assessment and intervention project. *JCOM-WAYNE PA-*, 14, (3) 155-160

Capezuti E 2004 Minimizing the use of restrictive devices in dementia patients at risk of falling *Nursing Clinics of North America* 39 625-647

Capezuti E Wagner LM Brush BL Boltz M Renz S Talerico KA. 2007 Consequences of an intervention to reduce restrictive side rail use in nursing homes *Journal of the American Geriatric Society* 55 334-341

Capezuti, E, Talerico, KA, Wagner L et al. 1999 'The effect of a low-height bed intervention on night falls in nursing home residents' *Gerontologist* vol 39 p.196.

Capezuti, E., Maislin, G., Strumpf, N., & Evans, L.K. 2002. Side rail use and bed-related fall outcomes among nursing home residents. *Journal of the American Geriatrics Society*, 50, (1) 90-97

Capezuti, E., Strumpf, N., Evans, L., & Maislin, G. 1999. Outcomes of nighttime physical restraint removal for severely impaired nursing home residents. *American Journal of Alzheimer's Disease*, 14, (3) 157-164

Capezuti, E., Talerico, K.A., Cochran, I. et al. 1999. Individualized interventions to prevent bed-related falls and reduce siderail use. *Journal of Gerontological Nursing*, 25, (11) 26-34

Capezuti, E., Talerico, K.A., Strumpf, N., & Evans, L. 1998. Individualized assessment and intervention in bilateral siderail use. *Geriatric Nursing*, 19, (6) 322-330

Capezuti, E., Wagner, L.M., Brush, B.L., Boltz, M., Renz, S., & Talerico, K.A. 2007. Consequences of an intervention to reduce restrictive side rail use in nursing homes. *Journal of the American Geriatrics Society*, 55, (3) 334-341

Catchen, H 1983 'Repeaters: Inpatient accidents among the hospitalised elderly' *The Gerontologist* vol. 23 no. 3 pp. 273-276

Center JR, T V Nguyen, D Schneider et al. 1999 Mortality after all major types of osteoporotic fracture in men and women: an observational study. *The Lancet* 353(9156):878-882

Centre for Reviews and Dissemination 2009 *Database of Abstracts of Reviews of Effects* Accessed at http://www.crd.york.ac.uk/crdweb/ShowRecord.asp?View=Full&ID=12008105744 on 21/5/10

Christie, J., O'Halloran, P. Stevenson, M. 2009 Planning a cluster randomized trial Nursing Research 58 2 128-134

Close J 2008 *Reducing the rate of in-patient falls: a whole hospital approach.* Presentation to the 3rd Australian and New Zealand Falls Prevention Society (ANZFPS) conference Accessed at http://www.anzfpconference.com/ on 10/6/10

Cohen-Mansfield L, Marx MC and Rosenthal AS 1989 A Description of Agitation in a Nursing Home *Journal of Gerontology* 1989 44(3):M77-M84;

Coleridge Smith P. 2006 The Causes of Skin Damage and Leg Ulceration in Chronic Venous Disease *The International Journal of Lower Extremity Wounds*, Vol. 5, No. 3, 160-168 (2006)

Connelly J. Critical realism and health promotion. Effective practice needs an effective theory. *Health Education Research* 2001; 16(2): 115-20

Corley, M.C. & Goren, S. 1998. The dark side of nursing: impact of stigmatizing responses on patients. *Scholarly inquiry for nursing practice*, 12, (2) 99-118

Coussement, J., De Paepe, L., Schwendimann, R. et al. 2008. Interventions for preventing falls in acute-and chronic-care hospitals: a systematic review and meta-analysis. *Journal of the American Geriatrics Society*, 56, (1) 29-36

Cullum, N, McInnes, E, Bell-Syer, SE & Legood, R 2004 'Support surfaces for pressure ulcer prevention,' *Cochrane Database Syst Rev* CD001735.

Cumming, R.G., Sherrington, C., Lord, S.R. et al. 2008. Cluster randomised trial of a targeted multifactorial intervention to prevent falls among older people in hospital. *BMJ*, 336, (7647) 758-760

Czernuszenko, A. 2007. Risk factors for falls in post-stroke patients treated in a neurorehabilitation ward. *Neurologia i Neurochirurgia Polska*, 41, (1) 28-35

Davis, P., Lay-Yee, R., Briant, R. et al. 2002. Adverse events in New Zealand public hospitals I: occurrence and impact. *Journal of the New Zealand Medical Association*, 115, 1167v624

Department for Health. 1999 *National Service Framework for Mental Health* Department of Health; London

Department for Health. 2001 *National Service Framework for Older People* Department of Health; London

Department of Health 1994 *Safety Action Bulletin Use of Hospital Bed safety Sides and Side Rails* Department of Health; London

Department of Health 2000 *An organisation with a memory: report of an expert group on learning from adverse events in the NHS*. London: The Stationery Office, 2000.

Department of Health 2007 *Chief Executive Bulletin:* Issue 358 23 February - 2 March 2007 Accessed 19/9/09 http://www.dh.gov.uk/en/Publicationsandstatistics/Bulletins/theweek/Chiefexecutivebulletin/DH_072405

DeVincenzo, D.K. & Watkins, S. Accidental falls in a rehabilitation setting. *Rehabilitation nursing: the official journal of the Association of Rehabilitation Nurses*, 12, (5) 248-252

Dibartolo V. Nine steps to effective restraint use. *Registered Nurse* 1998; 61: 23-4.

Diccini, S., de Pinho, P.G., & da Silva, F.O. 2008. Assessment of risk and incidence of falls in neurosurgical inpatients. *Revista Latino-Americana de Enfermagem (RLAE)*, 16, (4) 752-758

DiNunno N Vacca M Costantinides F DiNunno C Death following atypical compression of the neck *American Journal of Forensic Medicine and Pathology* 2003 24 4 364-368

Donald, I.P., Pitt, K., Armstrong, E., & Shuttleworth, H. 2000. Preventing falls on an elderly care rehabilitation ward. *Clinical Rehabilitation*, 14, (2) 178-185

Donner A, Klar N. 2000 Design and Analysis of Cluster Randomised Trials in Health Research. *Stat Med* 2001; 20 (3): 329–330

Donoghue, J., Graham, J., Mitten-Lewis, S., Murphy, M., & Gibbs, J. 2005. A volunteer companion-observer intervention reduces falls on an acute aged care ward. *International Journal of Health Care Quality Assurance*, 18, (1) 24-31

Donovan J, Mills N, Smith M et al. Quality improvement report: Improving design and conduct of randomised trials by embedding them in qualitative research *BMJ*. 2002 Oct 5;325(7367):766-70

Donovan, K.A., Greene, P.G., & Shuster, J.L. 2002. Treatment preferences in recurrent ovarian cancer. *Gynecologic oncology*, 86, (2) 200-211

Downs, S.H. & Black, N. 1998. The feasibility of creating a checklist for the assessment of the methodological quality both of randomised and non-randomised studies of health care interventions. *Journal of Epidemiology and Community Health*, 52, (6) 377-384

Drahota, A., Gal, D., & Windsor, J. 2007. Flooring as an intervention to reduce injuries from falls in healthcare settings: an overview. *Quality in Ageing and Older Adults*, 8, (1) 3-9

Dunbar JM Neufeld RR 1999 Attitudes to siderails in Nursing homes *The Gerontologist* 39 p.500

Dunton, N., Gajewski, B., Taunton, R.L., & Moore, J. 2004. Nurse staffing and patient falls on acute care hospital units. *Nursing Outlook*, 52, (1) 53-59

Dykes, P.C., Carroll, D.L., Hurley, A.C. et al. 2009. Why do patients in acute care hospitals fall? Can falls be prevented? *J.Nurs.Adm*, 39, (6) 299-304 available from: PM:19509605

Ekman, A. H. Mallmin, K. Michaëlsson, S. Ljunghall 1997 External Hip Protectors to Prevent Osteoporotic Hip Fractures *The Lancet*, 350 (9077)563-564

Enloe, M., Wells, T.J., Mahoney, J. et al. 2005. Falls in acute care: an academic medical center six-year review. *Journal of Patient Safety*, 1, (4) 208-214

Evans D Wood J Lambert L 2003 Patient injury and physical restraint devices: a systematic review *Journal of Advanced Nursing* 41 3 274-282

Evans D, Wood J, Lambert L, Fitzgerald M 2002 *Physical restraint in acute and residential care; a systematic review* The Joanna Briggs Institute for Evidence Based Nursing and Midwifery Adelaide

Evans D, Woods J, Lambert L. 1998 *Falls in hospital. Best Practice.* The Joanna Briggs Institute: Melbourne Accessed on 30/6/07 at http://www.joannabriggs.edu.au/pubs/best_practice.php?pageNum_rsBestPractice=2&totalRows_rsBestPractice=52

Everitt V, Bridel-Nixon J 1997 The use of bedrails: principles of patient assessment *Nursing Standard* 12(6)44-47

Falkenbach, A., Korinek, W., Waltl, S. et al. 2006. Retrospective analysis of falls in an inpatient rehabilitation centre for rheumatic and orthopaedic diseases. *Die Rehabilitation*, 45, (6) 354-358

Fischer, I.D., Krauss, M.J., Dunagan, W.C. et al. 2005. Patterns and predictors of inpatient falls and fall-related injuries in a large academic hospital. *Infection Control and Hospital Epidemiology*, 26, (10) 822-827

Flanders, S.A., Harrington, L., & Fowler, R.J. 2009. Falls and patient mobility in critical care: keeping patients and staff safe. *AACN.Adv.Crit Care*, 20, (3) 267-276 available from: PM:19638748

Fonad, E., Emami, A., Wahlin, T.B.R., Winblad, B., & Sandmark, H. 2008. Falls in somatic and dementia wards at Community Care Units. *Scandinavian Journal of Caring Sciences*, 23, (1) 2-10

Fonad, E., Wahlin, T., & Winblad, B. 2008. Falls and fall risk among nursing home residents. *J Clinical Nursing*, 17, (1) 126-134

Fonda, D., Cook, J., Sandler, V., & Bailey, M. 2006. Sustained reduction in serious fall-related injuries in older people in hospital. *Medical Journal of Australia*, 184, (8) 379-382

Francis R.M. 2008 Editor's view *Age and Ageing* 37 4 p.359

Frengley J, Mion L. 1998 Physical restraints in the acute care setting. Issues and future direction. *Clin Geriatr Med* 14(4): 727-43.

Frengley, J.D. 1999. Bedrails: do they have a benefit? *J.Am.Geriatr.Soc.*, 47, (5) 627-628

Gaebler, S. 1993. Predicting which patient will fall againà and again. *Journal of advanced nursing*, 18, (12) 1895-1902

Gallinagh R Nevin R McIlroy D et al. 2002b The use of physical restraints as a safety measure in the care of older people in four rehabilitation wards: findings from an exploratory study *International Journal of Nursing Studies* 39 147-156

Gallinagh R Slevin E McCormack B 2002a Side rails as physical restraints in the care of older people: a management issue *Journal of Nursing Management* 2002 10 299-306

Gallinagh R, Nevin R, McAleese L, Campbell L 2001a Perceptions of older people who have experienced physical restraint *British Journal of Nursing* 2001a 10;13;852-859

Gallinagh, R., Nevin, R., Campbell, L., Mitchell, F., & Ludwick, R. 2001b Relatives' perceptions of side rail use on the older person in hospital. *British journal of nursing (Mark Allen Publishing)*, 10, (6) 391-399

Gastmans C, Milisen K. 2006 Use of physical restraints in nursing homes: clinical-ethical considerations. *J Med Ethics* 32: 148-52.

George, J., Bleasdale, S., & Singleton, S.J. 1997. Causes and prognosis of delirium in elderly patients admitted to a district general hospital. *Age and Ageing*, 26, (6) 423-427

Gibson, M. J. S., Andres, R. O., Isaacs, B. et al. 1997 The prevention of falls in later life. *Dan. Med. Bull.* 34 Suppl. 4, pp. 1–24.

Giles, L.C., Bolch, D., Rouvray, R. et al. 2006. Can volunteer companions prevent falls among inpatients? A feasibility study using a pre-post comparative design. *BMC geriatrics*, 6, 11 doi10.1186/1471-2318-6-11

Gillespie LD, Robertson MC, Gillespie WJ et al. 2009 Interventions for preventing falls in older people living in the community. *Cochrane Database of Systematic Reviews* 2009, Issue 2. Art. No.: CD007146.

Goldsmith, D., Zuyev, L., Benoit, A. et al. 2009. Usability testing of a Falls Prevention Tool Kit for an inpatient acute care setting. *Stud.Health Technol.Inform.*, 146, 801-802 available from: PM:19592989

Goodman, M., Smith, J., Gilchrist, M., & Buck, L. 2007. Developing a risk assessment tool for using bedrails. *Nursing times* 103, (20) 30-31

Govier I, Kingdom A. 2000 The rise and fall of cot sides *Nursing Standard* 14 31 40-41

Gowdy, M. & Godfrey, S. 2003. Using tools to assess and prevent inpatient falls. *Joint Commission Journal on Quality and Patient Safety*, 29, (7) 363-368

Gray CS Gaskell D 1990 Cot sides: a continuing hazard for the elderly *Geriatric Medicine* 20 21-22

Grenier-Sennelier, C., Lombard, I., Jeny-Loeper, C. et al. 2002. Designing adverse event prevention programs using quality management methods: the case of falls in hospital. *International Journal for Quality in Health Care*, 14, (5) 419-426

Grue, E.V., Kirkevold, M., & Ranhoff, A.H. 2009. Prevalence of vision, hearing, and combined vision and hearing impairments in patients with hip fractures. *Journal of Clinical Nursing*, 18, (21) 3037-3049

Guyatt, G.H., Oxman, A.D., Vist, G.E. et al. 2008. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. *British Medical Journal*, 336, (7650) 924

Haigh & Hayman 1936 cited in Brush, L & Capezuti, E 2001 'Historical analysis of siderail use in American hospitals', *Journal of Nursing Scholarship*, vol 33, no. 4, pp. 381-386.

Haines T Hill AM 2010 Meta-analysis where outcomes are recurrent events: Inconsistency between analyses using patient and study-level data *Journal of Clinical Epidemiology* (in press)

Haines, T. & Hill, K. 2005. Difficulties encountered in hospital falls prevention research. *Age and Ageing*, 34, (3) 31-312

Haines, T.P., Bennell, K.L., Osborne, R.H., & Hill, K.D. 2004. Effectiveness of targeted falls prevention programme in subacute hospital setting: randomised controlled trial. *BMJ*, 328, (7441) 676-679

Haines, T.P., Cornwell, P., Fleming, J. et al. 2008. Documentation of in-hospital falls on incident reports: Qualitative investigation of an imperfect process. *BMC Health Services Research* , 8, (1) 254-258

Haines, T.P., Hill, K., Walsh, W., & Osborn, R. 2007. Design-related bias in hospital fall risk screening tool predictive accuracy evaluations: systematic review and meta-analysis. *Journals of Gerontology Series A: Biological Sciences & Medical Sciences*, 62A, (6) 664-673

Haines, T.P., Hill, K.D., Bennell, K.L., & Osborne, R.H. 2006. Patient education to prevent falls in subacute care. *Clinical Rehabilitation*, 20, (11) 970-979 available from: http://cre.sagepub.com/cgi/content/abstract/20/11/970

Haines, T.P., Hill, K.D., Bennell, K.L., & Osborne, R.H. 2007. Additional exercise for older subacute hospital inpatients to prevent falls: Benefits and barriers to implementation and evaluation. *Clinical Rehabilitation*, 21, (8) 742-753

Haines, T.P., Massey, B., Varghese, P.et al. 2009. Inconsistency in classification and reporting of in-hospital falls. *Journal of the American Geriatrics Society*, 57, (3) 517-523

Haines, T.P., Russell, T., Brauer, S.G.et al. 2009. Effectiveness of a video-based exercise programme to reduce falls and improve health-related quality of life among older adults discharged from hospital: a pilot randomized controlled trial. *Clinical Rehabilitation*, 23, (11) 973-985

Halfon, P., Eggli, Y., Van Melle, G., & Vagnair, A. 2001. Risk of falls for hospitalized patients A predictive model based on routinely available data. *Journal of clinical epidemiology*, 54, (12) 1258-1266

Haller 2007 Giving incident reporting systems a chance *BMJ Rapid Responses* http://www.bmj.com/cgi/eletters/334/7584/79 Accessed 1.5.10

Hamers, J.P.H., Meyer, G., Kopke, S. et al. 2009. Attitudes of Dutch, German and Swiss nursing staff towards physical restraint use in nursing home residents, a cross-sectional study. *International journal of nursing studies*, 46, (2) 248-255

Hammond, M. & Levine, J.M. 1999. Bedrails: choosing the best alternative. *Geriatric Nursing*, 20, (6) 297-300

Hanger, H.C. 2009. The effect of bedrails on falls and injury. *Age Ageing*, 38, (3) 355 -356

Hanger, H.C., Ball, M.C., & Wood, L.A. 1999. An analysis of falls in the hospital: Can we do without bedrails? *Journal of the American Geriatrics Society*, 47, (5) 529-531

Hansard 2007 http://www.parliament.the-stationery-office.com/pa/cm200708/cmhansrd/cm071212/text/71212w0018.htm

Hansard 2007 http://www.publications.parliament.uk/pa/cm200708/cmhansrd/cm080618/text/80618w0024.htm

Harada, A., Mizuno, M., Takemura, M. et al. 2001. Hip fracture prevention trial using hip protectors in Japanese nursing homes. *Osteoporosis international*, 12, (3) 215-221

Hartikainen, S., Lonnroos, E., & Louhivuori, K. 2007. Medication as a risk factor for falls: critical systematic review. *Journals of Gerontology Series A: Biological and Medical Sciences*, 62, (10) 1172-1181

Hauer, K., Lamb, S.E., Jorstad, E.C., Todd, C., & Becker, C. 2006. Systematic review of definitions and methods of measuring falls in randomised controlled fall prevention trials. *Age and Ageing*, 35, (1) 5-10

Haumschild, M.J., Karfonta, T.L., Haumschild, M.S., & Phillips, S.E. 2003. Clinical and economic outcomes of a fall-focused pharmaceutical intervention program. *American Journal of Health-System Pharmacy*, 60, (10) 1029-1032

Hayes, N. Preventing falls in hospital - time to change step? *British Journal of Nursing* 2007 16(13): 770-771 (12 Jul 2007)

Healey F & Scobie S for the National Patient Safety Agency. 2007a *Slips trips and falls in hospital* NPSA: London

Healey F & Stephenson E for the National Patient Safety Agency. 2007b *Using bedrails safely and effectively* NPSA: London

Healey F and Oliver D. 2006 Preventing falls and injury in hospitals: where are efforts best directed? *Healthcare Risk Repor*t 12(7) 15-17

Healey F for the National Patient Safety Agency. 2007c *Resources for reviewing or developing a bedrail policy* NPSA: London

Healey F for the National Patient Safety Agency.2007d *Bedrails - reviewing the evidence* NPSA: London

Healey F. 2009 A safer night's sleep *Public Service Review* Health issue 21 http://www.publicservice.co.uk/article.asp?publication=Health&id=406&content_name=Health%20and%20safety&article=13150 Accessed 10/4/10

Healey F. 2010 Nursing by numbers: we must use clinical judgement to assess risk *Nursing Times* 106 14 p.8

Healey, F. & Oliver, D. 2009. Bedrails, falls and injury: evidence or opinion?: a review of their use and effects. *Nursing Times*, 105, (26) 20-24

Healey, F. & Oliver, D. 2009. Reply. *Age and Ageing*, 38, (1) 129-130

Healey F. 2005 Reply *Age and Ageing*, 34, (3) 311-312

Healey, F. & Scobie, S. 2007. Keeping a balance: preventing patient falls in hospital. *British Journal of Healthcare Management* , 13, (3) 87-90

Healey, F. 1994. Does flooring type affect risk of injury in older in-patients? *Nursing Times*, 90, (27) 40-41

Healey, F. 1995. The reliability and utility of pressure sore grading scales. *T Tissue Viabil*, 5, (4) 111-114

Healey, F. 1996. Classification of pressure sores: 2. *British Journal of Nursing*, 5, (9) 567-574

Healey, F. 1996. Using incidence data to improve risk assessment. *J Tissue Viability*, 6, (1) 3-9

Healey, F. 1996. Waterlow revisited. *Nursing Times*, 92, (11) 80-84

Healey, F. 2000. Risk assessment tools in the prevention of pressure ulcers. *Journal of Tissue Viability*, 10, (1) 34-35

Healey, F. 2006. Letter to the Editor *Canadian Journal of Nursing Research*, 38, (3) 3-4

Healey, F. 2006. Root cause analysis for tissue viability incidents. *J Tissue Viability*, 16, (1) 12-15

Healey, F. 2009. Decisions on bedrails must not be made through emotive arguments. *Nurs.Times*, 105, (26) 11

Healey, F. 2010. Low specificity and high false-positive rates limit the usefulness of the STRATIFY tool and clinical judgement in predicting falls in older patients in an acute hospital setting. *Evidence Based Nursing*, 13, (2) 54

Healey, F., Monro, A., & Cockram, A. et al. 2004. Using targeted risk factor reduction to prevent falls in older in-patients: a randomised controlled trial. *Age & Ageing*, 33, (4) 390-395

Healey, F., Oliver, D., Milne, A., & Connelly, J.B. 2008. The effect of bedrails on falls and injury: a systematic review of clinical studies. *Age and Ageing*, 37, (4) 368-378

Healey, F., Scobie, S., Oliver, D. et al. 2008. Falls in English and Welsh hospitals: a national observational study based on retrospective analysis of 12 months of patient safety incident reports. *Quality & Safety in Health Care*, 17, (6) 424-430

Healey, F., Stevenson, E., & Oliver, D. 2007. A national bedrail safety project to help reduce falls. *Nursing times* 103, (21) 30-31

Healey, F.M., Cronberg, A., & Oliver, D. 2009. Bedrail Use in English and Welsh Hospitals. *Journal of the American Geriatrics Society*, 57, (10) 1887-1891

Health & Safety Executive 1995 *Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995*. Accessed at http://www.hse.gov.uk/riddor/index.htm on 10/6/10

Health and Social Care Information Centre (UK). *Hospital Episode Statistics* http://www.hesonline.nhs.uk/Ease/servlet/ContentServer?siteID=1937&categoryID=889 Accessed on 24/4/10

Health Protection Agency (UK) *Results from the mandatory surveillance of MRSA bacteraemia* 2007 http://www.hpa.org.uk/web/HPAweb&HPAwebStandard/HPAweb_C/1233906819629 Accessed on 1.5.10

Healthcare Commission *Inspection guide 2007/08 HC 2008a Accessed at* http://www.cqc.org.uk/_db/_documents/Core_standard_C1a_incidents_reporting_and_learning_all_sectors.pdf

Healthcare Commission *Standards for better health* HC 2008b Accessed at http://www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/dh_4086665

Heinze, C., Halfens, R.J., & Dassen, T. 2007. Falls in German in-patients and residents over 65 years of age. *Journal of Clinical Nursing*, 16, (3) 495-501

Higgs, M 2007 *Life in the Victorian and Edwardian Workhouse,* The History Press, London, UK.

Higher Education Funding Council for England *2009 Research Excellence Framework* HEFCE Consultation draft Accessed at http://www.hefce.ac.uk/research/ref/ on 29/5/10

Hignett S, Griffiths P Do Split-side rails present an increased risk to patient safety? *Quality and Safety in Health Care* 2005;14;113-116

Hignett, S. & Masud, T. 2006. A review of environmental hazards associated with in-patient falls. *Ergonomics*, 49, (5) 605-616

Hill A-M, Hoffmann T, Hill K et al. 2010 Measuring Falls Events in Acute Hospitals-A Comparison of Three Reporting Methods to Identify Missing Data in the Hospital Reporting Systems J Am Geriatr Soc. 2010 May 7. [Epub ahead of print]

Hill, A., McPhail, S., Hoffmann, T. et al. 2009. A randomized trial comparing digital video disc with written delivery of falls prevention education for older patients in hospital. *Journal of the American Geriatrics Society*, 57, (8) 1458-1464

Hill, A.M., Hill, K., Brauer, S. et al. 2009. Evaluation of the effect of patient education on rates of falls in older hospital patients: description of a randomised controlled trial. *BMC.Geriatr.*, 9, 14

Hill, K.D., Vu, M., & Walsh, W. 2007. Falls in the acute hospital setting - impact on resource utilisation. *Australian Health Review*, 31, (3) 471-478

Hitcho, E.B., Krauss, M.J., Birge, S. et al. 2004. Characteristics and circumstances of falls in a hospital setting. *Journal of General Internal Medicine*, 19, (7) 732-739

Hoffman SB, Powell-Cope G, MacClellan L, Bero K. BedSAFE - A Bed Safety Project for Frail Older Adults. *Journal of Gerontological Nursing* 2003 29(11): 34-42

Hughes R (ed) 2009 *Reducing restraints in health and social care: practice and policy perspectives* MA Healthcare: London

Hughes, R. 2008. Older People Falling Out of Bed: Restraint, Risk and Safety. *The British Journal of Occupational Therapy*, 71, (9) 389-392

Hutchinson, A., Young, T.A., Cooper, K.L. et al. 2009. Trends in healthcare incident reporting and relationship to safety and quality data in acute hospitals: results from the National Reporting and Learning System. *Quality and Safety in Health Care*, 18, (1) 5-10

Irving K. 2004 Inappropriate restraint practices in Australian teaching hospitals *Australian Journal of Advanced Nursing* 21 4 23-28

Isaakidis, P. & Ioannidis, JPA 2003 Evaluation of Cluster Randomized Controlled Trials in Sub-Saharan Africa *Am J Epidemiol* 2003; 158:921-926.

Jack, C.I.A., Smith, T., Neoh, C. et al. 1995. Prevalence of low vision in elderly patients admitted to an acute geriatric unit in Liverpool: elderly people who fall are more likely to have low vision. *Gerontology*, 41, (5) 280-285

Jarvis N, Kerr K, Mockett S. 2007 Pilot study to explore the feasibilityof a randomised controlled trial to determine the dose effect of physiotherapy on patients admitted to hospital following a fall.*Practical Evidence* 2(2):4–12.

Jehan W 1999 Restraint or protection? The use of bedside rails *Nursing Management* 6 2 9-13

Johnston C, Liddle J. The Mental Capacity Act 2005; a new framework for decision making. *J Med Ethics* 2007; 33(2): 94-7.

Joint Commission for the Accreditation of Healthcare Organizations 2009 *Sentinel Event Statistics* http://www.jointcommission.org/sentinelevents/statistics/ Accessed 24/4/10

Jorstad EC, Hauer K, Becker C et al. 2005. Measuring the Psychological Outcomes of Falling: A Systematic Review. *Journal of the American Geriatrics Society*. 53(3):501-510,

Kanis, J.A., Johnell, O., De Laet, C et al. 2004. A meta-analysis of previous fracture and subsequent fracture risk. *Bone*, 35, (2) 375-382

Kannus, P., Parkkari, J., Niemi, S. et al. 2000. Prevention of hip fracture in elderly people with use of a hip protector. *The New England journal of medicine*, 343, (21) 1506-1513

Kato, S., Tsuru, S., & Iizuka, Y. 2009. Framework for preventing accidental falls in hospitals - management plan for ADL, medication and medical conditions. *Stud.Health Technol.Inform.*, 146, 450-454

Kerzman, H., Chetrit, A., Brin, L., & Toren, O. 2004. Characteristics of falls in hospitalized patients. *Journal of advanced nursing*, 47, (2) 223-229

Kessler, D. Summerton, N. Graham J et al. 2006 Effects of the medical liability system in Australia, the UK, and the USA *The Lancet,* 368 (9531) 240-246

Kiel, D.P., Magaziner, J., Zimmerman, S. et al. 2007. Efficacy of a hip protector to prevent hip fracture in nursing home residents: the HIP PRO randomized controlled trial. *JAMA*, 298, (4) 413-422

Kilpack, V., Boehm, J., Smith, N., & Mudge, B. 1991. Using research-based interventions to decrease patient falls. *Applied Nursing Research*, 4, (2) 50-56

Kitson A, G Harvey and B McCormack 1998 Enabling the implementation of evidence based practice: a conceptual framework *Quality in Health Care*;7:149-158

Koh SLS, Hafizah N, Lee JY et al. 2009 Impact of a fall prevention programme in acute hospital settings in Singapore *Singapore Med J* 50:4 425-432

Koh, S.S.L., Manias, E., Hutchinson, A.M., & Johnston, L. 2007. Fall incidence and fall prevention practices at acute care hospitals in Singapore: a retrospective audit. *Journal of Evaluation in Clinical Practice*, 13, (5) 722-727

Koike, T., Orito, Y., Toyoda, H. et al. 2009. External hip protectors are effective for the elderly with higher-than-average risk factors for hip fractures. *Osteoporosis international*, 20, (9) 1613-1620

Kottner, J., Raeder, K., Halfens, R., & Dassen, T. 2009. A systematic review of interrater reliability of pressure ulcer classification systems. *Journal of Clinical Nursing*, 18, (3) 315-336

Krauss MJ Evanoff B Hitcho E et al. 2005 A case-control study of patient, medication and care-related risk factors for inpatient falls *Journal of General Internal Medicine* 20 2 116-122

Krauss, M.J., Nguyen, S.L., Dunagan, W.C. et al. 2007. Circumstances of patient falls and injuries in 9 hospitals in a midwestern healthcare system. *Infect Control Hosp Epidemiol*, 28, 544-550

Krauss, M.J., Tutlam, N., Costantinou, E. et al. 2008. Intervention to Prevent Falls on the Medical Service in a Teaching Hospital. *Infect Control Hosp Epidemiol*, 29, 539-545

Kron M Loy S Sturm E et al. 2003 Risk indicators for falls in institutionalized frail elderly *American Journal of Epidemiology* 158 7 645-653

Kwok, T., Mok, F., Chien, W.T., & Tam, E. 2006. Does access to bed-chair pressure sensors reduce physical restraint use in the rehabilitative care setting? *J.Clin.Nurs.*, 15, (5) 581-587

Lamb, S.E., Jorstad-Stein, E.C., Hauer, K., & Becker, C. 2005. Development of a common outcome data set for fall injury prevention trials: the Prevention of Falls Network Europe consensus. *Journal of the American Geriatrics Society*, 53, (9) 1618-1622

Lauritzen, J.B., Petersen, M.M., & Lund, B. 1993. Effect of external hip protectors on hip fractures. *The Lancet*, 341, (8836) 11-13

Leape, L.L., Brennan, T.A., Laird, N. et al. 1991. The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II. *New England Journal of Medicine*, 324, (6) 377-391

Lemeshow, S. & Hosmer Jr, D.W. 1982. A review of goodness of fit statistics for use in the development of logistic regression models. *American Journal of Epidemiology*, 115, (1) 92-106

Leutell D., Beaumont, K., & Healey, F. 2007. *Recognising and responding appropriately to early signs of deterioration in hospitalised patients*. London: NPSA

Levine, J.M., Hammond, M., Marchello, V., & Breuer, B. 2000. Changes in bedrail prevalence during a bedrails-reduction initiative. *J.Am.Med.Dir.Assoc.*, 1, (1) 34-36

Lilford, R., Edwards, A., Girling, A. et al. 2007. Inter-rater reliability of case-note audit: a systematic review. *Journal of health services research & policy*, 12, (3) 173-180

Lord, S.R., Sherrington, C., & Menz, H.B. 2007. *Falls in older people: risk factors and strategies for prevention* Cambridge Univ Pr.

Lundstrom, M., Olofsson, B., Stenvall, M. et al. 2007. Postoperative delirium in old patients with femoral neck fracture: a randomized intervention study. *Aging clinical and experimental research*, 19, (3) 178-183

Mador, J.E., Giles, L., Whitehead, C., & Crotty, M. 2004. A randomized controlled trial of a behavior advisory service for hospitalized older patients with confusion. *International journal of geriatric psychiatry*, 19, (9) 858-863

Magee, R., Hyatt, E.C., Hardin, S.B. et al. 1993. Institutional policy: use of restraints in extended care and nursing homes. *Journal of gerontological nursing*, 19, (4) 31-39

Mahoney, J.E. 1998. Immobility and falls. *Clinics in geriatric medicine*, 14, (4) 699-726

Marcy-Edwards, D. 2005. Is there an up side? *Canadian Nurse*, 101, (1) 30-34

Mason J, McCall-Smith R, Laurie G. 2002 *Law and Medical Ethics*. 6th ed. London: Butterworths. 311-4.

Mayer D 2004 *Essential Evidence Based Medicine* Cambridge: Cambridge University Press

Mayo, N.E., Gloutney, L., & Levy, A.R. 1994. A randomized trial of identification bracelets to prevent falls among patients in a rehabilitation hospital. *Archives of physical medicine and rehabilitation*, 75, (12) 1302-1308

McColl, E., Jacoby, A., Thomas, L. et al. 2001. Design and use of questionnaires: a review of best practice applicable to surveys of health service staff and patients. *Health Technol Assess*, 5, (31) 1-256

Meade, C.M., Bursell, A.L., & Ketelsen, L. 2006. Effects of nursing rounds: on patients' call light use, satisfaction, and safety. *AJN The American Journal of Nursing*, 106, (9) 58-68

Medical Devices Agency 1997 *Hazard Notice 1997/11 Bed Side Rails (Cot sides) – Risk of entrapment* London: Medicine and Healthcare products Regulatory Agency

Medical Devices Agency 1999 *Hazard Notice 1999/36 Bed Side Rails (Cot sides) – fitted with telecosping crossbars - risk of movement and subsequent patient injury* London: Medicine and Healthcare products Regulatory Agency

Medical Devices Agency 2000 *Hazard Notice 2000/10 Bed Side Rails (Cot sides) – Risk of death from entrapment and asphyxiation from beds fitted with incompatible side rails* London: Medicine and Healthcare products Regulatory Agency

Medical Devices Agency 2001 *Device Bulletin 2001(04) Advice on the safe use of bedrails* London: Medicine and Healthcare products Regulatory Agency

Medical Devices Agency 2002 *Bed safety equipment; an evaluation* Medical Devices Agency, London, UK.

Medical Devices Agency 2004 *Hazard Notice 2004/14 Replacement mattresses for hospital beds used in hospitals and the community* London: Medicine and Healthcare products Regulatory Agency

Medical Research Council 2008 *Developing and evaluating complex interventions: new guidance* MRC Accessed at http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC003372 on 10/5/09

Medicine and Healthcare products Regulatory Agency 2006 *Device Bulletin 2006(06) The safe use of bedrails* London: Medicine and Healthcare products Regulatory Agency

Medicine and Healthcare products Regulatory Agency 2007 *Device Alert 2007/009 Bed Rails and Grab Handles* London: Medicine and Healthcare products Regulatory Agency

Medicines and Healthcare products Regulatory Agency 2004 *MDA/2004/007 13 February 2004 Bed rails: twin bar designs - entrapment and asphyxiation* London: Medicine and Healthcare products Regulatory Agency

Meyer, G., Warnke, A., Bender, R., & Muhlhauser, I. 2003. Effect on hip fractures of increased use of hip protectors in nursing homes: cluster randomised controlled trial. *British Medical Journal*, 326, (7380) 76-81

Mildner S Snell A Arora A et al . 2003 The prevalence of bedrail use in British hospitals *Age and Ageing* 32 555-556

Miles S, Parker K 1998 Pictures of fatal bedrail entrapment *American Family Physician* 58 8 1755-1756

Miles S. 1996 A case of death by physical restraint: new lessons from a photograph *Journal of the American Geriatrics Society*, vol. 44, no. 3, p. 291-2,

Miles S. 2002 Deaths between bedrails and air pressure mattresses *Journal of the American Geriatric Society* 50 1124-1125

Miles, S.H. 2009. Autopsy findings in asphyxia in medical bed rails. *American Journal of Forensic Medicine and Pathology*, 30, (3) 256-261

Milisen, K., Staelens, N., Schwendimann, R. et al. 2007. Fall prediction in inpatients by bedside nurses using the St. Thomas's Risk Assessment Tool in Falling Elderly Inpatients (STRATIFY) instrument: a multicenter study. *Journal of the American Geriatrics Society*, 55, (5) 725-733

Miller, P. 1989 Safe in a cocoon. *Nursing Times*, 85, (41) 38-40

Milutinovic, D., Martinov-Cvejin, M., & Simic, S. 2009. Patients' falls and injuries during hospitalization as quality indicators of work in hospitals. *Med.Pregl.*, 62, (5-6) 249-257

Minnick, A.F., Mion, L.C., Johnson, M.E. et al. 2007. Prevalence and variation of physical restraint use in acute care settings in the US. *Journal of Nursing Scholarship*, 39, (1) 30-37

Minnick, A.F., Mion, L.C., Johnson, M.E. et al. 2008. The who and why's of side rail use. *Nursing Management*, 39, (5) 36-44

Minns, J., Nabhani, F., & Bamford, J.S. 2004 Can flooring and underlay materials reduce hip fractures in older people? *Nursing older people*, 16, (5) 16-20

Mion LC, Minnick A, Palmer, et al. 1996 Physical Restraint Use in the Hospital Setting: Unresolved Issues and Directions for Research *The Millbank Quarterly* 74 3 411-417

Mitchell J, Jones J, Mc Nair, B & McClenahan J 1998 *Better beds for health care: report of the King's Fund Centenary Bed Project*, King's Fund Publishing, London, UK.

Mitchell, A.N.N. & Jones, N. 2007. Striving to prevent falls in an acute care settingùaction to enhance quality. *Journal of Clinical Nursing*, 5, (4) 213-220

Moher D Cook JC Eastwood S et al. 1996 Improving the quality of reports of meta-analyses of RCTs; the QUORUM statement *The Lancet* 134:1896-1900

Montero-Odasso, M., Wells, J.L., Borrie, M.J., & Speechley, M. 2009. Can cognitive enhancers reduce the risk of falls in older people with Mild Cognitive Impairment? A protocol for a randomised controlled double blind trial. *BMC.Neurol.*, 9, 42

Morningside Hospital v. Pennington 1941 cited in Brush, L & Capezuti, E 2001 ‘Historical analysis of siderail use in American hospitals’, *Journal of Nursing Scholarship*, vol 33, no. 4, pp. 381-386.

Morse, J.M. 1996. *Preventing patient falls* Sage Publications, Inc.

Morse, J.M. 2006. The safety of safety research: The case of patient fall research. *Canadian Journal of Nursing Research*, 38, (2) 74-88

Murphy, T.H., Labonte, P., Klock, M., & Houser, L. 2008. Falls prevention for elders in acute care: An evidence-based nursing practice initiative. *Critical Care Nursing Quarterly*, 31, (1) 33-39

Murray, G.R., Cameron, I.D., & Cumming, R.G. 2007. The consequences of falls in acute and subacute hospitals in Australia that cause proximal femoral fractures. *Journal of the American Geriatrics Society*, 55, (4) 577-582

Nadkarni, J.B., Iyengar, K.P., Dussa, C. et al. 2005. Orthopaedic injuries following falls by hospital in-patients. *Gerontology*, 51, (5) 329-333

Naessens, J.M., Campbell, C.R., Huddleston, J.M. et al. 2009. A comparison of hospital adverse events identified by three widely used detection methods. *International Journal for Quality in Health Care*, 21, (4) 301-307

National Institute for health and Clinical Excellence 2003 *Head injury; triage, assessment, investigation and early management of head injury in infants, children and adults* NICE (UK)

National Institute for health and Clinical Excellence 2004 *The assessment and prevention of falls in older people* NICE 2004 http://www.nice.org.uk/CG021 Accessed 17/4/10

National Institute for health and Clinical Excellence 2006 *NICE clinical guideline 29: Pressure ulcers: The management of pressure ulcers in primary and secondary care* Accessed at http://www.nice.org.uk/nicemedia/live/10998/30318/30318.pdf on 10/6/10

National Institute for health and Clinical Excellence 2006 *NICE clinical guideline 42: Dementia: supporting people with dementia and their carers in health and social care* Accessed at http://www.nice.org.uk/nicemedia/live/10998/30318/30318.pdf on 10/6/10

National Institute for health and Clinical Excellence 2009 *NICE clinical guideline 91: Depression: the treatment and management of depression in adults* Accessed at http://guidance.nice.org.uk/CG90 on 10/6/10

National Institute for health and Clinical Excellence 2010 *Alendronate, etidronate, risedronate, raloxifene, strontium ranelate and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women (amended)* NICE (UK)

National Patient Safety Agency 2002 *Potassium solutions: risks to patients from errors occurring during intravenous administration* NPSA: London

National Patient Safety Agency 2004a *Improving infusion device safety* NPSA: London

National Patient Safety Agency 2004b *Establishing a standard crash call telephone number in hospitals* NPSA: London

National Patient Safety Agency 2005 *Building a memory: the first report of the patient safety observatory* NPSA: London

National Patient Safety Agency 2006 *Safety in Mind; the second report of the patient safety observatory* NPSA: London

National Patient Safety Agency 2008 *Five actions to improve patient safety reporting* NPSA: London

National Patient Safety Agency 2009 *Organisational patient safety reports* NPSA: London http://www.nrls.npsa.nhs.uk/patient-safety-data/organisation-patient-safety-incident-reports/directory/?entryid33=26014&char=Y Accessed 2.5.10

Neale, G., Woloshynowych, M., & Vincent, C. 2001. Exploring the causes of adverse events in NHS hospital practice. *JRSM*, 94, (7) 322 517-519

Neufeld RR Dunbar JM 1999b Attitudes of staff and residents to siderails in Nursing homes The Gerontologist 38 p.226

Neufeld RR Dunbar JM. 1999a Siderails and injuries in Nursing homes The Gerontologist 39 p.500

Ng, K.P., McMaster, F.R., & Heng, B.H. 2008. The effectiveness of bedrails in preventing falls. *Singapore Nursing Journal*, 35, (4) 10-17

NHS Counter Fraud and Security Service 2008 *Prevention and management of violence where withdrawal of treatment is not an option* NHS Business Services Authority (UK)

NHS Estates 2001 *Health Building Note 04-01: Adult in-patient facilities* Accessed at http://www.nric.org.uk/IntegratedCRD.nsf/ef3917a95e2ae33e8025755c005bf1ea/ac21658443319447802571ca0052345a?OpenDocument on 10/6/10

NHS Litigation Authority 2008 *Acute, PCT and Independent Sector Standards 2008/09* NHSLA Accessed at http://www.nhsla.com/RiskManagement/ on 23/6/09

Noone I Fleming H 1998 Hospital Cotsides: who are they really helping? *The World of Irish Nursing* May 1998 20-21

Nyberg, L. & Gustafson, Y. 1995. Patient falls in stroke rehabilitation: a challenge to rehabilitation strategies. *Stroke*, 26, (5) 838-842

Nyberg, L., Gustafson, Y., Janson, A. et al. 1997. Incidence of falls in three different types of geriatric care: a Swedish prospective study. *Scandinavian Journal of Public Health*, 25, (1) 8-13

O'Keeffe ST 2004 Down with bedrails? *The Lancet* 363 9406 343-344

O'Keeffe, S 2009 'The effect of bedrails on falls and injury' *Age and Ageing,* vol 38, no. 1, p 129.

O'Byrne-Maguire 2009 *Epidemiological study of falls in Ireland based on incident and claims data created on STARSWeb from 2004-2008* Abstract presented at the 10th International Conference of Falls and postural stability Blackpool 7.9.2009

O'Connell, B. & Myers, H. 2001. A failed fall prevention study in an acute care setting: Lessons from the swamp. *International journal of nursing practice*, 7, (2) 126-130

O'Connor BB 1998 Culture and the use of patient restraints *HEC Forum* Issue Volume 10, Numbers 3-4 / December, 1998

Office of National Statistics. 2010 *National statistics online* 2005-2010 http://www.statistics.gov.uk/CCI/nugget.asp?ID=6 Accssed on 10/4/10

O'Halloran, P.D., Cran, G.W., Beringer, T.R.O. et al. 2004. A cluster randomised controlled trial to evaluate a policy of making hip protectors available to residents of nursing homes. *Age and Ageing*, 33, (6) 582-588

O'Hart K 2008 *Improving the falls services within your oragnisation* (conference presentation) Accessed at http://www.laterlifetraining.co.uk/documents/FallsApril.pdf on 10/6/10

O'Keeffe S, Jack CIA. Lye M. 1996 Use of restraints and bedrails in a British hospital. *Journal of the American Geriatrics Society* 44:9 1086-1088.

O'Keeffe, S. 2009. The effect of bedrails on falls and injury. *Age Ageing*, 38, (1) 129-130 available from: PM:19029101

O'Keeffe, S.T. 2004. Down with bedrails? *Lancet* , 363, (9406) 343-344 available from: PM:15070560

Olgilvie D Egan M Hamilton V Petticrew M 2004 Promoting walking and cycling as an alternative to using cars: systematic review *BMJ* 329 763-767

Olgilvie D Egan M Hamilton V Petticrew M 2005 Systematic reviews of health effects of social interventions: 2. Best available evidence: how low should you go? *Journal of Epidemiology and Community Health* 59 886-892

Oliver D and Healey F. 2006 Preventing Falls and injury in hospitals: the evidence for intervention *Healthcare Risk Report* 12(7) 12-14

Oliver D, Healey F, and Haines T. 2010 (in press) Preventing falls and fall-related injuries in hospitals *Clinics in Geriatric Medicine*

Oliver D. 2009 Development of services for older patients with falls and fractures in England: successes, failures, lessons and controversies *Arch Gerontol Geriatr.* 49 Suppl 2:S7-12.

Oliver, D. & Healey, F. 2009. Falls risk prediction tools for hospital inpatients: do they work? *Nursing Times*, 105, (7) 18-21

Oliver, D. & Healey, F. 2008. Interpreting the null result. *British Medical Journal*, 336, (7649) 847

Oliver, D. 2002. Bed falls and bedrails - what should we do? *Age Ageing*, 31, (5) 415-418

Oliver, D. 2004. Prevention of falls in hospital inpatients. Agendas for research and practice. *Age and Ageing*, 33, (4) 328-330

Oliver, D. 2008. Preventing falls and falls-injuries in hospitals and long-term care facilities. *Reviews in Clinical Gerontology*, 17, (02) 75-91

Oliver, D., Britton, M., Seed, P. et al. 1997. Development and evaluation of evidence based risk assessment tool (STRATIFY) to predict which elderly inpatients will fall: case-control and cohort studies. *BMJ*, 315, (7115) 1049-1053

Oliver, D., Connelly, J.B., Victor, C.R. et al. 2007. Strategies to prevent falls and fractures in hospitals and care homes and effect of cognitive impairment: systematic review and meta-analyses. *British Medical Journal*, 334, (7584) 82-87

Oliver, D., Daly, F., Martin, F.C., & McMurdo, M.E.T. 2004. Risk factors and risk assessment tools for falls in hospital in-patients: a systematic review. *Age and Ageing*, 33, (2) 122-130

Oliver, D., Hopper, A., & Seed, P. 2000. Do hospital fall prevention programs work? A systematic review. *Journal of the American Geriatrics Society*, 48, (12) 63-67

Oliver, D., Killick, S., Even, T., & Willmott, M. 2008. Do falls and falls-injuries in hospital indicate negligent care -- and how big is the risk? A retrospective analysis of the NHS Litigation Authority Database of clinical negligence claims, resulting from falls in hospitals in England 1995 to 2006. *Qual.Saf Health Care*, 17, (6) 431-436

Oliver, D., Martin, F., & Seed, P. 2002. Preventing patient falls. *Age and Ageing*, 31, (1) 75-76

Oliver, D., Papaioannou, A., Giangregorio, L. et al. 2008. A systematic review and meta-analysis of studies using the STRATIFY tool for prediction of falls in hospital patients: how well does it work? *Age and ageing*, 37, (6) 621-627

Osnes, E.K., Lofthus, C.M., Meyer, H.E. et al. 2004. Consequences of hip fracture on activities of daily life and residential needs. *Osteoporosis international*, 15, (7) 567-574

Owen, R.A., Melton III, L.J., Ilstrup, D.M. et al. 1982. Colles' fracture and subsequent hip fracture risk. *Clinical Orthopaedics and Related Research*, 171, 37-43

Oxford Centre for Evidence Based Medicine. 2001 *Levels of Evidence*. OCEBM: Oxford Accessed at http://www.cebm.net/index.aspx?o=1025 on 10/5/10

Parker K Miles SH 1997 Deaths caused by bedrails *Journal of the American Geriatric Society* 44 797-802

Parker MJ, Gillespie WJ, Gillespie LD. 2005 *Hip protectors for preventing hip fractures in older people.* Cochrane Database of Systematic Reviews 2005, Issue 3.(NOTE edited with no change in conclusions 2009)

Patient Safety First 2009 *The 'How to' guide to reducing harm from falls* National Patient Safety Agency: London

Peterson, J.F., Kuperman, G.J., Shek, C. et al. 2005. Guided prescription of psychotropic medications for geriatric inpatients. *Archives of internal medicine*, 165, (7) 802-807

Pope, C. & Mays, N. 2009. Critical reflections on the rise of qualitative research. *BMJ*, 339, (sep15 2) b3425

Poster, E.C., Pelletier, L.R., & Kay, K. 1991. A Retrospective Cohort Study of Falls in a Psychiatric Inpatient Setting. *Hospital & Community Psychiatry*, 42, (7) 714-720

Potter et al. v. Dr WH Groves 1940 cited in Brush, L & Capezuti, E 2001 'Historical analysis of siderail use in American hospitals', *Journal of Nursing Scholarship*, vol 33, no. 4, pp. 381-386.

Potter, J. & George, J. 2006. The prevention, diagnosis and management of delirium in older people: concise guidelines. *Clinical Medicine, Journal of the Royal College of Physicians*, 6, (3) 303-308

Powell, C., Mitchell-Pedersen, L., Fingerote, E., & Edmund, L. 1989. Freedom from restraint: consequences of reducing physical restraints in the management of the elderly. *CMAJ: Canadian Medical Association Journal*, 141, (6) 561-564

Prevention of Falls Network Europe (ProFaNE) 2007 *Discussion board* http://www.profane.eu.org/phpBB3/viewtopic.php?f=2&t=296&p=790&hilit=bedrails#p790 Accessed 22/5/10

Prevention of Falls Network Europe (ProFaNE) 2008 *July 2008 newsletter* http://www.profane.eu.org/news.php Accessed 21/5/10

Prevention of Falls Network Europe (ProFaNE) 2009 *October 2009 newsletter* http://www.profane.eu.org/news.php Accessed 21/5/10

Public Service Journal 2009 'Could single rooms reduce HCAI transmission in hospitals?' Health Issue 19 2009 Accessed at http://www.publicservice.co.uk/article.asp?publication=Health&id=386&content_name=Digest&article=11743 on 8/6/10

Quigley, P.A., Hahm, B., Collazo, S. et al. 2009. Reducing serious injury from falls in two veterans' hospital medical-surgical units. *J.Nurs.Care Qual.*, 24, (1) 33-41

Rabadi, M.H., Rabadi, F.M., & Peterson, M. 2008. An analysis of falls occurring in patients with stroke on an acute rehabilitation unit. *Rehabil.Nurs.*, 33, (3) 104-109

Ralphs-Thibodeau, S, Knoefel, F, Benjamin, K et al. 2006 'Patient choice; an influencing factor on policy-related research to decrease bedrail use as physical restraint' *Worldviews on evidence based nursing* vol 3 no. 1 pp. 31-9

Raw, J. & Stacey, S. 2004. Are the days of bedrails coming to an end? *Age Ageing*, 33, (6) 641

Reason, J. 1990 *Human Error.* Cambridge University Press: Cambridge

Registered Nurses Association of Ontario. 2004 *Clinical Practice guidelines; Prevention of falls and fall injuries in the older adult* RNAO: Ontario Accessed on 30/6/07 at http://www.rnao.org/Page.asp?PageID=924&ContentID=810

Reid K, Morrison M. 1994 Towards a consensus: classification of pressure ulcers. *J Wound Care* 3(3): 157–60

Research for Patient Benefit 2010 *Reducing Falls for INpatients with Dementia (FIND); a pilot cluster-randomised trial of a multidisciplinary intervention.* RPB (UK)

Retsas A 1997 The use of physical restraints in Western Australian nursing homes *Australian Journal of Advanced Nursing* 14:3 33-39

Retsas, A.P. & Crabbe, H. 1997. Breaking loose. Use of physical restraints in nursing homes in Queensland, Australia. *Collegian.*, 4, (4) 14-21

Retsas, A.P. 1998. Survey findings describing the use of physical restraints in nursing homes in Victoria, Australia. *Int.J.Nurs.Stud.*, 35, (3) 184-191

Retsas, AP & Crabbe H 1998 'Use of physical restraints in nursing homes in New South Wales, Australia,' *International Journal of Nursing Studies* vol. 35, no. 3, pp. 177-183.

Robertson, M.C., Campbell, A.J. 2008 *Optimisation of ACC's fall prevention programmes for older people* University of Otago: New Zealand Accessed at http://www.acc.co.nz/PRD_EXT_CSMP/groups/external_ip/documents/reference_tools/pi00349.pdf on 10/6/10

Robertson, M.C., Campbell, A.J., & Herbison, P. 2005. Statistical analysis of efficacy in falls prevention trials. *Journals of Gerontology Series A: Biological and Medical Sciences*, 60, (4) 530

Rohde, J.M., Myers, A.H., & Vlahov, D. 1990. Variation in risk for falls by clinical department: implications for prevention. *Infection Control and Hospital Epidemiology*, 11, (10) 521-524

Rollins, M.O. 2006. Safety issues surrounding the use of bedrails. *Nurs.Older.People.*, 17, (10) 20-21

Rothman K Greenland S 2001 *Modern Epidemiology* New York: Lippencourt

Royal College of Nursing. 1996 *Restraint: rights, risks and responsibilities* RCN London (edition 1)

Royal College of Nursing. 1999 *Restraining, holding still and containing young people* RCN London (edition 1)

Royal College of Nursing. 2001 *Restraint revisited: rights, risks and responsibilities* RCN London (edition 2)

Royal College of Nursing. 2003 *Restraining, holding still and containing young people* RCN London (edition 2)

Royal College of Nursing. 2004 *Restraint revisited: rights, risks and responsibilities* RCN London (edition 3)

Royal College of Nursing. 2008 *Let's talk about restraint: rights, risks and responsibilities* RCN London 2008 www.rcn.org.uk/__data/assets/pdf_file/0007/157723/003208.pdf Accessed 11/4/10

Royal College of Physicians. 2009 *National Audit of the Organisation of Services for Falls and Bone Health of Older People* RCP Clinical Effectiveness and Evaluation Unit London http://www.rcplondon.ac.uk/CLINICAL-STANDARDS/CEEU/CURRENT-WORK/FALLS/Pages/Audit.aspx#nfbhop Accessed on 17/4/10

Rubenstein, H.S., Miller, F.H., Postel, S., & Evans, H.B. 1983. Standards of medical care based on consensus rather than evidence: The case of routine bedrail use for the elderly. *L.Med.& Health Care*, 11, 271-276

Rubin BS Dube AH Mitchell EK 1993 Asphysixial deaths due to physical restraint; a case series *Arch Fam Med* 2 405-408

Ryu, Y.M., Roche, J.P., & Brunton, M. 2009. Patient and family education for fall prevention: involving patients and families in a fall prevention program on a neuroscience unit. *J.Nurs.Care Qual.*, 24, (3) 243-249

Sahota, O. 2009. Vitamin D and in-patient falls. *Age and Ageing*, 38, (3) 339

Salkeld, G., Cameron, I.D., Cumming, R.G. et al. 2000. Quality of life related to fear of falling and hip fracture in older women: a time trade off study *British Medical Journal*, 320, (7231) 341-346

Sari, A.B.A., Sheldon, T.A., Cracknell, A., & Turnbull, A. 2007. Sensitivity of routine system for reporting patient safety incidents in an NHS hospital: retrospective patient case note review. *British Medical Journal*, 334, (7584) 79-82

Savage, T. & Matheis-Kraft, C. 2001. Fall occurrence in a geriatric psychiatry setting before and after a fall prevention program. *Journal of Gerontological Nursing*, 27, (10) 49-53

Schioler, T., Lipczak, H., Pedersen, B.L. et al. 2001. Incidence of adverse events in hospitals. A retrospective study of medical records. *Ugeskrift for Laeger*, 163, (39) 5370-5378

Schmid, N.A. 1990. Reducing patient falls: a research-based comprehensive fall prevention program. *Military medicine*, 155, (5) 202-207

Schott, J. & Force, R.W. 1999. Do bedrails decrease falls in hospitalized patients? *J.Fam.Pract.*, 48, (8) 579 available from: PM:10496631

Schwendimann, R., Buhler, H., De Geest, S., & Milisen, K. 2008. Characteristics of hospital inpatient falls across clinical departments. *Gerontology*, 54, (6) 342-348

Schwendimann, R., Buhler, H., De, G.S., & Milisen, K. 2006a. Falls and consequent injuries in hospitalized patients: Effects of an interdisciplinary falls prevention program. *BMC Health Services Research*, 6, 69

Schwendimann, R., De Geest, S., & Milisen, K. 2006c. Evaluation of the Morse Fall Scale in hospitalised patients. *Age and Ageing* , 35, (3) 311-313

Schwendimann, R., Milisen, K., Brown, C.W., & De Geest, S. 2006b. Fall Prevention in a Swiss Acute Care Hospital Setting: Reducing Multiple Falls. *Journal of Gerontological Nursing*, 32, (3) 13-22

Scobie, S., Thomson, R., McNeil, J.J., & Phillips, P.A. 2006. Measurement of the safety and quality of health care. *Medical Journal of Australia*, 184, (10) 51-56

Scott, V., Votova, K., Scanlan, A., & Close, J. 2007. Multifactorial and functional mobility assessment tools for fall risk among older adults in community, home-support, long-term and acute care settings. *Age and Ageing*, 36, (2) 130-139

Scottish Intercollegiate Guidelines Network 2006 *Clinical Guideline 88: Management of suspected bacterial urinary tract infection in adults* Scottish Quality Improvement Network Accessed at http://www.sign.ac.uk/pdf/sign88.pdf on 8/6/10

Semin-Goossens, A., van der Helm, J.M.J., & Bossuyt, P.M.M. 2003. A failed model-based attempt to implement an evidence-based nursing guideline for fall prevention. *Journal of nursing care quality*, 18, (3) 217-225

Serpa, L.F., de Gouveia Santos, V.L.C., Gomboski, G., & Rosado, S.M. 2009. Predictive Validity of Waterlow Scale for Pressure Ulcer Development Risk in Hospitalized Patients. *Journal of Wound Ostomy & Continence Nursing*, 36, (6) 640

Shanahan, D. & Evans, A. 2009. An audit of bedrail use and implications for practice. *Br.J.Nurs.*, 18, (4) 232-237

Sherrington, C., Whitney, J.C., Lord, S.R. et al. 2008. Effective exercise for the prevention of falls: a systematic review and meta-analysis. *J Am Geriatr Soc*, 56, (12) 2234-2243

Shorr R, Mion L, Rosenblatt L, Lynch D, Kessler L. 2007 Ascertainment of patient falls in hospital using an evaluation service: comparison with incident reports. *J Am Geriatr Soc* 55(4) Supp S1-246.

Shorr R., Minnick L. et al. 2010 Trial of Proximity Alarms to Reduce Patient Falls. National Institute on Aging, NIH. 1R01AG025285. (funding dates: 2005-2008). (Abstract to American Geriatrics Society, 2010). AGS Supplement. http://www.americangeriatrics.org/annual_meeting/2010_meeting_handouts/ Accessed 22/5/10

Si, M., Neufeld, R.R., & Dunbar, J. 1999. Removal of bedrails on a short-term nursing home rehabilitation unit. *Gerontologist*, 39, (5) 611-614

Simpson, A., Lamb, S., Roberts, P.J., Gardner, T.N., & Evans, J.G. 2004. Does the type of flooring affect the risk of hip fracture? *Age and ageing*, 33, (3) 242-246

Sleight, P. 2000. Debate: Subgroup analyses in clinical trials: fun to look at- but don't believe them! *Current Controlled Trials in Cardiovascular Medicine*, 1, (1) 25-27

Sloan Devlin, A. Arneill, AB 2003 Health Care Environments and Patient Outcomes A Review of the Literature *Environment and Behavior*, Vol. 35, No. 5, 665-694

Smith, G. & Pell, J.P. 2003. Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials. *British Medical Journal*, 327, (7429) 1459-1461

Social Care Institute for Excellence. 2009 *Exploring restraint* SCIE: London 2009 http://www.scie.org.uk/publications/elearning/restraint/restraint01/index.asp Accessed on 10/4/10

Spetz, J., Jacobs, J., & Hatler, C. 2007. Cost-Effectiveness of a Medical Vigilance System to Reduce Patient Falls. *Nursing Economics*, 25, (6) 333-338

Stenvall, M., Olofsson, B., Lundstrom, M. et al. 2007. A multidisciplinary, multifactorial intervention program reduces postoperative falls and injuries after femoral neck fracture. *Osteoporosis international*, 18, (2) 167-175

Stern, C. & Jayasekara, R. 2009. Interventions to reduce the incidence of falls in older adult patients in acute-care hospitals: a systematic review. *International Journal of Evidence-Based Healthcare*, 7, (4) 243-249

Sutton J, Standan P, Wallace A. 1995 Patient accidents in hospital: incidence, documentation and significance. *Br J Clin Practice* 48: 63-66.

Sweeting, H.L. 1994. Patient fall prevention-a structured approach. *Journal of Nursing Management*, 2, (4) 187-192

Talerico, K.A. & Capezuti, E. 2001. Myths and facts about side rails. *American Journal of Nursing*, 101, (7) 43-49

Tan-K-M, Austin-B, Shaughnassy-M, et al. 2005 Falls in an acute hospital and their relationship to restraint use *Irish Journal of Medical Science* 174:3 28-31

The Freedom of Information Act 2000 Her Majesty's government (UK)

The Lancet 1984 (anonymous editorial). ‘Cotsides – protecting whom against what?’ *The Lancet* 2 8399 p383-384

The Mental Capacity Act 2005 Her Majesty's government (UK) 2005

The South Australian Department of Health 2007 *Safe use of hospital bed rails* issued in May 2007 Accessed at http://www.health.sa.gov.au/Default.aspx on 21/5/10

Thomas, E.J. & Brennan, T.A. 2000. Incidence and types of preventable adverse events in elderly patients: population based review of medical records. *British Medical Journal*, 320, (7237) 741-744

Thomas, E.J., Studdert, D.M., Burstin, H.R. et al. 2000. Incidence and types of adverse events and negligent care in Utah and Colorado. *Medical Care*, 38, (3) 261-271

Thomson, R., Luettel, D., Healey, F. et al. 2007. *The fifth report from the Patient Safety Observatory: Safer care for the acutely ill patient: learning from serious incidents*. London: National Patient Safety Agency

Tideiksaar, R., Feiner, C.F., & Maby, J. 1993. Falls prevention: the efficacy of a bed alarm system in an acute-care setting. *The Mount Sinai journal of medicine, New York*, 60, (6) 522-527

Tinetti ME, Inouye S, Gill T, Doucette J. 1995 Shared risk factors for falls, incontinence and functional dependence. *JAMA* 273: 1348-53.

Tinetti, M.E., De Leon, C.F.M., Doucette, J.T., & Baker, D.I. 1994. Fear of falling and fall-related efficacy in relationship to functioning among community-living elders. *The Journal of Gerontology*, 49, (3) M140

Todd C, Skelton D. 2004 *What are the main risk factors for falls amongst older people and what are the most effective interventions to prevent these falls?* World Health Organisation: Geneva http://www.euro.who.int/document/e82552.pdf Accessed 17/4/10

Todd JF Ruhl CE Gross TP 1997 Injury and death associated with hospital bed side-rails: reports to the US Food and Drug Administration from 1985 to 1995 *American Journal of Public Health* 87 10 1675-1677 plus erratum 87 12 2052

Torgerson DJ, Iglesias CP, Reid DM. 2001 The economics of fracture prevention. In: *The Effective Management of Osteoporosis.* London: Aesculapius Medical Press, 111–21.

Torgerson, D.J. & Sibbald, B. 1998. Understanding controlled trials. What is a patient preference trial? *BMJ: British Medical Journal*, 316, (7128) 360-364

Towse A, Danzon P. 1999 Medical negligence and the NHS: an economic analysis. *Health Econ* 8: 93-101

Tutuarima JA Semin-Goosens A Hart AAM Sengkerij- Koolstra M. 2003 De prevelentie van vrijheidsbeperkende middelen in een Academisch Ziekenhuis. *Tijdschr Gerentol Geriatr* 34: 113-7.

Tutuarima, J.A., Haan, R.J., & Limburg, M. 2008. Number of nursing staff and falls: a case-control study on falls by stroke patients in acute-care settings. *Journal of advanced nursing*, 18, (7) 1101-1105

Tutuarima, J.A., Van der Meulen, J.H.P., De Haan, R.J., Van Straten, A., & Limburg, M. 1997. Risk factors for falls of hospitalized stroke patients. *Stroke*, 28, (2) 297-301

Tzeng, H.M. & Yin, C.Y. 2009. Are Call Light Use and Response Time Correlated With Inpatient Falls and Inpatient Dissatisfaction? *Journal of nursing care quality*, 24, (3) 232-242

Tzeng, H.M. 2009. Understanding the Prevalence of Inpatient Falls Associated With Toileting in Adult Acute Care Settings. *J.Nurs.Care Qual.*

Tzeng, H.M., Yin, C.Y., Tsai, S., Lin, S., & Yin, T.J.C. 2007. Patient falls and open visiting hours: a case study in a Taiwanese medical center. *Journal of nursing care quality*, 22, (2) 145-151

Uden, G., Ehnfors, M., & Sjostrom, K. 1999. Use of initial risk assessment and recording as the main nursing intervention in identifying risk of falls. *Journal of advanced nursing*, 29, (1) 145-152

University of Portsmouth 2009 *Hip-hop flooring study* http://www.port.ac.uk/research/hiphop/aboutthestudy/ accessed 21/5/10

USA Food and Drug Administration 2005 *Hospital Bed System Dimensional and Assessment Guidance to reduce Entrapment* http://www.fda.gov/cdrh/beds/guidance/1537.html accessed on 30/6/07

USA Food and Drug administration 2006 *A Guide to Bed Safety Bed rails in Hospitals, Nursing Homes and Home Health Care: the facts* accessed on 30/6/07 at www.fda.gov/cdrh/beds/bed_brochure.html on 30/6/07

van der Helm, J., Goossens, A., & Bossuyt, P. 2006. When implementation fails: the case of a nursing guideline for fall prevention. *Joint Commission Journal on Quality and Patient Safety*, 32, (3) 152-160

van Leeuwen M Bennett L West S Wiles V Grasso J 2001 Patient falls from bed and the role of bedrails in the acute care setting *Australian Journal of Advanced Nursing* 19 2 8-13

Van Schoor, N.M., Smit, J.H., Twisk, J. et al. 2003. Prevention of hip fractures by external hip protectors: a randomized controlled trial. *Jama*, 289, (15) 1957-1962

Vassallo, M., Amersey, R.A., Sharma, J.C., & Allen, S.C. 2000. Falls on integrated medical wards. *Gerontology*, 46, (3) 158-162

Vassallo, M., Poynter, L., Sharma, J.C., Kwan, J., & Allen, S.C. 2008. Fall risk-assessment tools compared with clinical judgment: an evaluation in a rehabilitation ward. *Age and Ageing*, 37, (3) 277-281

Vassallo, M., Sharma, J.C., & Allen, S.C. 2000. Characteristics of single fallers and recurrent fallers among hospital in-patients. *Gerontology*, 48, (3) 147-150

Vassallo, M., Stockdale, R., Sharma, J.C. et al. 2005. A comparative study of the use of four fall risk assessment tools on acute medical wards. *JAGS* 53 (6) 1034-1038

Vassallo, M., Stockdale, R., Wilkinson, C. et al. 2004. Acceptability of fall prevention measures for hospital inpatients. *Age and Ageing*, 33, (4) 400-401

Vassallo, M., Vignaraja, R., Sharma, J.C. et al. 2004. Predictors for falls among hospital inpatients with impaired mobility. *JRSM*, 97, (6) 266-269

Vassallo, M., Vignaraja, R., Sharma, J.C. et al. 2004. The effect of changing practice on fall prevention in a rehabilitative hospital: the Hospital Injury Prevention Study. *Journal of the American Geriatrics Society*, 52, (3) 335-339

Vassallo, M., Vignaraja, R., Sharma, J.C. et al. 2004. The relationship of falls to injury among hospital in-patients. *International journal of clinical practice*, 59, (1) 17-20

Vassallo, M., Wilkinson, C., Stockdale, R. et al. 2005. Attitudes to restraint for the prevention of falls in hospital. *Gerontology*, 51, (1) 66-70

Vincent, C., Neale, G., & Woloshynowych, M. 2001. Adverse events in British hospitals: preliminary retrospective record review. *British Medical Journal*, 322, (7285) 517-519

Vlahov, D., Myers, A.H., & Al-Ibrahim, M.S. 1990. Epidemiology of falls among patients in a rehabilitation hospital. *Archives of physical medicine and rehabilitation*, 71, (1) 8-12

von Renteln-Kruse, W. & Krause, T. 2004. Fall events in geriatric hospital in-patients. Results of prospective recording over a 3 year period. *Zeitschrift f³r Gerontologie und Geriatrie: Organ der Deutschen Gesellschaft fur Gerontologie und Geriatrie*, 37, (1) 9-14 von Renteln-Kruse, W. & Krause, T. 2007. Incidence of in-hospital falls in geriatric patients before and after the introduction of an interdisciplinary teamûbased fall-prevention intervention. *Journal of the American Geriatrics Society*, 55, (12) 2068-2074

Wagner, L.M., Capezuti, E., Brush, B. et al. 2007. Description of an advanced practice nursing consultative model to reduce restrictive siderail use in nursing homes. *Research in Nursing & Health*, 30, (2) 131-141

Watanabe, Y. 2005. Fear of falling among stroke survivors after discharge from inpatient rehabilitation. *International Journal of Rehabilitation Research*, 28, (2) 149-152

Waterlow, J. 1985 Pressure sores: a risk assessment card. *Nursing Times*, 81, (48) 49-55

Watson R Brunton M 1990 Restrain yourself *Nursing the Elderly* 2 5 20-21

Weintraub, D. & Spurlock, M. 2002. Change in the Rate of Restraint Use and Falls on a Psychogeriatric Inpatient Unit: Impact of the Health Care Financing Administration's New Restraint and Seclusion Standards for Hospitals. *Journal of Geriatric Psychiatry and Neurology*, 15, (2) 91-94

Williams MD (in press) *Rebellion against the 'normal' to improve safety for patients* Accessed at http://www.euroma2009.org/Proceedings/Papers/FCXST-09068951-1564127-1.pdf on 8/6/10

Williams, D.J., Olsen, S., Crichton, W. et al. 2008. Detection of Adverse Events in a Scottish Hospital Using a Consensus-based Methodology. *Scottish medical journal*, 53, (4) 26-30

Williams, T.A., King, G., Hill, A. et al. 2007. Evaluation of a falls prevention programme in an acute tertiary care hospital. *Journal of Clinical Nursing*, 16, (2) 316-325

Wilson, R.M., Harrison, B.T., Gibberd, R.W., & Hamilton, J.D. 1999. An analysis of the causes of adverse events from the Quality in Australian Health Care Study. *Medical Journal of Australia*, 170, 411-415

Wilson, R.M., Runciman, W.B., Gibberd, R.W., Harrison, B.T., Newby, L., & Hamilton, J.D. 1995. The quality in Australian health care study. *Med J Aust*, 163, 458-471

Woodward S for the National Patient Safety Agency 2008 *Implementation toolkit* NPSA: London

Wootton, R., Bryson, E., Elsasser, U. et al. 1982. Risk factors for fractured neck of femur in the elderly. *Age and Ageing*, 11, (3) 160-168

World Health Organization 2009 *Project to develop the patient safety event taxonomy* WHO Geneva http://www.who.int/patientsafety/taxonomy/Final_Report_of_Drafting_Group05.pdf Accessed 1.5.10

Wright E 2007 *Evaluation of Slips trips and falls in hospital NPSA: London Accessed at* http://www.npsa.nhs.uk/EasysiteWeb/getresource.axd?AssetID=6359&type=Full&servicetype=Attachment 21/5/10

Wright, L 2004 *Warm and snug: a history of the bed*, Sutton History Classics, London, UK.

Yardley, L., Donovan-Hall, M., Francis, K., & Todd, C. 2006. Older people's views of advice about falls prevention: a qualitative study. *Health education research*, 21, (4) 508

Young, J. & Inouye, S.K. 2007. Delirium in older people. *British Medical Journal*, 7598, 842-846

Zermansky A, Alldred D, Petty D, et al. 2006 Clinical medication review by a pharmacist of elderly people living in care homes – a randomised controlled trial. *Age Ageing* 35: 555-7

Zijlstra, G. A. ; van Haastregt R, Jolanda C. M. et al. 2007 Interventions to Reduce Fear of Falling in Community-Living Older People: A Systematic Review. *Journal of the American Geriatrics Society.* 55(4):603-615

GLOSSARY

A&E	Accident and Emergency department
ACSQH	Australian Council for Safety and Quality in Healthcare (later the Commission on)
aOR	Adjusted odds ratio
BGS	British Geriatrics Society
CAS	Central Alerting System (previously SABS)
CFSMS	Counter Fraud and Security Management Service
CI	Confidence intervals
FDA	Food and Drug Administration (USA)
HEFCE	Higher Education Funding Council for England
HES	Hospital Episode Statistics (UK)
HSE	Health and Safety Executive
ICU	Intensive Care Unit
ITU	Intensive Therapy Unit
LRMS	Local Risk Management System
MDA	Medical Devices Agency (later the MHRA) (UK)
MHRA	Medicines and Healthcare products Regulatory Agency (previously MDA) (UK)
MRC	Medical Research Council
NHSLA	NHS Litigation Authority
NICE	National Institute for Clinical Excellence/for Heath and Clinical Excellence
NPSA	National Patient Safety Agency
NPV	Negative Predictive Value
NRLS	National Reporting and Learning System
NS	Not significant
OBDs	Occupied bed days
OR	Odds ratio
PCT	Primary Care Trust
ProFaNE	Prevention of Falls Network Europe
PPV	Positive Predictive Value
PSO	Patient Safety Observatory (NPSA, UK)
RCN	Royal College of Nursing
RCP	Royal College of Physicians
RCT	Randomised Controlled Trial
REF	Research Excellence Framework
ROC	Receiver Operating Characteristic
SABS	Safety Alert Broadcast System (later CAS) (UK)
SCIE	Social Care Institute for Excellence
SIGN	Scottish Intercollegiate Guidelines Network
TPV	Total predictive value