Pilot Cluster Randomised Controlled Trial of Flooring to Reduce Injuries from Falls in Elderly Care Units: Final Report

December 2011

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Trial registration: ClinicalTrials.gov: NCT00817869; UKCRN ID: 5735.
Funding: This work was supported by The Dunhill Medical Trust [grant number R37/0207]; Julie Udell received a PhD studentship from The National Osteoporosis Society [grant number: NOS-2007-10]. The funders had no role in the design, execution, analysis, interpretation of data, or writing of the study.

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i. SCIENTIFIC SUMMARY

Background: Falls are an issue disproportionately affecting older people who are at increased risk of both falls and injury. This pilot study investigates shock-absorbing flooring for fall-related injuries in wards for older people.
Objectives: To inform future research by: evaluating fall-related injuries on the intervention and existing flooring; assessing the sustainability of the flooring in ward environments; estimating the cost-effectiveness of the floor; and assessing how the floor affects patients and other users.
Design: This pilot study utilises mixed methods: a pilot cluster randomised controlled trial; observation via mechanical testing; and interviews. Eight participating wards (clusters) were randomised using a computer generated list. No blinding is incorporated into the study. Each site allocated one (4-8 bed) bay as the 'Study Area'. Sites had a baseline period of two to five months. Then, four sites received the intervention floor, whilst four continued using standard floors. Sites were then followed up for approximately one year.
Participants: Any person admitted to a bed in the Study Area of a participating ward could be entered into the trial. Orientated patients, visitors, and any hospital staff who use the floor in a Study Area were eligible for inclusion in an interview.
Intervention: An 8.3mm thick vinyl floor covering with PVC foam backing (Tarkett Omnisports EXCEL).
Outcomes: The primary outcome is fall-related injuries. Severity of injuries, falls, cost-effectiveness, user views, and mechanical performance (shock absorbency and slip resistance) were also assessed.
Results: As this is a pilot study the results are indicative and we are not claiming statistical significance (note the confidence intervals). The findings indicate that the flooring may help reduce fall-related injuries (there were no moderate-major injuries in the intervention group but 6 in the control group, and the overall incident rate ratio for any injury was 0.46 (95% CI = 0.11 to 1.97); however there is a risk that the flooring may also increase falls (IRR = 1.33, 95% CI = 0.44 to 4.03). It is unclear as to whether the observation of increased falls is due to chance (random error), potential performance or detection bias (systematic error), an inherent property of the floor itself (adverse effect). Staff using the intervention floor raised concerns about pushing wheeled equipment, and one pulled back was documented but which did not require medical attention. The mechanical testing undertaken on the floors in the study indicated that there was no deterioration over time, and although more shock-absorbent, the intervention floor was no more slippery than the control floors (and slightly less slippery when wet). The cost-effectiveness of the floor hinges on whether or not it increases the falls risk; should the risk of falling remain the same, then the estimated injuries avoided would be very likely to lead to the flooring representing a dominant economic strategy (that is, it would be cost saving and would lead to health-related quality of life benefits). However should the flooring increase the risk of falls (even if the risk of injuries are reduced) the morbidity and mortality associated with falling would lead to health-related quality of life losses (and therefore would not be a viable option). Interviews with staff provided some impetus for assuming that performance bias has an influence on the study findings, and highlighted concerns about manoeuvring wheeled equipment on the intervention flooring. Patients were generally positive or neutral about the floor (in intervention and control sites).
Conclusions: Future research should seek a floor with better 'push/pull' properties, consider ways to further minimise risk of bias, and determine the risk of increased falls. It is estimated that a future trial will need approximately 10 - 12 sites (each with 2 bays) in each arm, followed up for 2 years.

ii. LAY SUMMARY

Falls in hospital are a major problem, especially for older people who are more at risk of injury. This study explored whether a 'shock-absorbing' floor (normally used in sports halls) might be useful for reducing injuries from falls in elderly care wards. This was a small study which aimed to inform future research in this area of health care. Eight hospital wards took part across the United Kingdom. Each ward chose one bay area to be part of the study. Any patient admitted to that bay could take part. Four bays were randomly assigned to receive the new floor, and four bays kept their old floor. We measured the falls and injuries of patients who were enrolled into the study, took measurements of how slippery and shock-absorbent the floors were over time, asked people who were using the study bays what they thought about it, and estimated how cost-effective the new flooring might be. We found that whilst the new floor may reduce injuries, it may also increase falls. These findings are simply an estimate of what we may find if we were to do a much bigger study. There may be many ways to explain our findings: 1) our estimates may be wrong, because this study is small we cannot be too confident in our conclusions; 2) it is possible healthcare staff were behaving slightly differently in hospitals that had the new floor, for example: patients who were more likely to fall may have been put in to the study bay to a greater extent at sites with the new floor; or staff may have been better at reporting falls at sites with the new floor; 3) it is possible that something about the floor (perhaps because it is softer to walk on) makes it more likely for a someone to fall. We did not find any important difference in slipperiness between the new flooring and old floors (the new floor was slightly less slippery when wet), however the new flooring was more shock-absorbent. If the new flooring does make it more likely for someone to fall, then it will not be appropriate for hospitals to use. If the flooring does not increase the number of falls, then it will be cost-effective for hospitals based on our estimate of the number of injuries it may save. Although many hospital staff thought the floor may help patient safety, they did not like the fact that it was harder to push equipment across it; one staff member reported that they had pulled their back on the floor (although they did not require medical attention). Whichever type of floor they had, patients were mostly positive or neutral towards it. Future research should: seek a shock-absorbing floor which is easier for staff to push wheeled equipment across; try to find ways to reduce the risk of staff behaving differently across study groups; and explore whether shock-absorbing flooring increases the chances of falling. If a major study was carried out, we estimate that it will need to have about 10-12 wards in each control and intervention group (20-24 in total), each ward should have two bays as part of the study, and these will need to be followed up for about 2 years. We hope a major study of this size will be able to confirm whether or not a shock-absorbing flooring is beneficial.

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1. SECTION 1: STUDY CONTEXT

1.1 Background

Despite the large quantity of work carried out on falls prevention,[1] falling in hospital remains a significant problem,[2] and one of international concern.[3] This issue is set to become increasingly prominent given that older people are most at risk of falling and this population is growing.[4] There is an age-related increased risk of sustaining an injury from a fall,[4,5] and older people additionally have an increased risk of falling due to a number of age-related risk factors.[6] Approximately 30% of patient falls result in an injury,[2,7] creating a substantial financial burden on healthcare resources in terms of costs of continued and additional care and litigation.[8-10] As efforts continue to research the effectiveness of falls prevention strategies,[11] an additional area of research focuses on strategies that prevent injuries from falls, since the occurrence of some falls is inevitable.

A systematic review has assessed the use of hip protectors with older people living in the community or in institutional care as one potential method for reducing hip fractures from falls.[12] The review reveals that compliance with this intervention is poor due to discomfort and practicality, and the effectiveness of hip protectors looks doubtful in light of the current evidence. The environment requires no compliance on the part of the patient, thus we want to study the environment as an intervention for reducing injuries from falls.

Modifying the hospital environment to promote patient safety is currently high on the agenda,[13] and it is generally acknowledged that putting careful thought into the design and planning of hospital environments could be highly beneficial in terms of reducing long-term running costs and improving patient outcomes.[14] Falls most often result in a person landing on the ground, therefore flooring as an intervention for injury prevention is a logical step to research. Given the weight of importance applied to flooring requirements in children's play areas (e.g. British Standard BS EN 1177) it is surprising that such little attention has been paid to the shock-absorbing qualities of flooring in healthcare settings.

A number of studies in the UK, Canada, and the USA, have assessed the various shock-absorbing properties of flooring types using mechanical testing techniques to simulate falls.[15-20] However, laboratory-based falls simulators provide only a simple approximation of how a person may fall from a stationary position,[16] and they do not account for how easy the flooring is to walk on and use in a real-world setting. Although testing rigs can evaluate the dampening effect on impact forces of various floor types, injuries are also dependent on the fall dynamics and bone strength of the faller,[21] which are aspects that only field studies can truly capture; the degree to which laboratory test results reflect the effectiveness of "real world" application is questionable.[22]

Some field studies have been conducted on broadly categorised flooring types (such as carpet vs. vinyl),[22-23] but the findings are largely inconclusive due to weak study designs and lack of specificity in describing the types of floors assessed. There is a justifiable need for a prospective study that will provide important and relevant evidence to the international research and health community. One unpublished single-centre controlled before-and-after study has been conducted in Northumberland, UK of 2mm non-slip vinyl with 4mm thick 'Altro Everlay B' underlay as compared to carpet.[24] Although this study is small in size, and the control areas are not directly comparable to the intervention area, it has addressed some of the methodological issues posed by previous research, through conducting a prospective intervention study in a clinical setting. A more rigorous research methodology is necessary for studies of this nature if valid conclusions are to be drawn. In terms of a "gold standard" methodology, a cluster randomised controlled trial would be the most rigorous approach to take in this field; since this has never been done, a pilot study was

justified. A 'cluster' randomised trial is required because it is not feasible to administer 'the floor' as an intervention at the individual patient-level in a hospital environment with multi-bedded bays; but 'the floor' can be administered to a group (or cluster) of people.

In this study we want to gauge the effectiveness of using shock-absorbing flooring against existing regular flooring in reducing injuries from falls and to ascertain the required information for a power calculation. Tarkett Omnisport EXCEL has undergone materials testing to demonstrate its qualities as shock-absorbent, with comparable slip properties to that of regular vinyl floors found in hospitals. The flooring is composed of 20 – 25% recycled materials, and is recyclable. The flooring also meets the technical requirements for NHS floors from an infection control perspective.

1.2 Objectives

The overall aims of the proposed research are to inform a power calculation for future research, and assess the appropriateness of the flooring in terms of sustainability, cost-effectiveness, and user views. This will be achieved by meeting the following specific objectives:

1) To evaluate the difference in the fall-related injury rate (per patient bed-days) between the intervention flooring and existing flooring.
2) To periodically assess the sustainability of the flooring types, recording surface irregularities, slip-resistant and shock-absorbent properties.
3) To estimate the cost-effectiveness of the intervention flooring.
4) To assess the views of staff, patients, and visitors who use the flooring.

1.3 Study design

The first objective is addressed using a cluster randomised controlled trial design. The second objective is addressed utilising standardised observation techniques with repeated measures. The third objective is addressed through an economic evaluation of data obtained from the first two objectives. The fourth objective is addressed through qualitative interviews with patients, visitors, and staff. The approach to meeting each objective is detailed in the associated Sections of this report. Figure 1.1 (pg 12) provides an overall view of the structure of The HIP-HOP Flooring Study.

1.4 Ethical Considerations

1.4.1 Ethical approval

Approval for this multi-centre study was obtained from the Southampton & South West Hampshire NHS Research Ethics Committee (A), which has been flagged to deal with applications falling within the scope of the Mental Capacity Act.

1.4.2 Informed consent

For this pilot study, patients (or their consultee) received an information sheet explaining the study. Should the patient be unable to consent then their consultee was approached for advice. Our procedure was in accordance with the Mental Capacity Act 2005 Code of Practice. Participation was purely voluntary and non-participation did not affect the patients' healthcare treatment in any way. Patients (and consultees) were free to withdraw from the study at any time. A separate informed consent procedure took place for all individuals willing to be interviewed about their views on the flooring.

1.4.3 Data Management and confidentiality

All data was kept in a locked cabinet in the research team's office and electronically in a secure password-protected file. Patient confidentiality was maintained by ensuring that no individual is

identifiable from the data reported in the final analysis. This has been monitored by the Steering Committee.

1.5 Study Management and Monitoring

A Steering Committee was established with a wide range of expertise, reflecting the interdisciplinary nature of the study. This group met approximately every four months (nine times between November 2008 and October 2011) to monitor the progress of the study, ensure adherence to the research protocol and to oversee the publication of any reports or papers generated from the study. Additionally, although a change in the flooring represents a very low risk to patients, there was the possibility that the change may temporarily affect the rate of hospital-acquired infections (which have been shown to increase during periods of reconstruction).[14] With this in mind, pre- and post-intervention data on all reported hospital-acquired infections were sought. During the study (and as part of the third objective), any surface breakages or irregularities such as grooving were monitored by ward staff and any need for maintenance was recorded. The study investigators and flooring companies were to be informed and appropriate action taken to mend any fault arising. All sites were provided with Adverse Event Forms on which they could document and relay any problems arising which may have been related to the floor.

Service users were represented on the Steering Committee, as well as key figures within the NHS and academics with specialist expertise. The Steering Committee consisted of the following members, including patient and public representatives:

- Nigel Caldwell (Centre of Research in Purchasing and Supply - CRiSPS, University of Bath)
- Prof. Taraneh Dean (Head of Centre for Research and Knowledge Transfer, University of Portsmouth)
- Prof. Simon Dixon (Health Economist, University of Sheffield)
- Amy Drahota (Research Fellow in Healthcare Environments, University of Portsmouth)
- Diane Gal (Former Steering Committee member, University of Portsmouth) Public Health Research Consultant
- Kate Greenwood (R&D Manager, Portsmouth Hospitals NHS Trust)
- Kevin Hallas (Pedestrian Safety Specialist, Health & Safety Laboratory)
- Frances Healey (Joint Head of Clinical Review and Response, National Patient Safety Agency)
- Bernie Higgins (Medical Statistician, University of Portsmouth)
- Nick Latimer (Senior Lecturer in Health Economics, University of Sheffield)
- Heather Mackenzie (Former Steering Committee member, Research Associate, University of Portsmouth);
- Jonathan Millman (Head of Knowledge and Information, Estates and Facilities Division, DoH);
- Prof. Julian Minns (Consultant Clinical Scientist, formerly Newcastle General Hospital)
- Prof. Martin Severs (Associate Dean [Clinical Practice], University of Portsmouth)
- Dia Soilemezi (Research Associate, University of Portsmouth)
- Steve Thorpe (Principal Scientist at the Health & Safety Laboratory; Chair of the United Kingdom Slip Resistance Group)
- Julie Udell (PhD student, University of Portsmouth)
- Derek Ward (Research Fellow, University of Portsmouth)
- Keith White (member of Engage, a service user research advisory group)
- Julie Windsor (Clinical Nurse Specialist Falls Prevention, Nursing Directorate, Portsmouth Hospitals NHS Trust)
- Patricia Young (formerly design specialist National Patient Safety Agency, now at DNV [Det Norske Veritas]).

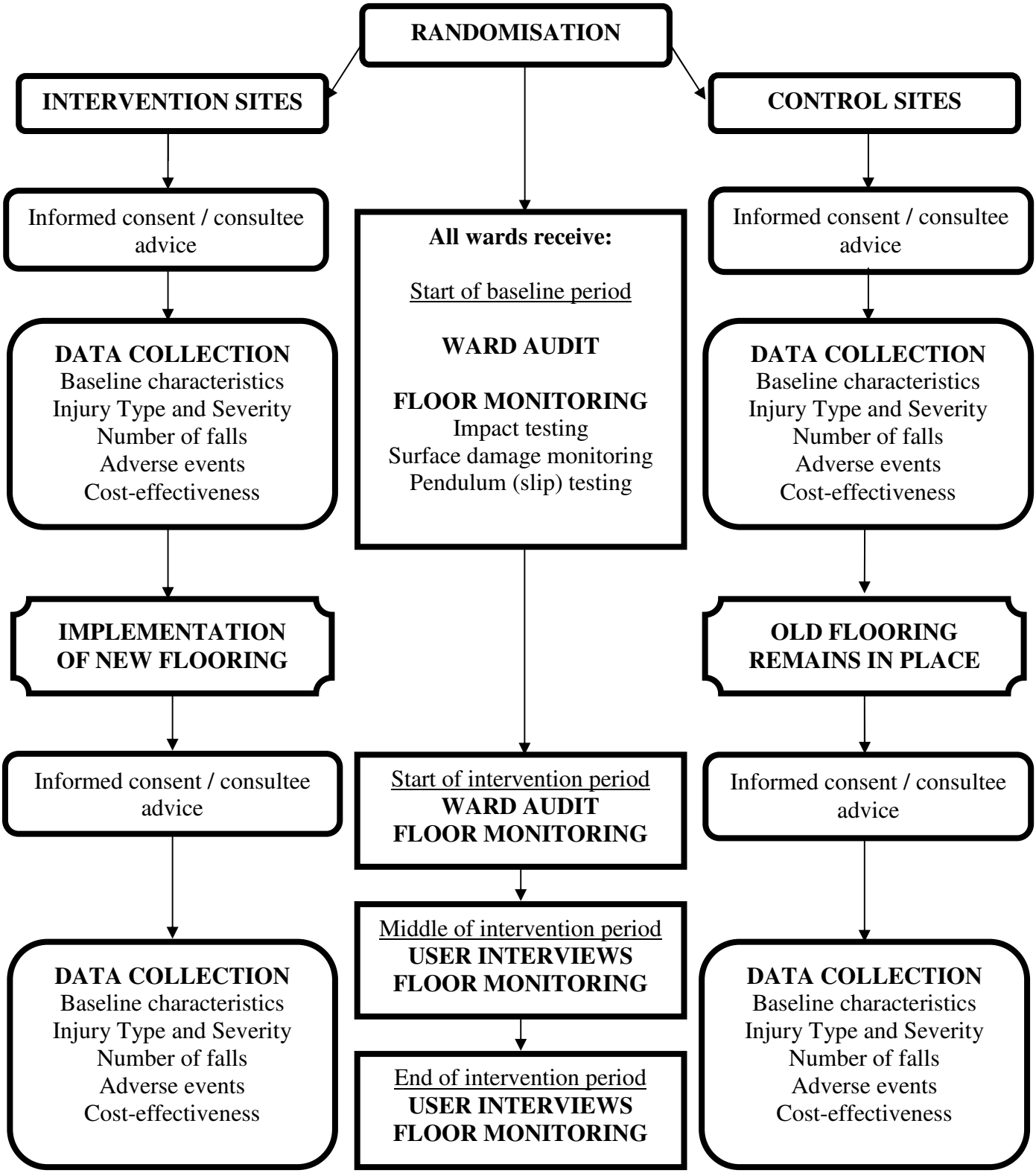

Figure 1.1: Study design

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2. SECTION 2: CONTEXTUAL INFORMATION ABOUT THE STUDY SITES

2.1 Introduction

There are a number of tools already available for environmental auditing of healthcare facilities, although in the field of environments for older people (particularly dementia and Alzheimer's care), the majority of these are geared towards nursing home environments and American-style Special Care Units. These tools include protocols for rating environmental aspects such as lighting, flooring, handrails, privacy and access. Barnes provides a comprehensive critique of some of the tools developed for assessing care environments for older people,[1] including: the Multiphasic Environmental Assessment Procedure (MEAP)[2]; the Professional Environmental Assessment Protocol (PEAP)[3]; the Therapeutic Environmental Screening Scale (TESS)[4]; and the Environment-Behaviour (E-B) Model.[5] The TESS has undergone some development,[6] and is now marketed as TESS-NH to include the Special Care Unit Environmental Quality Scale (SCUEQS).[7] The Sheffield Care Environment Assessment Matrix (SCEAM)[8] has been developed for UK care environments for older people however this too focuses on residential care as opposed to acute care settings.

There has been some development of hospital environmental assessment tools in the UK to include AEDET evolution (Achieving Excellence in Design Evaluation Toolkit) with the addition of ASPECT (A Staff and Patient Environment Calibration Tool).[9] However these were deemed to be unsuitable for the present study as they have been designed for use during general hospital renovations and new builds and scoring involves consensus ratings obtained through workshops with stakeholders. Additionally they take a more generic focus with little to no emphasis on older people and falls specific considerations.

Due to the lack of tools currently available for acute care settings for older people, we developed our environmental audit based on tools and techniques already available, with added items to include falls- and injury-specific environmental factors that are highlighted as issues in much of the falls prevention guidance.[10]

2.2 Methods

In accordance with the study protocol, we conducted site audits at two points during the study period to gain an understanding of the characteristics of the hospitals, wards and bays included in the study. The first ward audits were completed at the beginning of the study baseline period (between May 2010 and July 2010). As many of the aspects included in the audit had the potential to change over the study duration, the audit was repeated during the early part of the intervention phase of the study (after the new floors had been installed at intervention sites) between September 2010 and October 2010. We liaised with staff at the study sites to try to ensure we were informed of any changes to ward policy or procedures. Each included site (N=8) therefore underwent two extensive audits. Audits included the collation of data on environment, staffing levels, and policies and practices. The audit tool was in the form of a checklist (see Appendix 1).

2.2.1 Number and timing of audits

One control site received a third audit as the number of beds reduced during the intervention period and the function of the ward also changed. This audit took place in August 2011.

2.2.2 Time of Audits

During the first round of audits, five site audits commenced in the morning (two intervention sites and three control sites), with the remaining three audits taking place in the afternoon (two intervention sites and one control site). During the second round of audits, four audits began in the morning (one intervention site and three control sites), and four audits took place in the afternoon (three intervention sites and one control site).

2.3 Ward Level Information

Table 2.1 provides background information on the location of the hospital, the site of the ward within the hospital, the approximate age of the hospital building, and recent ward refurbishment history.

Table 2.1 Hospital and ward characteristics.

Location	Location of Hospital	Type of building ward located in	Floor ward located on	Approximate dates in which building was constructed	Approximated date of last ward refurbishment
Intervention Sites					
A	Suburban	Single Storey	Ground	1951-2000	2005
B	Suburban	Multi-Storey	Second	1951-2000	Within last 5 years
C	Suburban	Two-Storey	First	2001-present	2005
D	Urban	Multi-Storey	Second	1951-2000	2010 (repainted)
Control Sites					
E	Suburban	Multi-Storey	Second	1951-2000	2005
F	Suburban	Multi-Storey	Sixth	1951-2000	2009 (partial)
G	Urban/Suburban	Multi-Storey	Second	1951-2000	Unknown
H	Suburban	Multi-Storey	First	2001-present	2005 full refurbishment

The study groups were similar with regard to hospital characteristics particularly in respect to date of construction and location. However control sites were more likely to be multi-storey buildings.
The exact refurbishment history was unclear in many of the study sites with approximate dates being provided and similarly, information relating to the nature of the refurbishment being only partial.

Table 2.2 Ward Classification and Periods of Bay Closure.

Location	Baseline Type of Ward	Intervention Type of Ward	Date of any Change	Known Bay Closures during Study Period (other than when floor installed)
Intervention Sites				
A	Elderly general rehabilitation	Elderly general rehabilitation (with sub-acute care)	March 2011 (Intervention Period)	Approximately two weeks, Norovirus Infection
B	Elderly general rehabilitation.	No change	N/A	None reported
C	Elderly general rehabilitation	No change	N/A	None reported
D	General care of the elderly ward	Care of the elderly - fractured neck of femur	June 2011 (Intervention Period)	Between 29/5/11 until 13/06/11 there was a period of transition as the ward changed patient profile. No recruitment took place
Control Sites				
E	Medical Ward (Predominately elderly)	No change to type of ward although Consultant team changed	Intervention Period	None reported
F	Acute elderly care ward - mixed rehab/mental health	No change to type of ward but bay changed from female to male patients.	April 2011 (Intervention Period)	None reported
G	Elderly Medicine Older People - General Rehabilitation	No change	N/A	None reported
H	Stroke & Care of the Elderly	Stroke	April 2011 (Intervention Period)	April 2011: 1 week closure due to diarrhoea and vomiting outbreak. June 2011: 1 week due to diarrhoea and vomiting outbreak. July 2011: 3 weeks for construction work

Table 2.2 highlights the extent of reported change, with only two intervention sites and one control site not being subject to any reported major changes or ward closures over the study period.

Two intervention sites reported a change in the profile of the patients admitted to the study bay during the study. One site was originally defined as a 'General Care of the Elderly' ward but during the intervention period (June 2011) became a 'Care of the Elderly Fractured Neck of Femur' ward. This site did not recruit to the study for an approximate two week period whilst the ward changed. A further intervention site also reported that during the intervention period, the profile of the patient group changed slightly as they begun to take more 'sub-acute care elderly patients' rather than just 'elderly general rehabilitation'. This site also had a period of non-recruitment during the intervention period when it was closed for approximately two weeks due to an infectious outbreak

Two of the control sites' patient groups remained constant throughout the study period and did not report any periods where the ward or bay were closed. One control site changed from being a 'Stroke and Care of the Elderly ward to a 'Stroke' ward during the intervention period (April 2011). This site also reported three closure periods totalling approximately five weeks during the intervention period due to infection outbreaks and construction work. The remaining control site changed from admitting female's to the bay to a male admission bay.

2.3.1 Ward Maps

Maps of the study ward layouts were obtained from Hospital Estates and Facilities departments and the study bay was highlighted on them (Appendix 2). NB. These maps additionally mark where participant falls occurred during the study period (see Section 3 of this report).

2.3.2 Ward Facilities

Table 2.3 details the ward facilities at each of the study sites throughout the trial period. Overall, there appears little difference in the type and level of facility between the control and intervention sites throughout the duration of the study. One control and intervention site had access to a bathroom directly from the study area. All others had separate bathrooms and toilets.

Intervention sites were more likely to have access to separate administration offices but fewer had access to a cleaners store based within the ward. Control site H had a minor change in facilities during the study period due to a change in the patient group admitted. This change resulted in a reduction in the number of beds within the bay thereby proving more space for the addition of a dining table and chairs within the bay plus the change of use of some rooms. The ward facilities for the remaining sites remained constant over the duration of the trial.

Table 2.3. Ward facilities

	Intervention sites				Control sites			
Facility	**A**	**B**	**C**	**D**	**E**	**F**	**G**	**H**
Separate Day Room	✗	✓	✓	✗	✗	✓	✓	✗
Dining Room	✓ *	✗	✗	✗	✗	✗	✗	✱ *^
Therapy Room	✓ +	✓ $	✗	✗	✗	✗	✓ +	✱ ^
Separate Bathrooms	✓	✓	✓	✓ ~	✓	✓ ~	✓	✓
Clinical Treatment Room	✓	✗	✓	✓	✓	✓	✗	✱ ^
Clinical Equipment Store	✓	✓	✓	✓	✓	✓	✓	✓
Clinical Staff Station	✓	✓	✓	✓	✓	✓	✓	✓
Senior Staff Office	✓	✓	✓	✓	✓	✓	✓	✓
Administration Office	✓	✓	✓	○	✗	✗	✗	✱ #
Cleaners Store	✗	✓	✓	✗	✓	✓	✓	✓
Relatives Room	✓	✗	✓	✓	✗	✓	✗	✓
Kitchen	✓	✓	✓	✓	○	✓	✓	✓
Outside area	✓	✗	✗	✗	✗	✗	✗	✗

✓ = Yes ✗ = No ✱ = change ○ = shared with others
*Dining area within bay ^ present on last visit + for physiotherapy $ OT kitchen
~ Plus en-suite # absent on last visit

2.3.3 Ward Bed Capacity

Table 2.4 provides details of the bed capacity for each of the wards. These remained static across the trial period except for control site H whose bed numbers were reduced from 28 to 20 as the ward altered its patient profile.

Table 2.4 Bed capacity

Site	Baseline Period	Intervention Period
Intervention sites		
A	26	26
B	29	29
C	30	30
D	25	25
Control sites		
E	26	26
F	30	30
G	25	25
H	28	28 (reduced to 20)

All sites had a variety of bedroom configurations, comprising single occupancy rooms to multi-occupancy bays. Table 2.5 illustrates these configurations.

Table 2.5 Bed numbers and room configuration

Site	Bed Numbers and Room Configuration	No. of bays
Intervention sites		
A	26 (3 singles; 2 doubles; 1 four-bed; 3 five-bedded bays)	9
B	29 (5 singles; 4 six-bedded bays)	9
C	30 (6 singles; 6 four-bedded bays)	12
D	25 (5 singles; 4 five-bedded bays)	9
Control sites		
E	26 beds (6 singles; 2 four-bedded; 2 six-bedded bays)	10
F	30 beds (6 singles; 4 six-bedded bays)	10
G	25 beds (1 single; 4 six-bedded bays)	5
H	28 beds (4 singles; 2 four-bed; 2 eight-bedded bays) 20 beds (4 singles; 4 four-bedded bays - from 01.04.2011)	8 8

2.4 Bay Level Information

Table 2.6 provides details of the size of the bays (Study Areas) and the number of beds per bay. The median bay size is marginally smaller for the intervention bays, 54m^2 (range=59m^2 to 42m^2) compared to control bays, 55m^2 (range=77m^2 to 50m^2). There was no change in the size of the bays between the baseline and intervention periods for any of the sites.

Table 2.6 Study bay size and number of beds

Location	Bay size (sq.m)	No. beds in bay: Baseline Period	No. beds in bay: Intervention Period
Intervention sites			
A	59	5	5
B	58	6	6
C	42	4	4
D	50	5	5
Median	**54**	**5**	**5**
Control sites			
E	55	6	6
F	50	6	6
G	55	6	6
H	77	8	8 (4)
Median	**55**	**6**	**6**
Overall Median	**55**	**6**	**6**

The median number of beds was also lower in the intervention bays, 5 (range 4 to 6) compared with 6 (range 4-8) for the control bays although the total number of beds was reduced when one control site went from eight to four beds during the intervention period. The number of beds for the intervention bays did not alter during the trial.

2.4.1 Physical characteristics of trial bays

2.4.1.1 Steps and observable dips and slopes

There were no steps within any of the study bays during the trial. The ward audits aimed to report on observable dips and slopes in the study bay area, as well as the method used to accommodate any changes in height at the transition threshold between the study bay and any external area. Table 2.7 illustrates this information; slopes and transitions were only observable in intervention sites

Table 2.7 Observable dips, slopes and transition management

Site	Observable dips, slopes and transition management	
Intervention sites	**Baseline Period**	**Intervention Period**
A	Slight 'bump' where sleeping area extends into sitting area. Slight raised 'lip' at transition between ward and corridor.	Transition between bay and corridor managed by use of gradual gradient.
B	No observable dips or slopes. No transition area.	Transition between bay and corridor managed by use of black transition strip.
C	No observable dips or slopes. No transition area.	Transition between bay and corridor managed by use of gradual gradient.
D	No observable dips or slopes. No transition area.	Transition between bay and corridor managed by use of black transitional strip. Transition between bay and ensuite bathroom managed by use of gradual gradient.

Control sites	Baseline Period	Intervention Period
E	No observable dips or slopes. No transition threshold.	No observable dips or slopes. No transition threshold.
F	No observable dips or slopes. No transition threshold.	No observable dips or slopes. No transition threshold.
G	No observable dips or slopes. No transition threshold.	No observable dips or slopes. No transition threshold.
H	No observable dips or slopes. No transition threshold.	No observable dips or slopes. No transition threshold.

2.4.1.2 Threshold Transitions

The four control sites did not have a height difference between the study bay floor and other flooring adjoining the bay. Due to the increased thickness of the intervention flooring, the intervention sites needed to manage the small height difference at thresholds and this they achieved in one of two ways. Two sites used black threshold strips. One of these sites also had a threshold into a toilet area and this was managed by a gradual gradient. The installation of a gradient into the external corridor was also adopted by two other intervention sites. Photos 1 and 2 below show the two different approaches used to accommodate the height difference at the thresholds of the intervention study bays.

Photo 1. Gradient Transition

Photo 2. Transition Strip

2.4.1.3 Sub-Floor and Floor Covering

Although we sought information regarding flooring types at the ward audits, most sites were unable to provide the necessary detail. Therefore, we referred back to the original site surveys completed by the flooring company during the initial stage of the study. The sub-floor material for seven sites was reported as being concrete, with one of the intervention sites being unsure, although believing it to be concrete. At baseline, the floor coverings varied. Three control sites had 2mm vinyl, and one 2mm thermoplastic tiles. The age of the floor coverings ranged from five years to reportedly over thirty years. The intervention sites original floor coverings were 2mm vinyl, 2mm or 2.5mm linoleum, having been laid in two sites' in 2005. The two other sites were unsure of its age. The control sites flooring remained constant throughout the study whilst the intervention sites received the new shock absorbent flooring. Table 2.8 provides details.

Table 2.8 Sub-floor material and floor covering

	Baseline Period			**Intervention Period**		
Site	**Floor covering**	**Sub-floor material**	**Age of floor**	**Floor covering**	**Sub-floor material**	**Age of floor**
Intervention sites						
A	2.5mm Linoleum	Concrete	2005	Omnisports EXCEL, 8.3mm	Concrete	2010
B	2mm Linoleum	Unknown (believed to be concrete)	Unknown	Omnisports EXCEL, 8.3mm	Unknown (believed to be concrete)	2010
C	2mm Vinyl	Concrete	2005	Omnisports EXCEL, 8.3mm	Concrete	2010
D	2mm Vinyl	Concrete	Unknown	Omnisports EXCEL, 8.3mm	Concrete	2010
Control sites						
E	2mm Vinyl	Concrete	2005	2mmVinyl	Concrete	2005
F	2mm thermoplastic tiles	Concrete	>30 years	2mm thermoplastic tiles	Concrete	>30 years
G	2mm Vinyl	Concrete	2006 (Partial re-furb')	2mm Vinyl	Concrete	2006 (Partial re-furb')
H	2mm Vinyl	Concrete	2005	2mm Vinyl	Concrete	2005

2.4.1.4 Mats

There were no mats or other removable floor coverings observed in any of the study bays throughout the trial period. Although not observed, we were made aware during the staff interviews that crash mats were in use at one of the control sites.

2.4.1.5 Physical Appearance of the Floor

During both ward audits a visual inspection of the floor was made to ascertain the general appearance. For the control sites, during the baseline period, all floors but one had noticeable 'scuff marks', with two having small indentations by the bay entrance and in-between some beds. Similar scuff marks were also observed at three of the intervention sites whilst one further floor had a small tear (30cms). One intervention site also had small indentions by the bay entrance. During the second ward audit the control sites floors again presented with a number of scuff marks and one had a tear that was temporarily repaired with 'hazard' tape.

The intervention sites second ward audit occurred after the new floor had been installed (four days, 20 days, 56 days, and 71 days after installation). For the site where the floor had been down for four days, there were no observable marks. For the site with a 20 day lapsed period, small but pronounced indentations left by the bed wheels were observable, although staff reported these disappeared after a period of time (See also Section 6) . Similarly, for the intervention site with a 56

day interval between floor installation and ward audit, indentions and scuff marks were observered, although these were more difficult to spot due to the colour/pattern of this floor. The site's where the floor had been installed the longest had some scuff marks and indentations around the bed wheels, again these were reported to lessen after a time (See Section6).

The overall appearance of the new floor was a topic that was re-visited during interviews at the intervention sites. These interviews did provided an opportunity for staff, patients and visitors to comment upon the appearance and the 'wear and tear' of the flooring. This will be commented upon in the qualitative interviews (Section 6). Similarly, comments and observations regarding cleaning of the floors are reported later in this section. In addition, there was one reported incident of damage to an intervention floor. This is reported upon in the Section 3 (Adverse Events).

2.4.1.6 Colour and Pattern of the Floor

Photos 3 to 14 below show the colour, patterns and overall appearance of the Study Area floors in both the baseline and intervention periods.

Photos 3-6. Control Bays: Floor colour and pattern for study duration (floor remained constant)

Photo 3: Site F. Floor colour and pattern

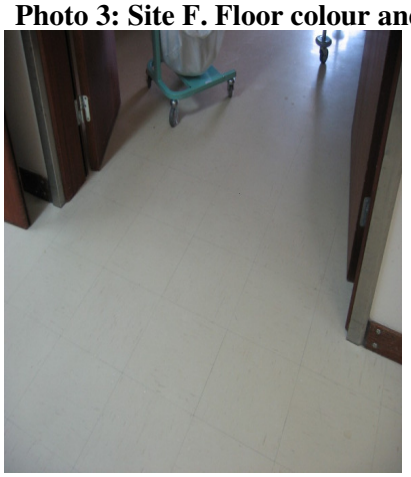


Photo 4: Site G. Floor colour and pattern

Photo 5: Site H. Floor colour and pattern

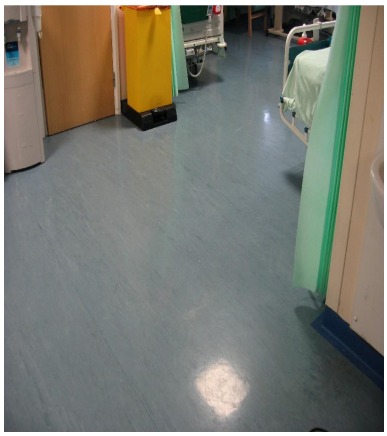


Photo 6: Site E. Floor colour and pattern

Photos 7-14. Intervention Bays: Floor colour and pattern

Photo 7: Site A. Baseline Period

Photo 8: Site A. Intervention Period

Photo 9: Site B. Baseline Period

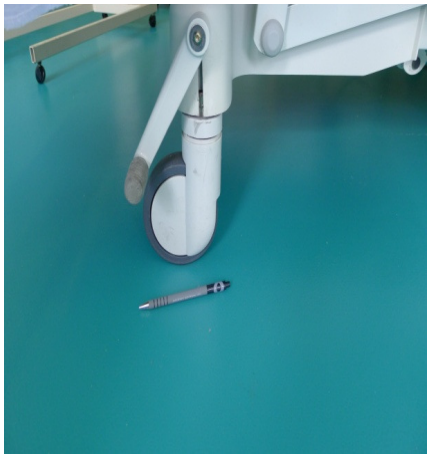
Photo 10: Site B. Intervention Period

Photo 11: Site C. Baseline Period

Photo 12: Site C. Intervention Period

Photo 13: Site D. Baseline Period

Photo 14: Site D. Intervention Period



2.4.1.7 Aspect of study bay

The intention of noting the bay aspect was to get a broad indication of the potential amount of natural light that the bay area may receive during the day and at different times of the year. The aspect for the control sites varied with one facing East, one North-West, one faced South, and the other North. For the intervention sites, two had a Westerly aspect, one South-East, and one Northern.

2.4.1.8 External and Internal Window area

We collected information on the area of external glazing of each study bay to gain an indication of the amount of natural light each bay receives. Information relating to internal glazing was also gained as this may impact upon the amount of light entering the bay. In addition, internal glazing may have a role in the observation that is possible by staff of patients within the bay. Table 2.8 provides information on the area and the overall percentage of the study bay wall area that was either externally or internally glazed.

Study Areas at control sites typically had more, and a less variable amount glazing than intervention sites. There was a wider range of externally glazed area within the intervention bays ($2.9m^2$ to $8.7m^2$, median $=5.9m^2$) when compared with the control bays ($5.0m^2$ to $6.8m^2$, median = $6.5m^2$).

With regard to internal glazing, one intervention site and one control site did not have any (the control site had a wide opening as opposed to a door). The range for the remaining intervention sites ($0.8m^2$ to $3.5m^2$) was again wider compared to ($2.3m^2$ to $3.0m^{2)}$ the remaining control sites. Overall, there was a wide range in the overall percentage of the bay wall that was glazed (intervention sites: median = 9.2%, range = 5% to 15.1%; control sites: median = 11.7%, range = 6.6% to 12.7%). The area and percentage of the bay walls that were either external or internal glazing remained constant during the study period.

Table 2.9 Area and percentage of bay walls glazed (internal & external)

Site	Area of external glazing (m^2)	% of walls that is external glazing	Area of internal glazing (m^2)	% of wall area that is internal glazing	Total area of glazing in bay (m^2)	Total % of bay wall that are glazed
Intervention sites						
A	7.5	9.3	0	0	7.5	9.3
B	2.9	3.9	0.8	1.1	3.7	5.0
C	4.3	6.2	2.1	2.9	6.4	9.1
D	8.7	10.9	3.5	4.2	12.1	15.1
Control sites						
E	6.4	9.1	2.3	3.2	8.6	12.3
F	6.8	8.8	3.0	3.9	9.8	12.7
G	6.6	8.1	2.3	2.9	8.9	11.0
H	5.0	6.6	0	0	5.0	6.6

2.4.1.9 Window coverings

A variety of window coverings were used by the study sites for both external and internal glazing. Within the control sites two sites used vertical blinds, with curtains being used by the other sites. Intervention sites used curtains, horizontal blinds and vertical blinds.

2.4.1.10 Light Levels in Bay Area (Lux readings)

At both ward audits Illuminance (Lux) levels within the bay were recorded. These levels were measured using an 'Alphatek 1336 Digital Light (Lux) Meter' (set at 2000 units), and were taken at floor level. The date and time of the readings were recorded. A Lux reading was taken at a number of positions within the bay to give a range of readings. More specifically, within each bay a reading was taken by the main external window, in the centre of the bay, the entrance to the bay and in an area that appeared to be in shadow (usually between two beds). Data in Table 2.10 provides information on the median and range of the Lux readings within each study bays.

The Chartered Institute of Building Services Engineers (CIBSE) produces a Code for Interior Lighting which gives lighting requirements for areas. For healthcare (wards) it notes that for general lighting the luminance should be 100 lux. [11] Using this as a guide, it can be observed that the median lux levels from all study bays were above this level. However, a further reference to the CIBSE Lighting Guide 2 [12] recommends that the general level of illuminance between the beds and in the central area of the ward should be a minimum average of 150 lux at floor level which was not always the case during our visits (Control sites F and H; NB. lighting levels are also dependent on aspect, time of day, and weather conditions).

Table 2.10 Lux readings.

Site	Audit Period	Approx' Time of Lux reading	Range of Lux Readings	Median Lux Reading	Natural Light	Bays Lights On/Off
A	Baseline	16:00	119-1300	260	Yes	Off
	Intervention	15:00	86-715	230	Yes	Off
B	Baseline	13:55	204-622	335	Unknown	Unknown
	Intervention	14:00	221-1116	351	Unknown	Unknown
C	Baseline	11:00	130-820	390	Unknown	Unknown
	Intervention	14:30	192-594	278	Unknown	Unknown
D	Baseline	15:55	50-243	168	Unknown	Unknown
	Intervention	11:10	43-470	238	Unknown	Unknown
E	Baseline	11:00	119-1124	392	Unknown	Unknown
	Intervention	10:15	170-343	256	Unknown	Unknown
F	Baseline	10:30	84-980	401	Yes	2 ceiling lights on
	Intervention	11.30	66-1600	127	Yes	Off
G	Baseline	16:00	78-1125	365	Unknown	Unknown
	Intervention	11:00	96-457	186	Unknown	Unknown
H	Baseline	11:10	70-305	135	Yes	Yes
	Intervention	15:00	125-133	130	Yes	Yes

2.4.1.11 Light Distribution

An attempt was made during the ward audits to assess the evenness of light distribution and the presence of dominant areas of shadow within the study bays. CIBSE Lighting Guide 2 (2007)[12] notes that ward lighting should be well diffused and free from distracting glare or harsh contrasts. Illuminance (Lux) readings, as noted previously, were taken at different locations of the study bay at floor level. Ideally, this would have been undertaken in both natural and artificial light condition but due to the clinical demands during ward audits, this was not always possible. In addition, observations for evenness and prominent shadows under natural lighting were possibly effected by the time of the audit and the weather. The wide range of Lux readings (noted in Table 2.10) at all but one of the study bays during both ward audits would suggest an unevenness of light distribution and the presence of shadows within the bay environment. One control bay (H), during the audit in the intervention period, did present a much narrower range of Lux readings, although these were comparatively low readings. It proved difficult during the ward audits to ascertain the amount of glare reflected from the bay floors and a more systematic and objective assessment of this would need to be included in the protocol of a any future study.

2.4.1.12 Number and Type of Bay Lighting.

Table 2.11 details the number and type of artificial lighting within the bays. This was mainly a mixture of ceiling mounted fluorescent lights and spotlights, and individual patient wall mounted lamps sited above or near patient beds. Whilst actual numbers of ceiling mounted light differed from bay to bay so did the dimension of the lights themselves. This study did not attempt to identify the light manufacturers or the lighting specifications of each light. The lighting configuration for the bays did not alter during the trial.

Table 2.11 Ward lighting

Site	Number and type of ceiling mounted lights	Number of wall mounted lights	No. of lights
Intervention sites			
A	3 Fluorescent; 5 Spotlight	5 Individual patient lights	13
B	3 Fluorescent; 2 Spotlight	6 Individual patient lights	11
C	2 Fluorescent	4 Individual patient lights	6
D	2 Fluorescent	5 Individual patient lights. 1 wall mounted.	8
Control sites			
E	3 Fluorescent; 2 Spotlights	6 Individual patient lights	11
F	9 Fluorescent	6 Individual patient lights	15
G	3 Fluorescent	6 Individual patient lights	9
H	4 Fluorescent; 8 Spotlights	8 Individual patient lights	20

2.4.1.13 Night-time Lighting

All study bays reportedly used an array of night-time lighting, including the use of dedicated night spotlights, dimmed main lighting, and individual lights situated above or close to the patient's beds. These bedside lamps were controllable by the patient. Recordings of night time Lux levels were not taken.

The study cannot report with any confidence the extent of light pollution at night time within the study bays. No direct observations were made and information obtained was from discussions with ward staff. It would be reasonable to suggest that due to the presence of internal windows, open doors and entrances (usually on to main corridors) and the need for patient observation, that light from outside the bays entered during the night period.

2.4.1.14 Light Sensors

There were no automatic light sensors in any of the study bays.

2.4.1.15 Bay Doors and Entrances

Entrances and doors to the study bays are described in Table 2.12. Overall, there were few differences between the number, type, construction and the opening direction apart from the opening mechanism of the door to each of the bays (one control site differed from the majority by having four entrances to the bay, one a wide open access to the bay that did not have doors and another that was a smaller open access point at the rear of the bay into an adjoining bay, again without doors). Apart from the management of the thresholds in the intervention sites once the intervention floor was installed, there were no other changes to study bay entrances or doors during the study period.

2.4.1.16 Internal Partitions and Handrails

There were no fixed, internal partitions in any of the study bays. Each site had ceiling mounted curtain tracks that provided privacy for each bed. Similarly, no fixed handrails were observed within any of the study bays.

Table 2.12. Study bay entrances and doors

Site	No. of Entrance/ Exit Doors	Type of door	Width of Entrance/ Exit (cm)	Door Material	Type of Glass in door	Direction of door opening	Opening mechanism
Intervention sites							
A	1	Double to corridor	186	Wood	Clear	Inwards	Handle
B	1	1.5 split to corridor	205	Wood	Clear	Inwards	Handle
C	1	$^{2}/_{3}$ - $^{1}/_{3}$ split to corridor	154	Wood	Clear	Inwards	Handle
D	2	1.5 split to corridor	139	Wood	Clear	Inwards	Handle
		1 to toilet	90	Wood	N/A	Inwards	Handle
Control sites							
E	1	1.5 split to corridor	136	Wood	Clear	Inwards	Handle inside, push plate outside
F	2	1.5 split to corridor	140	Wood	Clear	Inwards	Handle inside, push plate outside
		1 to toilet	80	Wood	Clear/opaque stripes	Inwards	Handle inside, push plate outside
G	1	Double to corridor	178	Wood	Clear	Inwards	Handle inside, push plate outside
H	4	1 Double (Fire exit)	150	Wood	N/A	Outwards	Push plate
		1 to store	90	Wood	N/A	Outwards	Push plate
		1 open entrance	410	N/A	N/A	N/A	N/A
		1 open access to adjacent bay	140	N/A	N/A	N/A	N/A

2.4.1.17 Study Bay Furniture

Table 2.13 details the standard hospital furniture that was present during the site audits in each of the bays. As would be expected, each bay contained the requisite number of bedside cabinets, bedside trolleys/tables and easy chairs for the number of patients accommodated.

Table 2.13 Study bay furniture

Site	Study Period	No. of beds	No. of dining chairs	No. of easy chairs	No. of tables	No. of bedside cabinets	No. of bedside trolleys/ tables	No. chest of drawers
Intervention sites								
A	Baseline	5	4	7	1	5	5	0
	Intervention	5	5	5	1	5	5	0
B	Baseline	6	8	6	0	6	6	1
	Intervention	6	0	6	1	6	6	1
C	Baseline	4	0	4	0	4	4	0
	Intervention	4	0	4	0	4	4	0
D	Baseline	5	4	5	0	5	5	0
	Intervention	5	4	5	0	5	5	0
Control sites								
E	Baseline	6	6	6	0	6	6	0
	Intervention	6	4	6	0	6	6	0
F	Baseline	6	0	6	0	6	6	0
	Intervention	6	0	6	0	6	6	0
G	Baseline	6	4	6	0	6	6	0
	Intervention	6	6	6	0	6	6	0
H	Baseline	8	0	8	0	8	8	0
	Intervention	8	0	8	0	8	8	0
	Intervention 2*	4	5	7	3	4	4	0

*****The variation on numbers seen on a third ward audit reflects the reduction of beds within the bay. The space made available from the reduction in beds was used to accommodate two dining tables, a coffee table and dining chairs.

The series of photos below are illustrative of the type of standard ward furniture observed during the ward audit visits.

Photo 15. Easy Chair

Photo 16. Bedside Table

Photo 17. Bedside Cabinet

Photo 18. Bedside Cabinet

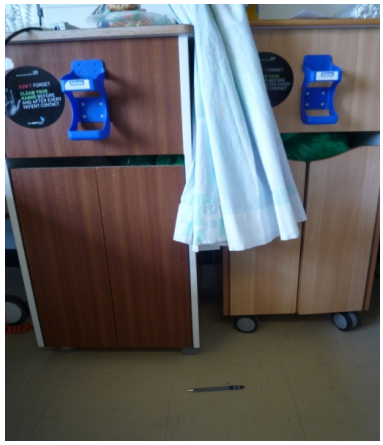


Photo 19a. Example of Beds

Photo 19b.

2.4.1.17.1 Types of Bed

All sites appeared to use a variety of beds, and the types of beds within the bays were unlikely to be constant during the study period. A member of staff from an intervention site noted:

"The most common used beds are "Static Metal Frame Beds" and "Huntleigh Enterprise 5000 and Contoura. We are also aware that Huntleigh "Hi/Low" beds are also used. All beds are moved in and out and around the hospital all the time and so there would be no way of tracking the serial numbers of the beds used". (intervention site B)

"Unfortunately the beds change all the time, they change with patients, they change because of flow type mattresses etc, they move different departments and wards regularly. I can write each code for each bed in the HIPHOP bay, but there is certainly no guarantee that the beds are the same now as they were at the beginning, in fact they won't be. They will have changed over the 18 months. Our beds are usually Contouras 880/560/460/480 and Bariatric 1080". (control site E)

Table 2.14 details the beds that were reported by the sites as used within the study bays.

Table 2.14 Type of beds in study bays

Site	Example types of bed
Intervention sites	
A	Hilrom; Pegasus; SIDHIL; Nesbit Evans and Co Ltd; Primo; ArjoHuntleigh.
B	Huntleigh Contoura
C	ArjoHuntleigh; Huntleigh Enterprise 5000; Huntleigh Nesbitt Evans.
D	Huntleigh Contoura 880.
Control sites	
E	Huntleigh Contoura.
F	Huntleigh Contoura 480; Liftcare Bed Company Protean.
G	Huntleigh HealthCare Contoura 460/480.
H	SIDHIL.

The following photos depict some examples of the beds used within the study bays.

Photo 20. Huntleigh Enterprise 5000

Photo 21. Huntleigh Contoura 460

Photo 22. Huntleigh Hi/Low

Photo 23. Contoura 1080 Bariatric

Photo 24. Liftcare Bed Company Protean

Photo 25. SIDHIL

2.4.1.17.2 Other types of furniture and equipment
In addition to the above information, other items of furniture or equipment that were routinely used within the study bay location were recorded during the site audit.

Mobile Hoists. Mobile hoists were not seen to be routinely stored in any of the bay areas although they were observed in use in one of the control bays during the ward audit. Additionally the construction work undertaken in one (control) site, was to install ceiling mounted hoists.
The photos below are types of hoist observed during Intervention bay audits.

Photo 26a. Mobile hoists

Photo 26b.

Wheelchairs: Wheelchairs were observed in several of the bays during the ward audits. However, only one intervention site reported storing wheelchairs within the bay during the study, whilst at another intervention bay wheelchair storage was noted on the second ward audit. Below are two examples of wheelchairs seen during audits of the intervention bays.

Photo 27a. Wheelchairs observed during audit

Photo 27b.

Trolleys: A number of trolleys (equipment, treatment, laundry, medicine, League of Friend's Library, etc.) were observed to be in use in the study bays. Only one Intervention site was noted to store trolleys in the study bay area. Photos below are illustrative of the variety of trolleys observed and the range of wheel diameters (NB. Pens have been placed by wheels to provide perspective for the photographs; no pens were found on the floor during audits).

Photo 28a. Trolleys observed during audits

Photo 28b

Photo 28c

Photo 28d

Photo 28e

Photo 28f

Drip Stands: Drip stands were reportedly stored in one intervention bay at the first round of ward audits although not at the second audit. Similarly, for one control bay it was noted that drip stands were stored in the bay area on the second audit, but not on the first. For the remainder of the sites they were observed in use (but were deemed not to be stored in the bay area), or were secured to the wall (two control bays and one intervention bay).

Portable Screens: All the study bays had ceiling mounted curtain tracks around the beds, to ensure patient privacy. No other types of screen were noted to be stored or in use, in any of the bays on either ward audit.

Oxygen Cylinders: Oxygen cylinders were not observed to be stored in any of the study bays on either of the two audits. All study bays had wall mounted oxygen supplies.

Walking aids: A range of walking aids were observed in all the study bays during both ward audits. These included zimmer frames, wheeled zimmer frames, sticks and forearm gutter frames with wheels. Whilst there was no dedicated storage area in any of the study bays for personal walking aids, the aids were routinely stored next to the patient's bed for ease of use. The following photos show the type of walking aids observed.

Photo 29. Wheeled-Zimmer Frame

Photo 30. Forearm Gutter Frame

Photo 31. Zimmer Frame

Photo 32. Wheeled Walking Trolley

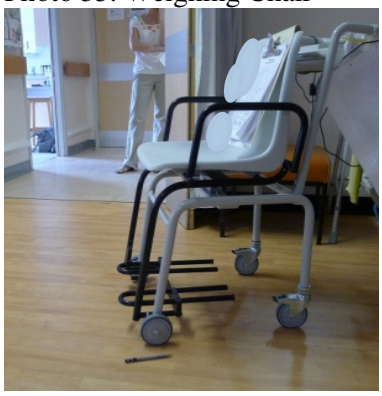
Other Equipment: A range of health care equipment was either observed or reportedly used on the bays. None of the bays had dedicated storage areas for any additional equipment although one intervention bay did have a small stacking storage system for small items. The type of equipment included footstalls, electric fans, wheeled weighing chairs, shower chairs, patient transport trolleys and portable monitors. A further piece of equipment that was reported to be used to varying degrees on the bays were rota stands. These assist transfer from one seated position to another.

Photos below show some of the health care equipment that was observed in use in the study bays during ward audits

Photo 33. Cardiac Monitor

Photo 34. Rota-stand

Photo 35. Weighing Chair



2.4.1.18 Patient Observation

None of the study bays had a nursing station located within them. During the ward audits a judgement was made as to the level of observation from the nursing station to the study bay. An assessment was made as to whether the bay entrance was in direct line of sight from the nursing station and then the number of beds that could be seen was commented upon. Finally, a measurement was taken of the distance from the bay entrance to the nursing station. Table 2.15 details these findings.

Table 2.15 Patient observation from nurses' station

Site	Direct line of sight from nursing station to bay	Approximate distance from nursing station to bay entrance (metres)
Intervention sites		
A	Yes, although not full observation of all beds.	4
B	No.	15-20
C	Yes, although not full observation of all beds.	4
D	Yes, although not full observation of all beds.	3
Control sites		
E	Yes.	1.5
F	Yes, although not full observation of all beds.	2
G	Yes, although not full observation of all beds.	3
H	Yes.	2

The entrance of the study bay could be seen from the nursing station in all the control sites and for all the intervention sites except one, where the nursing station was located some distance away. However, in those bays where the entrance was in direct line of sight, only two control sites had full observation of all the beds, the remaining bays (both control and intervention) had only partial observation of the beds. This situation did not alter pre and post intervention audits.

2.4.1.19 Floor Cleaning Regimes

As part of the ward audit process, all sites were asked to provide information on the cleaning regimes used in the study bays. Prior to receiving the new intervention flooring, the manufacturers cleaning recommendations for the intervention floor were provided to the intervention study sites (see Appendix 3).

The information obtained regarding ward cleaning regimes is incomplete and as such is difficult to comment upon. Some sites provided detailed NHS Estates and Facilities Cleaning Manuals but we were unable to obtain detailed ward based information. For others, the converse applied, with ward based information being made available but not the wider Trust policy. It has also proven difficult to ascertain if cleaning regimes altered between the baseline and intervention periods as the amount and level of detail of information relating to cleaning practice obtained at each audit was largely dependent on opportunistic discussion with ward cleaning staff. What is also unclear is the extent to which the intervention sites amended (or not) their regular cleaning regimes in accordance with the guidance provided by the manufacturers of the intervention floor (see also Section 6).

Staff, patients and visitors views on the apparent cleanliness and the cleaning process of the study bay floors were part of the qualitative interviews and summary information from these are reported below. In addition, comments received from the Health and Safety Laboratory, gained by them when testing the various floors' slipperiness are also noted. Table 2.16 provides a summary of information received relating to cleaning regimes.

Table 2.16 Ward cleaning regimes

Site	Information obtained	Additional Information
Intervention Sites		
A	NHS Cleaning Manual: • Damp-mopping (single bucket, single solution) using chlorine-based disinfectant cleaning product. • Damp-mopping (single bucket, single solution) using conventional cleaning product. • Damp-mopping (double bucket, double solution) using chlorine-based disinfectant cleaning product. • Spot-mopping using conventional cleaning product. • Flat-mopping using chlorine-based disinfectant cleaning product. • Spray cleaning using high speed rotary machine. • Ultra high-speed buffing and burnishing. • Floor scrubbing using standard speed rotary machine. • Floor-scrubbing using an automatic scrubber-dryer. • Cleaning with pressurised steam – routine cleaning. • Cleaning with pressurised steam – deep clean of equipment. • Deep-cleaning initiatives.	No change in cleaning regime between baseline and intervention period reported at second site audit.

B	Operational Cleaning Manual: • Cleaning schedules • Work schedules • Management of mops	Cleaning regime reportedly changed between baseline and intervention periods. The changes appear to refer to a cessation of 'buffing' the floor and in the type and timing of wet and dry mopping. In addition a comment was noted that the cleaning product changed from 'detergent' to 'pine floor gel'.
C	Daily Cleaning Task: • Equipment and materials required • Method	No apparent change in cleaning regime between baseline and intervention period. Materials reportedly used included Hospec and Actichlor.
D	• Domestic Daily Cleaning Schedule • Ward Compliance Assessment for Clostridium Difficile Infection Standard	No apparent change in cleaning regime between study periods reported.
Control Site		
E	Directorate of Facilities Management Cleaning Manual: • Management of the Domestic services. • Infection Control. • Health and Safety. • Definition of Cleaning Standards. • Work Planning. • Ward Cleaning Standards. • Technical Methods Statement. • Measuring and Reporting.	No apparent change in cleaning regimes. Products reportedly use include Chlorclean, Brial Top and Flash.
F	Cleaning and Environmental Strategy (2009). The prevention and control of infections. Care quality commission Inspection Report (2010). Domestic Assistants Work Schedules. A Systematic Approach to Cleaning.	No apparent change in cleaning regimes. Products reportedly used include Chlorclean and Actichlor.
G	Patient Services Cleaning Duties- Clinical Ward/Departments: Daily duties. Weekly duties. Monthly duties Three monthly duties Six monthly duties.	No apparent change in cleaning regimes. Products reportedly used include Actichlor, Sani 100 and Sprint 200 NC.
H	No documentation received	Unable to comment

2.4.1.19.1 Respondents Comments

During site audits and interviews with patients, staff and visitors, comments were received regarding cleaning and the bay floors. These comments were received from both intervention and control sites. Whilst it is not appropriate to attribute definitive meaning to these comments they do

begin to provide an example of staff, patient and visitor perceptions of the floor's cleanliness and views on its cleaning.

A comment received from a member of staff at an intervention site highlighted the perception that visitors and patients may look at the floor and assume that if it has a 'shine' it will be an indicator that it is clean:

"It never really looks clean because it's sort of a matt finish so we can't get a shine on it and I'm not really concerned about that. I think a lot of people who are looking at floors in hospitals, visitors for instance, patients, they look at the floor and they think if it's got a shine on it it's cleaner. I don't take that view but I think that's how it seems but it never looks, when it's been cleaned it looks worse sometimes because….it just doesn't produce a good effect, but I don't think that has any bearing on how effective it is". (Intervention site D).

A further comment was made from another intervention site staff member, noting:

"*I'm a cleaner, I can say it, I think it looks dirty, worse than other rooms because as I say before when I sweep the dust is everywhere again, I don't know, and I sweep again and clean with dry mop and again, I don't know why". (Intervention site D)*

Comments were also made regarding the intervention floors surface finish (hammer blow effect) and whether this may create cleaning problems. One respondent noted for example:

"it must be harder for the cleaners to do, I've noticed as well, so it must be harder to keep clean with it being bobbled you know, hygiene-wise" (Intervention site D).

When followed up the respondent stated that it was an opinion and cleaning staff had not reported this. A similar comment from the same intervention site also noted that:

"I think it must be dirty with it being bevelled I think it must be harder to clean as well" (Intervention site D).

However, a staff respondent from another intervention site noted:

"I wouldn't say there's you know not really any difference with regards to cleanliness" (Intervention site C).

A further comment received from a staff member at an intervention site also offers a view on the perceived cleanliness of the intervention flooring:

"Well it doesn't matter how many times you mopped it (old floor), it never looked clean and fresh, but with this one once it's mopped it looks quite, still as new as it was when it first went down, in my opinion anyway" (Intervention site B) .

Additional comments about how the floor 'looked' were also received. For example:

"….for some reason it seems to collect the dust more and I don't know whether that's because it's a plain blue floor and the normal floor is patterned so you don't notice it as much, but it seems to take, I have to go over it two or three times because there's dust, you know fluff over it so it takes me a bit longer" (Intervention site C).

"Yeah, as I say, it gets dustier but once it's, it's easier to mop I think, I don't have a problem" (Intervention site C).

Respondents from the intervention sites also noted other perceived attributes of the floor. These included that they felt it 'dried' quicker:

"Yeah, the new floor dry really quick because what we like to do, because….when they're busy, we want the floor quickly to dry, this floor yeah, I think is quick dry, easy to clean as well" (Intervention site D).

And:

"…a lot easier to mop than the other floors, as I say any marks on it you just go over with the mop and it comes off" (Intervention site B).

We also received comments indicating that the staff, patients and visitors at the control sites also had differing perceptions on how the floor looked and views on its ease of cleaning:

"The floor surface is very difficult to keep clean and get a lot of marks off, there's a lot of ingrained marks within the floor surface, um, and despite the cleaning of it, it never looks completely clean" (Control site F).

"this place is like one big bedroom so every day there's fluff and dust, patients can't be get up so there's always stuff on the floor, you know, you can go clean somewhere up come back an hour later and they'll be bits all over the floor" (Control site E).

"Well, I mean it's quite old now so it, even when its clean, there are times when it, if it's got scuff marks and things on it, it looks dirty but it's not dirty if, do you see what I mean" (Control site E).

Within the interviews there are examples of how the cleaning process itself may have an effect on a floors functioning and appearance. An intervention site respondent commented upon the impact of not adhering to the prescribed regime with regard to perceptions as to how 'slippy' the floor surface felt:

"I think that was more down to the cleaning product that was used, I think we had some bank domestics on the ward and they had used something on it which did make it very, very slippy, this was must have been about two/three weeks ago and I had actually called the domestic supervisor and get somebody up to re-clean it, but otherwise, you know, that's the only occasion, I think, like I said when a bank staff used the wrong type of cleaning sort of product on it and it did make it very slippy, but otherwise that's the only time" (Intervention site C).

Similar comments were made by respondents from control sites:

"….regarding the cleaning of it, if you look at all the floors, you will see there's a film, you could actually put your finger through it….I spoke to the domestic and I said why is it like that and she said I've probably put too much chlorine tablets so obviously it's really important that they put the correct solution in….if it does go to a film it will obviously….well you could possibly slip on it. I think that's important, the solution consistency" (Control site F).

"… if the domestic staff have put too much detergent in the water then it becomes extremely slippery and if they've put excess water on the surface then it tends to just lie on the top and it makes it even worse" (Control site).

The possibility that the actual cleaning regime may have an impact on the appearance and function of the floor was also commented upon by the Health and Safety Laboratory representative who accompanied the research team during the ward audits. It was noted that at one intervention site there appeared a build up dust within the 'dimples' which suggested inadequate mopping technique. In addition, the 'weld' lines also appeared contaminated from the use of minimal cleaning solution. Guidance and advice was subsequently provided to this site.

It was also noted that the solid block colour of floor tended to show dust, which would normally be 'disguised' by the marbled appearance of most hospital vinyl flooring. Conversely, the intervention floor, when laid in solid block colour did highlight the cleanliness or otherwise of the floor in the ward. A point that was not missed by staff members from two separate intervention sites:

"I suppose with the floor being all one colour things can be slightly more noticeable, it's not camouflaged so well, but then that's probably a good thing isn't it" (Intervention site C.)

"I think it's a good thing because then I'll get the domestic to clean it up, if I don't see it and I think everything's okay and that would put me in a false picture wouldn't it? (Intervention site B)

2.4.2 Discussion

It is difficult to identify from the information gleaned through interviews and discussion with staff, patients, and visitors, the degree to which the comments were based upon individual perceptions, actual inherent characteristics of the flooring material or by the cleaning regimes in place at the sites. Obtaining detailed information regarding the cleaning regimes proved problematic and in a future study, a more systematic approach to acquiring such documentation may prove to be beneficial. Such information would facilitate a greater understanding of people's perceptions of hospital floors with respect to their appearance, function and cleanliness, and consequently permit a more informed debate as to the role of such factors in the investigation of falls and injuries.

2.5 Ward Staffing Levels: Baseline and Intervention Periods

Information was sought about staffing levels throughout the trial and of any change in establishment or shift patterns between the baseline and intervention periods. Tables 2.17 and 2.18 below summarise the information received.

Table 2.17 Ward staffing levels: Intervention sites

Site	Staffing Levels		Comments
	Baseline Period	**Intervention Period**	
A	Establishment: Trained: 8 Full Time & 5 Part Time Untrained: 7 Full Time & 10 Part Time (2 Maternity Leave).	No change.	Staff reported that staffing levels on the ward have not changed since the study began. Early: Seven staff with at least two of them being trained. Late: Five staff with at least two of them trained. Night: Three staff with at least one being trained. Full Establishment. No long term sickness. Not carrying vacancies.
B	Early: 07:00-15:00 6 staff - 3 trained & 3 untrained. Late: 13:00-21:00 5 staff – 3 trained & 2 untrained. Night: 20:45-07:30 3 Staff - 2 trained & 1 untrained. Twilight: 20:45-01:00 1 staff.	Early: 07:00-15:00 7 staff - 3 trained & 4 untrained. Late: 13:00-21:00 5 staff – 3 trained & 2 untrained. Night: 20:45-07:30 3 Staff - 2 trained & 1 untrained. Twilight: 20:45-01:00 1 staff.	Staff reported that staffing increased over study duration by one extra staff in the morning. Twilight post now permanent. 3 staff on maternity leave. Not carrying vacancies.
C	Early (weekdays): 07:30-15.30: 10 staff – 4 trained & 4 untrained. Plus Ward Manager and Housekeeper. Early (weekends): 8 staff – 3 trained & 5 untrained. Late: 13:00-21:00: 6 staff – 3 trained & 3 untrained. Nights: 20:45-07:45 – 5 staff – 3 trained & 2 untrained.	No change.	No change.
D	Early: 7 staff, 3 trained & 4 untrained. Late: 5 staff, 2 trained & 3 untrained. Nights: 3 staff, 2 trained & 1 untrained.	No change until June 2011.	When patient group changed, (June 2011) staffing levels altered. Early: 6 staff, 3 trained & 3 untrained. Late: 5 staff, 3 trained & 2 untrained. Nights: 4 staff, 2 trained & 2 untrained.

Table 2.18 Ward staffing levels: Control sites

Site	Baseline	Intervention	Comments
E	Early (weekdays): 6 staff, 3 trained & 3 untrained. Late: 3 staff, 2 trained & 1 untrained. Night: 3 staff, 2 trained &1 untrained. Weekends: Not available.	Weekdays: 7 staff, 3 trained & 4 untrained. Weekends: 7 staff, 2 trained & 5 untrained. Night: 3 staff, 2 trained & 1 untrained.	Unable to comment on any changes as staffing information provided does not allow.
F	Information not available	Information not available	N/A
G	Information not available	Information not available	N/A
H	Not available.	Establishment: Band 2 11.63 WTE. Band 3 2.79 WTE. Band 5 16.00 WTE. Band 6 1.00 WTE. Band 7 1.00 WTE.	Unable to comment on any changes as staffing information provided does not allow.

The ability to comment fully upon the staffing levels both within the sites and across the sites during the baseline and intervention periods has been compromised by the difficulty to obtain full and comparable data. Where data has been obtained, it is often recorded in ways that hinder comparisons, this being particularly true of the control sites where we are unable to comment. However, it appears that for two intervention sites there has been no change to staffing during the study duration. For two other intervention sites, one had seen a modest increase in staffing which was reportedly to assist the manual handling of equipment during the busy morning periods. For the other intervention site, it appeared that overall staffing levels remained constant although the ratio of trained to untrained altered slightly as did the shift patterns. It should be noted that this site also experienced a change of patient group during the intervention period. This site did verbally report that an increase in night staff cover was in response to concerns regarding the movement of equipment in the bay during the night (see also Section 6).

2.6 Slip, Trips and Falls Policy Documentation

Table 2.19 provides information on the falls policies and initiatives provided by the study sites. Clearly, all host NHS Trusts were pro-active in promoting fall policies and all had overarching strategies that governed practice within the study sites. Several provided additional information relating to their falls policies, for example, falls risk assessment tools and care flow-charts. Many of the Falls Policy Strategy documentation also included examples like these within them.

We were keen to identify if there had been any specific change in falls policies at both the Trust or Ward level during the trial and whether the study sites were participating in any other falls related initiative or research. For three intervention sites the Trust Falls Policy was reviewed or updated during the study period. The remaining site's Falls Policy was reviewed just as the site began recruitment although supplementary falls related tools supplied by this site indicate that they were introduced or amended whilst the study was running. A similar picture emerged for the control

sites, with three sites policies being reviewed or amended during the trial period. The remaining site having just been reviewed prior to the study commencing.

With respect to changes at ward level or involvement in other falls related initiatives, one intervention site reported the introduction of the use of falls alarms during the study period; the remaining three reported no changes in policy or practice. All the control sites noted the introduction of an initiative. For two of the control sites this was an introduction of the use of fall sensors for patients assessed to be at risk of falling. For one of these it appears this was a trial period and did not cover all patients. One site started a 'safe footwear programme'. The final control site reported that the ward lights were dimmed for an hour after lunch. Whilst this did not appear to be linked to a falls initiative we feel it is a noteworthy policy.

As this component of patient care is such an area of high importance, it is reasonable to suggest that there may have been other changes to falls management within the study sites that the research study has failed to capture. During site visits, we observed notice boards dedicated to falls information and the presence of information to promote falls awareness.

Table 2.19. Slip, trips and falls policy documentation

Location	Falls Policy Received	Update of Falls Policy during trial period (Trust level)	Reported change in falls policy during trial period (Ward level) or involvement in other external falls initiatives	Additional Falls Policy Documents
Intervention Sites				
A	Policy for the Assessment & Management of Patient, Slips, Trips and Falls (September 2009)	October 2010	Falls alarms introduced (August 2010)	N/A
B	Policy for the Prevention of Slips, Trips and Falls in Hospital (November 2009).	September 2010. January 2011.	None reported.	Stay Steady – Stay Independent (Patient Information, 2007).
C	Falls Policy including assessment and management of patients who are at risk of falling or have already fallen (February 2009).	November 2010.	None reported.	N/A
D	Slip Trips and Falls Policy: Employee. (March 2010). Slip Trips and Falls Policy: Patient. (May 2008).	June 2010. June 2010.	None reported.	Falls Prevention Observation Tool (July 2010) Post Falls Flow Chart (April 2011) Supplementary AIRS form for Falls and Found on Floor (July 2010).
Control Sites				
E	Falls Prevention Policy (January 2009). Falls Prevention Policy (May 2011).	May 2011.	Falls sensors provided to patients assessed as being at risk of fall.	N/A
F	Management and Prevention of Patient Slips, Trips Falls Policy (October 2009). Strategy for the Prevention of Slip, Trips and Falls (January 2010).	N/A	Safe Footwear Initiative	SAFE (ST) Falls Assessment and Intervention Tool.
G	Policy for the prevention and management of Adult In-Patients at risk of falling or who have already fallen (Issue 6. January 2011).	Issue 6 January 2011	August 2011. Falls alarm trialled within study ward.	Policy for the Use of Bedside Rails for Adult Patients (Issue 2. February 2011).
H	Falls Prevention and Management Policy (March 2007). Protocol for Falls Prevention (May 2011).	March 2010. April 2011. N/A	Intervention Period: Lights on ward dimmed for one hour after lunch.	An example of an individually targeted falls care plan. (2009) Falls Risk Assessment.

2.7 Number of Falls on Ward

We requested ward level audit information detailing the total number of falls that had occurred throughout the duration of the trial. The information received was incomplete.Only two of the intervention sites forwarding full information, with a further one supplying partial data. Fron control sites, only two provided data. The information received was also difficult to interpret as for some study sites it did not cover the full trial period and for others, as the change-over between baseline and intervention periods happened mid- month, the data was not detailed enough to determine at which point of the month an actual fall occurred. However, whilst acknowledging these limitations the falls data has been used to provide an approximation of the falls rate for the sites for which data was available. These are presented in Table 2.20 NB. The rates presented here have been calculated differently than the pilot study data, as we have no information on number of fallers (including recurrent fallers), or the occupancy levels on the ward (we have assumed 100% occupancy); here the fall rate per 1000 patient bed-days is calculated as: (Total number of falls / (no. of beds*no. of days in period))*1000.

Table 2.20. Number of falls on ward (ward audit data)

Location	Baseline Period		Intervention Period		Total No. of falls on ward.	Overall Falls Rate
	No. of falls on ward.	Falls Rate	No. of falls on ward.	Falls Rate		
Intervention Sites						
A	Not known	Not known	Not known	Not known	Not known	Not known
B	27	8.1	91	11.7	118	10.6
C	Not known	Not known	68	6.0	Not known	Not known
D	22	11.4	77	11.7	99	11.7
Control Sites						
E	44	14.5	121	13.1	165	13.1
F	Not known	Not known	Not known	Not known	Not known	Not known
G	47	14.3	68	7.4	115	9.2
H	Not known	Not known	Not known	Not known	Not known	Not known

2.8 Fall-related Injuries

For intervention Site B there were no fractures recorded in either baseline or intervention periods. The injuries sustained at intervention Site C were recorded as: 30 ‘no injury’; 36 ‘minor’; two ‘moderate’; no ‘major’; and no ‘catastrophic’ (56 injuries per 100 falls).

For control Site E there were two fractures in the baseline period (5 fractures per 100 falls). The falls in the intervention period resulted in no fractures, 83 ‘near miss’ (no injury), two ‘no injury’, 31 ‘tissue injuries’ (i.e. bruises, skin tears etc), four ‘muscular-skeletal injuries’ and, one ‘threatening to condition/life injury’ (30 injuries per 100 falls). Control Site G recorded as 13 ‘minor non-permanent harm’ and 34 ‘no obvious harm’ fall-related injuries in the baseline period (28 injuries per 100 falls). For those in the intervention period, 26 were noted as ‘minor non-permanent harm’ and 42 ‘no obvious harm’ (38 injuries per 100 falls).

2.9 References

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3. SECTION 3: THE PILOT CLUSTER RANDOMISED CONTROLLED TRIAL

3.1 Introduction

This section of the report relates to our primary objective: To evaluate the difference in the fall-related injury rate (per patient bed-days) between the intervention flooring and existing flooring. This objective seeks to explore differences in injury rates through a pilot study, in order to inform future research.

3.2 Methods

3.2.1 Study Design

This pilot cluster randomised controlled trial included 8 wards across England. Each ward had one designated bay for the study (the 'Study Area'). Patients were therefore 'clustered' at the bay (study area) level, and group allocation within the study was based on clusters. A cluster design was deemed necessary due to the nature of the intervention (flooring) which, given the largely 'multi-bed bay' design of hospitals within the NHS, had to be administered to groups of people, as opposed to individuals. It was also deemed unfeasible to randomise individuals to rooms (with or without the flooring), due to logistics (e.g. single-sex bays, the requirements of observation bays, bed availability, etc.). All participants were therefore exposed to the allocation of the cluster within which they were recruited, However not all participants fell, and of those who did, not all of the falls happened within the designated study area.

Data was collected for two to five months (median = 4) before the shock-absorbing flooring was laid in intervention sites (the timing varied due to staggered start dates and timing of flooring implementation). After the new flooring was installed in four of the study areas, data was collected for a further 12 to 13 months (median = 12) from all eight sites. The intervention period began from the day patients were readmitted to the bay after the new flooring was laid for intervention sites, or the median date of the floors being laid for the control sites (30th August 2010). All sites had an end date of 31st August 2011 for the intervention period. No blinding was incorporated into the study design. This was deemed unfeasible due to the nature of the intervention.

3.2.2 Randomisation

Wards are allocated to be in the intervention or control groups based on a computer-generated random list, in blocks of four. An independent statistician generated the sequence ensuring allocation concealment. The block randomisation was not revealed to the researchers until after the sites had been allocated. Once sites had received full governance approval to participate in the trial, the study researchers contacted the statistician to reveal the group allocation. The final three sites to receive governance approval were randomised at the same time (in the order in which the approvals were gained) so not to break the allocation concealment. Sites were informed of their group allocation at the beginning of the baseline period in order to allow the intervention sites time to organise and plan the flooring installation.

3.2.3 Intervention

The intervention floor in this study is an 8.3mm thick vinyl floor covering over fibreglass mat with PVC foam backing (Tarkett Omnisports EXCEL). Following the baseline period, the flooring was installed into the study area (a four- to eight-bedded bay) of the four intervention sites. The flooring is not suitable for areas usually wet (e.g. bathrooms) and so was only installed into the bedroom area. Sites planned for their study area to be empty for a one-week installation, with bays either being gradually 'run down' by not admitting new patients into the bay, or by transferring patients to vacant beds elsewhere in the ward or hospital. The installation of the new floors was planned

directly between the hospital estates and facilities departments and the prime contractors installing the floor. Each site had the choice of floor colour/design from the Omnisports EXCEL range, and also decided how they wished to manage the threshold between the new (thicker) floor and the standard floors in any adjoining areas (e.g. by choosing a transition strip or a gradual 'seamless' gradient). The intervention floors were provided to hospitals as theirs to keep; installations took place between August and September 2010. All installations were carried out by the same prime contractor (Tyndale Flooring Limited). Control sites received no change to their existing flooring.

In the original grant proposal to the Dunhill Medical Trust, we proposed to assess a different floor covering (Sorbothane). There followed a series of delays, as the company providing the underlay sought to scale it up from a laboratory-based product to being mass produced, and identify a suitable means to adhere the top-layer to the shock-absorbing underlay. Utilisation of this product eventually ceased when the flooring provider went into administration. Following a scoping exercise, the final intervention used in this trial (Omnisports EXCEL) was identified as an appropriate alternative to progress the trial with.

3.2.4 Institutions

Wards considered as being predominantly for elderly care use (elderly general rehabilitation and elderly mental health) in England, were eligible for inclusion. Originally we planned to recruit four of each type of elderly care ward, however this restriction was lifted to facilitate recruitment. These wards are representative of two groups at high risk of falling due in part to low cognitive function and disability, respectively.[1] The study set out to recruit eight sites across England, with no restrictions placed on location. Wards were screened for humidity levels in the sub-floor, to assess the need for special membranes required when laying the floor on bases with high humidity. Included sites were to have floors with a slip resistance rating of no more than 'R9'. This was to ensure that the overlay materials across sites are comparable, and to ensure that we do not replace a floor covering with one of lower slip resistance (the intervention floor has a rating of R9).

Each site designated a bay as the 'study area' for use during the study, decisions on which bays to use was made prior to randomisation. Eligible bays ranged from 4 to 8 beds in size. No restriction was placed on gender usage of the bays. Hospital sites had the choice of which bay to use for the study; decisions could be based on where patients at high risk of falls are placed (e.g. for observation purposes), or for logistical reasons (e.g. to enable easy access/cordoning off the ward for new flooring to be fitted, should the site be allocated to the intervention group). Of the intervention sites, three chose their observation bay as the study area (where high risk patients tend to be placed) and one selected a bay based on the logistics of fitting a floor; Of the control sites, three chose their observation bay, and one selected a bay both because it had better access for flooring installation and because it was their female bay (deemed to be at higher risk of injury).

3.2.5 Participants

Participants were identified and recruited through the above-mentioned institutions. Patient-specific data was only collected from those patients who had consented (or, when appropriate, for whom consultee advice had been gained) for their data being utilised for the trial. Participant recruitment began in a staggered start between April and June 2010, and continued until the end of August 2011.

3.2.5.1 Inclusion criteria

All adults admitted to a bed in the 'study area' at a participating site.

3.2.5.2 Exclusion criteria

Flooring has implications for all people residing in the area, and as such there were no exclusion criteria.

3.2.6 Sample size

This is a pilot study and there is no previous research on this specific flooring intervention and its effect on injuries from falls. The data collected from this study will be utilised to inform a power calculation to underpin further research (see also section 3.4.8.'Design effect and power calculations'). Laboratory tests of the flooring product predicted that the energy absorbed from impact would be sufficient to avoid hip fracture in the majority of fallers; the effect of the flooring on other injury types was unknown however, and the validity of the assumptions on which laboratory tests are based, had not been pragmatically assessed in this context. Only a marginal number of falls result in fracture (for example Hitcho et al., quote 1%;[2] and the 2005/2006 audit data we gathered to inform the protocol of this study had rates ranging from 0%-2.63%, averaging at 1.3%); it was therefore deemed likely that a study will have to be very large in order to be sufficiently powered to find a significant effect on hip fracture reduction alone. Hence, we collected data on other types of injury (stratified by severity), to enable a more generic view of the overall impact of the flooring intervention.

This study aimed to provide information to assist estimating an effect size for injury reduction to enter into a future power calculation. Additionally, some inflation to allow for clustering (the 'design effect') would need to be included in these estimates.[3] Originally we perceived that this pilot study would enable the calculation of the intracluster correlation coefficient (used to calculate the design effect) to better inform a power calculation for a large-scale cluster randomised controlled trial. However, we have since determined that the coefficient of variation is a more appropriate determinant for power calculations of studies utilising rate data.[4]

A cluster randomised controlled trial has not been attempted for this intervention before or indeed in the field of hospital design more broadly;[5] therefore embarking on a full-scale trial before conducting a pilot would have been inappropriate. No effect size was known for the intervention (in terms of injury reduction) and no formal power calculation informed the pilot study, rather we felt that four wards per arm was a modest and feasible number to begin our investigation. This number of clusters was deemed appropriate as it will enable us to gauge the intervention effect as well as gauge the variation within and between clusters which will inform future clustered trials.[6] This pilot cluster randomised controlled trial will additionally help inform a larger study by enabling us to explore the issues unique to clustered trials; such as standardising procedures across sites and dealing with irregularities in environmental designs. Additionally we felt that the inclusion of a number of sites would improve the generalisability of the findings, increase the amount of data that can be used to inform future research, and enable an assessment of the validity of assumptions made in laboratory-based testing.

3.2.7 Participant recruitment

Patients admitted or transferred to the Study area within the timescale of the pilot study (April 2010 – August 2011) were informed about the study through a Participant Information Sheet. All patients were assessed for capacity to consent by a clinical member of staff/research nurse, who offered support to the patient to help them understand the information and make a decision as to whether to participate or not (in accordance with the Mental Capacity Act 2005 Code of Practice). If patients did not have the capacity to consent, a consultee was sought. In the first instance a personal consultee was be sought (e.g. family or friend), and if not available then a nominated consultee was appointed (e.g. a paid care worker). The consultee was provided with a Consultee Information

Sheet, which explained what it means to act as a consultee as well as what it would involve for the patient to take part in the study.

The patients or consultees were able to contact the research team prior to participating in the trial should they have any questions. Where required, study information could be translated for foreign language speaking patients and consultees (during the study period one request was made for foreign translation. However the patient was discharged soon after, prior to being approached for consent). Personal data was not collected about patients, until they had been recruited on to the trial.

Each patient admitted or transferred to the study area was assigned a unique identification number (ID) using a table maintained at the site. The study site notified us when a new patient was admitted (faxing the ID number, date, and reason for internal transfer, if made, via a secure line). Internal transfers were monitored to help identify if staff were allocating high risk patients to the new flooring because they thought it may help them (since this may be a source of bias in the results, leading to a higher number of falls on the new floors which is due to a change in patient risk as opposed to a change flooring).

The protocol specified that every patient admitted or transferred to the study area should be approached for consent for participation in the study (or a consultee sought for advice). Patients should have been given at least 24 hours, if they needed it, to decide if they wished to take part. Patients may have consented (or refused) within 24 hours if they did not need longer to decide. If patients were transferred out of the study area before they had the opportunity to decide, then we asked to be informed, so that this could be monitored. All patients who were approached, were asked to consent to having their date of birth, sex, and ethnicity recorded for the purposes of the research (even if they did not want to take part in the study). Some patients therefore, consented to having these brief demographic details recorded but not for their personal health-related data be recorded for the study. We wanted to record date of birth, sex, and ethnicity of all patients in order to assess the similarities between those who take part in the study and those who do not. Once collected, all data were made anonymous with a unique number on the research database, and with the decryption key held by the Co-ordinating Centre.

3.2.8 Data Collection

The primary outcome measurement is the fall-related injury rate per patient bed days. In addition, we collected data on: site audits (see Section 2), patient baseline characteristics, falls per patient bed days, proportion of recurrent fallers, length of stay, fall-related healthcare interventions for the injuries sustained, and admission of fallers to other wards or institutions (see Section 5).

Upon discharge or transfer to an external ward a Discharge Form was completed and faxed to the Co-ordinating Centre to notify us of the patient's location. Three months after this time, we attempted to follow-up with the General Practitioner (GP), and patient or consultee, to collect data for the cost-effectiveness analysis (Section 5).

If a participant was transferred to another room within the same ward but outside of the study area, we asked to be informed. Any falls that occurred from participants who had been internally transferred were documented. This enabled all participant falls occurring both within and outside of the study area to be monitored. It was possible that if the participant remained on the ward, they may have returned to the study area and fallen over.

3.2.8.1 Standardisation procedures

Prior to the onset of data collection, staff at each site were trained in the study protocol. Standardised forms were implemented across the sites to record baseline characteristics, falls, and injuries, for the purposes of the study. We conducted checks during ward audits, and by cross-checking submitted forms through-out the study period, to ensure that data were being logged appropriately. Data monitoring was conducted through-out the study period and any anomalies or inconsistencies were followed up. All data was double-entered into encrypted datasets and verified for accuracy.

3.2.8.2 Baseline characteristics

Participant baseline data was collected to characterise the intervention and control groups. Baseline characteristics included:

- Age
- Sex
- Patient's usual place of residence
- Use of ambulatory aids
- Functional ability (Barthel Index)
- Reason for admission
- Medication.
- Diagnosis/conditions/co-morbidities
- Fall history
- FRAX® assessment (risk of fracture tool).

The World Health Organisation Fracture Risk Assessment tool (FRAX®) was chosen as it is the most recently developed tool to assess patients' risk of fracture.[7] Previously, clinicians relied on patients bone mineral density (BMD) to assess risk of fracture but the use of BMD alone yielded a low detection of fracture risk.

Developed in 2008, the FRAX® tool uses algorithms to assess a patient's 10 year probability of major fracture risk through an analysis of the patient's clinical factors which may increase their fracture risk. As FRAX® is relatively new and still requires some validation with different groups of people it is recommended that it is used in addition to clinical judgement when determining if a patient needs to receive treatment.[8] However, in a research setting FRAX® may provide an ideal means of classifying participants' levels of fracture risk for analysis purposes, thus we decided to utilise it for this pilot study.

3.2.8.3 Fall-related Injury rate per patient bed days (primary outcome)

All events of patient falls and injuries were recorded on a standardised form. This included: time; exact fall location; positioning of faller; nearby objects; footwear of faller; bed positioning (high/low); use of bed rails; lighting status; diagnosis; and injuries received. The injuries were stratified by injury severity: (*None*; *Minor*: complaint of pain, requires ice, dressing, cleaning of wound, elevating limb or medication; *Moderate*: requires suturing, steri-strips, splinting or temporary bed-rest; *Major* requires surgery, casting, traction, neurological consultation for change in level of consciousness; *Death*) and type (to include location and type of injury, etc). To calculate the injury rate, patient bed days were also calculated based on date of admission to date of event (or date of discharge if there was no event).

3.2.8.4 Fall rate per patient bed days

The fall rate per 1000 patient bed days was calculated to assess whether the intervention flooring has an additional effect on the number of falls occurring as well as the number of injuries sustained.

3.2.8.5 Proportion of recurrent fallers

As many patients tend to fall more than once, and having fallen before is one of the main risk factors for falling,[9] the number of falls per individual was recorded to calculate the proportion of recurrent fallers. Recording this information and being able to characterise the study population that falls, will inform future research by highlighting potential issues for data analysis.[10]

3.2.8.6 Length of Stay

The length of stay (LOS) was calculated. This outcome aimed to capture any change in LOS occurring with and without the intervention as a result of injuries prevented/sustained, to inform the analysis in Objective 3 (See Section 5).

3.2.8.7 Injury related healthcare interventions

We aimed to follow up any serious (major and moderate) injuries resulting from falls that required additional care in the three months following the fall, including such interventions as surgery, through the local institutions' patient administration systems (See Section 5).

3.2.8.8 Admission to other ward or institution

In order to measure the impact of the injury on patient care, any change from the original ward to another ward or institution for intensive monitoring or additional care related to the injury was followed (See Section 5).

3.2.9 Statistical analysis

Given that this is a pilot study, the statistical analyses are geared toward informing future research as opposed to significance testing. Primarily, we describe each ward in terms of the incidence rate ratio (IRR) for fall related injuries and the IRR for falls both before and after the intervention. This will enable the estimation of the treatment effect in order to facilitate future sample size calculations. Additionally, we initially planned to calculate the intracluster correlation coefficient (ρ); however, a more appropriate method of deriving a power calculation for a cluster trial using rates is actually to use the coefficient of variation (k) as opposed to the intracluster correlation coefficient (ρ).[11]

Secondary outcomes are summarised and described for each ward in each study group. Participants are profiled according to their risk of fracture (FRAX® score). Entering participants' data into the FRAX® tool was undertaken to assess their 10 year probability of major fracture risk and present it as a percentage. Participants were then categorised as at low, intermediate or high risk of major fracture, according to the National Osteoporosis Guidance Group (NOGG). These classifications were then used to profile participants according to their fracture risk, and cross-tabulated against the actual fall-related injuries sustained (to be reported elsewhere).

Incident rate ratios (effect estimates) for injuries and falls were calculated utilising a negative binomial regression, adjusting for clustering. This analysis uses the time to the first event as the exposure time, and thus disregards recurrent falls and injuries (see Box 3.1 for a simple explanation of how the rates were calculated). When falls occurred on the first day of admission (time to event = 0; N = 4), zero counts were replaced with 0.5 to satisfy the requirements of the regression model. Events and bed-days for individuals who were re-admitted during the same study period (N = 6) were combined into a single summary for each individual to overcome a unit of analysis error which would occur by including the same participants twice in the analysis. Data for participants who were admitted during the baseline period and then re-admitted during the intervention period (N = 3) have not been combined, as baseline and intervention periods have been reported

separately. Participants who were still inpatients in the ward at the end of data collection had their length of stay censored at the final day of data collection (31st August 2011). Individuals with missing date of discharge (N=7) were not incorporated in the analysis as no exposure time was known. None of these participants had documented falls, and all of them were in the intervention group. This will have led to a somewhat inflated falls rate in the intervention arm.

Analyses were conducted by 'randomised treatment' (akin to intention-to-treat; incorporating all falls/injuries regardless of whether they occurred inside or outside the Study Area, but without replacing missing values), and by 'treatment received', in which only events occurring within the Study Areas were incorporated. The primary purpose of this study is to estimate an effect size and inform further research, rather than undertake statistical probability testing; therefore, we are not presenting p-values associated with the effect estimates, but we do present confidence intervals to ensure that care is taken with the interpretation of these findings. Injury rates are described using three different thresholds: (1) All injuries (minor, moderate, major); (2) moderate and major injuries; (3) major injuries. These groupings are presented to inform the size of future studies, as the higher the threshold of injury severity selected as the primary outcome measure, the larger the future study will need to be. Participants who were documented as receiving more than one class of injury severity from the same fall, were coded according to the most severe injury type.

An exploratory analysis of falls data was additionally undertaken utilising the Andersen-Gill model (which is a modified Cox Regression, enabling the incorporation of recurrent events)[13] to provide an effect estimate (Hazard Ratio) which makes better use of all the data collected. Multiple falls were experienced by 13 participants (5 intervention and 8 control), and 5 of these experienced multiple minor injuries as a result of recurrent falls. Given the limited number of multiple injuries experienced by participants who had recurrent falls, and given the complexities of basing a power calculation on this data, we have not utilised the Andersen-Gill model to look at injury outcomes. However we would anticipate that any power calculation based on the negative binomial regression data would some-what over-estimate the sample required for an Andersen-Gill model. Five participants experienced more than one fall on the same day, or a fall on the same day as admission or discharge; To fit the data to this model (which requires time-to-event to be greater than zero), 0.5 was added to the event times for these cases (with 0.2 and 0.5 added to the event times for one person who fell twice on the same day as they were discharged).

Incident Rate per 1000 patient bed-days:	Incident Rate Ratio:
$\left(\frac{\text{N. First Events}}{\text{Time-to-event}}\right) \times 1000$	$\frac{\text{Incident Rate for Intervention}}{\text{Incident Rate for Control}}$
Box 3.1 Calculating rates.	If IRR = 1 there is no difference; If IRR < 1 there were fewer events in the intervention group; If IRR > 1 there were more events in the intervention group.

There are a number of ways to calculate injury rates (the incident rate per 1000 patient bed-days is our primary measure); for comparison (and description purposes) we have also calculated the number people injured as a function of the number of fallers (injury rate per 100 fallers: No. of people injured/No. of people who fall *100). This method of looking at the data may be useful as it standardises the falls risk (i.e. if there are more fallers in one group than the other, the incident rate of injuries per 1000 patient bed-days may be altered as a function of an increased falls rate, whereas the number of injuries per 100 fallers is simply looking at the risk if a person does fall over). Unit of

analysis is a problem when calculating the injury rate per 100 fallers, as some people may fall over multiple times and only injure themselves once (in which case the injury rate per 100 fallers will over-estimate the risk of injury). Alternatively, if the unit of analysis was taken as the number of injuries by the number of falls (without considering who was falling), the same person may be entered numerous times into the same calculation (creating another unit of analysis error).

3.3 Changes from the original plan

We originally planned to assess the impact of a different flooring product (Sorbothane), however the company we were utilising ceased trading and we had to select a different flooring product (Tarkett Omnisports EXCEL). We originally planned to recruit four of each Elderly Mental Health and Elderly General Rehabilitation wards to the study, but lifted this restriction to facilitate recruitment.

Due to the unforeseen delays caused by the changes to the flooring product, the timescales of the pilot study were adjusted. We had originally planned to have a 6 month baseline period, however this reduced to a median of 4 months (range 2 to 5 months) to accommodate the delays in getting started.

The main change from our original analysis plan was the description of information required for a power calculation. Originally, we planned to present the intracluster correlation coefficient (ρ) but subsequently realised the coefficient of variation (k) is a more appropriate measure of the clustering effect when the outcome is a rate. Given that this is a pilot study, we have also explored other methods of handling the multiplicity in the data (as supplementary analyses) by using the Andersen-Gill model to calculate hazard ratios for falls, as well as describing the injury rate per 100 fallers.

3.4 Results

3.4.1 Recruitment Flow

Figure 3.1 displays the flow of recruitment throughout the trial. We successfully recruited our target of 8 sites; however, 44 sites were assessed for eligibility. Much liaison was conducted via email and telephone, and for those who continued to express interest, site visits were arranged in order to meet with key staff (e.g. potential Principal Investigators, Research Nurses, Ward Managers, Matrons/Ward Sisters, Falls Specialists, Estates and Facilities personnel, Infection Control personnel, Research & Development personnel). Face-to-face meetings were arranged with 25 sites (follow-up meetings were held as necessary). For sites who continued to express an interest, site surveys (N = 9) were undertaken by the flooring contractors.

Of the 36 sites who did not take part, four presented multiple reasons for not taking part. Reasons for exclusion were: 7 sites did not meet the inclusion criteria (4 were not elderly care wards; 3 already had a safety floor in situ[a]); 26 declined to participate (12 sites provided no reason -primarily contact was lost through lack of response from the primary contact person at the site; 4 were concerned over the level of disruption (and times of high pressure), e.g. bed closures, winter pressures, swine flu; 4 had an upcoming reconfiguration of the hospital or services; 3 had upcoming capital work/refurbishment; 3 were concerned about workload capacity; 1 was lacking support from the estates department; 1 expressed concerns over doorway thresholds). Other reasons

[a] One of these sites also documented concerns about cleaning the new floor as the related guidance did not match their current practices, as well as concerns about recruiting patients with cognitive impairment.

for exclusion were: 2 sites had a wooden subfloor[b] (one of these sites also had an upcoming reconfiguration so declined anyway); and 2 sites provided their expression of interest too late for the research schedule.

The study protocol specified that all patients admitted to the Study Area be allocated a Study ID. This was to enable tracking of recruitment rates. Adherence to this element of the protocol was poor at certain sites. One control site only allocated 30 IDs over the whole study period and one intervention site had phases of slow recruitment (due to staff turnover) and allocated 64 IDs by the end of the study. Of the 540 and 566 IDs allocated at intervention and control sites respectively, 142 (26.3%) patients were not approached in the intervention sites, and 187 (33.0%) were not approached in the control sites (these figures are likely to have underestimated the true numbers due to the issues highlighted above). Of those not approached in the intervention group: 62 were due to the patient being discharge prior to consent, prior to consultee decision, or a consultee being appointed; 5 were because the patient passed away prior consent; and 3 were due to it being felt inappropriate to approach the patient (because they were dying, suicidal, or the Consultant had directed the researcher not to approach); 1 person was missed twice (with no reasons given); and the remainder were not coded (71). Of those not approached in the control sites: 156 were due to the patient being discharge prior to consent, prior to consultee decision, or a consultee being appointed (1 person was missed twice due to this); 12 were because the patient passed away prior to consent; 9 were due to it been deemed inappropriate to approach the patient for consent; 2 are unknown; and 8 reasons were not coded.

Reasons for Refusal:
The primary known reason for refusal was ‘not wanting the bother’ (28.2% of the intervention group refusals, and 43.3% of control group refusals). This category includes times when patients stated they did not want to participate due to their physical condition (e.g. poor memory, old age, deafness, being confined to bed), having too many other things to deal with, concerns over family members feelings, wanting to be left alone, not wanting to sign anything, not wanting a follow-up, or because they were going home soon. Future research may consider ways to further lift the burden of the research for participants, for example by enabling participants to agree to the 3 month follow-up separately to the rest of the trial, in order that it can be emphasized to patients that they need not actually have to do anything after signing the consent form. Alternatively, if a future trial could be designed in which personal identifiable data were not collected, then it may be possible to justify not requiring patient consent.

Readmissions:
Nineteen people were admitted to the Study Area on two separate occasions. Of these 7 were entered to the trial on one admission but not the other (3 of these declined on the first admission but agreed on the second; 2 agreed on the first admission but declined on the second; and 2 agreed on the first admission but were not approached on the second admission), 2 were not approached on both occasions, 1 was not approached on the first admission and declined on the second, and 9 patients agreed to participate on both occasions.

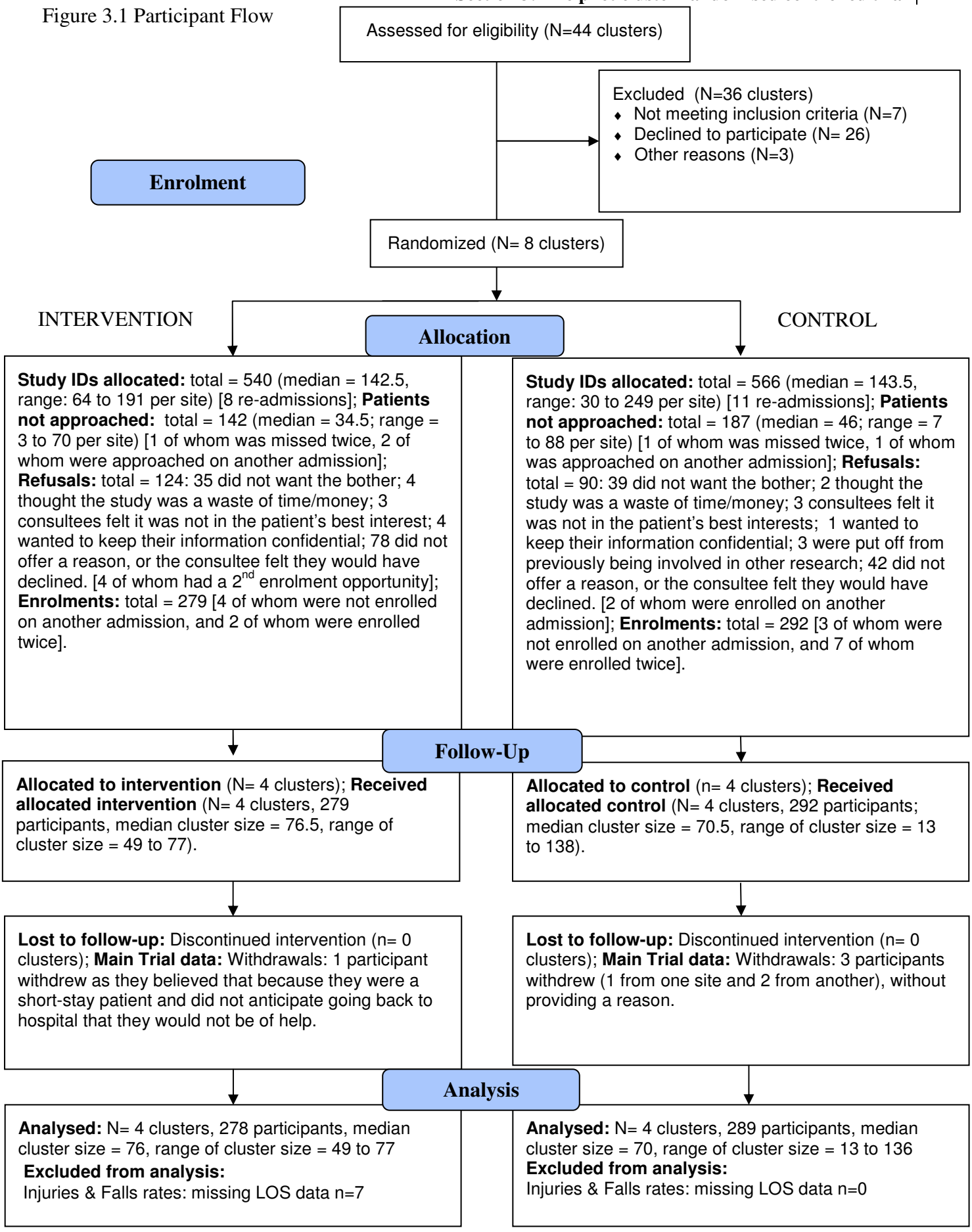
[b] The original flooring company specified that the flooring would not suit wooden subfloors. Following the liquidation of this company, we enlisted a new contractor with a different shock-absorbing floor which was suitable for use on wooden subfloors. None of our participating eight sites had wooden subfloors.

Withdrawls:
Four people later withdrew from the study; one person withdrew from the intervention group for reasons unrelated to the flooring, and 3 people withdrew from the control group for unknown reasons. All sites remained in the study until the end of data collection.

3.4.2 Differences between participants and non-participants

Of the 535 people who did not participate at all in the study, 66 (12.3%) provided their gender and ethnicity. One person who declined on the first admission and agreed on the second was of mixed ethnicity, the remainder of participants and non-participants that we know about were white. Of those we know of, 62 (94%) of non-participants were female, compared to 181 (83.5%) of participants. It should be remembered however, that bays were single-sex and the majority of sites had female bays during the study. One site changed from a female bay to a male bay part way through the study, at this site recruitment prior to the gender change was 40.6% (52/128) of all IDs assigned, and 42.2% (19/45) after. The one site which had a male bay throughout the study, recruited 74.5% of all patient IDs assigned, which is above the average of the other six female bays (median = 49.1%, range = 39.3% to 76.6%). It is possible therefore that males were more inclined to take part than females.However, it could simply be that the site which was predominantly male had a very good recruitment rate against the number of patient IDs issued (and unrelated to gender). Non-participants appeared slightly older (mean =87.8 years old, SD = 8.6) than participants (mean = 81.5 years old, SD = 11.6), but there were 469 non-participants with missing data and only 1 missing age for participants.

Figure 3.1 Participant Flow



3.4.3 Baseline information

3.4.3.1 Study Sites

The baseline period across sites ranged from 2 to 5 months and therefore offers very limited data with regards to injuries and falls. There were 53 participants recruited across the intervention sites, and 69 participants recruited across control sites, during the baseline period. With very few events we cannot be certain of how similar or not sites were prior to any new floors being installed (Table 3.1). The injury rates appear slightly lower (IRR = 0.58, 95% CI = 0.06 to 5.93) in intervention sites (1.89 injuries per 1000 patient bed-days) compared to control sites (3.26 injuries per 1000 patient bed-days) – it is important to notee the very wide confidence intervals. However (as the number of falls also varied between intervention and control sites at baseline), when injuries are considered as a function of the number of falls, there appears to be even less difference between study groups (40.0 injuries per 100 falls in intervention sites, and 38.5 injuries per 100 falls at control sites).

		N of events, Incident rate per 1000 patient bed-days		
		Intervention	Control	Adjusted IRR (95% CI)
Injuries	All areas	N = 2, IR = 1.89	N = 5, IR = 3.26	0.58 (0.06 to 5.93)
	Study areas	N = 1, IR = 0.94	N = 5, IR = 3.26	0.29 (0.03 to 2.96)
Falls	All areas	N = 5, IR = 4.81	N = 13, IR = 10.44	0.47 (0.11 to 2.02)
	Study areas	N = 5, IR = 4.81	N = 9, IR = 6.35	0.90 (0.10 to 8.19)

Table 3.1 Injuries and falls during the baseline period

3.4.3.2 Study Participants

Most participants were classified as 'intermediate' fracture risk (Table 3.2). Fracture risk was relatively evenly distributed across study groups during the intervention period. There were some imbalances during the baseline period (more high risk in the intervention group, and more low risk in the control); however the numbers of participants were also small during this period.

Table 3.2 Fracture risk by study period

	Baseline Period		Intervention Period	
FRAX® fracture risk categories	Intervention	Control	Intervention	Control
Low	5 (9%)	13 (19%)	56 (25%)	53 (24%)
Intermediate	30 (57%)	38 (55%)	92 (41%)	120 (54%)
High	13 (25%)	3 (4%)	32 (14%)	34 (15%)
Not known	5 (9%)	15 (22%)	45 (20%)	16 (7%)

Table 3.3 describes the baseline characteristics of participants. Participants were of similar age, body mass index, and Barthel scores across groups, but there were more males, use of ambulatory aids, and previous fractures in the intervention group compared to control. Many more people were admitted with instability in the control group (61%) compared to the intervention group (36%). Overall the control group had more documented co-morbidities associated with fall risk: diabetes, dizziness, falls/fractures/injuries, incontinence, prolonged immobility, and reduced mobility/gait. Medication usage was largely similar across groups, except that more people in the control group were on anti-diabetic drugs.

Table 3.3 Baseline characteristics of participants

		Baseline Period		Intervention Period	
		Intervention	Control	Intervention	Control
Participants	Total N	53	69	225	223
Age at admission	Mean (SD)	84.02 (7.80)	80.01 (11.26)	81.10 (10.96)	80.58 (12.95)[a]
Gender	female	49	69	153	202
	Male	4	0	72	19
Length of stay	Missing N (%)	1 (1.8%)	0 (0%)	6 (2.7%)	0(0%)
	Median (Range)	14 (3 to 76)	17 (1 to 86)	14 (1 to 91)	16 (0.5 to 118)
BMI	Missing, N (%)	5 (9.4%)	15 (21.7%)	45 (20%)	16 (7.2%)
	Mean (SD)	23.96 (5.700)	25.60 (8.57)	24.76 (6.29)	25.66 (6.47)
Barthel Index Score	Missing, N (%)	4 (7.5%)	3 (4.3%)	11 (4.9%)	9 (4.0%)
	Mean (SD)	60.20 (28.94)	69.92 (27.25)	60.37 (30.00)	60.00 (29.06)
No. using ambulatory aids (%)		37 (69.8%)	49 (71.0%)	171 (76.0%)	152 (68.2%)
No. with a previous fracture (%)		22 (41.5%)	12 (17.4%)	85 (37.8%)	67 (30.0%)
No. diagnosed with osteoporosis (%)		10 (18.9%)	12 (17.4%)	31 (13.8%)	37 (16.6%)
Reason for admission, N (%): Incontinence		4 (7.5%)	1 (1.4%)	17 (7.6%)	18 (8.1%)
Immobility		32 (60.4%)	10 (14.5%)	81 (36.0%)	71 (31.8%)
Instability		18 (34.0%)	42 (60.9%)	80 (35.6%)	136 (61.0%)
Intellectual / Psychological condition		6 (11.3%)	14 (20.3%)	41 (18.2%)	59 (26.5%)
Respite		6 (11.3%)	4 (5.8%)	17 (7.6%)	7 (3.1%)
Respiratory Problems		9 (17.0%)	10 (14.5%)	47 (20.9%)	56 (25.1%)
Pain		2 (3.8%)	6 (8.7%)	11 (4.9%)	32 (14.3%)
Other Physiological disruption		9 (17.0%)	19 (27.5%)	61 (27.1%)	77 (34.5%)
Co-morbidities, N (%):Cardiac arrhyhmias		25 (47.2%)	11 (15.9%)	75 (33.3%)	86 (38.6%)
Coeliac disease		0 (0%)	0 (0%)	3 (1.3%)	4 (1.8%)
Delirium		7 (13.2)	2 (2.9%)	33 (14.7%)	26 (11.7%)
Dementia		7 (13.2%)	12 (17.4%)	39 (17.3%)	41 (18.4%)
Diabetes		13 (24.5%)	14 (20.3%)	29 (12.9%)	49 (22.0%)
Dizziness		9 (17.0%)	19 (27.5%)	32 (14.2%)	51 (22.9%)
Falls/fractures/minor injuries		31 (58.5%)	41 (59.4%)	126 (56.0%)	163 (73.1%)
Hyperparathyroidism		1 (1.9%)	2 (2.9%)	10 (4.4%)	4 (1.8%)
Incontinence of bowel or bladder		13 (24.5%)	19 (27.5%)	72 (32.0%)	122 (54.7%)
Inflammatory bowel disease		3 (5.7%)	2 (2.9%)	19 (8.4%)	14 (6.3%)
Orthostatic hypotension		1 (1.9%)	9 (13.0%)	7 (3.1%)	22 (9.9%)
Parkinson's disease		1 (1.9%)	4 (5.8%)	7 (3.1%)	13 (5.8%)
Prolonged immobility		10 (18.9%)	3 (4.3%)	35 (15.6%)	54 (24.2%)
Reduced mobility/gait		37 (69.8%)	41 (59.4%)	149 (66.2%)	167 (74.9%)
Respiratory disease		6 (11.3%)	17 (24.6%)	75 (33.3%)	62 (27.8%)
Stroke		6 (11.3%)	12 (17.4%)	34 (15.1%)	32 (14.3%)
Thyrotoxicosis		0 (0%)	0 (0%)	5 (2.2%)	1 (0.4%)
Transient ischemic attacks		4 (7.5%)	10 (14.5%)	17 (7.6%)	21 (9.4%)
Medications, N (%)					
Anti-diabetic drugs		9 (17.0%)	13 (18.8%)	27 (12.0%)	41 (18.4%)
Anticonvulsants/hypnotics/tranquilisers		8 (15.1%)	8 (11.6%)	30 (13.3%)	40 (17.9%)
Diurectics		31 (58.5%)	30 (43.5%)	122 (54.2%)	122 (54.7%)
Digoxin, etc		26 (49.1%)	30 (43.5%)	117 (52.0%)	128 (57.4%)
Other psychotropic/psychoactive drugs		8 (15.1%)	9 (13.0%)	30 (13.3%)	20 (9.0%)
Polypharmacy		20 (37.7%)	46 (66.7%)	146 (64.9%)	147 (65.9%)

[a] 1 missing data point

3.4.4 Injuries

During the one-year intervention period (Table 3.4), 8 participants experienced one or more fall-related injuries in the intervention group (time spent injury free = 4399.5 days; IR = 1.82 injuries per 1000 patient bed-days). In the control group 12 participants experienced one or more fall-related injuries in the control group (time spent injury free = 4385.5 days; IR = 2.74 injuries per 1000 patient bed-days). From these findings we can estimate that laying the shock-absorbing flooring just in the patient bay will reduce the rate of injuries by approximately 54% of that experienced by patients without the flooring (adjusted IRR = 0.46, 95% CI = 0.11 to 1.97). There is much uncertainty about this estimate; the confidence intervals indicate the effect to be anywhere between 11% of that experienced in the control group, to a 97% increase of injury rate, relative to control. From a pragmatic viewpoint, these figures indicate that even though the flooring was only laid in the bay area, its estimated effect on overall injury rates (regardless of where the patient fell) indicates a potential benefit. When considering only the falls that occurred inside the study areas, the estimated effect is further increased to an approximate benefit of a 71% reduction in the fall-related injury rate relative to control (adjusted IRR = 0.29, 95% CI = 0.05, 1.55); again, caution must be taken not to over-interpret this finding as the confidence intervals suggest potentially up to a 55% increase in injury rate relative to the control group. These estimates, based on the falls occurring in the study areas, provide an indication of the potential benefit to overall injury rates of laying the flooring in corridors and bathrooms as well as in the bay areas.

Figure 3.2 displays the severity of injuries experienced during the intervention period for all falls. Given that future studies may seek to explore the effect of flooring on more severe injuries, we have also calculated effect estimates (incident rates) for moderate to major injuries, and major injuries alone (NB. none of the falls in our study directly resulted in death, so this is not estimable, although see cost-effectiveness analysis, (Section 5). It should be highlighted that these estimates are based on very sparse data; there were no moderate or major injuries in the intervention group (exposure = 4482 days), and only 2 major and 4 moderate injuries in the control group (exposure = 4520 days), of which only 1 major and 3 moderate injuries occurred within the study area. In this instance a statistical anomaly occurs (due to the zero events in one arm of the study), making the calculation of incident rate ratios a problem; so here we present the incident rate for each study arm: Moderate-Major injuries all areas (intervention group IR = 0; control group IR = 1.33 injuries per 1000 patient bed-days); Major injuries all areas (intervention group IR = 0; control group IR = 0.44 injuries per 1000 patient bed-days). It should be emphasised that care be taken when interpreting these figures as these data will be highly sensitive to one or two events occurring in the intervention group. Nonetheless, these are encouraging figures, indicating that the shock-absorbing floor may be of benefit in reducing even the most severe injuries.

Table 3.4 Falls and injuries during the intervention period (all areas)

			No. of participants experiencing an event (no. of people experiencing multiple events; no. of events)					
Study Group	Incident Rate (all injuries)	Did not fall	Falls (all)	Minor	Mod.	Major	Death	Total N Pt.
Intervention	IR = 1.82	194	31 (5; 35)	8 (1; 9)	0 (0; 0)	0 (0; 0)	-	225
Control	IR = 2.74	201	22 (8; 33)	6 (4; 10)	4 (0; 4)	2 (0; 2)	-	223
Total	Adj. IRR=0.46 (95% CI = 0.11 to 1.97)	395	53 (13;68)	14 (5; 19)	4 (0; 4)	2 (0; 2)	-	448

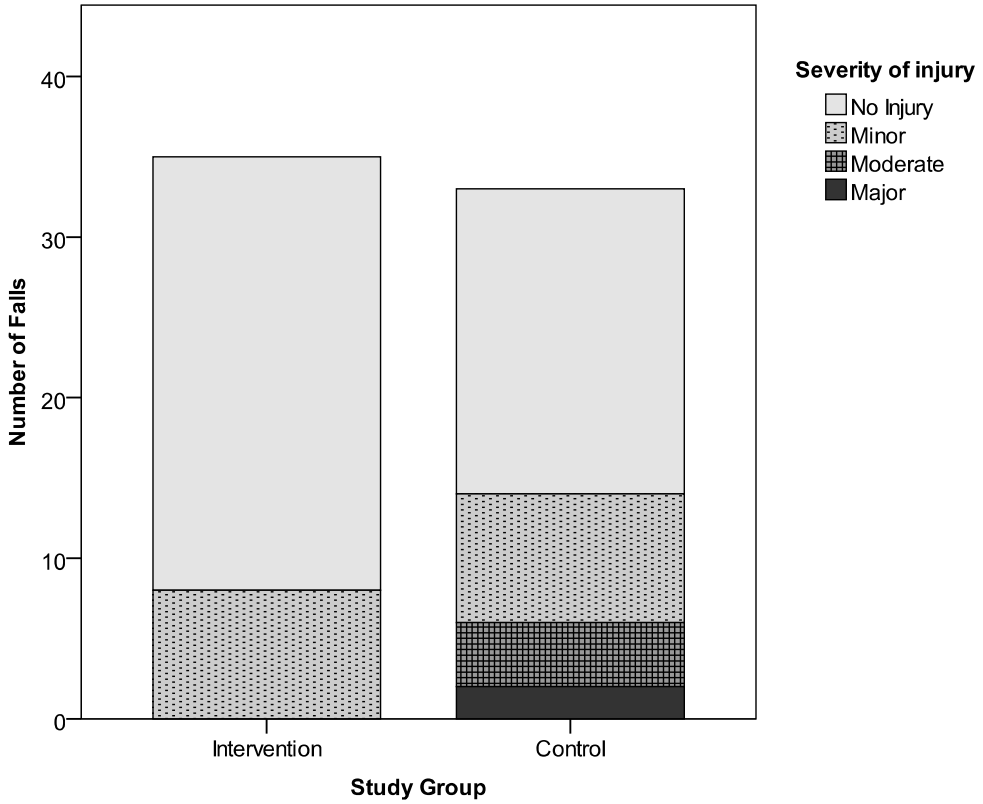


Figure 3.2 Severity of injury experienced from falls during the intervention period (includes recurrent fallers and all areas).

For site-specific incident rates see Appendix 4.

3.4.4.1 Injury rates per 100 patient fallers

An alternative means of summarising the injury rates is per 100 fallers (Table 3.5). This method describes the number of people who injured themselves (one or more times) regardless of how many times they fall. Hence, this method somewhat overestimates the rate of injury in recurrent fallers who may not have injured themselves on every fall (of which there were more in the control group). Similar to the incident rate per 1000 patient bed-days, these data show that the intervention group had an injury rate (25.8 injuries per 100 fallers) over halve that of the control group (54.5 injuries per 100 fallers). See Appendix 4 for a breakdown by site.

Table 3.5 Injury rates per 100 fallers

Group	Fallers (N)	Rate per 100 fallers: All areas			Fallers (N)	Rate per 100 fallers: Study areas		
		All injuries	Moderate-Major injuries	Major injuries		All injuries	Moderate-Major injuries	Major injuries
Intervention	31	25.8	-	-	24	25	-	-
Control	22	54.5	27.3	9.1	17	58.8	23.5	5.9

3.4.5 Falls

It is important that any flooring designed to reduced injuries does not inadvertently increase the risk of falls. Our findings indicate that more people fell in the intervention group (N = 31 fallers; 7.72 fallers per 1000 patient bed-days) than did in the control sites (N = 22 fallers; 5.18 fallers per 1000

patient bed-days), during the intervention period. The estimated effect of the flooring on falls is an increase of approximately a third relative to control group (all areas: adjusted IRR = 1.33, 95% CI = 0.44 to 4.03; study areas: adjusted IRR = 1.34, 95% CI = 0.46 to 3.90). Again, it should be noted that the confidence intervals are very wide, and in reality the flooring may serve to decrease the incidence rate of falls, or make no difference at all.

Over the course of the study, 93 falls were documented, from 70 fallers, of whom 14 (20%) were recurrent fallers. Summarising the data from the intervention period using hazard ratios (to take into account recurrent falls), reduces this observed difference further (All areas: adjusted HR = 1.13, 95% CI = 0.83 to 1.55).

3.4.6 Description of falls

Here we describe the characteristics of all falls (including recurrent fallers), of which there were 68 in the intervention period and 25 in the baseline period. Falls were discovered in a similar way across study groups, and this was predominantly by the patient being found on the floor. During the intervention period, 21 falls in the intervention group and 22 in the control group were identified this way, (see Appendix 5). Falls typically occurred inside the study area (See Appendix 2 for individual ward maps, and Appendix 6 for a summary). There were three occasions when the floor was documented as wet at the time of fall (2 intervention group, and 1 control group), and one of these (in the intervention group) resulted in a minor injury. Five people in the control group were documented as wearing protective clothing at the time of fall (and none in the intervention group). Protective clothing included: 2 hip protectors, 1 padded helmet, 1 leg brace, and 1 not described. One person wearing a hip protector sustained a minor injury to their hand, the remainder were not injured. Protective clothing could be considered a confounder, however given that all those documented with additional protection were in the control group, if anything, this would make our estimates more conservative. Footwear was generally not considered (by the staff completing the forms) to be a contributing factor to fall events. The majority (45%; Appendix 7) of falls were documented as occurring with bare feet (Baseline period N = 4 in the intervention group and 5 in the control group; Intervention period, N = 17 in the intervention group and 12 in the control group; NB. One person in the intervention group also had a bandage on one foot). More people in the control group (Baseline period N = 6; Intervention period N = 13) were documented as wearing slippers at the time of fall compared to the intervention group (Baseline period N = 1; Intervention period N = 9).

For 25% of the time, it was not known what patients were doing at the time of the fall (Figure 3.3). The most frequent activity documented (27%) was related to toileting, either trying to get out of bed/chair to go to pass urine/open bowels (more common at intervention sites), or getting on/off the commode/toilet (more common at control sites).

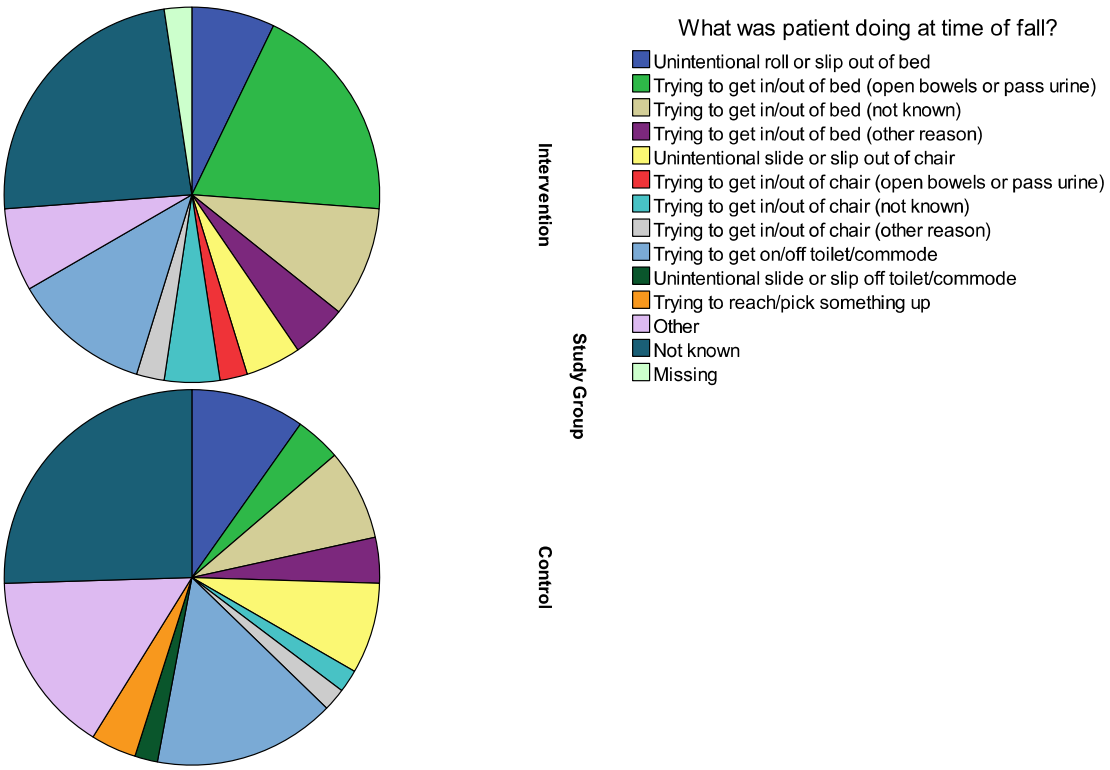


Figure 3.3 Description of what patients were doing at the time of the fall.

Table 3.6 indicates the medications taken in the 24 hours prior to the fall (note that this table includes recurrent fallers: 5 in the intervention group; 9 in the control group). Although medication usage was similar at baseline, medication usage just prior to the falling was broadly more prevalent in the control group (e.g. opiate analgesics, anticonvulsants/hypnotics/tranquilizers, diuretics, and laxatives).

Study Group N (%)	**Intervention**		**Control**	
	Intervention period	TOTAL	Intervention period	TOTAL
No. of Falls	35	42	33	51
Simple analgesics	18 (51.4%)	23 (54.8%)	17 (51.5%)	28 (54.9%)
Opiate analgesics	2 (5.7%)	2 (4.8%)	7 (21.2%)	8 (15.7%)
Anticonvulsants / hypnotics / tranquilizers	3 (8.6%)	6 (14.3%)	15 (45.5%)	18 (35.3%)
Anti-diabetic drugs	6 (17.1%)	6 (14.3%)	3 (9.1%)	7 (13.7%)
Digoxin / betablockers / ACE inhibitors / calcium channel blockers	17 (48.6%)	20 (47.6%)	15 (45.5%)	18 (35.3%)
Diuretics	7 (20%)	9 (21.4%)	17 (51.5%)	24 (47.1%)
Laxatives	6 (17.1%)	6 (14.3%)	8 (24.2%)	13 (25.5%)
Polypharmacy	17 (48.6%)	18 (42.9%)	16 (48.5%)	25 (49.0%)

Table 3.6 Medication in the 24 hours prior to the fall

3.4.7 Adverse Events

3.4.7.1 Movement of Equipment on the Intervention Flooring

In October 2010, we became aware that staff at one intervention site had expressed verbal concerns to the research nurse concerning the movement of equipment and furniture on the intervention floor. These concerns were communicated through email exchanges between the research nurse and ourselves (the Co-ordinating Centre). No formal communication was received from clinical or managerial staff at the NHS Trust concerned. No Adverse Events Forms or Hospital AIRS forms were received. We were informed by the research nurse in January 2011, that these internal concerns had been escalated and that the hospital's Trust Manual Handling Specialist had been asked to undertake a risk assessment of moving equipment on the floor. This was completed in January 2011 and recommendations made.

In February 2011, an Adverse Event Form was received from another intervention site. The Adverse Event Form did not report an actual injury or event but raised a general concern about the difficulty of moving objects across the intervention flooring.

The concerns noted in the Adverse Event Form, the aforementioned email exchanges, and the Report completed by the Manual Handling Specialist were formally taken to the Steering Committee (1st March 2011) for discussion. We appraised these reports as not being 'serious adverse events', but rather an issue that required further investigation and recommendations. This decision was supported by the Steering Committee.

The Steering Committee agreed a number of recommendations and these were circulated to all study sites. The primary recommendation was to immediately commission an independent and expert assessment of the risks associated with the movement of equipment on the intervention flooring. Consequently, the Health & Safety Laboratory were commissioned to undertake an ergonomic appraisal of the manual handling (push-pull) risk factors in areas using the shock-absorbing flooring (see Appendix 8 and Appendix 9 for the briefing paper and the covering letter from the study's Chief Investigator circulated to all sites).

A full independent Health and & Safety Risk Assessment was completed 23rd & 24th March 2011 at one of the intervention sites in order to inform The HIP-HOP flooring study regarding the forces exerted during performance of typical push-pull tasks, to evaluate the risk of injury and to advise on possible risk reduction measures.

On March 30th 2011, we received by fax, five Adverse Event Forms from the intervention site that had first raised concerns. These were accompanied by five Hospitals Adverse Incident Reporting System (AIRS) forms. These Reports raised concerns about moving of patients on equipment, four of which did not result in any injury, and one of which reported a pulled lower back whilst moving a patient on a trolley; however this did not require medical attention. The forms reported retrospectively events occurring between October 2010 and March 2011.

The Health and Safety Laboratory final report Ergonomics appraisal of the manual handling (push-pull) risk factors in areas using the impact absorbing flooring (2011),[11] was received on 14th June, 2011. This Report was circulated on the same day to all study sites and their respective Research and Development departments with an explanatory covering letter by the Chief Investigator (See Appendix 10 for covering letter). We informed the Research Ethics Committee of the situation, its management and resolution (20.06.11).

At the time of this report (December 2011), no further AIRS forms have been received from any of the study sites pertaining to movement of objects on the floor. However, concerns relating to the movement of equipment on the floor from the intervention site that originally raised concerns and from other intervention sites have remained. The issue of moving equipment on hospital floors was an area that was explored in qualitative interviews and is noted in Section 6 of this report.

3.4.7.2 Material Damage to Intervention Flooring

During May 2011, an Adverse Event Form was received from an intervention site reporting a 'split' in the intervention flooring along a seam. This prompted communication with the site's Estates and Facilities Department and the flooring manufacturer. The damage was inspected by the Estate and Facilities Department who confirmed that it was a 20-30cm slit along a 'weld' and was likely to be as a result of the installation process rather an inherent problem with the floor. The floor was subsequently repaired and monitored. No further reports have been received.

3.4.8 Design effect and Power calculations

Sample size calculations have been conducted utilising the trial data and based upon the guidance of Hayes and Bennett (1999),[12] using the coefficient of variance (k) to adjust for the clustering effect. If k equals zero, the required size of a clustered study will essentially be the same as what would be needed for a randomised controlled trial (with randomisation done at the patient level). The higher the value of k, the larger the sample size required for a cluster trial. Table 3.7 displays the estimates for a variety of scenarios, based on data from any falls and injuries (regardless of where they occur), and just falls and injuries occurring within the study areas. The estimated number of clusters has been rounded up to the next integer. We have also made crude estimations of the number of clusters required if each cluster were to be followed up for a longer period of time, or increased in size through the addition of extra bays. To make this estimation, we have assumed that k will not change. However, it is likely that as the cluster size increases, so will the variability (thus altering k). However the likely direction of this adjustment would mean that we have over-estimated the number of clusters required (although see warnings below).

Our primary outcome (incident rate of injuries based on injuries in any area) provides a coefficient of variation (k) of 0.258, which is about that which is often anticipated from cluster designs.[11] In this scenario the Design Effect is 1.2, which means we will need to increase the sample size by 20% of that required in a standard RCT. As these are all estimations, the likelihood is, that we would need to recruit somewhere between the number of clusters estimated if k = 0 and the number estimated when adjusting for k (so for a one-year study, between 39 and 47 clusters per arm). The estimates provided for a one year study are clearly not appropriate (or a cost-effective study design) based on our logistical experience of recruiting sites and the amount of time and effort that requires. It would be more sensible to either increase the follow-up time and/or increase the size of the study area within each cluster (e.g. have 2 bays instead of one). The duration of follow-up chosen should also consider the speed of change observed in our pilot study around the structure and organisation of services provided by the sites. One option could be,, for example, to recruit 10 - 12 sites per arm (20 – 24 in total), have two bays per site entered into the study, and follow them up for 2 years. This is estimated to be large enough to detect a 33% reduction in injuries relative to control, (NB. when adjusted for clustering this difference was a relative reduction of 54%), and a 49% increase in falls relative to control, (NB. when adjusted for clustering this difference was a relative increase of 33%). If the effect size for falls was indeed smaller than that estimated in Table 3.7, the larger sample required to detect a change in injuries, may also be sufficient to detect a change in falls.

Some warnings about our data:

- In the scenario where we consider what may happen if the floor were to be laid over the entire ward, the between cluster variance for injury rate becomes negative and so k is set to zero; it is likely that in reality this has underestimated k and the associated clusters required.
- The data on which we are basing these calculations is very sparse, and is therefore more prone to error. Emphasis should be placed on the fact that these are estimations.
- These calculations are based on a poisson distribution, but it is likely that we will need to analyse our data utilising a negative binomial distribution (due to over-dispersion), which may require larger samples than those specified here.
- If our data has over-estimated the effect size of the new flooring, or underestimated k, then these estimated sample sizes may be insufficient to detect a smaller effect if one does in fact exist.

Table 3.7 Estimated number of clusters required for a full trial (exploring different scenarios)

			1 year follow-up* with 1 bay per cluster		2 year follow-up° Or 1 yr with 2 bays		4 year follow-up° Or 2 yrs with 2 bays	
Outcome	Scenario	Assumptions	Estimated n. of clusters per arm (adjusting for k)	Estimated n. of clusters per arm (if k = 0)	Estimated n. of clusters per arm (adjusting for k)	Estimated n. of clusters per arm (if k = 0)	Estimated n. of clusters per arm (adjusting for k)	Estimated n. of clusters per arm (if k = 0)
Injury rate (all injuries)	Floor in one bay	Incident Rate: I = 1.818 C = 2.736 K = 0.258	47	39	24	20	12	10
Fall rate	Floor in one bay	Incident Rate: I = 7.72 C = 5.19 K = 0.365	31	16	16	8	8	4
Injury rate (all injuries)	Floor throughout ward[×]	Incident Rate: I = 1.369 C =2.257 K = 0[^]	33	33	17	17	9	9
Fall rate	Floor throughout ward[×]	Incident Rate: I = 5.825 C = 3.92 K = 0.313	32	20	16	10	8	5

*Assumes there are approximately 1100 patient bed-days per cluster (this varies slightly by scenario)
°Assumes k will not change given larger cluster sizes (this is likely to over-estimate the number of clusters)
×Assumes we will still recruit from one or two (high risk) bays (as specified by follow-up); recruiting from the entire ward will also reduce number of clusters.
^Between cluster variance is negative (implying variation within a cluster is greater than that between clusters, most likely due to sampling error); therefore k is set to zero.

3.5 Discussion

Whilst the injury data appears encouraging, the falls data does not bode well for the prospects of a future trial. There may be a series (or combination) of explanations for these figures, however, which may or may not be related to the floor, as discussed below:

This is a small trial which happened to show an effect estimate for falls as larger than 1, yet as the confidence intervals indicate, the true effect may in fact be no difference, or the floor may even be of benefit. Additionally missing data points in the current dataset (N=7) will have led to an unknown over-estimation of falls rates in the intervention sites.

Inspection of the baseline characteristics indicates some imbalances between the intervention and control groups, in that participants in the control group tended to have more fall-related co-morbidities and were more frequently admitted with instability than those in the intervention group. On the one hand this is counter-intuitive to what would be expected if there was indeed a higher falls rate in the intervention group; alternatively, it could be hypothesised that those in the control group were under higher observation, and possibly more bed-bound than those with fewer indications for falls, and hence were less likely to fall. Length of stay was also slightly shorter at intervention sites (who had a higher turnover of patients) which coupled with more internal transfers (see below0, may have led to increased disorientation and higher falls rates.In a larger trial, these baseline imbalances should be further minimised through the power of randomising more sites.

This study was not blinded, so it is potentially subject to performance bias, whereby high risk fallers may have been moved into the study area at intervention sites to a greater degree than they were at control sites. Analysis of the internal transfers (and reasons provided) indicates that the risk of internal transfer was higher in the intervention group (non-significant), which in itself may be a risk factor for falls (as patients maybe more disorientated when transferred, regardless of the reason for transfer). When looking at the fall-related reasons given for transfer the difference between the intervention and control group is minimised. Additionally, if performance bias was a problem, it may not have been consistently so across all sites; according to one intervention site's Admission Forms (in which the study bay was not their observation bay) they were doing the opposite of what would be expected should performance bias have been playing a role (i.e. moving patients into the Study Area to free up beds for people at high falls risk in another bay closer to the nursing station). However, information obtained from an interview at this site suggested that not all staff were operating like this. A staff member noted:

> *"I think basically if there's a bed, if the bed's empty there, normally my kind of criteria would be if the patients falling a lot when I'm about to admit a patient I would just say right, we'll just move people round so that we can look after them nearer to the nurses station, now I don't do that, I just put them in there, so that's different to how I used to operate"* [B05 - Staff interview].

A member of staff at a different intervention site also indicated a change in practice:

> *"I'm more aware of saying 'are they high risk of falls?' because then I can make sure I've got a bed space in that bay, um and that's probably something we will work towards, whereas before it was kind of like, where the nurses' station is we can't really look round any corners so it doesn't, we try to put them in B Bay coz they are more physical but it was kind of, and now we really work towards it so, yeah, it's probably just admittances different*" [C04 - Staff interview].

But not all staff at this site considered there to have been a change in practice:

> *"that bay has always been the high risk patient bay there is, so if we've had a new admission and there's a patient in there who's a low risk and they were perhaps put in there because there any many risk patients in there, coz that's just how the ward is, we will swop people anyway, because B bay has always been our risk bay anyway, so having the flooring is an added bonus to that bay being our most observable area, um, so no we haven't consciously put people in there in addition, we've always done that."* [C07- Staff interview]

Apart from potential changes to admissions, a further risk of performance bias may have stemmed from staff feeling more re-assured about patients being safer on the floor, and potentially relaxing observation:

> *"although potentially for patients who are at risk of falling is still always a priority and concern to nurses, however having that flooring in there to me at the back of my mind, I know that if for any reason we are engaged somewhere else, like we were with the emergency the other night, and there was no staffing near that bay at the time because of the priority and that patient fell, having at the back of my mind on a day to day basis that that flooring is in there, to save lives and injury, is a comfort, so it's a conscious comfort coz you can't be everywhere at once and having that there knowing that you know they're not going to come in, fall and then get worse, um is definitely, yeah it is a relief."* [C07- Staff interview]

The interviews also indicated that some staff were not fully aware of the purpose of the new flooring (confusing injury reduction with falls reduction), implying that a 'sham' floor may be a potential means of reducing the influence of performance bias in future research.

As this study was not blinded it is potentially subject to detection bias, whereby staff at intervention sites may have been better at reporting the falls and possibly better at reporting those that resulted in no injury (which would have affected the injury rates as well as the falls rates). In fact two control sites submitted falls data (18 falls, including 4 minor injuries) retrospectively at the end of the study; one fall (no injury) was reported at 204 days after the event in an intervention site. Our data suggests that on average, falls forms were completed a median of 3 days (range = 0 to 204; inter-quartile range = 6) after the fall event at intervention sites, and 7 days (range = 0 to 531; inter-quartile range = 67) days after the fall event at control sites. Intervention sites reported more falls and faster than control sites. However, we do not know what data may be missing; we have assumed that if we have not received a falls report form then a fall did not occur. Future studies should consider more robust monitoring processes to ensure the adequacy of outcome reporting.

It could be hypothesised that the floor may be more slippery than regular floor coverings; however the mechanical testing conducted on the floor indicates otherwise (see Section 4).

Hypothetically, it is feasible that the feeling of the softer flooring underfoot somehow increases the risk of mis-stepping, or tripping (e.g. by being harder to detect), or by influencing the ability to use walking aids effectively. Analysis of our interview data indicated that of the patients we interviewed, they could not always detect the difference between the intervention flooring and other floors on their ward:

"I haven't thought about it, um, I've not felt any difference really.[…] I haven't noticed particularly, I haven't notice any difference, you know I'm always careful so I don't feel any particular difference. […] Well it's like any other floor that looks like this. […] I'm unsteady on my feet anyway, you know, no [concerns], normal, like any floor, coz my legs give away, but I don't think it's the floor's fault, I think it's my legs (laughs)" [A02 –Patient interview].

"They're [floors] all the same to me (laughs). […] To me no difference. […] I've never given it a thought [what the floor feels like to walk on], no idea. […] As I said before I'm, all I'm concerned is to be able to stay upright, that's all I'm concerned with." [A01 – Patient interview].

Some staff had opinions on patients' ease of walking on the floor:

"I must admit compared to the other patients the patients in that bay don't complain that they feel the floor is slippy underneath their feet, which is something that they do say in other bays that they can't stand up because the floor's slippy, that's very much less of an issue in that bay. […] getting up for example if you've got a patient that's not particularly, doesn't find it easy getting up, the new floor is easier for them than the old floor was, um, so it does have its benefits in that sense." [A02 – Staff interview]

"They [patients] do tend to not be able to clear the floor as well, they struggle to get that foot clearance off the floor, so there's a lot of shuffling seems to go on in that bay, um, compared to other bays, but whether again that's the patients that are in there, its hard to differentiate, but I do think they find it harder to get that foot clearance.[…] Possibly because it's a bit thicker than the other floor coverings and because there does seem to be a bit of a sponginess to it, that it just requires more effort from the patients to be able to clear it, as opposed to this kind of hard, thin floor, where its quite easy to pick your feet up just that little bit." [A02 – Staff interview]

"I think for the patients the flooring seems to be absolutely fine, um, you know they seem to walk on it with no more difficult than I would thing that they would on lino, um, you know, a little bit maybe with pushing, having to push the frame a little bit harder, um, or you know in not running as well as it does on the lino or as fast as it does on the lino, but that's not necessarily a negative, um, because of the carpet, because it's similar to carpet in that way." [B10 – Staff interview]

"from reports it definitely feels less slippy, and anecdotally I've gone no evidence to support this but um, I've been told that the physio's are saying that it's quite tricky to get a patient to move with a zimmer frame on it, coz its sort of bedding down in the floor, but as I say that's purely anecdotal, I've no evidence of that, but um, it definitely does feel tackier underfoot" [D11 – Staff interview]

Future research should assess the implications of thicker floors on walking ability and use of walking aids. See also Section 6.

3.6 References

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4. SECTION 4: MECHANICAL PERFORMANCE OF THE FLOOR

4.1 Introduction

This Section of the report relates to our second objective: To periodically assess the sustainability of the flooring types, recording surface irregularities, slip-resistant and shock-absorbent properties. An article in *Hospital Development* stated that flooring needs to have a 10-20 year lifetime and corresponding low lifecycle costs;[1] it went on to highlight the necessity of delivering long-term value, meeting the demand of better design and rising to the challenges of healthcare environments. This is in line with the environmental strategy being implemented within the NHS.[2] We did not propose to follow the performance of the floor for the entirety of its life-time; instead we hoped to gauge the performance of the floor over a relatively short period, in order to make an informed judgement of its long-term suitability for healthcare environments. We assessed any changes occurring to the new floor material and compared this to damage sustained in the old flooring (within the same time period).

We did not predict that the new flooring would sustain an unusual amount of damage, since it has undergone materials testing demonstrating it to have good compression set characteristics (i.e. it returns to its' regular shape after compression). However, since Tarkett Omnisport EXCEL had not been assessed in a ward bedroom environment before, we did not want to overlook this important factor. For this objective we planned to monitor the performance of the flooring: a) to ensure it does not sustain any surface irregularities such as grooving, b) that the surface material maintains a degree of slip-resistance comparable to the control flooring, and c) that it maintains its added value (i.e. its shock-absorbent properties). The physical assessments made under this Objective will additionally characterise and inform the comparability of the wards involved.

4.2 Institutions

All study sites (intervention and control) were included in this component of the study. The flooring of each designated bay ('Study Area') was assessed.

4.3 Data collection

The flooring was assessed once during the baseline period, and at three time-points during the intervention period. This was in line with the advice of the Health and Safety Executive (HSE), who recommended that floors be assessed every 3-6 months (depending on the context) to fully take into account the wear characteristics of floor surfaces over time.[3] Each site had two locations (test areas) mapped in the Study Area. The chosen test areas targeted a high traffic and a low traffic area. All data collection was carried out with a standardised procedure and equipment. Procedures were duplicated at each test area, and repeated at each set time point (as detailed above).

4.3.1 Surface irregularities and wear

Surface irregularities and wear of the floor was ascertained through visual inspection of the whole study area (See Section 2, detailing the findings of the ward audits).

4.3.2 Slip resistance

Slipperiness assessments were undertaken using standard Health & Safety Laboratory (HSL)/Health & Safety Executive (HSE) techniques in accordance with The UK Slip Resistance Group Guidelines[4] where appropriate. An assessment of the slip-resistant properties of the floor was made using the "pendulum co-efficient of friction (CoF) test", [i] in the as-found dry condition, and [ii] in the water-wet condition (subject to the British Standard BS 7976). Measurements of the floor surface Pendulum Test Value (PTV), closely related to coefficient of dynamic friction, were made

using a calibrated Stanley Pendulum instrument. The pendulum CoF test (regarded as the "gold standard") is designed to simulate the action of a slipping foot; the method uses a swinging arm which contacts, via a dummy heel (test slider), a set area of flooring in a controlled manner. The test slider used was Slider 96 Rubber, developed to represent a footwear material of moderate slip resistance. The slip resistance of the flooring is measured by the over swing of the pendulum (Pendulum test value) and is directly affected by the slipperiness of the floor. The Rz surface microroughness of the flooring was also measured, giving a secondary indication of the slip resistance in wet conditions. Interpretation of the slip potential was based on UK Slip Resistance Group Guidelines (see Table 4.1). These assessments were undertaken by a trained independent professional from the Health & Safety Laboratory. The instrument requires a competent operative both to use it and interpret the results.

Table 4.1 Interpretation of slip potential based on mechanical testing

Pendulum Test Value	Slip Potential
0 – 24	High
25 – 35	Moderate
36 +	Low

Rz Surface Roughness (µm)	Water-Wet Slip Potential
Below 10 µm	High
10 - 20 µm	Moderate
20 + µm	Low

Adapted from: 'The Assessment of Floor Slip Resistance:
The UK Slip Resistance Group Guidelines', Issue 3, 2005.

4.3.3 Shock absorbency testing

A portable impact tester was designed and built for this study which comprised of a 2.75Kg weight with the striker shaped to represent the geometry of the greater trochanter with a spherical radius of 65mm, contained within a tube aligned vertically. The test uses a striker fitted with an accelerometer, which measures the deceleration of the striker as it impacts with the floor very much like the instrumentation in BS1177 (1998)[5]. This apparatus was used to assess the impact properties (that is the energy absorption) of the flooring at the participating intervention and control sites. Data is logged via DASYLab software, at a sampling rate of 20KSamples/s. At each location the striker was released four times from heights of 20 & 30cm (see changes from original plan below). The highest recorded g on first impact (≈ peak g) was extracted for analysis. On control floors, the duration of the impact combined with the sampling rate of the g data from the accelerometer means that the peak g was not always recorded. The signal from the accelerometer was subject to a considerable amount of electronic noise from vibrations in the drop rig when testing the hard control floors, and due to this noise, no attempt was made to extrapolate the peak g from the recorded values, where the peak lies between sampling points. However, the difference between the control and the intervention floors up to an order of magnitude was so great that this small error was not considered to be of concern. An identical protocol was used to measure the impact of the flooring in the control and intervention sites' Study Areas, in high and low traffic areas, and at each of the four allocated time points. An error occurred with the impact testing equipment at one of the control sites during the first visit (baseline period), and as such we do not have shock-absorbency data for the high traffic area for this site An additional anomaly occurred during the third visit of another control site, in which the g-force values were abnormally low indicating an error with the equipment (this was due to a loose mounted accelerometer and these values have been excluded from the analysis).

4.4 Data analysis

Due to missing data points for shock-absorbency, coupled with a violation of the assumption of equality of variance, we have decided to report on this outcome descriptively. The effects of the intervention on slipperiness was explored through repeated measures analyses of variance (ANOVA), in which the different time points were considered as the levels of one factor (within-subjects) in each analysis and the study group as a second factor (between-subjects) in the analysis (only data from visits during the intervention period were included in this analysis). We additionally factored the variable contamination (wet/dry) into the analysis of slipperiness as a between-subjects factor. We tested the assumptions of repeated measures ANOVA: Scores were approximately normally distributed (when accounting for wet and dry conditions); Maunchly's test of Sphericity was calculated for the different time points, and as it was significant ($p = 0.015$, indicating the sphericity assumption for ANOVA had been violated) we selected a more conservative F value (Greenhouse-Geisser) and associated level of significance; the assumption of homogeneity of variance was also violated, however given that ANOVA is relatively robust to these assumptions (with equal number of scores and normally distributed data),[6] we decided to proceed as planned. Rz surface microroughness readings were not analysed, but were used by the data collector as a validation check of the Pendulum Test Values (PTV) in the wet, as it is the PTV which is considered the primary measure of slipperiness.

4.5 Changes from the original plan

We set out to measure the impact properties of the floor from four drop heights (20cm, 30cm, 40cm, and 50cm). Following data collection for the first two time-points, the Steering Committee approved the decision to discontinue data collection from 40cm and 50cm heights. The rationale for this decision was two-fold: (1) it was felt this data contributed limited added value (the equipment was not as sensitive to measuring the g-forces from the higher drop heights, meaning that the findings were more prone to measurement error); and (2) higher drop heights created louder noises (particularly at the control sites, which had harder floors), which was unpleasant for patients residing the room.

4.6 Results

4.6.1 Shock absorbency

Although g forces were similar at sites during the first visit (prior to any new floors being installed; intervention sites mean = 961g, 95% CI 901.15 to 1021.13, control sites mean = 972.65g, 95% CI 897.36 to 1047.94), following the installation of the new floors at the intervention sites the shock absorbency of the floor at these sites was increased (expressing lower g forces), and much more so than that of control sites (Table 4.2; Figure 4.1). Additionally, although the shock absorbency was much more variable at control sites over time (most likely related to the increased 'noise' in the data caused by the harder floors), following the installation of new floors, the shock-absorbency of the floors in intervention sites did not deteriorate over the course of the study.

Table 4.2 Shock absorbency of floors in Study Areas

	G force, Mean (95% CI)			
Study Group	Visit 1 (Baseline)	Visit 2	Visit 3	Visit 4
Intervention	961.14 (901.15, 1021.13)	191.24 (144.33, 238.15)	161.02 (133.64, 188.39)	164.72 (115.40, 214.04)
Control	972.65 (897.36, 1047.94)	1116.52 (1057.64, 1175.39)	828.00 (793.65, 862.36)	1089.25 (1027.35, 1151.14)

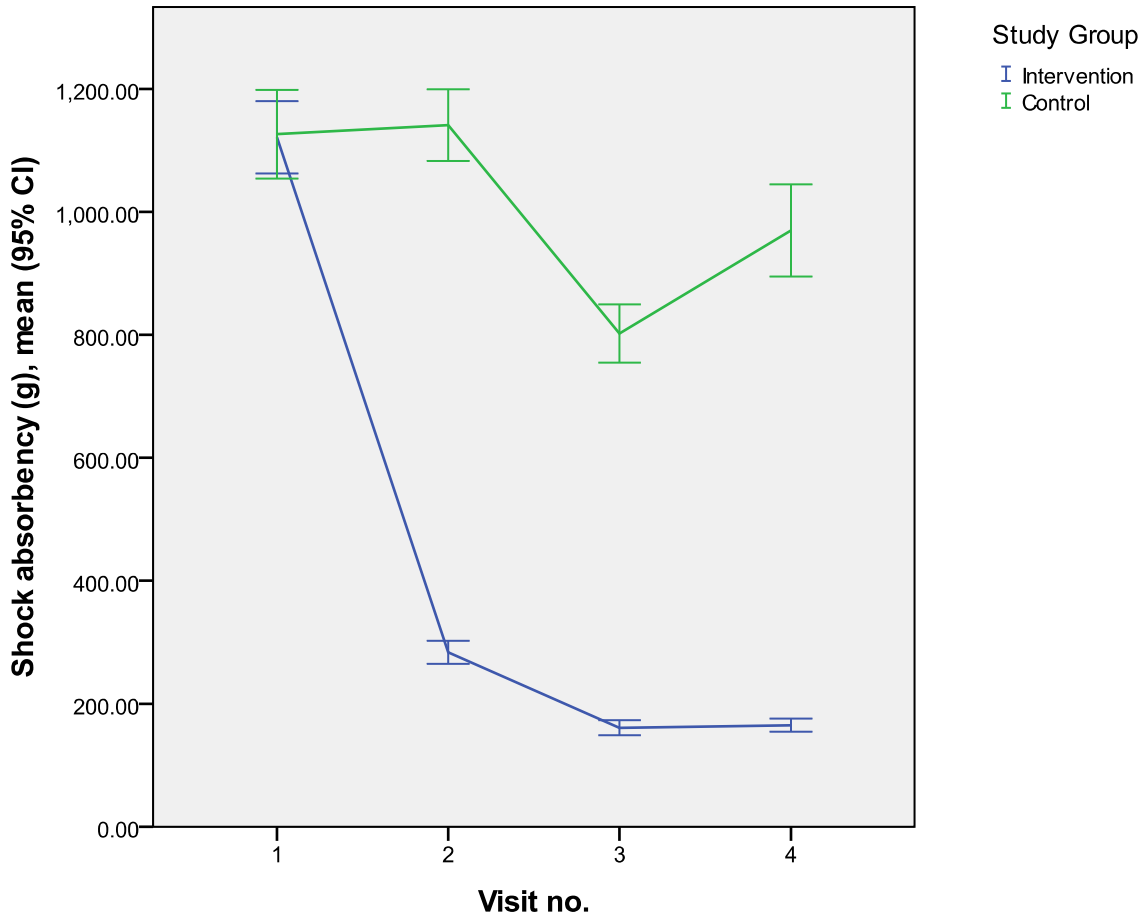

Figure 4.1. Shock absorbency of floors at intervention and control sites over time.

4.6.2 Slip resistance

Figure 4.2 displays the slipperiness data for the floors at intervention and control sites (including the baseline visit), in wet and dry conditions. PTV scores of 36 and greater indicate low slip potential, and scores of 24 and under represent high slip potential. All of the floors in the study can be considered of low slip potential when dry (mean PTV = 69.10, SD = 5.63), and high slip potential when wet (mean PTV = 16.43, SD = 4.08); wet floors are statistically more slippery than dry ($F_{1, 92}$ = 5694.47, $p < 0.001$). Figure 4.2 demonstrates that when wet, the shock-absorbing flooring has slightly lower slip potential (overall mean PTV = 18.85, SD = 2.20) than control floors (overall mean PTV = 14.01, SD = 4.11), although this is still considered a high slip potential; in the dry these differences are less pronounced (intervention group overall mean PTV = 69.06, SD = 4.58; control group overall mean PTV = 69.15, SD = 6.55). This may explain a significant interaction between the slipperiness scores in wet and dry conditions across study groups ($F_{1, 92}$ = 12.47, p = 0.001). Although statistically significant, all floors performed similarly according to the guideline interpretations of PTV scores, and therefore the clinical relevance of these differences is questionable. Similarly, overall the intervention floor had statistically better slipperiness scores than control sites ($F_{1, 92}$ = 11.51, p = 0.001), but with questionable clinical relevance.

Analysis of variance indicates that overall the slipperiness statistically improved over time ($F_{1.8, 169.2}$ = 12.32, $p < 0.001$), however the clinical relevance of this is questionable, since the overall slip potential according to guideline PTV thresholds did not change. There was no interaction between

study group and slip potential over time ($F_{1.8,\ 169.2} = 2.68$, $p = 0.76$) indicating that any changes that did occur in slipperiness over time were consistent across study groups. There was a statistically significant interaction between contamination and slipperiness over time ($F_{1.8,\ 169.2} = 14.64$, $p < 0.001$), indicating that slipperiness scores improved over time in dry conditions (mean PTV (SD): 2nd visit = 66.42 (4.66), 3rd visit = 69.37 (6.33), 4th visit = 71.52 (4.62)), and largely stayed the same in wet conditions (mean PTV: 2nd visit = 16.52 (4.26), 3rd visit = 16.48 (4.57), 4th visit = 16.29 (3.42)). Again, although statistically significant the real-world relevance of these changes is questionable. The interaction between contamination and time was similar across study groups ($F_{1.8,\ 169.2} = 0.11$, $p = 0.88$).

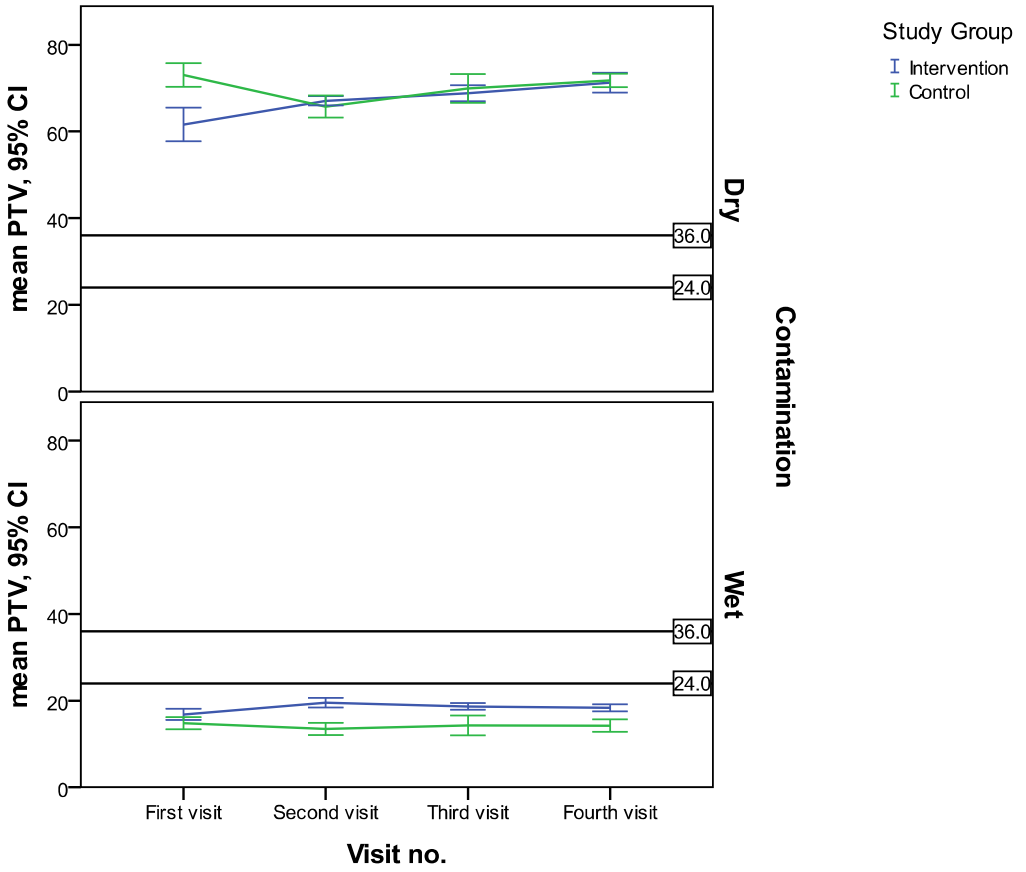

Figure 4.2. Slipperiness of floors in wet and dry conditions; guideline thresholds are indicated at 24 (high slip potential) and 36 (low slip potential) PTV.

4.7 Discussion

The mechanical testing indicated that the shock absorbing flooring performed better with regards to g forces produced, and was marginally less slippery (particularly when wet). The differences between floors were consistent over the course of the study. Differences in the slipperiness between intervention and control floors, and between time points, although statistically significant, do not represent clinically relevant differences according to the current guidelines. Taken in conjunction with the falls and injuries data from the main trial, these findings give credence to the hypotheses that the shock-absorbency of the intervention floor may be sufficient to influence the injury rates, and the slip-resistance of the intervention floor is unlikely to have influenced the falls rates.

This study piloted a mechanical means of assessing the shock-absorbency of floors via a portable impact tester. Future studies may consider the following improvements to this technique: (1)

selecting drop heights of 20 – 30cm appears reasonable with regards to the quality of data obtained and decreased disruption caused, thus eliminating the 40-50cm drop heights would enable a smaller, more convenient (portable) impact tester to be built; (2) the equipment could incorporate a higher sampling rate to obtain more accurate peak values; and (3) future methodology should incorporate a reliability check of the impact testing equipment (e.g. dropping the plunger onto a specific surface with a known expected value) to enable potential errors to be identified during data collection, as opposed to retrospectively.

4.8 References

[1] Munden D. Transatlantic flooring. *Hosp Dev* 2006;38:31.

[2] Department of Health. Sustainable development: Environmental strategy for the National Health Service. The Stationary Office: London 2006.

[3] Health & Safety Executive, Slips Assessment Tool website (frequently asked questions). http://www.hsesat.info/satFAQ.asp (accessed November 2006).

[4] UK Slip Resistance Group. *The assessment of floor slip resistance*, Issue 3, 2005.

[5] British Standards Institute. BS1177:1998 Impact absorbing playground surfacing. Safety requirements and test methods. British Standards Institute. London. 1998.

[6] Dancey CP, Reidy J. Statistics without maths for psychology. *Using SPSS for Windows* (2nd Ed). Pearson Education Limited, Harlow. 2002.

5. SECTION 5: COST EFFECTIVENESS EVALUATION

5.1 Introduction

This section focuses on the third objective, to determine the likely cost-effectiveness of laying an 8.3mm thick vinyl floor covering with PVC foam backing (Tarkett Omnisports EXCEL) in hospital wards for older people, compared to keeping standard hospital ward flooring. We also aim to outline where key uncertainties lie, to help determine where future research should be directed.

A cost-utility analysis has been undertaken from the NHS and personal social service (PSS) perspective. Costs and utilities were estimated for individual patients using data collected from hospitals, GPs and patient questionnaires combined with standard cost and valuation sources. Cost effectiveness is described using an incremental cost effectiveness ratio. A model-based approach has been used in order that costs and outcomes beyond the end of the trial could be estimated.

5.2 Changes to the original plan

Due to the lack of data on key input parameters probabilistic sensitivity analysis has not been undertaken as parameter distributions would have been based primarily on guess-work and results may have been misleading. Instead scenario analysis has been run to demonstrate which parameters are particularly influential for the cost-effectiveness results. This helps identify where future research would be of most value.

5.3 Model Design

A decision tree economic model was designed to estimate the likely cost effectiveness of the intervention over time. The decision tree tracks potential pathways that participants could take from the point at which they are admitted to hospital until death, taking into account whether or not a fall occurs, how severe a fall is if one occurs, and subsequent probabilities of being discharged to different locations upon their discharge from hospital. The model is illustrated in Figure 5.1. For simplicity the full tree is not shown – at the initial hospital admission stage a patient can be allocated to either a Ward with cushioned flooring or a Ward with standard flooring. Also, within this section of the tree the complete pathway is only illustrated for ‘Fall’ followed by ‘No injury’. The branches subsequent to this are identical for the ‘Minor Injury’, ‘Moderate Injury’, and ‘Major Injury’ nodes. Also, in the ‘No Fall’ section, the branches subsequent to ‘Discharged to another Ward/hospital’ are the same as those shown in the ‘Fall’ ‘No Injury’ section.

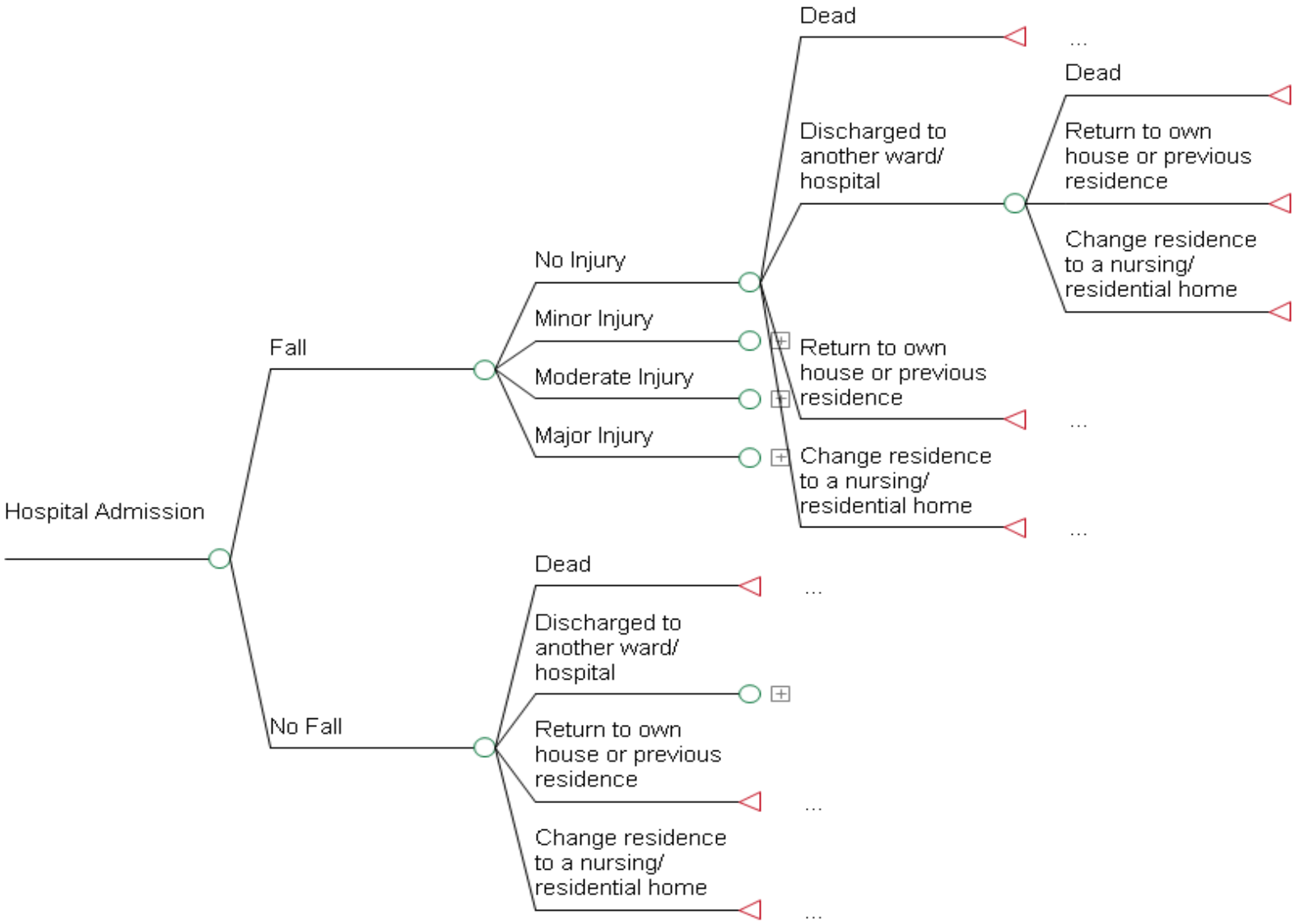

Figure 5.1 Decision Tree

A more elaborate economic model was considered, whereby the full range of potential discharge locations would be included (for example, responses received included a different ward; another hospital; own house, flat or bungalow (independent); own house, flat or bungalow (dependent); other person's house, flat or bungalow; housing with warden support; nursing home; residential home; rehabilitation; resource centre) but the proportions of participants going to some of these locations was very small. Given this and the relatively large extent of missing cost and quality of life data in the study it was deemed not possible to model these usefully – though this might be possible following a full RCT. Instead, we decided that the most important locations of discharge from a resource use and quality of life perspective that had a non-negligible prevalence in our dataset were nursing and residential homes. If a patient initially lived in their own home (either dependently or independently), someone else's home, or in housing with warden support then their costs to the NHS and PSS would be minimal. However, if following hospitalisation (and potential fall) these patients were discharged to a residential or nursing home there would be a substantial cost to the NHS. Hence we included this change in residence location in the model. For patients who already lived in a nursing or residential home and were discharged back to their initial location we did not include any incremental costs or disbenefits because their end location was not related to their hospitalisation – it is *changes* in location following hospitalisation that we wish to capture in our model.

5.4 Inputs

5.4.1 Effectiveness

The proportion of patients who follow each pathway included in the decision tree was determined – where possible – by the HIP-HOP data. For some chance nodes after the occurrence of relatively rare events (such as moderate and major falls) assumptions were made based on the literature (where possible). The probability values for a patient falling used in the model are listed in Tables 5.1 and 5.2. Following the Fall severity and No Fall nodes the probabilities of the different pathways are dependent only upon fall type, not randomisation group. The probabilities of falls are taken from the intervention period of the trial, whereas destinations and resource use probabilities after a fall has occurred are taken from all data collected in the trial – including both the baseline and intervention periods. Note that if a patient fell more than once, and the severity of the fall differed, the fall type for use in the economic model was the most severe of the falls that occurred.

Table 5.1 Probabilities of falls included in the model

Node	**Probability Value**		**Difference (95% CI)**	**Justification**
	Intervention Group	**Control Group**		
Fall	13.6%	9.8%	-3.9% (-9.8% to 2.1%)	Based on trial data
No Injury	10.1%	4.0%	-6.1% (-10.9% to -1.4%)	Based on trial data
Minor Injury	3.5%	3.1%	-0.4% (-3.7% to 2.9%)	Based on trial data
Moderate Injury	0.0%	1.8%	1.8% (0.05% to 3.5%)	Based on trial data
Major Injury	0.0%	0.9%	0.9% (-0.3% to 2.1%)	Based on trial data
No Fall	86.3%	90.2%	3.9% (-2.1% to 9.8%)	Based on trial data

Table 5.2 Probabilities of events following falls

Node	Probability Value				
	No Fall	**Fall – No injury**	**Fall – Minor injury**	**Fall – Moderate injury**	**Fall – Major injury**
Dead (during hospitalisation in study ward)	5.9%	13.5%	14.3%	14.3%	14.3%
Discharged to another Ward/hospital	16.4%	22.9%	22.9%	22.9%	22.9%
Return to own house/previous residence	65.3%	33.9%	33.2%	0.0%	0.0%
Change residence to nursing/residential home	12.4%	29.7%	29.7%	62.9%	62.9%
Dead in hospital following transfer to another Ward/hospital	5.9%	13.5%	14.3%	14.3%	14.3%
Return to own house/previous residence following transfer to another Ward/hospital	81.6%	56.8%	56.0%	0.0%	0.0%
Change residence to nursing/residential home following transfer to another Ward/hospital	12.4%	29.7%	29.7%	85.7%	85.7%

Note: justifications and methods for calculating each of the values in this table are presented in Appendix 1

5.4.2 Costs and Outcomes

Costs, utilities, future survival time and resource use are applied to each of the terminal nodes in the decision tree. These are discussed below.

5.4.3 Quality of Life

Participants were followed up 3 months after discharge from hospital, and the EQ5D questionnaire[1] and resource use questionnaires were administered at this time point. EQ5D data were available for 123 patients. These data allowed estimates of utility associated with different fall types to be calculated. The utility scores used in the model for the different fall types are listed in Table 5.3

Because there was very little utility data on patients who sustained a minor, moderate or major injury due to a fall we estimated utility scores for these patients by applying a relative risk to the 'fall – no injury score'. The relative risks were calculated from data presented by Iglesias and colleagues (2009).[2] Details on the Iglesias and colleagues (2009)[2] study and how the study findings were incorporated into our analysis are presented in Appendix 14.

Table 5.3 Utility by fall type

Fall Type	Utility Score	Justification
No fall	0.38	From trial data
Fall – No injury	0.36	Use of relative risk versus no fall based on utility model reported by Iglesias et al (2009) from the Hip Protector trial[2]
Fall – Minor injury	0.34	Use of relative risk versus no fall based on utility model reported by Iglesias et al (2009) from the Hip Protector trial[2]
Fall – Moderate injury	0.32	Use of relative risk versus no fall based on utility model reported by Iglesias et al (2009) from the Hip Protector trial[2]
Fall – Major injury	0.27	Use of relative risk versus no fall based on utility model reported by Iglesias et al (2009) from the Hip Protector trial[2]

In the economic model we intended to assume that the utility decrement associated with a fall was maintained for a maximum of 1 year, as Iglesias and colleagues (2009) found that the utility effect associated with a fall was insignificant after one year.[2] However, as will be discussed below, based on HIP-HOP data we estimated that the only patient group that would have a mean survival time of greater than 1 year would be those who did not fall, and so instead we simply assumed that the utility decrement associated with a fall was maintained for fallers until death.

It is noticeable that the utility scores estimated directly from the HIP-HOP trial are substantially lower than the baseline score from the Hip Protector trial. This demonstrates the poor health related quality of life experienced by patients recruited to the HIP-HOP trial. A potential limitation of using the Iglesias and colleagues (2009) data to estimate relative risks for utility is that the impact of a fall may be different in this group of patients than in the HIP-HOP patient population. In addition, the Hip Protector study was exclusively in female patients, whereas females made up 86% of the HIP-HOP study population. However, since data on minor, moderate and major falls were so sparse from the HIP-HOP trial, it is reasonable to use the Iglesias and colleagues (2009) data.

We made utilities time-dependent, so that they reduce each year according to a relative risk estimated using Ara and Brazier's (2011) algorithm, which itself was calculated using Health Survey for England (1996) data.[3] This has little effect in the model as life expectancy is very short. In addition quality adjusted life year (QALY) estimates were adjusted on a pro-rata basis such that utility is accrued for an equivalent amount of time for each fall type – i.e. a patient with a major fall who stays longer in hospital does not accrue utility over a longer time period than a minor faller who spends less time in hospital, despite both being followed up at 3 months after discharge from hospital. Where applicable (ie for non-fallers who were expected to live for longer than 1 year), future QALY gains were discounted at 3.5%.

5.4.4 Mortality

An estimated survival time had to be applied to each terminal node of the decision tree model so that costs and utilities could be accrued over a reasonable time period. Given the population recruited to the HIP-HOP trial it was appropriate to take a lifetime perspective in the economic model. As stated in the 'effectiveness' section above, the death rates while in hospital observed in the trial were applied in the economic model (amended for some fall-types through assumptions due

to a lack of data). For patients who were alive at discharge we estimated expected survival times based upon proportions that remained alive at 3 month follow-up using exponential parametric survival models. Models were fitted for fallers and non-fallers – separate models could not be fitted for the different types of fall due to the limited event numbers. Initially we planned to apply a relative risk such that expected survival time would be shorter for fallers who sustained major or moderate injuries compared to those who sustained minor or no injury. However, the expected survival time even for non-fallers and fallers who sustained no injury were so low based upon the trial data that we could identify no data sources from which we could elicit suitable relative risks for more serious falls. For example, in economic analysis conducted for the NICE Hip Clinical Guidelines published in 2011, 12 month follow-up data was used from a study conducted by Siegmeth et al (2005) to estimate mortality in hip surgery patients with a mean age of 81.[4-5] Using the figures quoted in the guideline combined with GAD life table data these patients would be expected to live approximately 2.45 years. However, based upon the HIP-HOP data, even patients who experienced no fall had an expected survival time of only 1.24 years, and fallers had estimated mean survival of 0.83 years. Hence, the HIP-HOP population had a very low expected survival time, and without further data it is difficult to estimate how more serious falls may affect this.

The exponential models applied to fallers and non-fallers are illustrated below.

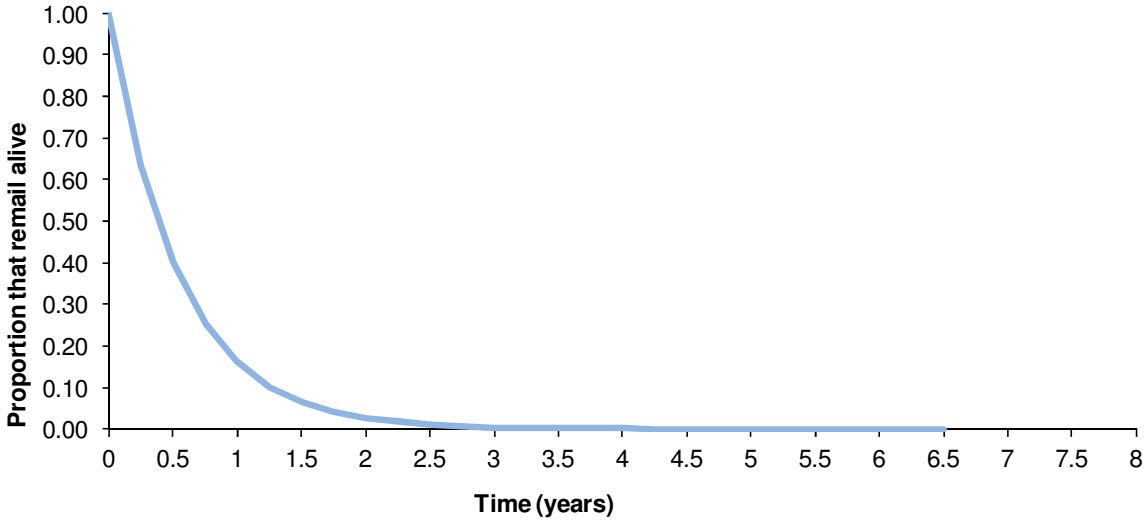

Figure 5.2 Exponential model of survival time – Non-fallers

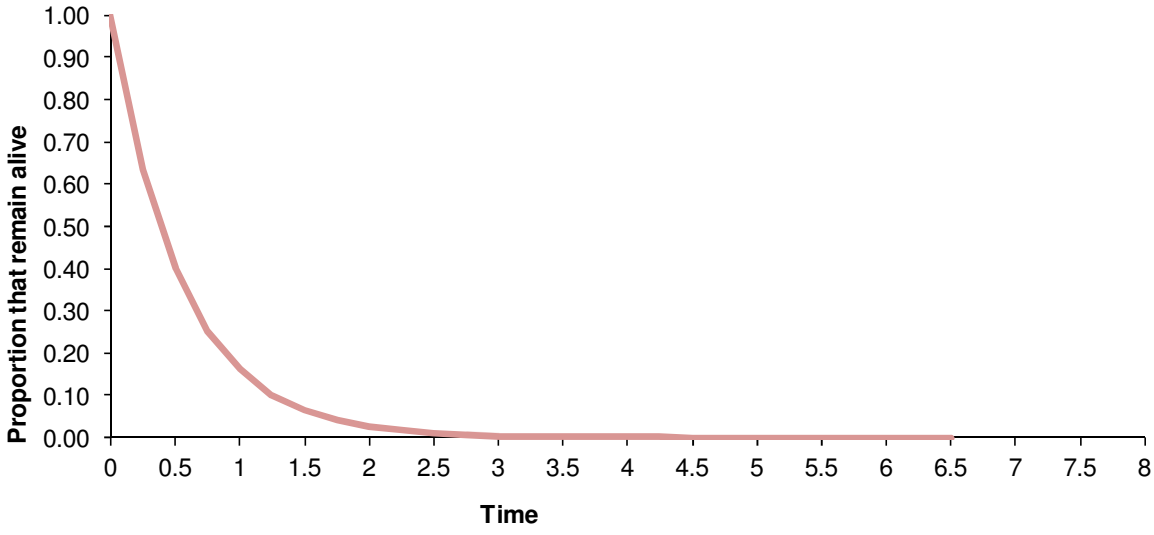

Figure 5.3 Exponential model of survival time – Fallers

The survival models were directly estimated from the HIP-HOP data. At 3 months there was survival data on 238 patients who had not experienced a fall and who were alive at discharge from hospital. 48 of these patients had died by 3 months. Fitting an exponential survival model to this data resulted in a mean survival estimate of 1.24 years for non-fallers. Hence non-fallers accrued costs and benefits for 1.24 years following discharge from hospital in the economic model. There was survival data at 3 months on 33 patients who had experienced some kind of fall and who remained alive at discharge from hospital, and 10 of these had died at 3 months. Fitting an exponential survival model to this data resulted in a mean survival estimate of 0.83 years, and so fallers accrued costs and benefits for 0.83 years following discharge from hospital in the economic model. Obviously the survival estimate for fallers is more uncertain than that for non-fallers, due to the much smaller amount of data available. Also, there was a substantial amount of missing data at 3 months, which could potentially cause our estimates to be subject to attrition bias.

5.4.5 Costs

The costs borne by the NHS and PSS accrued by patients in the HIP-HOP trial and included in the economic model come under three main headings: intervention costs; hospital costs; post-discharge resource use costs. These are discussed below.

5.4.5.1 Intervention Costs

The key intervention cost is the laying of the cushioned flooring. The flooring manufacturers, Tarkett, state that the flooring requires no additional maintenance compared to standard hospital flooring (Geoff Lewin, personal communication), and so the incremental cost of the flooring is assumed to be the upfront cost of installation. The installation of the flooring used in the HIP-HOP study was believed not to represent an accurate cost of the floor, because charges were based upon the known budget of the study, and the fact that various quotes had to be made for Bays that did not end up being part of the intervention group. Instead, a cost per square metre of the flooring was calculated using a quote made by Tyndale flooring company (the installers of the floor) to Airedale hospital for the installation of the flooring in a Ward that was not part of the HIP-HOP study. For Airedale hospital, the total cost of installing the flooring was quoted as £5,742 including VAT, for a Bay of 35 square metres, equivalent to a cost per square metre of £164 (details supplied by personal communication, Tyndale Flooring). This was significantly lower than the average cost per square metre for installing the flooring in the HIP-HOP study Bays, which ranged between £200 and £277 per square metre, with an average of £230 per square metre. For each of these figures the cost of laying the floor included all aspects of the installation, such as: uplift of existing floor; remove existing skirting; remove existing latex; apply new smoothing compound and 6mm ply packers; apply new flooring and skirting; install ramped thresholds.

In total, the Bays included in the intervention arm of the HIP-HOP trial totalled 209 square metres, and therefore, using the cost per square metre from the Airedale hospital quote, the total upfront cost of installing the intervention floor can be estimated as £34,297 (£164*209). In total there were 20 beds in the intervention arm of the HIP-HOP trial, and the average length of stay in these beds was 21.46 days. Therefore, 340.5 ((365.25/21.46)*20) patients can be expected to benefit from the new flooring in these Bays per year, assuming 100% occupancy. In reality, 100% occupancy is unlikely, and therefore we conservatively assumed that the occupancy rate would be 50% in these Bays, reducing the number of benefitting patients to 170 per year. Tarkett state that their flooring is warranted for 10 years, and that they would expect the floor to last at least 15 years. Over a 15 year time period, assuming 50% occupancy, 2,554 patients could be expected to benefit from the intervention flooring installed in the HIP-HOP intervention Bays. Therefore, the cost per patient of the intervention flooring is £13.43 (£34,297/2,554).

The cost per patient of the intervention flooring is therefore estimated to be very low. Hence the cost effectiveness of the flooring will depend almost entirely upon whether the intervention is successful in providing beneficial health outcomes for patients, and whether and future resource use costs or savings are generated. It is therefore unlikely that assumptions made around the exact cost of the flooring and occupancy rates will have large impacts on the results of the economic analysis.

5.4.5.2 Hospital Costs

The costs of the initial hospitalisation included in the economic model are based upon length of stay data from the HIP-HOP trial combined with relative risks for different severity of falls estimated using Department of Health Reference Cost data.[6] The estimates used in the model and justifications for them are given in the following table.

Table 5.4 shows that the estimated length of stay for all patients is very high, again reflecting the state of health of the patients included in the HIP-HOP trial. It may be considered that the length of stay estimated for moderate and major injuries as a result from falls is particularly high, but given the poor health related quality of life and life expectancy observed in the trial, these appear reasonable.

Table 5.4 Hospitalisation Costs – length of stay and cost per day

Fall Type	Length of Stay (LOS)	Cost per day of excess LOS	Justification
No fall	19.80	no excess LOS	From trial data
Fall –No injury	30.86	£310.67	Length of stay taken from trial data – assume that a fall that causes no injury and a fall that causes minor injury will have the same implications for length of stay. Made this assumption because based solely on the trial data the mean length of stay for fallers who sustained no injury was 31.64 days, compared to 29.5 in minor fallers, which seems counter-intuitive. Thus fallers who sustained no injury were combined with minor fallers. The cost per day of the excess stay caused by such a fall was estimated from Department of Health Reference Costs, Falls with intermediate complications (average unit cost divided by average number of days)[6]
Fall –Minor injury	30.86	£310.67	From trial – see above.
Fall – Moderate injury	51.02	£415.47	There were only 4 observations for length of stay in patients who sustained moderate injuries from a fall in the trial, and length of stay estimates based on these events were counterintuitive (length of stay was 27.5 days). Therefore we used relative risks versus a fall with minor injury based on Department of Health Reference Costs (2009/10).[6] According to the Reference Costs falls with intermediate complications (we used intermediate complications rather than zero complications to reflect the age group) had an average length of stay of 4.88 days. We used this as a proxy for the length of hospitalisation associated specifically with a minor fall. As a proxy for an moderate

			fall we used all minor non-elective procedures on legs or arms due to trauma, with complications (again to reflect the old age group), which had a mean length of stay of 8.07 days, resulting in a relative risk of 1.65 between minor fall and moderate fall. The cost per day of the excess stay was estimated from the same reference costs as those used to generate the relative risk estimate.[6]
Fall – Major injury	76.76	£489.38	There were only 2 observations for length of stay for patients who sustained a major injury from a fall in the trial, and the length of stay for those individuals was 55 days for one, and 11 for the other. Due to the lack of data we again used a relative risk estimate based upon Department of Health Reference Costs to estimate length of stay in major fallers.[6] As a proxy for major fallers we used all moderate and major non-elective procedures on legs or arms due to trauma, with complications to reflect the old age group. This gave a mean length of stay attributable to such injuries of 12.15 days – giving a relative risk of 2.49 compared to a minor fall. The cost per day of the excess stay was estimated from the same reference costs as those used to generate the relative risk estimate.[6]

Excess stay costs compared to non-fallers were included in the economic model rather than total costs of stay because incremental costs rather than total costs are of interest in the economic evaluation. Excess stay costs were calculated for each fall type by multiplying the excess stay (compared to length of stay for non-fallers) by the estimated unit cost per day for each fall type. These costs are shown below for each fall type (Table 5.5).

Table 5.5 Excess Hospital Stay Costs

Fall Type	Excess Stay Cost
No fall	£0
Fall – No injury	£3,436.25
Fall – Minor injury	£3,436.25
Fall – Moderate injury	£12,972.28
Fall – Major injury	£27,877.49

For patients who were transferred to another hospital or Ward upon discharge from the HIP-HOP bay the cost of this additional hospitalisation was included in the model. Based on trial data from 39 patients the average length of stay after transfer for these patients was 29.69 days. As a unit cost per day we calculated the weighted average cost per day from all elective and non-elective inpatients, long stay (greater than 1 day), using the Department of Health Reference Costs 2009/10.[6] This resulted in a cost per day of £634.75 and a cost for each transfer patient of £18,847.

Initially we planned to use HRG codes to calculate excess length of stay from the HIP-HOP trial more accurately, as this would allow case-mix to be accounted for. However, substantial amounts of HRG data were missing, and there are legitimate concerns of whether HRG codes and associated average costs and lengths of stay are suitable for application in such an elderly, poor prognosis group. Therefore we based our analysis of hospital costs on length of stay without taking into account HRG codes.

5.4.5.3 Post-discharge resource use costs

Post discharge NHS and PSS resource use data was collected using patient questionnaires, and by gathering information from GPs. Patients were asked about GP consultations, hospital admissions,

outpatient appointments and visits from nurses or other health care professionals in the three month time period since they were discharged from hospital. They were also asked about their living arrangements, which allowed us to determine estimates of the time spent in nursing or residential homes by patients discharged to such homes instead of their usual place of residence. There was a substantial amount of missing data at the 3-month follow-up – of the 576 initially randomised patients follow-up data either from the patient themselves or the GP on the various different resource uses were available for between 41.3% and 43.7% of patients. The pool of patients who were discharged to a nursing or residential home was considerably smaller – of 80 patients who changed residence to a nursing or residential home at discharge from hospital, data of their whereabouts at 3 months were available for 34 patients. For a small proportion of patients data on resource use were available both from the patient and their GP, when the data conflicted, the data from the GP was given preference.

Resource use data were combined with unit cost data from standard sources (PSSRU National Unit Costs,[7] DH Reference Costs[6]) using their most up-to-date versions in order to calculate costs for inclusion in the economic analysis. The post-discharge resource use was estimated separately for fall type and for place of residence (as those who lived in a nursing or residential home can be expected to require different amounts of NHS resource use compared to those who do not live in such a home – in the HIP-HOP trial this was borne out, with these patients generally receiving less post-discharge health care). Given the large proportion of missing data, and the relatively few fall events that occurred, various assumptions had to be made, and relative risks were applied using the Iglesias et al (2009) paper for the more serious falls.[2] The resource use per 3 months used in the model is shown below for the different places of residence (Table 5.6).

Table 5.6 Post-Discharge health care resource use

	Value				
Resource Use (per 3 months)	No Fall	Fall – No injury	Fall – Minor injury	Fall – Moderate injury	Fall – Major injury
Number of GP consultations if live in own home	1.57	1.57	1.57	1.75	1.93
Number of GP consultations if live in nursing/residential home	0.50	0.50	0.50	0.56	0.62
Number of hospital readmissions if live in own home	0.45	0.45	0.45	0.54	0.64
Number of hospital readmissions if live in nursing/residential home	0.44	0.44	0.44	0.53	0.63
Number of outpatient appointments if live in own home	1.32	1.32	1.32	1.63	1.94
Number of outpatient appointments if live in nursing/residential home	0.51	0.51	0.51	0.64	0.76
Number of community nurse visits if live in own home	13.70	13.70	13.70	33.79	53.88
Number of community nurse visits if live in nursing/residential home	8.56	8.56	8.56	21.11	33.66

Note: justifications and methods for calculating each of the values in this table are presented in Appendix 3

We applied costs from the PSSRU[7] and Reference Costs[6] to the 3 month resource use estimates, and multiplied this according to expected lifetimes for the different groups to calculate total post-discharge resource use costs (hence often costs will be highest in non-fallers, as they live the

longest and therefore accrue costs for longer). These were adjusted on a pro-rata basis to allow for the fact that some fall categories have a longer initial hospital stay than others. The total costs applied in the model are shown in Table 5.7.

The discharge of patients to nursing or residential homes rather than their usual home creates an additional cost to the NHS. We estimated this cost be estimating how long patients who changed residence to a nursing or residential home would stay there, and multiplying this by the cost per week of a nursing/residential home stay, adjusted by a multiplier for the proportion of patients who would be expected to locate to a nursing or residential home and would be publicly funded.

Table 5.7 Post-Discharge total costs of health care resource use

Resource Use Costs	Value				
	No Fall	Fall – No injury	Fall – Minor injury	Fall – Moderate injury	Fall – Major injury
GP consultations if live in own home	£278.67	£187.49	£187.49	£209.55	£231.61
GP consultations if live in nursing/residential home	£193.24	£102.07	£102.07	£114.08	£126.09
Hospital readmissions if live in own home	£33,172	£22,319	£22,319	£27,171	£32,023
Hospital readmissions if live in nursing/residential home	£32,819	£21,967	£21,967	£26,742	£31,517
Outpatient appointments if live in own home	£610.92	£411.04	£411.04	£507.99	£604.93
Outpatient appointments if live in nursing/residential home	£442.92	£243.05	£243.05	£300.37	£357.69
Community nurse visits if live in own home	£1,828	£1,230	£1,230	£3,033	£4,837
Community nurse visits if live in nursing/residential home	£1,519	£921	£921	£2,272	£3,622

Note: justifications and methods for calculating each of the values in this table are presented in Appendix 3

At 3 month follow-up there was location data for 35 patients who had been discharged to a nursing or residential home instead of their usual home. 7 had returned to their usual home and 9 had died. We fitted an exponential model to this data and estimated that the mean time spent in a nursing or residential home for these patients was 0.56 years. The exponential model is shown below (Figure 5.4).

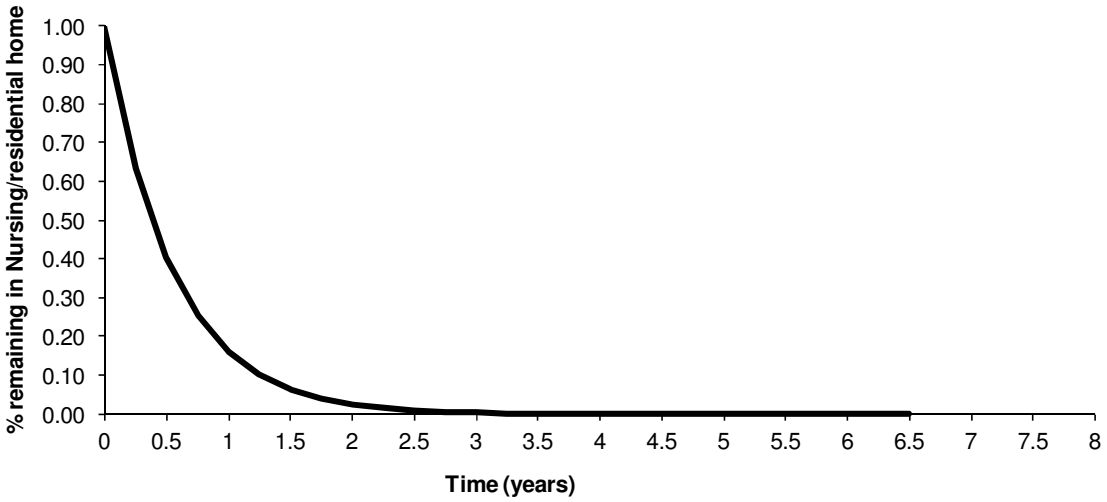

Figure 5.4 Exponential model of time spent in a nursing or residential home

Netten et al (1998) estimate that 70% of people in nursing or residential homes are publicly funded.[8] The latest PSSRU unit costs estimate a cost per week of nursing/residential home care of £986.[7] Therefore, we estimated an NHS/PSS cost of £20,737 per patient discharged to such a home instead of their usual home.

The total costs applied in the model are summarised in Table 5.8 below.

Table 5.8 Cost Summary

Costs (per patient)	Value				
	No Fall	Fall – No injury	Fall – Minor injury	Fall – Moderate injury	Fall – Major injury
Intervention cost	£13.43				
Hospital stay cost (excess)	£0	£3,436	£3,436	£12,972	£27,877
Post-discharge cost (live in own home)	£35,889	£24,147	£24,147	£29,215	£32,959
Post-discharge cost (nursing/residential home)	£55,011	£43,269	£43,269	£46,734	£48,664
Additional cost if discharged to another hospital/Ward	£18,847				

5.5 Results

5.5.1 Deterministic

The results of the deterministic analysis are shown in the table below.

Table 5.9 Base case deterministic results.

	Per person treated				
	Cost	*QALYs*	*Incremental Cost*	*Incremental QALY*	*ICER*
Control	£39,034	0.426			
Intervention	£38,180	0.4202	-£854.14	-0.006	£ 140,410

The intervention is estimated to be marginally cost saving compared to usual care, but it is also estimated to result in a marginal QALY loss. This makes the interpretation of the incremental cost effectiveness ratio (ICER) difficult, but essentially means that an additional QALY is lost due to the intervention for a cost saving of £140,410. Strictly speaking, the intervention could be classed as cost effective based upon an ICER threshold of £20,000 per additional QALY gained, as the costs saved per QALY foregone are greater than £20,000. However, such a conclusion is difficult to make, given the estimated ineffectiveness of the intervention. An ICER represents the additional costs associated with the intervention and the additional benefits associated with the intervention (measured in QALYs) as a ratio. In the UK, typically an intervention is classed as cost effective if it provides one additional QALY for an incremental cost of £20,000 or less, which is equivalent to an ICER of £20,000. Hence, an intervention that provides one less QALY for a saving of £20,000 or greater could be regarded as cost effective.

The base case results must be interpreted with great care, as there are many uncharacterised uncertainties within the model. The intervention is estimated to be cost saving because cost increases associated with the increase in proportion of patients falling observed in the intervention arm of the trial combined with the very low cost per patient of the intervention are outweighed by the reduction in costs associated with moderate and severe falls. However, due to the high utility decrement applied in the model to fallers who sustained minor or no injuries, the QALY loss associated with the increase in proportion of patients falling observed in the intervention arm of the trial outweighs the QALYs saved through the reduction in moderate and severe falls. Hence the intervention is estimated to result in both cost savings and QALY losses.

5.5.2 Sensitivity Analysis

The results of the economic evaluation are uncertain due to parameter uncertainty as well as structural uncertainty associated with the model structure. Given that there is little data upon which to base parameter distributions for several key model parameters, we deem that probabilistic sensitivity analysis (which allows the uncertainty around the sampling distributions of parameter values to be characterised in the economic analysis) would be unhelpful and results could be misleading. Therefore, we instead conduct scenario analysis.

5.5.3 Scenario Analysis

The results of the deterministic analysis are very marginal. Altering key parameter values changes the results substantially. Here we present results of the cost effectiveness analysis when changes are made to key parameters within the model.

5.5.3.1 Scenario 1: Risk of falling

In particular, it is unclear whether it is reasonable to assume that the intervention flooring results is a higher proportion of patients falling. In the HIP-HOP trial, 13.7% of the intervention group patients fell, compared to 9.8% in the control group. Potentially this could be due to patients at higher risk of falling being placed into the intervention Bays, or, on the other hand, patients may find the intervention flooring more difficult to walk on. If we assume that the proportion of patients who fall is the same in the intervention group as in the control group (9.8%), and the severity of falls is spread between fall-types as seen in the HIP-HOP trial, the following cost effectiveness results are obtained:

Table 5.10 Scenario 1 results – equal risk of falling

	Per person treated				
	Cost	*QALYs*	*Incremental Cost*	*Incremental QALY*	*ICER*
Control	£39,034	0.426			
Intervention	£38,353	0.428	- £680.50	0.0013	Dominant

In this scenario, the intervention becomes dominant compared to the control group – it generates marginal cost savings and QALY gains. The cost savings are actually lower than in the base case, because patients who do not fall incur relatively high costs because they are estimated to live significantly longer than fallers. The QALY gain is very small (but positive) because even with the standard flooring the proportion of patients who experience moderate or major falls is very low, and the general quality of life and life expectancy of the population under study are very low – causing potential gains to be very restricted.

5.5.3.2 Scenario 2: Utility Scores

The utility scores collected at 3 month follow-up in the HIP-HOP trial were very low, even for non-fallers. This might reflect the poor health of the population under study, but it might also be considered that the scores are unrealistically low. In this scenario we assume that the utility score of a non-faller is higher (0.62) based upon the Iglesias and colleagues (2009) utility model and that fallers incur a decrement according to the relative risks estimated from the Iglesias and colleagues (2009) paper and used in the base case version of the model. Therefore, utility scores are:

Table 5.11 Utility scores for scenario analysis 2

State	Utility score
Non-faller	0.62
Faller – No injury	0.59
Faller – Minor injury	0.55
Faller – Moderate injury	0.52
Faller – Major injury	0.44

Applying higher utility scores generates higher scope for QALY differences between the intervention and control group. The results of this scenario are shown below (Table 5.12):

Table 5.12 Scenario 2 results

	Per person treated				
	Cost	*QALYs*	*Incremental Cost*	*Incremental QALY*	*ICER*
Control	£39,034	0.695			
Intervention	£38,180	0.685	-£854.14	-0.010	£86,188

In this scenario, the intervention is once again cost saving, but like in the base case, QALY losses are generated. In fact, the QALY losses are higher than in the base case, because the higher utility

scores mean that the QALY loss associated with the increase in proportion of fallers outweighs by relatively more the QALY gain associated with the reduction in moderate and major falls. Therefore, again the results of this scenario are driven by the increase in fallers in intervention group. Again, strictly speaking, in this scenario the intervention remains cost effective with a cost effectiveness threshold of £20,000 because it generates cost savings of over £20,000 for every QALY foregone.

5.5.3.3 Scenario 3: Equal risk of falling and increased utility scores

In this scenario we combine scenarios 1 and 2. That is, we assume that the risk of falling is not increased by the intervention floor, and the utility scores are higher. The results of this scenario are shown in Table 5.13

In this scenario the intervention flooring is again dominant. The QALY gain is approximately double that observed in scenario 1, due to the higher utility scores applied in the model. However, the QALY gain is still very small, due to the very low proportion of moderate and severe falls observed, and due to the low life expectancy associated with the population group.

Table 5.13 Scenario 3 results

	Per person treated				
	Cost	*QALYs*	*Incremental Cost*	*Incremental QALY*	*ICER*
Control	£39,034	0.695			
Intervention	£38,354	0.697	-£680.50	0.0021	Dominant

5.5.3.4 Scenario 4: Diminished cost difference between fall types

For a number of model parameters – for example proportion discharged to nursing/residential home, length of initial hospital stay, number of GP visits, number of nurse home visits, number of hospital readmissions, number of outpatient appointments – we assumed that resource use was greater for moderate and major fallers. We based parameter values of relative risks derived from the literature because data from the HIP-HOP trial were almost non-existent for the more serious fall types. Hence, these parameter values are uncertain. To test the sensitivity of the model to these parameters, we undertook a scenario analysis where each of the parameter values for moderate and major falls were set equal to the values for minor falls. This would be expected to remove the cost advantage that the intervention floor has over the control floor through the reduction in moderate and major falls observed. QALY estimates will also alter slightly due to the reduction in patients discharged to nursing and residential homes in both groups. The results of this scenario are presented below (Table 5.14).

Table 5.14 Scenario 4 results

	Per person treated				
	Cost	*QALYs*	*Incremental Cost*	*Incremental QALY*	*ICER*
Control	£38,371	0.4265			
Intervention	£38,180	0.4202	-£190.97	-0.0063	£30,333

The results show that the cost saving associated with the intervention flooring is reduced in this scenario, although a saving still exists. Further analysis of the model results reveals that this is due to the relatively higher costs incurred by non-fallers in the model, because they live longer than fallers and accrue costs over a longer time period. Hence, the cost saving associated with the intervention flooring estimated by the economic model is largely due to the difference in risk of falling observed between the two groups, rather than the cost penalties associated with more serious (but very rare) falls. Again, this demonstrates the importance of the model parameter that determines the risk of falling.

Despite the reduced cost saving in this scenario, the intervention would still be considered cost effective at a cost effectiveness threshold of £20,000 per QALY because savings are greater than £20,000 for every QALY foregone.

5.5.3.5 Scenario 5: Equal risk of falling and Diminished cost difference between fall types

In this scenario we combine scenarios 1 and 4. That is, we assume that the risk of falling is not increased by the intervention floor, and we diminish the cost and resource use difference between fall types. The results of this scenario are shown below:

Table 5.15 Scenario 5 results

	Per person treated				
	Cost	*QALYs*	*Incremental Cost*	*Incremental QALY*	*ICER*
Control	£38,371	0.4265			
Intervention	£38,354	0.4276	-£17.33	0.0011	Dominant

In this scenario the intervention flooring produces a marginal QALY gain, and also maintains a small incremental cost saving. Thus, the intervention is dominant in this scenario. This occurs despite the fact that we have removed the majority of the cost benefits associated with avoiding moderate and major falls. The incremental cost saving is maintained because although we have assumed that all future resource uses are similar between faller types, we have retained the assumption that the cost per day associated with the initial hospital stay is more expensive for patients who experienced more serious falls. This alone is enough for the cost savings associated with the intervention to outweigh the intervention cost.

5.5.3.6 Scenario 6: Base Case with 100% occupancy

We investigated the sensitivity of the results to the occupancy rate assumed when costing the intervention flooring. If a 100% occupancy rate rather than a 50% occupancy rate was assumed, the results would be as shown in Table 5.16, below.

Table 5.16 Scenario 6 results

	Per person treated				
	Cost	*QALYs*	*Incremental Cost*	*Incremental QALY*	*ICER*
Control	£39,034	0.426			
Intervention	£38,173	0.420	- £860.86	-0.0061	£141,514

As can be seen, the results are not very sensitive to the occupancy rate assumption. This is due to the very low cost per patient of the intervention, which is out-weighted by other costs included within the model. The intervention remains cost saving, but also leads to QALY losses. Again, strictly speaking, it could be classed as cost effective as for each QALY lost cost savings of £141,514 are made.

5.5.3.7 Scenario 7: Equal Fall Risk with 100% occupancy

We combined scenario 6 with scenario 1 in order to estimate the cost effectiveness of the intervention if fall rates were equal between the two groups, and if an occupancy rate of 100% was assumed. The results of this analysis are shown in Table 5.17.

Table 5.17 Scenario 7 results

	Per person treated				
	Cost	*QALYs*	*Incremental Cost*	*Incremental QALY*	*ICER*
Control	£39,034	0.4263			
Intervention	£38,347	0.4276	-£687.22	0.0013	Dominant

The results again show that the occupancy rate does not have a large impact upon the results of the model. With an occupancy rate of 100% the intervention remains dominant, with cost savings being slightly larger than would be expected with an occupancy rate of 50%.

5.6 Discussion

Given the lack of data differentiating cost and utility impacts associated with different fall types, it is difficult to draw firm conclusions from conducting an economic analysis alongside the HIP-HOP clinical trial. It has been necessary to model the trial rather than to directly analyse the trial data, due to the very small event numbers. Our base case analysis suggests that the intervention flooring is cost saving, but produces QALY losses due to increasing the proportion of patients who fall. Various scenario analyses show how sensitive the economic evaluation is to specific parameter values.

Figure 5.5 illustrates the scenario analysis on the cost effectiveness plane. The diagram shows that the base case, scenario 2, scenario 4 and scenario 6 suggest that the intervention will be cost saving but QALY reducing. However all the scenarios lie beneath the cost effectiveness threshold line (drawn on the diagram to represent a cost-effectiveness threshold of £20,000 per QALY), and therefore these scenarios suggest the intervention is cost effective (even though QALYs are foregone). Scenarios 1, 3, 5 and 7 suggest that the intervention will lead to cost savings and QALY gains, making the intervention a dominant strategy.

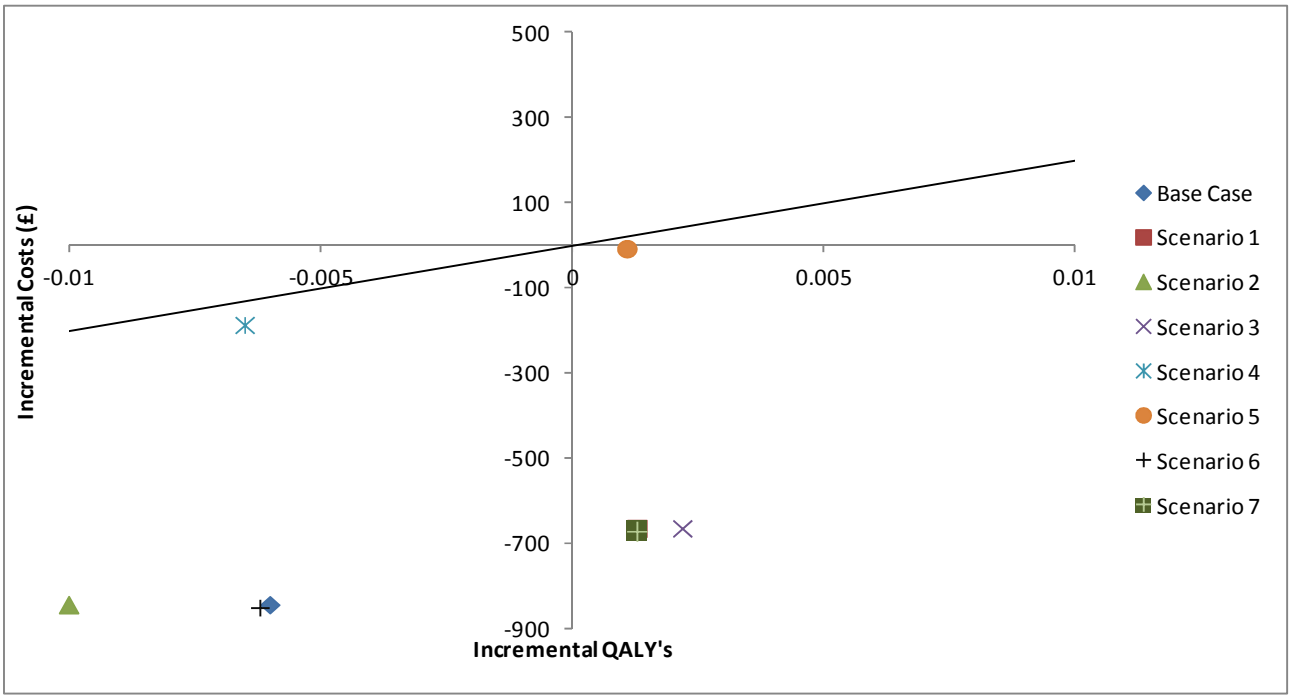

Figure 5.5 Scenario analysis on the cost effectiveness plane

Although all of the scenarios considered here suggest that the intervention will be cost effective, it is clear that further information is required in order to more confidently conclude whether or not the intervention is likely to QALY losses or gains. Our scenario analysis has helped us draw conclusions about which model parameters are likely to be of most value for future research. These conclusions are based upon certain assumptions that can be made with reasonable confidence, given the very low cost per patient of the intervention:

1. If the intervention flooring does not cause more falls to occur, it is likely to be a dominant (cost saving and QALY producing) or cost effective strategy, providing:
    a. There exist some cost and resource use penalties associated with minor, moderate and major falls compared to falls that cause no injury.
2. If the intervention flooring does cause more falls to occur, it is likely that it will result in QALY losses.

Hence, it is clear that it is of most value to concentrate on determining whether the intervention flooring is likely to cause more falls than standard flooring. The answer to this question is likely to determine whether the intervention flooring is a cost-effective one, or one that results in QALY losses. In addition, it is of value to determine more accurate estimates of cost differences according to fall severity both in terms of hospitalisation costs and post-discharge costs. This will determine whether or not the intervention can be expected to lead to cost savings. Linked to this, more information on the difference in life expectancy between different fall types would also be of value as patients who sustain no injuries or only minor injuries from falls may actually incur higher lifetime health costs than patients who sustain moderate or major injuries – which impacts upon the incremental costs associated with the intervention.

Given the 0.001 incremental QALY gain observed in scenarios 1, 5, and 7, when it is assumed that the intervention flooring does not cause additional falls, incremental costs of £20 or less per patient would be required for the intervention to have an ICER of £20,000 or less. If higher utility rates

were used in the model (as in scenario 3) and it were assumed that the intervention does not cause additional falls, the intervention could lead to QALY gains of 0.002, meaning that incremental costs of £40 or less per patient would be required for the intervention to have an ICER of £20,000 or less. The cost per patient of the intervention is £13.43 (assuming 50% occupancy rate) and therefore there is scope for the intervention to be cost effective. Intuitively, it would seem likely that the cost savings associated with avoiding moderate and major falls would cause the intervention to be cost saving overall, and our analyses suggests that this will be the case, although it might be considered that this may not be the case if the patients who experience less serious falls go on to live longer than those who experience more serious falls and therefore accrue greater costs.

Figure 5.5 shows that there is less variability in the model estimates of QALY gains than there is in incremental costs. The key effectiveness parameter is linked to whether or not the intervention causes more falls. If it does not, the QALY gain can be expected to be approximately 0.001-0.002 per patient. Given this, it is likely to be more valuable to target future research at determining fall rates and resource use implications than at utility scores.

We have not undertaken scenario analysis on life expectancy parameters, but these outcomes are potentially important to the results of the economic model. However, given that the life expectancy of even non-fallers in the trial is very low, the scope for QALY gains due to avoiding serious falls is low (which, as touched upon above, makes further research into utility scores relatively less valuable). Our scenario analysis shows that QALY gains in a range of different scenarios are very low, and that these are positive if the intervention flooring does not cause more falls to occur, and negative if the intervention floor does cause more falls to occur. Hence, it is more important to determine whether or not the intervention is likely to cause more falls, than it is to determine how much longer someone who experiences a less serious fall may live compared to someone who experiences a more serious fall. Therefore, analysis of the model results again points towards further research into fall rates associated with the intervention flooring compared to standard flooring being of greatest value.

5.7 Conclusions

The cushioned flooring intervention has the potential to be cost effective compared to standard flooring, but conclusions on the actual cost-effectiveness cannot be confidently made based on data from the HIP-HOP study. We have not been able to adequately characterise the parameter uncertainty in the economic model, and this and other structural uncertainties can only be resolved through a larger dataset/study. Low patient and event numbers and missing data meant a simplified economic model was used.

Further research should primarily be directed towards determining whether the intervention flooring causes more falls to occur than standard flooring. Of secondary importance, further research would be desirable regarding cost and resource use differences between different fall types compared to non-fallers. Further research on utility scores and life expectancy by fall type would be beneficial, though such information is likely to be of relatively less value.

5.8 References

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6. SECTION 6: USER VIEWS

6.1 Introduction

This section of the report relates to our fourth objective: To explore user views and perceptions on the intervention flooring and existing flooring. This objective seeks to draw comparisons between patients, visitors, medical and cleaning staff as well as between opinions on the standard flooring versus the intervention flooring, in order to inform future research.

As there are a number of issues that may otherwise go unnoticed or overlooked, we assessed the views of staff, patients in, and visitors to the wards. Thorne carried out a qualitative assessment of a number of flooring materials in geriatric wards [1] which highlighted issues relating to: installation, maintenance, attractiveness, comfort, slipperiness, noise, marking, and sealing. Interviewees may have particularly pertinent insights into otherwise unmeasured impacts of the floors under study. For example, staff may notice changes in patients' behaviour when walking across the new floor, and may notice differences when pushing trolleys around. Staff in control wards may hold views about their standard flooring, which remain particularly pertinent due to the fact they have not experienced the new flooring; they may also experience different issues with their standard flooring than experienced by intervention sites. Additionally, patients and visitors may have opinions as to what the floor is like to walk on and whether or not they feel safe walking on it. Additionally, interviewing people from across the included sites will further enable an assessment of the cultural differences between ward environments, in attitudes and opinions towards the floors in use.

6.2 Participants

The sample consisted of twelve patients, eight visitors and seventy seven members of staff. All patients admitted or transferred to a bed in the 'study area', their visitors and hospital staff using the floor were eligible for an interview. Interviews were carried out between March and August 2011. Equal numbers of patients and visitors were interviewed in both intervention and control sites. More staff members were interviewed in the intervention sites (61 interviews in total) than in control sites (36 interviews). This difference can be explained in part by the voluntary nature of the interviews, and given that the intervention sites had received a new floor it is probable that more staff members at these sites had an opinion they wanted to share.

Sampling of patients staying in the Study Area, and visitors of patients in the Study Area, was restricted to those who are orientated to person, time, and place, and at either an intervention or control site during one of the final two site visits. Sampling therefore was done on a convenience basis. A clinical member of staff was consulted before approaching patients to ensure mental capacity and eligibility for participation. Sampling of ward staff was also purposive, targeting those who have worked at one of the study wards. All eligible staff were invited to interview in an attempt to obtain as representative sample as possible (e.g. from across different working roles, etc.). Table 6.1 presents the sample grid used to ensure a range of professionals were interviewed in all sites.

Table 6.1 Sampling Grid of Interviews

	Intervention				Control sites			
	A	**B**	**C**	**D**	**E**	**F**	**G**	**H**
Patients	2	2	1	1	1		3	2
Visitors		2	2			1	1	2
Ward managers / Deputy Sisters	1	2	1	3	1	2	1	
Doctors		1	1		1	1		
Staff Nurses	1	2	2	4		2		3
Nursing Assistant / Support worker	2	3		4			1	1
Physiotherapists / Assistant/student physiotherapists	1	2	2	3		1		2
Occupational Therapists	1	1			1	1		1
Domestic Assistants	2	1	1	2	1	1	1	
Other allied health professionals and staff roles		3		5	1	2		1
Total per site	**10**	**19**	**10**	**22**	**6**	**11**	**7**	**12**
Grand total	**97**							

6.3 Data collection

Researchers visited all four intervention sites (A,B,C,D) and three of the control sites (E,F,H) twice and one control site (G) only once to complete the interviews with patients, visitors and staff. All ninety seven participants were informed about the study through a participant information sheet and were asked to sign an informed consent form. Telephone interviews were offered as a choice for people that were not present on the day (although no telephone interviews were undertaken). Interviewees were made aware that they could terminate the interview at any time, that both positive and negative views were equally valued, and that their opinions were made anonymous. A semi-structured interview schedule was developed concerning four main areas: (1) fitting the floor (for the intervention sites only), (2) the experience of using the floor, (3) perceptions and thoughts around the floor, and (4) behaviour on the floor. More prompts and probes were added as participants generated new themes, allowing them to highlight the issues that are of highest importance. The staff interview schedule was tailored towards the role of the staff member and the duties that they perform in the ward.

Twelve interviews were conducted with patients staying in the study area (four interviews in control sites and four in intervention sites). All patients staying in the Study Area were screened first by nursing staff and then not approached if they were considered to be illegible (lacking mental capacity) or too unwell to converse. Eight interviews were conducted with visitors (four in intervention and four in control sites). The sample was restricted to the visitors who could be located on the day of the visit and short visiting times. Ninety one interviews were conducted on a one-to-one basis and three interviews were conducted with couples (two-to-one) on request of the participants. Reasons for not recruiting patients were: (a) patients approached for an interview but declined to take part, (b) nurses advised the researchers against approaching patients staying in study bay at that time as they were medically unstable or cognitively impaired and therefore not eligible for an interview, (c) there were spare beds in the study area at the day of the interviews, (d) patients who were admitted to hospital on the day of the interview and were too worried, unsettled, and unaware of the study and therefore not approached.

Interviews were audio-recorded and transcribed verbatim with the participants made anonymous through the assignment of an interviewee number. The interviews lasted between 5 to 35 minutes and were mainly conducted within the ward setting in order that the flooring can be used to cue conversation topics.

6.4 Data analysis

The content of the interviews were analysed through a process of thematic content analysis.[2] Transcripts were open coded, and from these codes themes were generated and then validated through corroboration between the research team. Transcripts were coded according to these themes and written up accordingly, drawing comparisons between the patients, visitors, and different staff roles, as well as between opinions on the standard flooring versus the intervention flooring. Transcriptions were sent back to participants who requested it for additional validation. Summary of the themes emerged from all interviews will be sent to all participants who requested it upon final in-depth analysis.

6.5 Changes to the original plan

We extended our inclusion criteria to include visitors as well as staff at control sites (in the original plan we were only going to interview patients at intervention and control sites, and staff at intervention sites). We decided it would be worthwhile to interview visitors, as they too have utilised the floor, and many of the patients in the study areas were too unwell to meet the inclusion criteria of an interview. We also decided it would be valuable to interview staff at control sites, to bring a further perspective from those who had experienced the new floor.

6.6 Results

A range of opinions were expressed across sites and across patients, visitors and staff. Participants had different opinions on how the floor performs and what they perceived as positives and negatives qualities of the floor. Patients and visitors shared more common themes across sites. Staff had different opinions about the floor across sites and within sites. Participants in the control groups were drawing comparisons between the normal hospital floors with other types of floor, although the participants in the intervention groups were asked to compare the new type of shock-absorbing floor to other floors on the ward. It is important to note that the themes presented here are the initial results of our analysis. Further in depth analysis is anticipated which may result in further elaboration of the main themes and their subthemes which will be reported in additional papers.

6.6.1 Patients and Visitors Views

Twelve patients were interviewed in total, six patients in the control sites (all female) and six in the intervention sites (5 female, 1 male). Four patients in the control sites had experienced a fall before or whilst in the hospital. In the intervention sites three of the patients had had a fall before their admission and one patient had a fall whilst staying in the study bay. Eight interviews were completed with visitors in the study sites (4 control, and 4 intervention). One participant in the control site was visiting a patient who had recently experienced a fall whilst residing in the study bay. Visitors in site H and C requested to have a joint interview.

Opinions on the floor gathered from patients and visitors were found to be similar and thus, for the purposes of this report, were decided to be grouped and presented together. Three main themes emerged from the interviews which are presented in the diagram below.

Figure 6.1. Summary of themes from interviews with patients and visitors in control and intervention sites.

6.6.1.1 Theme 1: 'It's just a floor'

In general, patients in the control sites had less to comment on their experience on the floor, they did not seem very concerned about it and most of them admitted they had not noticed or thought about the floor before the interview as they were more worried about their recovery. As with the patients in the control sites, none of the visitors had thought about or paid much attention to their interaction with the floor:

> *'Well quite honestly, you come and you go and it's just there….um, yes it's just a hospital floor, I've got no struggle with it'* (F01 -visitor in control site)

> *it's just a floor, as far as I'm concerned, a floor's a floor's a floor...' I'm just lucky that I can put one foot before the other at the moment' (*H01 -patient control site*)*

Interestingly, not all the patients and visitors in the intervention sites noticed that they were in a bay

with a different type of flooring. Like the patients in the control sites some patients had not noticed or worried about the floor and thought it was just a normal hospital floor:

> 'I *haven't noticed any difference to any other flooring, but that's probably because I wasn't aware of it, but I haven't noticed any particular difference'* (B01 -visitor in intervention site)

> *'I haven't thought about it, um, I've not felt any difference really...I haven't notice any difference it's like any other floor that looks like this'* (A02- patient in intervention site)

Some patients in intervention group did however notice the different flooring:

> '*I noticed immediately that it was a different kind of floor... it was more tactile and softer, sort of padded feel...'* (C01- patient in intervention site)

> *'when I was brought into this ward that was the first thing that hit me, I just thought 'oh, this is nice', so I didn't know that it was a new floor... It's a lot nicer to walk on and it's pleasant to look at... it's pleasanter than hospital floors... Because the floor's smoother... see I'm used to carpets and so this is softer than an ordinary hospital floor'* (D01- patient in intervention site)

6.6.1.2 Theme 2: Floor is perceived as a part of a system

Patients from control and intervention sites expressed how their interaction with the floor is part of a dynamic system (of environmental, social, and personal factors). Those who stated they felt safe to walk on the floor often attributed the reasons for this to other factors and not necessarily the qualities of the floor. Visitors as well as the patients in the control and intervention sites highlighted factors, such as suitable footwear, the patients' physical condition, staff supervision, floor cleanliness and walking aids as contributing to their overall safety.

> '*it depends what shoes you've got on, doesn't it really*? (A01- patient in intervention site)

> *'It's not the floor's fault, it's my legs'* (A02- patient in intervention site)

> *'I don't know if that's because of his problem that he already has or something on the floor, I don't know... I think the majority of people in here have walking problems in any case so it's whether it's associated with the floor or not, um, I didn't associate G's problems with the floor, I thought it was just with his particular um, movement problem'* (F01- visitor in control site)

> *'there's always somebody there, I don't like to be on my own, but there's always somebody there, for my confidence if nothing else'* (A02- patient intervention site)

> '*because they clean it so often so you know there's no dust or anything, there's never anything spilt on it... because I walk around in trainers I've got a very good grip'* (E01- patient in control site)

> *'I find some aids are slippery to tread on and others aren't'* (A01- patient in intervention site)

6.6.1.3 Theme 3: Perception about floor attributes

This theme refers to opinions patients and visitors expressed about their daily experience using the floor as related to its' physical attributes. They mainly commented on things around slipperiness, hardness (and softness) attractiveness (also related to cleanliness), ease of movement, and noise. They are all explained below.

6.6.1.3.1 Perceived Slipperiness of the floor

Regarding the floor's slipperiness, patients expressed mixed comments. In general, patients from both control and intervention sites liked the floor in the study bays. They thought it was not slippery and they could feel a good grip when walking or using walking aids on the floor. In terms of safety all the visitors from the intervention sites agreed that it is a safe floor as they felt it was not slippery, for example:

> '*it's definitely less slippery in the sense that um, you feel it instinctively when you go out onto the corridor... there is a big difference, yeah'* (C01- patient in intervention site)

> *'Absolutely perfect because it doesn't slip...I felt quite secure'* (H01- patient in control site)

On the other hand, some patients in both intervention and control sites thought the study bay floor was slippery:

> *'It's slippery now'* (A02- patient in intervention site)

> *'I do find sometimes my feet tend to slip on it'* (G02- patient in control site)

Another participant from a control site thought the floor gets sticky and as a result her feet and frame get stuck:

> *'...I think it's awful...your foot gets stuck...occasionally I might start walking without realising that one shoe has come off... it seems so sticky, it doesn't seem to want to let you go, you know... it's a nuisance, you know, I wish this wouldn't stick, you know...I think it's the texture of the floor'* (G03- patient in control site).

It was evident that patients, even on the same bay, held different perceptions about the floor. One patient in site G stated that she finds the floor slippery because it is polished frequently and it shines. Another patient in the same ward thought the opposite, that shininess does not necessary mean slipperiness.

6.6.1.3.2 Perceived Hardness of the floor

Only patients from control sites seemed to have negative comments around the hardness of the floor:

> *'I don't think it's very safe to be truthful, that floor, I don't think so, it's too hard, it is too hard, seriously and when I fell on one of it, I know'* (G01- patient in control site)

Two visitors from a control site speculated that a softer floor would be beneficial in terms of comfort for patients and staff. Visitors from the intervention sites noticed the different thickness of the floor and expressed how soft it felt:

> *'it was very conscious, when you walked on it; it was so different from the ward hallway, extremely conscious... It was more comfortable to walk on; definitely... just surprised it was very nice'* (C02- visitor IN intervention site)

> *'I would say this floor is, you know, a safer option in terms of if people do accidentally trip or fall, um, then you know it would cushion any fall that someone would have so yeah, it would be a safer option... it makes it less hard underfoot and also I suppose for patients ... if they did fall or fell out of bed or whatever then, you know the impact is less and that potential damage is much less as well….I would imagine for staff who are on their feet a lot of the day it probably helps them quite a lot just in terms of being on their feet and it being softer, I would have thought really and I suppose assistant people or supporting people it would also help' (*B01- visitor in intervention site)

6.6.1.3.3 Perceived Appearance of the floor

Cleanliness and attractiveness of the floor were discussed by patients and visitors from both study groups, for example:

> *'It's just clean, tidy, spotless... it's a suitable colour because if anything's dropped you can see it'* (F01- visitor in control site)

> *'this type of floor is, you know, more easily kept, kept clean'* (H02- visitor in control site)

> *'It's more attractive than the others, it's more homely. My mother says it looks more homely in here. I think that's why... my mother thought it looked beautiful'* (B02- visitor in intervention site)

> *'I should imagine that it would be easy to keep clean* (C01- visitor in intervention site)

> *'in terms of colour of the floor, that it would be better to err on the lighter side rather than a darker colouring... the overall impression within the ward is sort of fairly dark and I think that light is important in these sort of places. The only problem with the lighter colour is, it would be likely to, you would be more likely to see the scratches, this sort of thing, on the surface'* (H02- visitor in control site)

A visitor in a control site noticed some damage to the floor:

> '*you do see scratch marks but that's not detrimental, is it? I suppose trolley-use and that sort of thing'* (H01- visitor in control site)

6.6.1.3.4 Moving equipment on the floor

Another topic mentioned in the interviews was the movement of equipment on the flooring. In general, patients in control sites stated that they found it easy to move objects on the floor, e.g. bedside table:

> *'this is very easy to move'* (G02- patient in control site)

> *'It's on wheels and they run along quite well'* (G03- patient in control site)

However, some difficulty in moving the bedside table was noticed in both control and intervention sites:

> *'I can't say I had any difficulties or problems with it, except the one you know about I think that is moving of the bedside table... there is resistance to some heavy stuff like the bedside table otherwise, fine'* (C01- patient in intervention site)

> *'well, I have difficulty moving this (bedside table), I do know that... Yes, when I'm trying to move it, it was a bit difficult'* (F01- visitor in control site)

Some comments were received from patients from intervention sites that reflected not their own views but reportedly expressed views of ward staff:

> *'I heard them between themselves… when they rush around...it's not easy to move on this floor, that's the main thing... they don't seem to like the floor very much'* (patient intervention site A)

> *'two of them were moving a bed round one day and one of them said to the other "This blooming floor''... they were definitely grumbling about it'* (B02- patient in intervention site)

> *'I have heard on a small number of occasions members of the staff saying something to the effect that the floor is resisting and it's harder to push heavy trolleys and things'* (C01- patient in intervention site)

> *'There's one of the nurses here, said it's hard to move things across the ward'* (D01- patient in intervention site)

Regarding the use of walking aids, two visitors from both an intervention and control site noted:

> *'as I walked in there was a lady with a frame walking towards the bed and um she was absolutely fine you know there was no problem there, she was quite independent so I suspect that there isn't any problems with it'* (B01- visitor in intervention site)

> *'if somebody is using a walking aid, a firmer floor is necessary I think, if you were to have something that was too soft they could in fact get the stick sort of stuck, it would be more likely to stick when they were walking along, and could bring along some sort of accident'* (H02- visitor in control site)

6.6.1.3.5 Perceived Noise in the Study Area

Some visitors expressed views regarding the floor's influence on noise levels on the ward:

> *'the other floors are harder so they echo more I think'* (B02- visitor in intervention site)

> *'I have noticed that when I walk in here in heels, I feel as though I'm being very noisy'* (H01- visitor in control site)

6.6.2 Staff Views

In total, 77 staff interviews took place in eight study sites (26 control; 51 intervention). The majority of the interviewees were female (N=67). Information on age was gathered from 73 participants (M= 38.8 and SD= 12.2). Three participants age information was not obtained and one declined to disclose it. Staff interviewed had a wide range of experience of working in the study bays. The shortest time was one day and the longest was 18 years. Interviews lasted approximately 13 minutes (range = 5 to 35 minutes). There are five main themes that emerged from the interviews from both the control and intervention sites and are presented below.

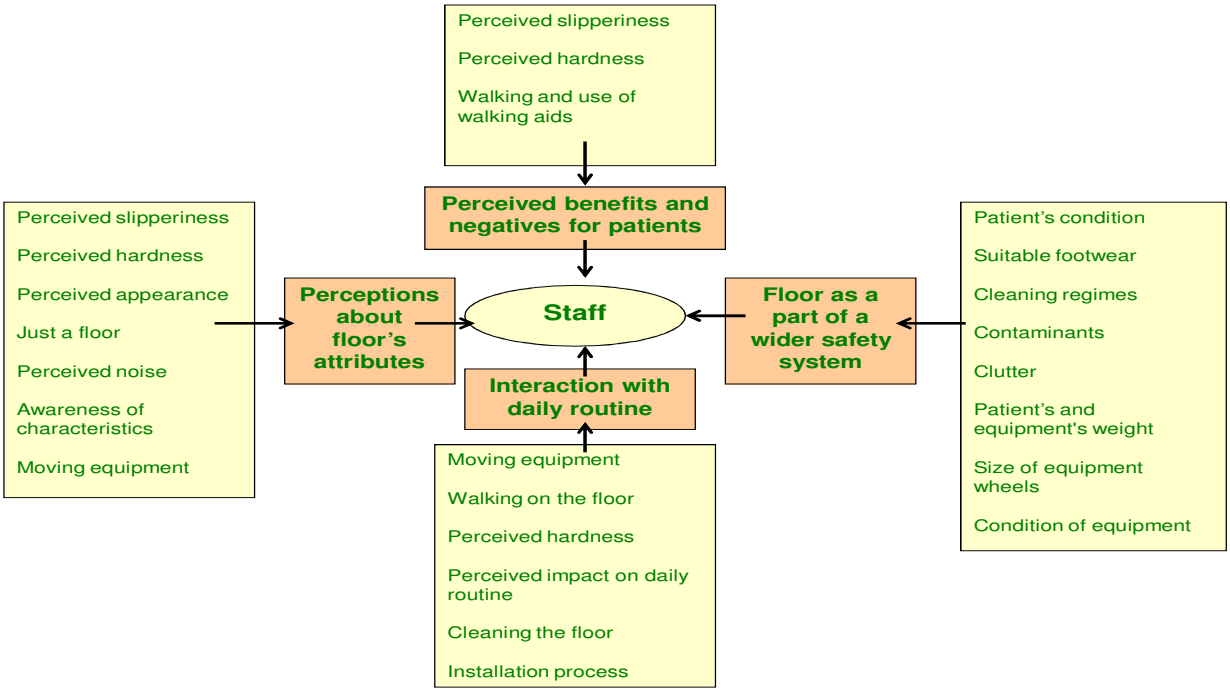


Figure 6.2. Summary of themes from staff interviews in control and intervention sites

6.6.2.1 Theme 1: Perceptions and awareness of floor attributes:

A plethora of opinions were expressed by clinical and cleaning staff about the study bay flooring. Again the issues discussed during the interviews were around slipperiness, hardness, noise, movement of equipment, looks and appearance. These are explained in detail below.

6.6.2.1.1 Perceived Slipperiness of the floor

The majority of the interviewees in the control sites reported that from their experience the standard floor in the study area (which is in fact the same type of floor around the ward), was slippery, especially when wet (some felt that the floor was not slippery when it was dry, though this was not always the case)**.** It was seen that staff within the same site, who work on the same floor had differing opinions over the level of slipperiness and whether this was a problem.

> *'it does tend to get very slippery, very easy and it does feel slippery even underfoot, even when I've got my designated work shoes on and things, there are times when I'm slipping and I'm thinking "Oh it must be wet or something on the floor" and you check the floor there's nothing on the floor... no I don't like walking on this floor, it's too slippery'* (E03- staff in control site)

> *'I think the only problems tend to be more when it's been mopped, it does seem quite slippy on the floor and you have to then wait for it to, make sure it's really dry before you can, especially mobilising with the patients… when we're trying to do washing and dressing we'll need to walk the patient out, um, that's, like this morning I had to wait for the floor to dry, or even get some tissue to make sure it was fully dry, um, before, just to make sure it's safe to the patient to walk across it* (H07- staff in control site)

> *'Obviously the friction levels of the floor are not particularly good…. so if it's dry it can be hazardous particularly if we've got patients that are high risk'* (H08- staff in control site)

> *'it can be quite slippy, um, certainly when it gets wet it's extremely slippy or if it's been buffed it's quite slippy despite the patients footwear and sometimes the brakes move on the beds, across the floor, even with the brakes on* (F03- staff in control site)

The issue of 'buffing' provides a clear example of how a standard process (buffing) can result in differing perceptions with regard to safety:

> *'I find that floor's quite safe, um, we have had discussions as to whether we should buff the floor, um, somebody said 'if we buff it, it could become too slippery', um, but I've always maintained that if you don't buff the floor, people can kind of stick and that can cause falls, whereas if you buff and you've got little old people with slippers on, they kind of glide a little bit better, so I think it's got, you know, arguments either way to be fair'* (H02- staff in control site)

From the majority of interviews in the intervention sites it appeared that most of the staff thought the intervention floor appeared less slippery:

> *'I don't think the slippiness is an issue, I think if anything it's not so slippery… Well, because of the resistance when you're doing anything and certainly, you know, when sometimes if talcum powder gets spilt on the floor on the normal floor, you kind of yourself, you have to stop yourself from falling, but on there I don't notice that, so I thought that was quite good, because you know sometimes I'm kind of powdering patients and some gets on the floor and you think, 'oh I'd better mop that up quick', but no, it's not an issue there'* (B05- staff in intervention site)

'it feels very safe to walk on that's what I can say, um, and it certainly doesn't feel slippery... I wouldn't be concerned about slipping on that floor and our normal floors are buffed occasionally, that doesn't make them slippery but I think it's um, it feels like your feet get a good purchase on the surface... it's a bit more resistance when I put my feet on it than there would be on the normal shiny floors, um, but that's probably a good thing, that's all I'd say really... it feels solid, safe and um, non slippery' (D02- staff in intervention site)

Conversely, some participants found that the intervention floor can appear slippery:

'it can be slippy if something gets dropped on it quite quick... maybe water or something... if a patients knocked some water over or something... probably about the same (slippy) really, I think... I don't find it any slippier or anything' (A03- staff in intervention site)

'just sometimes it can feel a bit slippy under your feet but it's not made any, you know, it's not made any difference to what we do' (D03- staff in intervention site)

6.6.2.1.2 Perceived Hardness of the floor

A number of participants from the control sites frequently reported that they felt that the standard hospital floor is 'hard'. For example:

'from experience patients and staff who have fallen it is quite a hard surface to fall on when there is an incident... not much sort of springiness at all and cushioning effect' (F03- staff in control site F)

'A floor's a floor, it's just as hard as if you were outside on the pavement isn't it, it's not, I mean that's concrete, but I should imagine that's concrete under here, there's not floorboards or anything like that, I don't know... Especially with banging their heads because floors are really, really hard and you can guarantee that they'll bang their heads whenever they fall' (H01- staff in control site)

Although some participants from control sites said that the standard floor is hard, this did not seem to mean that it was necessarily 'uncomfortable':

'I'm pretty happy with it from a comfort point of view' (H03- staff in control site)

One participant from an intervention site also remembered that the old floor, when compared with the new intervention was 'hard':

'well, they are, they're hard and it's like concrete isn't it, just walking on concrete, um, but I've really never given it much thought before the floor went down to be honest… It's the sort of you just take for granted, isn't it?' (D07- staff in intervention site)

Participants in the intervention sites, on the other hand, reported that they can feel the difference when walking on the new floor in the study area as it felt 'softer' (although there were a couple of cases where people did not notice the difference):

'It feels different under foot. You can feel, you know you're in there, if you were blindfolded and sort of led around and said 'where are you', you would know where you were, because

it does feel different under foot… It feels spongy… Yeah, softer… (A06- staff in intervention site)

'It just feels softer underfoot; when it was first put down it felt quite, well like when you get a new carpet and, you know, you're actually stepping into it but now it's kind of settled down, it's just a regular floor as far as I'm concerned... I do (notice the difference), yeah, it's, again, it's not a bad thing, you just feel different, it feels softer, like it could be carpeted as opposed to a wood floor... Soft. Like it's got an underlay or something like that' (D05- staff in intervention site)

'I don't think you're particularly aware of it being any softer, coz obviously you've got your shoes and socks and stuff on… actually to walk on it doesn't really feel that different' (D11- staff in intervention site)

'I've not found that to be different from anywhere else' (C02- staff in intervention site)

6.6.2.1.3 It is 'just a floor'

When asked to comment on study bay floors, some participants in both control and intervention sites did not appear to attribute any specific qualities to the bay floor. For example:

'It's just a normal floor to me, you know, it does its purposes, to walk on... Not really thought about it, it's okay' (F02- staff in control site)

'It just looks like the normal lino, what they have in a hospital' (D08- staff in intervention site)

'I don't really have any major problems with the floor… it just seems like a floor… it's just a floor... it doesn't really stick out in my mind either positive or negative I haven't really noticed the look of it that much' (H07- staff in control site)

'*It feels just like a normal floor in some ways, um, not much difference to it to walk on'* (B07- staff in intervention site)

However, several participants in the intervention sites thought that the floor was noticeable different to other floors on the ward because of its feeling underfoot (as described above on the 'hardness of the floor'):

'You can certainly tell the difference, yeah... Yeah, you can tell the difference when you're pushing things and you can even tell the difference when you've gone into that room, it does feel different under the feet... you can tell straight away' (D03, staff in intervention site)

Participants from intervention sites noted how their perception of floor altered over time, as they became accustomed to it:

'I think I did (notice) when I first started, because it was the first time I had come across one of the floors and I think I did sort of go "Oh, it is a bit spongier" but I don't think I notice it now, coz I'm used to it' (B09- staff in intervention site)

'You get used to it, yeah, definitely...to begin with it's like, 'blimey, it feels like so spongy', but after a while now, you get used to the difference, (C04- staff in intervention site)

6.6.2.1.4 Perceived Appearance of the floor

As expected, participants from different sites and even within sites expressed different opinions on things they like or dislike about the general appearance of the study bay floor. In terms of general appearance, the staff in intervention sites seemed to like the floor, whilst staff at one control site stated that although their standard floor appeared bland, this was probably more appropriate for a hospital:

'I like it, I do like it, I like um, I do like woodgrain, so it looks really nice... It's nice, I think it makes the room look bigger as well... the wood effect, when you walk in it, when they finished it, it looked a lot bigger did the room... It looks nice, it looks very smart' (B12- staff in intervention site)

'I think it's fine, yeah, it doesn't look unattractive and um it always, yeah, people have commented that it's a nice colour, the patients, so yeah, it doesn't look unattractive' (D03- staff in intervention site)

'Oh, it looks lovely, it's blue and it's, to me I see blue and I think of calm' (C07- staff in intervention site)

'Well, I think it's quite homely looking, isn't it?, which is not a bad thing, I do like it and I must say that I prefer in that kind of format than the hospital floor really' (B05- staff intervention site)

' would say just bland but you don't want anything too... you want something plain, you don't want anything too busy you know, with visual impairments and you know with someone with Parkinson's you don't want it too busy, you just want a plain surface really for walking... .which is what you need in a hospital, you don't want anything too overpowering with patients with impairments (F09- staff in control site)

'I think the colouring should be different so it's not so bright… I just think that maybe that's something they should consider, different colouring with people that are visually impaired, um and also like before with the fact that it gave you an idea of how far you're walking, you know if there was some sort of measurement in the flooring, I might be going a bit over the top here, but' (G03- staff in control site)

In terms of cleanliness, comments from a number of study sites indicate that most of the participants thought that the floor appeared clean, but even opinions within the sites differed highlighting the subjective nature of cleanliness. The matt finish of the intervention floor (seemingly less clean) and the new floor showing up fluff was commented upon, whilst at control sites staff highlighted the marks that old floors accumulate and their influence on the appearance (there were contrary opinions as to whether marks made the floor appear dirty).

'I think it has a cleaner look to it certainly, yes… the appearance of the floor it looks bright and clean…it's potentially the colour of it, um, I don't know, does it have a slight sheen?

I'm not sure; it just has a different appearance obviously to the other flooring' (B06- staff in intervention)

'I think it cleans up, to me it looks clean and I think that's one of the big things with certainly visitors in the hospital, that they come in and they can see that things are clean, so I do think that's a bonus point for it' (F05- staff in control site)

'*It mostly looks clean, the um, cleaners work really hard to keep it up together'* (G03- staff in control site)

'It never really looks clean coz it's um, sort of a matt finish so we can't get a shine on it and I'm not really concerned about that, but I think a lot of people who are looking at floors in hospitals, visitors for instance, patients, they look at the floor and they think if it's got a shine on it it's cleaner. I don't take that view but I think that's how it seems, but it never looks um, when it's been cleaned it looks worse sometimes because it's um, it just doesn't produce a good effect (D02- staff in intervention site)

'patients' relatives mentioned that to me, and when I actually sat, you know when you're walking in and out you don't get time to sit down and look and observe like relatives do when they sit down by the bedside they can see underneath the bed, so um, when she did mention it to me I sat down at her level and I could see the fluff on the floor so I did mention it to the domestic again that they have to be careful in terms of cleaning' (B05- staff in intervention site)

'it doesn't look dirty, but it's quite old and it's not very attractive, I think they would benefit from a new floor... there are marks, there's lots of marks on it but I don't think it's very hard to clean... I don't like the scratches and it looks old mainly' (E04- staff in control site)

'The floor surface is very difficult to keep clean and get a lot of marks off, there's a lot of ingrained marks within the floor surface, um, and despite the cleaning of it, it never looks completely clean' (F03- staff in control site)

'*Well it doesn't matter how many times you mopped it (old floor), it never looked clean and fresh, but with this one once it's mopped it looks quite, still as new as it was when it first went down, in my opinion anyway... I think some of the floors they get scratched and they get black marks on them and you can't get them off, but with this flooring it seems to, there's no black marks on it, once it's cleaned properly with the floor cleaner that we use, it looks nice, so I think it's good'* (B03- staff in intervention site)

'It looks, it always looks clean, I think wear and tear wise it does well, um, it's been a year in September so compared to other floors I think marks potentially don't show up on it as much, so in that respect I think it looks clean, it looks nice, it looks tidy, it looks neat, yeah… it brightens up the place definitely… it looks like it wears well… the seams look all nicely joined when I've been in, it looks well made' (D18- staff in intervention site)

Two quotes from respondents from the same intervention site illustrate the possible subjectivity of the perception of cleanliness of the floor:

'it never looks clean... yeah, it never looks clean' (A08- staff in intervention site)

'It's clean' (A02- staff in intervention site)

Regarding the maintenance of both intervention and control floors, most of the participants thought it did not appear to be an issue:

'I've never noticed any you know, indents or anything, that have gone through, so it seems pretty sturdy' (H03- staff in control site)

'Well, my immediate concern I think was um, it being punctured….so that was a concern thinking you know all this money, will it be worth it if it's punctured somehow or split, but I haven't noticed anything like that' (B01- staff in intervention site)

One aspect of the study bay flooring that elicited comments from only intervention sites was the appearance of temporary indentations on the floor left by heavy equipment:

"*It does dent but like a carpet it seems to rectify itself after about ½ an hour, but it does dent'* (B02- staff in intervention site)

'I think it does (dent), but not for long, I'm sure it springs back; I don't think it's a permanent mark… Yeah, it springs back, I don't walk around thinking "Oh, there was a bed there or a table there yesterday and there's still a foot mark or a table leg mark" (A06- staff in intervention site)

'you do sort of notice when something heavy's gone over it, you can see the indentations where it's been' (D11- staff in intervention site)

Participants from both control and intervention sites also offered a few comments on the colour of the floor and how it impacted on the ward.

"it's very bright, it's quite a light area, it makes the place look airy, I think if it was a dark colour it might have a different effect, but it's not horrible but it's not brilliant' (F06- staff in control site)

'I prefer the colour to the other floor to be honest... the other floor is grey and dull and miserable, whereas that has a bit of colour to it, I like a bit of colour, the room seems brighter as well, I don't know, I don't know if it does affect the atmosphere whenever I walk in there, it feels better than the other rooms, coz there's some colour, something different to look at, coz every other room in the hospital looks the same, with the same floors and stuff as well so… I like the colour' (D05- staff in intervention site)

'my own issue would be the colour, it's quite a dark colour in there, it very much lowers the whole room really and, you know, most of the other bays are quite airy and light and that one, I think the floor colouring takes it down a bit" (A02- staff in intervention site)

6.6.2.1.5 Perceived Noise in the Study Area

Again, diverse views were noted on noise levels of the control and intervention floor (with some differing opinions expressed within sites). Some participants in control sites thought that the floor

was noisy and also that the noise level could be more dependent on the footwear or moving large objects, than the floor:

> *'Well, at times when they're dragging those trolleys and anything big, you know, it does cause a lot of noise and it's kind of very hard if you're talking to somebody to hear as well...* (F08- staff in control site)

> *'it's quite noisy this floor as well, when you're sort of walking round, especially when in the night you hear bang, bang, bang, you know, it's quite a noisy floor… we get general comments that it is noisy at night, so um, maybe, I guess it's the fact that we're sort of walking round on the floor, maybe just staff being noisy (laughs)* (H05- staff in control site)

> '*No, I can't say that the flooring's noisy'* (G03- staff in control site)

Participants from the intervention sites were more confident that the intervention floor appeared less noisy:

> *'Pushing things is much quieter and calmer, yeah, when you're manoeuvring objects within the bay, it is yeah, definitely'* (A04- staff in intervention site)

> *'I couldn't hear anybody walking on it, whereas on the normal floor you can hear, especially if you've got cloppy shoes on, you can hear them walking around but I didn't hear anything... it does seem quieter to me rather than walking on the normal floor'* (D09- staff in intervention site)

> *'It's quieter, if something falls, it tends to give "dunk" instead of "clatter-clunk" (laughs)… I think to the patient it would make a big difference because when you're ill you know, noises can be quite toxic to your recovery...so I think that way it's definitely more therapeutic'* (C07- staff in intervention site)

6.6.2.1.6 Awareness of flooring characteristics

Staff's awareness of the characteristics of the study bay floor and how it may impact on patient safety, and staffing attitudes was also discussed:

> *'it[being in the study]'s made me think a lot more about their risk of falling and yes, people might have had a falls risk score done and they think 'oh well, they're level whatever that may be', but I think, you just think of the patient and oh yeah, they might fall so I need to keep an eye on them but if you think about what they might fall on to and the injury that they might sustain, it does make you think a bit more about the floor. I think it does, coz you might just think 'oh, they'll slide if they slide out of that little bed', but they might not slide, so yeah, it does make me think about the flooring a lot more... I think I'm just a bit more aware now when I am around patients either here or at…just to make sure there are no obstacles. If people are gonna get up then you just think oh no, what's that on the floor or is that gonna stop them from getting right round so yeah it has raised my own awareness about personal space for patients and workable space for nurses so, yeah'* (F06- staff in control site)

'maybe I'm being a little bit more aware of looking at the type of floor we've got and maybe taking it more into consideration but probably it wouldn't change my practise in any way' (H03- staff in control site)

'I wouldn't say it changes the way I work, but my knowledge, I'd say it helps possibly because I feel safer and I think my patients are safer as well'(A04- staff in intervention site)

'you're also aware of it coz the colour's different as well and you know, and generally I'm walking with patients, I'm talking to them about different floor types as well so again that's gonna highlight it to them and to myself that I'm walking on something different' (B10- staff in intervention site)

Comments received from staff demonstrate the degree to which patients' and visitors' were aware of the bay floor and its potential impact on safety:

'*Certainly the relatives notice, when you talk about the study they immediately take a lot more notice of the floor... They just say if it's wet it must be extremely slippy, so they do sort of look around and say, 'oh my mum's already had a fall', so, I think they're very much more aware um of where the relatives are being nursed'* (F06- staff in control site)

'I don't think they (patients) think a great deal about it unless they've fallen on it' (H08- staff in control site)

'some of them will say, 'this is a nice floor', but some of them are not really, they don't really understand that it's a different type of flooring and what it's about, all they know is that they need to go to the toilet and it's a floor with a bit of a cushion on it, it's a bit softer' (B03- staff in intervention site)

'sometimes they (visitors) have (noticed), when they get in they say "Oh, it's a different floor", a comment like that' (C05- staff in intervention site)

6.6.2.1.7 Moving equipment on the floor

Staffs views on the movement of equipment on the study site floors were also ascertained. Comments from staff working in the intervention sites indicated that it is more difficult to push equipment on the new floor:

'the only problem we find with it after it's been fitted is the fact that it makes it really difficult to move equipment, you know, it's harder to wheel things on it than a standard floor, so when you're moving patient beds or medicine trolleys, it is a lot heavier to move them around' (B11- staff in intervention site)

'it's quite a sticky floor and that can be quite difficult with getting the glide about nice and smoothly over really... it's again just to do with like the stickiness really of the flooring' (A07- staff in intervention site)

'It's really, really difficult, that's the main thing that we've found is if you went to push a bed or a hoist or a drugs trolley even on that floor, and then you compared it to pushing on

a normal floor you'll notice a big difference, it becomes a lot heavier and harder to push' (D03- staff in intervention site)

The topic of moving equipment was as a key component of many of the staff interviews. Their comments on the way this was seen to affect their daily tasks are described in more detail in the following section, of the report: 'Interaction with daily routine'.

6.6.2.2 Theme 2: Interaction with daily routine

We were very interested in finding out if the daily routine of the participants in the ward has been changed since the study took place. Little change was expected in the control sites as there was no change in the flooring. In the intervention sites, however, we wanted to find out if the installation had introduced any implications for the staff's daily routine and what should be taken under consideration for future studies.

6.6.2.2.1 Moving equipment

One topic of focus was the reported difficulty in moving equipment on the floor (this was a particularly pertinent topic at intervention sites, as the thicker floor did make a difference to the rolling resistance of equipment). The researchers anticipated that the qualities of the new floor may affect the friction levels and were very interested to find out the staff's views on this topic. Staff emphasised aspects like the size of equipment (with larger, heavier objects being harder to move), the relatively small wheels of equipment making it harder to move objects, the number of staff required to move objects (with more assistance being required on the intervention flooring), the sensation of it feeling like the breaks have been left on when trying to initiate the moving of an object, and the indentations in the floor created by an object making it difficult to initiate the movement of that object.

'the only problem is the fact that its heavier to push things on the floor... well I haven't trialled different things, I can only go by what we try and push and the medicine trolley is heavier to push, patient's beds and the bedside lockers and the tables are heavier to push... the patient's beds (are harder)... the one thing I don't like is how much heavier it is to push equipment on it' (B11- staff in intervention site)

'When I'm working with the floor I find it difficult if I've got a patient in a hoist to move the hoist, I find that um, it's very heavy to move, whereas if I've got a patient in a hoist in another area of the ward, it's quite a smooth transition when I'm moving and sort of, so that's difficult, the bed tables are a bit, as well, you have to kind of push, push those, they don't glide as smoothly … and I move beds on my own in other bays, I can move a bed from that end of the ward down to here just tootle it along, I can't in that bay. You think the breaks are on and all sorts, oh, the brakes are still on (laughs)' (A06- staff in intervention site)

'Very hard. Very hard, as I say on a night there's only 3 staff on, 2 Staff Nurses and 1 Health Care or Auxiliary, and so if you've got somebody to move or a bed to move there's, you can be down to 2 if somebody else is on a break or doing something else and, yeah, it's hard work moving anything on that floor… it's just something you do day by day, you just do it every day so it's just something you struggle with or do anyway, you know, you always do it, you always manage to do it, even if you've got to push it 2 or 3 times to get it across or

something like that, it's just something you do… I think it's a brilliant idea but I don't think it's working because of moving things on it… I've noticed the bedside tables, those are one of the hardest ones to push, I mean I've been pushing and thought the brakes still on, it's that hard… It's a shame but more you'd have to dislike it because of the heavy work it is moving things on it' (D06- staff in intervention site)

'the first time I was aware of the flooring was when some of the support staff raised concerns about the difficulty of moving patient transportation equipment over the flooring… I sort of directed them to fill in a AIR's form which is our Adverse Incident Reporting system, so then there's a record of that, that goes to our Risk and Legal Services Department and then they sort of follow up any work that needs doing from that and it's just a way of sort of properly recording people's concerns about anything really' (D11- staff in intervention site)

'(My experience)'s not positive, to be honest, um, I think moving and handling of anything on there is really difficult… Moving the patient on that floor in that (standing) hoist actually juddered because the floor was so soft, it's not an easy flow movement and she slipped so … it has (changed), it's actually harder work. I think it's harder work for staff and it's harder work for patients as well, especially this client group, I think maybe if you'd asked the people who were on this ward before it might be different because they had more mobile patients. I don't think it was so much of a problem as it is now with very dependent people needing equipment' (D16- staff in intervention site)

'we have to use moving and handling equipment which have very small wheels um and at the best of times they're heavy to move even on normal hard surfaces; in there (study bay) the main thing that all staff come up with is the resistance, um, in moving equipment, even beds you know, it takes two of you to sort of lean and put your back into it kind of thing, safely... that has been the main um, negative aspect that all members of staff have commented on' (C07- staff in intervention site)

Further comments received by two respondents from different intervention sites highlighted a concern about a possible difficulty in moving beds in emergencies:

'for example in an emergency situation the first thing that you should be doing is pulling the bed away from the walls so we can get in and manage the head of the patient and now you're having to wait until help comes to get you, I mean you can just about do it but it is a struggle and that and you can definitely notice the difference' (D07- staff in intervention site)

'I'm quite worried in a crash sort of situation how we're gonna suddenly pull out the bed without, you know, hurting our backs… so yeah, moving the furniture in there is slower and harder' (C04- staff in intervention site)

Participants from the intervention sites also expressed their concerns on possible risk of injuries to staff:

'I think it's a risk, like a risk to back injury um, from a staff point of view... It's just taking more effort and obviously your risk is if it moves that that could cause a back injury... I think the negative thing is the tray tables, which is now starting to turn into quite a theme and I'm

terribly sorry, um, but actually yeah, that bothers me... I think the only concern is the risk of back injury' (B10- staff in intervention site)

'we feel it on our backs, backs and our arms and our shoulders... The locker pulls, I haven't actually hurt, but the locker pulls, when you try and pull a locker out it does, you can feel it pulling on your arms and your wrists' (A08- staff in intervention site)

However, this issue was particularly prevalent from one intervention site (D):

'it's harder work for the staff and if you're putting more effort in and something goes wrong, the staff may potentially be at more risk of a manual handling injury or something like that as they're having to work harder' (D01- staff in intervention site)

'Some staff have complained that they felt their backs have been, a bit of soreness in their backs from pushing objects on it... It hasn't been (ongoing) and I followed it up and they've said 'no, it's okay now' but people have said, and I have found that when I've, I moved an electronic bed with somebody that I felt the strain so I just felt there was a bit of a risk there' (D02- staff in intervention site)

'I've actually hurt my neck today transferring a patient using a turntable um, the patient was stood on the turntable and when I went to turn it, it wouldn't turn at all um, and that's not usual for a turntable and it wasn't anything that the patient or myself or my assistant were doing, it was the floor that was stopping the turntable moving… I actually hurt my neck on it because the patient didn't move and I did move' (D16- staff in intervention site)

'Off sick with bad back with a week (laughs) has been my experience of this floor... I can tell that from my working experience here, coz I've been nursing since I was 18 years old and I've never had a bad back ever, we moved across here and within a couple of weeks I was off sick with a bad back... I can understand why it's a good idea, but practically on a ward like this with the sort of patients we've got with the staffing levels we've got, with the equipment we've got, it's gonna cause nurses bad backs' (D19- staff in intervention site)

Participants from this site explained that staffing levels may make a contribution to this potential difficulty:

'I mean I think if we had a lot more staff, it might change things but I think we would still find it's just the actual action of moving a heavy wheeled object on the floor that is quite difficult' (D02- staff in intervention site)

'it's been difficult for us, our patient group is different to the client group that the other ward had... I've been very concerned about the staff manual handling, my staffing complement is less than the previous incumbents for example I only have 2 staff members on a night shift, I have finally managed after much pressure to get that bumped up to 4 but that's only until the end of the trial… the recommendations were that we use 2 members of staff to move every piece of equipment... in my particular client group unless you're gonna change the staffing and change the equipment that I've got then it's not been a great success... the safety aspect has worried me greatly since we moved over here because they're already saying, well two nurses to do this and two nurses to do that, and I'm thinking, well I haven't got two nurses, you know' (D13- staff in intervention site)

> *'now in an ideal world if you've got two or three of us pushing the same bed against that floor, like I've just got another nurse to help me that side, that's okay, same with everything else, but when you're on a ward that's staffed to the level that this one is, the amount of patients we've got, you can't do that, you've got nurses working on their own'* (D19- staff in intervention site)

One participant noted a possible positive aspect to the perceived difficulty of moving equipment:

> *'sometimes we're not sure whether the brakes are off because it's that hard to move the bed, so that's quite a good thing as well if somebody forgot to put the brakes on at least the bed's not going to go flying and cause an accident'* (B05- staff in intervention site)

Two staff participants who intermittently worked in the intervention study area highlighted that they had not noticed any difference when moving equipment on the intervention floor:

> *'I haven't particularly noticed... I haven't noticed anything else with regards pushing people in a wheelchair or anything like that, um I have to say that could be me not being as observant as I might be but hopefully not, but I haven't truthfully noticed anything in that way... and I certainly haven't noticed when moving the beds about'* (B06- staff in intervention site)

> *'mostly, I'd be just be pushing light things, like the notes trolley around and that seems to be fine'* (C02- staff in intervention site)

Some of the participants working with the new floor, whilst acknowledging the difficulty with moving equipment, they felt that it did not interfere with their daily routine:

> *'I mean it really doesn't matter significantly... but no the fact that things are harder to push on it hasn't really affected what we have to do'* (B08- staff in intervention site)

> *'we have to hoist patients out of bed from time to time and things like that, I haven't noticed much of a difference when using them, but I'm a young, fit gentleman ... I don't see that as too much of an issue and all the tables that we use, the wheels are usually busted anyway so you're usually battling with them, so me personally it's not affected me at all... as I say it's not a big hindrance, it doesn't affect my work at all*' (D05- staff in intervention site)

> *'Disadvantages I would say difficult to um, to move equipment but with proper um, techniques probably it will, it can be sorted out'* (C05- staff in intervention site)

> *'I pushed a hoist on it and it was a bit harder but it's not like any kind of significant difference that would prevent you doing what you wanted to do, just coz the floor undulates a bit more, it doesn't really make it a hard job or unable to do'* (C06- staff in intervention site)

> *'Only a little bit (resistance), but not enough to be a problem… What it means is if I pushed a trolley in that room, coz you can just go 'wee' down the halls, it probably won't go as far… they have like a little sideboard to put their personal things in, there might be a little bit of resistance putting that in coz they're on castors I think, a bit of resistances but nothing problematic'* (C07- staff in intervention site)

Staff from control sites also commented on moving equipment in the study bay; whilst some staff commented that moving equipment on regular floors was easy, others at one site (G) highlighted that even on regular floors, moving equipment can be difficult:

> *'trolleys and things, they just tend to glide over it'* (E03- staff in control site)

> *'For us it's certainly easier I would say because we've got to move a lot of equipment around so equipment wise and the size of the equipment that we sometimes need to bring in these floors are a lot easier... the hoists easily glide on it, the wheeled zimmer frames move very easily across it, so I would say it does ease things... it's just as easy to move equipment over it...it certainly doesn't make moving them around any more difficult, certainly not'* (F05- staff in control site)

> *' it is nice and smooth so you can use equipment over it and that doesn't worry me at all'* (H03- staff in control site)

> *'Pretty tough to be honest, especially if the patient is on the larger side, you can normally do it with two but even with two it's a struggle sometimes… I think both (being stationary and moving) are a problem to be honest… I think the weight and sometimes even with two people it really is a struggle to turn corners and stuff when you've got a patient in that position… In that situation, yeah (it's the floor)… it's quite a, I've called it a grippy floor I guess, so when you're trying to run wheels on it, it kind of gets stuck, but it's a combination of that, turning the corners, making sure the patients not, you know, swinging around, you just need more manpower to do it really, probably three people to do that, but it's just unfortunate really, it's just not practical with um, you know the staffing levels and things'* (G01- staff in control site)

6.6.2.2.2 Walking on the floor

Another point identified by staff from most sites was their perception regarding how safe they felt walking on the study bays floor, staff highlighted that they themselves (with good balance and a regular gait pattern) did not have any difficulty walking on the floor (be it intervention or control), although some staff at control sites highlighted the difficulties of walking on the floor (when it is slippery, particularly when wet):

> *'Quite safe because I know, I balance um, fairly safe, yes'* (E04- staff in control site)

> *'I don't feel any instability when I walk there... For me I don't see any problems using that floor, stability wise'* (C05- staff in intervention site)

> *'I don't think I've had any problems walking on that floor... I feel relatively stable on my feet, um, but I've not tripped or slipped at all, so I guess from that point of view it's been fine'* (B10- staff in intervention site)

> *'Yes, I have (fallen)… I slipped on some water that was actually on the floor and fell quite hard onto the floor... I had some quite bad straining and spraining of my wrist due to that'* (F03- staff in control site)

'just hard and slippery for the staff and, some staff have fallen over, when they've slipped on things or when they've tripped over equipment and it, you hear them go down with a mighty bang, so yeah, it's not very pleasant' (H05- staff in control site)

Two participants from an intervention site explained that initially they felt unsteady walking on the floor:

'It feels a lot different... at first because I didn't know, I felt unsteady, um, so it was, it felt strange to me. Once I'd got used to it I was okay... once I'd walked on it a bit I was fine, (D09- staff in intervention site)

'I mean, first time I was walking on it, it was like walking on a, it was like I was gonna fall' (D14- staff in intervention site)

6.6.2.2.3 Perceived Hardness of the floor

A further point that was picked up by the staff interviews in control sites was about the hardness of the floor and the impact it may have on their feet:

'it's the staff, we moan about it (the floor), coz our feet hurts... Coz you're walking on cement, it's concrete, you're walking on, I do, I'm walking on it all day... not just me, the carers, nurses, it has an effect on your legs, it aches... They're made of cement and they make my feet ache' (E05- staff in control site)

'Your feet hurt at the end of the shift, that's about it really… coz we're pounding all the time, it's quite a hard floor but because we're pounding… Walking up and down, yeah, most of us wear these sort of Croc shoes which are quite good but at the end of the shift your feet do hurt' (H04- staff in control site)

Some participants from the control sites expressed a more neutral view regarding the floor:

'it's no more uncomfortable than any other (floor) really' (F05- staff in control site)

'just comfortable as a floor can be. I wouldn't write home about it being uncomfortable but then I haven't really noticed it as being kind of squidgy' (H06- staff in control site)

On the other hand, staff working on the intervention sites noticed how soft the new floor felt to walk:

'I wish the rest of the ward was fitted with it… Because it's nice on your feet, it doesn't, you know, as nurses we're pounding the corridors non-stop so it's really quite a comfort thing and um it's nice to walk on, I feel quite confident and comfortable on it' (B05- staff in intervention site)

'I think it's better for your feet and your legs as you're working, you know for staff wise, it's a lot, coz I think because its cushioned, whereas the other floors it's like full weight onto it whereas that's cushioned, so yeah, I think it's easier on your feet and your leg' (D06- staff in intervention site)

Staff also expressed their perception around the qualities of a shock absorbent floor, and how it influences perceptions of the patients' risk of injury:

> *'I wouldn't say its reassurance, coz obviously if an alarm goes off we're right there straight away to try and you know see what the patient is up to, so but it's kind of like well hopefully if, for any reason the patient did have a fall then hopefully we have reduced the risk by having that floor in of them actually injuring them more or less than what they would on one of the other types of floors that we have which are quite hard like I say and could definitely cause a bit higher injury than what they would on that floor'* (A07- staff in intervention site)

> *'because we've got that floor we know it's a special floor and we, and we put our vulnerable patients in that bay because we know if they fall and they fall on that floor then they're gonna be protected more than they would if they fell in another bay, um, you're more aware when you're in that bay that that floor is for vulnerable patients'* (A06- staff in intervention site)

Nursing and therapy staff mentioned that kneeling is one of their frequent tasks. Staff from control site reported that it is uncomfortable but they are used to it, and staff from intervention sites highlighted the comfort afforded by the intervention floor:

> *'it's bad for my knees (laughs), I do kneel down quite a bit if I'm doing med dressings or if you doing Ted stockings and the patients sat out and not in bed um, so yes, it's not very good for my knees and I'll probably find that out later in life'* (H01- staff in control site)

> *'it's very good for kneeling... yeah, it's very good for kneeling as a member of staff, coz often we have to do leg dressings and we have to wash them ....it probably the best type of flooring to kneel on, rather than a hard floor like the standard lino... I've said 'oh I like it for kneeling on'* (B02- staff in intervention site)

6.6.2.2.4 Perceived impact on daily routine

In general, it seems that daily routine of the study bays remained the same in both control and intervention sites and nothing has changed since the study began:

> *'it isn't any different, coz we soak our mops and use the same things... I use the same routine'* (C01- staff in intervention site)

> *'we just carry out our duties in the same way'* (F03- staff in control site)

> *'I don't think it's changed the way that I do anything with them (patients)... the flooring is just part of the environment so I don't think it's made any difference to how I conduct what I do'* (B06- staff in intervention site)

> *'We're aware of it, we're aware of why it's there but our actual day to day work with the patients hasn't changed, no'* (A02- staff in intervention site)

> *'I wouldn't say as it's actually affecting my personal work as such... I can see how it might affect the nursing staff, people that are having to hoist patients all the time to get them on to the toilet as such, I guess it could affect their work a little bit more than it would mine'* (A07- staff in intervention site)

However, some of the participants working with the intervention floor reported that they had to adapt their daily tasks. These adaptations included:

(a) Leaving equipment near the door or outside the study are:
'we sometimes leave the tea trolley or the drugs trolley outside and walk in and come back instead of pushing in' (D03- staff in intervention site)

'sometimes you've got to do their medication, I will just leave the trolley outside and take the medication out and then lock it again and get in, so which means that it's gonna take me longer to give my medication, than when I was in the bay, because I'd be watching my trolley so I could just go and give the patient the medication so I did' (D14- staff in intervention site)

(b) Requesting help from other colleagues:
'We just have a couple of members of staff or 3 trying to push. I mean we can push it but it's just, it's not like the other flooring where you can just move the bed, when you've got someone that's quite poorly and that's quite a big person you are struggling to move coz it's hard at the best of times'(B03- staff in intervention site)

'I had to tell the other (nurse), usually I can move the hoist with the patient in on my own and the other nurse will be clearing the area, so she will be moving the wires and making sure the bed, underneath the bed is clear um, and free of clutter, but when I'm in there she also has to help me push that… if you want to move a bed you need about 3 people to move a bed' (A06- staff in intervention site)

'I might anticipate that I might have trouble moving wheeled objects and get more help, depending on the level of staff that we have, yeah' (D02- staff in intervention site)

'we often say 'oh, can you give us a hand?' so what's normally a one-to-two person job, could be a two-to-three, so in that way it's more demanding on staff intensity to move that equipment at that time' (C07- staff in intervention site)

'at the moment we're having to have an extra staff on night times because of the floor, um, to help in there on a night because if the nurses are doing tablets for instance it would be my job or my colleague's job to be in there on my own and you know if I had to get on with stuff and I couldn't get anybody else so they'd give me an extra person for that room which isn't brilliant really, financially anyway' (D18- staff in intervention site)

Although it should be noted that other participants reported that they did not require assistance from their colleagues:

'No, it doesn't need an extra person, but it is significantly heavier to moved things on the floor' (B11- staff in intervention site)

'I wouldn't say we're using more staff to be able to use the hoist... it's not using any more staff, it's just a bit more manual handling if you like to try and get it into position' (A07- staff in intervention site)

'No, no, it's not affected anything with regards to (extra staff), you know, as I say my work, my work's absolutely fine and when I'd be on with physios and the nursing staff and HAD's moving the hoists, it's not affected them at all' (D05- staff in intervention site)

(c) Applying extra physical effort:
' you kind of put a bit more effort into pushing…I think if I kind of like a score out of 10, 10 being the maximum, and how hard it is, I would say it's on a level of 7…compared to the normal floor'(B05- staff in intervention site*)*

'it takes more physical effort from us to be able to move things about... Putting a bit more physical effort into it (laughs), that's the only way around it' (A02- staff in intervention site)

'you need more pressure to push things and pull things... sheer brute force basically, you need to push and pull harder than what we would in another bay' (A04- staff in intervention site)

'it takes extra effort and it's quite exhausting (laughs)... just put a bit more effort into it than normal' (D01- staff in intervention site)

'it's a question of requiring effort to push the hoist out of that indentation, which is quite um, it's quite difficult sometimes' (D02- staff in intervention site)

(d) Admitting more frail patients in study area:
'the main difference I would say was how I admit the patients… the only thing that I do differently is not move the patients that are at risk nearer to the nurses' station, I just leave them down in the bay that has the floor' (B05- staff in intervention site)

'only the fact of when we're admitting patients I'm more aware of saying 'are they high risk of falls?' because then I can make sure I've got a bed space in that bay, um and that's probably something we will work towards... just obviously about the admitting, that's the only thing that's changed really' (C04- staff in intervention site)

(e) Avoid moving objects unnecessarily:
'I'm more cautious with moving things and I try to avoid moving a lot, you know a lot of things, um, if I only have to move a tray table a short distance I will do, rather than sort of dragging it round' (B10- staff in intervention site)

(f) Being more aware of the intervention floor and proper manual handling techniques when working in the study bay:
'I just make sure that patients are aware that when they move on to the lino as they leave that bit of the ward or whatever the surface is I think it's lino, um, that it will run a little bit faster just so they know when they go through that doorway not to push too hard... I guess it highlights more the difference in flooring' (B10- staff in intervention)

'It makes me more aware when you're on that flooring definitely... I think I'm probably more aware and careful' (D06- staff in intervention site)

'it slows you down but it's good because your relying on your back as well… you need to do things the proper way' (C05- staff in intervention site)

'changing your technique is how you do work in there' (D15- staff in intervention site)

One respondent also reported that they choose not to allocate staff with back problems to the bay:

'if it's somebody who's been off with back pain I'll maybe put them down the other end of the ward…which is not what I want to do, I'd rather have the continuity of the same staff looking after the same patients, but we do, we're swapping round more to give people a break from it' (D13- staff in intervention site)

Another interviewee explained that they now mention the floor during the morning nursing handover:

'we mention it at safety briefing every morning, because I'm always conscious I might have staff who have not worked on the ward before, I might have agencies, I always mention it every morning anyway, saying 'remember, two staff to move a bed' (D13- staff in intervention site)

(g) Assessing patients outside the bay:
'we're having to take the patient out of that environment and put them, like we'll do therapy with them in that ward and we're like, oh they need 2 people coz they struggle to move the frame, we take them out of that environment... we don't tend to do as much mobility practise on there now to what we would in the other bays' (A07- staff in intervention site)

'it's harder to push it really, we take them out in the corridor' (D01- staff in intervention site)

(h) Taking longer to do tasks:
'it affects because it slows you down, and um, that's all I can say probably, yeah it affects us because it slows you down… it's not the biggest impact really, no, it just slows you down, but no, it will not entirely affect the (daily routine), I don't think so, it just slows you down a little bit, but that's it I think, it's not like slowing you down for 30 minutes, it's just… (that few extra moments)'(C05- staff in intervention site)

6.6.2.2.5 Cleaning the floor

Respondents from the intervention sites commented upon the apparent cleanliness of the floor and cleaning routines:

'it looked dirty and I had the domestic clean it up straight away but I think it also shows up a lot of fluff on the floor… I think it's a good thing because then I'll get the domestic to clean it up, if I don't see it and I think everything's okay and that would put me in a false picture, wouldn't it?... if anything I think I often have the domestic clean it more often really' (B05- staff in intervention site)

'it does attract a lot of dust, a lot of, and I think it's because of such a high shine and it's such a dark colour that you do see the dust because dust is grey to white, isn't it? So you do see the dust on there and it is, I think the domestics have a nightmare in there, sort of cleaning and whatever… Well, if it wasn't a plain green, maybe if it was mottled' (A06- staff in intervention site)

'so consequently when we've cleaned and mopped it and it stays wet the floor looks beautiful, but when it's dried it doesn't look like we've been in and cleaned... I prefer the other floors.... coz they always look clean and tidy and keep... it's always been difficult, right from day one' (A01- staff in intervention site)

'I think there is an issue with cleanliness, the um, domestics have said to me that it's difficult, more difficult to clean coz it's got a lot of little bumps and so it's not like a smooth surface that is easier to clean, I don't, I think um, they feel it's more difficult to clean... the surface, yeah, that's what I mean' (D02- staff in intervention site)

'I suppose with the floor being all one colour things can be slightly more noticeable, it's not camouflaged so well, but then that's probably a good thing, isn't it? So, no, I wouldn't say there's you know, not really any different with regards to the cleanliness' (C03- staff in intervention site)

'That (new floor) takes me longer, for some reason it seems to collect the dust more and I don't know whether that's because it's a plain blue floor and the normal floor is patterned so you don't notice it as much... I use the same routine as I say it just takes me a bit longer coz I have to keep going back to get the bits of dust (laughs)' (C01- staff in intervention site)

Conversely, other interviewees from intervention sites thought that the intervention floor is easy to clean:

'I know it's easy to clean and there's not been any problem... we moved to our chlor-cleaning regime which is pretty strong stuff um I can't remember what the concentration is but it's hydro-chlorate anyway and it's not as far as I can see, damaged the floor and it stood up to that quite well so that's a positive for it' (D13- staff in intervention site)

'for me, if I do, its quicker. Yeah, quicker, I don't have to worry when I go on this floor, when I mop... but this floor, one minute later, look, oh it's okay, so I don't have to worry about the floor too much when I work on this floor... I don't, I never count (how long), but I feel really different on here, it take me quicker' (D04- staff in intervention site)

'it's easy to clean, it really is, coz the marks just, you mop the marks and they come off, you don't have to really rub them, they just slide off,...it's an easy floor to do... a lot easier to mop than the other floors' (B12- staff intervention site B)

Similar comments were received from control sites about the floor cleanliness**:**

'this place is like one big bedroom so every day there's fluff and dust, patients can't be get up so there's always stuff on the floor, you know, you can go clean somewhere up come back an hour later and they'll be bits all over the floor... you have to keep on top of it' (E03- staff in control site)

'they (tiles) can easily crack or get holes in them and then it would become bevelled um, which can be more dangerous...if they're machining the floor or mopping the floor you're not getting into the hole properly, so you're getting the build up and then you've got to go round with a green pad or something and try and clean it up, which can be time consuming' (F04- staff in control site)

'they do it with not a really sopping mop, it's normally, and it doesn't take very long to dry' (H01- staff in control site)

'it seems to dry quickly so wet floors aren't normally a problem' (G01- staff in control site)

6.6.2.2.6 Installation process

In the intervention sites researchers also asked staff about the installation process, when the study bay had to shut down and how that had influenced their daily routine. Staff in most sites were not concerned about the installation period and thought it was a smooth and quick process:

'Very effective actually, I thought that they did a marvellous job, I was kind of, I envisaged you know a huge amount of dust, a lot of disruption and I was very impressed…There was some (dust), there was a tiny amount but you know they sealed everything up very well and then the deep clean happened so it was really good… I just thought, 'well I'm sure they know what they're doing' (laughs) and left them to it' (B05- staff in intervention site)

'it was fine, I think it was done within a day. I think they've done it, you know, totally down and that was it, and you could walk on it straight away, said you can go on it, you know, we thought it would have to dry or it would have to, but he said no, you can, you know, load everything back in… The installation, absolutely fine… It wasn't disruptive at all' (A06- staff in intervention site)

'they closed the bay off so I didn't see lots of it it wasn't too bad... a couple, three days, something like that... It didn't bother me coz they more or less shut the doors and got on and did it so I just kept walking by coz I didn't have to clean that bay.... the main disruption was when they did the bit in the middle of the corridor... it wasn't too bad, but when they had the glue down, we had to be very careful not to stand on it or you'd be stuck to it' (C01- staff in intervention site)

Some negative aspects of the installation process mentioned by staff were around, noise, glue smell, dust as well as operational management:

'I suppose the glue was quite strong but I didn't mind the smell, um, yeah, I suppose the main thing was it just the work going on and the smell of the glue… well, it was pretty self-contained in that room really, so apart from a little bit of background noise, not really that much interference to me personally' (C07- staff in intervention site)

'obviously there must have been some dust and that going around, um, no, I know, coz I think that was the hardest bit when the flooring was coming up, yeah... I think because of the dust, you know, the dust going around' (A08- staff in intervention site)

'they shut a bay while we were doing which means that it's a bit upheaval for patient and staff while it was being done…well, we were classed as over staffed so then we'd get moved somewhere else because we were down to 20 patients at the time, so the number of staff what we had is for 25 patients so we would have been moved or dispersed elsewhere' (D06- staff in intervention site)

6.6.2.3. Theme 3: Perceived benefits and negatives of the bay floor for patients

Staff in both sites explained the positive and negative qualities of the floor in terms of patients' safety and recovery. A wide range of opinions were exhibited across and within sites.

6.6.2.3.1 Perceived benefits and negatives: Slipperiness of floor

Staff from control sites reported that the standard floor felt slippery and many patients felt unsafe to mobilise on it and that affected their mobilising behaviour:

> *'...we did have one patient recently who was more or less petrified to stand coz her feet kept slipping every time she tried to stand, and so that was quite difficult, wasn't it? And then we took her home with her carpeted house and she was off trotting about…every time she tried to stand she felt her feet slipping so that you know, because she'd had a fall she'd lost her confidence anyway and she didn't feel (safe)'*(E01- staff in control site)

> *'Patients say all the time, they're very wary because it's got such a shiny surface as well, especially when it's just been cleaned, they're very wary even to stand up on it at times... They're very nervous about it... even when they've got somebody with them, they, you know they tend to lose their confidence'* (E04- staff in control site)

> *'I still think that it's not ideal flooring for our age group and for this type of ward. I think it should be more a non-slip type flooring'* (G03- staff in control site)

Comments received from staff from the intervention sites provided a range of opinions with regard to perceived slipperiness of the floor and its affect on patients' mobilisation:

> *'one of the things we often get on other wards is when people struggle to stand up um, and their feet slip away from that happens less there, that is a quite big… they've actually got more grip on the floor… because often their feet slip away so they can't stand up and we're having to actually block their feet, I think in that bay that happens less maybe because they're slightly more able patients but I think they tend to get slightly more grip on the floor, if they've got a rubber sole slipper on, they tend to have a bit more grip on the floor, yes'* (intervention site B)

> *'I must admit, compared to the other patients, the patients in that bay don't complain that they feel the floor is slippy underneath their feet, which is something that they do say in other bays that they can't stand up because the floor's slippy, that's very much less of an issue in that bay... getting up for example if you've got a patient that's not particularly, doesn't find it easy getting up, the new floor is easier for them than the old floor was, um, so it does have its benefits in that sense'* (intervention site A)

> *'It appears to me that it's not as slippery as the regular floors, you kind of get more friction which can be a bonus coz if you get like wetness on a floor, or somebody's got a dodgy pair of, well not a dodgy pair, but a well worn pair of slippers, sometimes when they go to stand up their feet will slip away from them, whereas with this floor it doesn't seem to happen, obviously the grip is better, they get up a lot easier, things like that'* (D05- staff in intervention site)

'a while back a patient did say to me that they felt the floor was a bit more slippier when they got up... they find the flooring a bit slippier but that's about it…. But once up they're okay' (A03- staff in intervention site)

'I've not noticed any difference... some patients have commented that it feels slippy to them... I think it's just when they're standing to mobilise and it's more slippy on the feet that the, um, from sitting on a chair to standing' (D03- staff in intervention site)

'It's maybe a little too sticky... I think they have to adapt the way they walk some of them I mean I'd be interested to see a Parkinsonian patient walking on that floor and see how they'd cope um, but I know certainly they cannot slide their feet which does affect as post-op patients' (D16- staff in intervention site)

We received comments from both control and intervention sites staff that related to patients' perception of how slippery the floor looked and how it impacted on patients' confidence:

'it just has that shiny, slippy feel to it, when you look at it, I can't see how it would instil confidence in someone who's had a fall and is already anxious about mobilising, do you know what I mean?' (G03- staff in control site)

'I think they're more confident in themselves because in the old flooring when they put their feet down and their foot is sliding all over the place and they kind of like can become quite frightened, but now I noticed that if you just said right okay, push up and stand, then they can do that without their feet going or sliding underneath them' (B05- staff in intervention site)

'I guess it's a bit more reassuring for them (patients), comfort-wise if it's softer… *also coz it looks less slippery, patients um, probably like that because they, the shiny floors, even if they aren't slippery, they look slippery, so they get anxious about them so that maybe helps a little bit, make them feel better about standing up potentially'* (C06- staff in intervention site)

'one thing I would say about these floors are a lot of the elderly patients, because they've got a sheen to them, think that they're slippy so they get quite anxious, whereas if you're on a wooden based floor or a wooden looking floor, they don't get quite so anxious coz they don't make it slippy, anything shiny they think it's slippy' (F05- staff in control site)

6.6.2.3.2 Perceived benefits and negatives for patients: Hardness of the floor

Another aspect of the floor that was frequently mentioned among staff mainly in control sites was the hardness of the floor and how the perceived danger of this for patients who fall (as described above). On the other hand, comments from staff in intervention sites indicated that they perceived the cushioning effect of the floor would be beneficial to patients care, and elaborated with some examples:

'it's very good, I think I can see what the floor's about now when patients do fall, they tend to bounce, it's not like a, well not bounce but, you know, when on the general flooring

they'll fall and then you'll hear the crack and that will be it ... And the floor isn't as harsh, I think it's not hurting them as much if they do' (B03- staff in intervention site)

'in terms of patients falling, well we had a patient fall but nothing, you know she hasn't broken anything, so that was a pretty good thing, because you think, 'oh my God, is something going to happen to a patient?' because normally if they have fallen, you know, you get cuts and grazes as the norm, well she didn't! I mean the way she landed was quite good, she didn't break anything, we didn't see any bruising as a result, so that was quite good' (B05- staff in intervention site)

'it's been, what, since October now, um, I don't know if you've got the information, how many falls there's been since then, um, and none of them have been severe injuries, they've all been minor injuries and I personally think that's down to the flooring, I think there could have been, seeing the type of falls that have happened and I'm here quite a few of the times that the falls have happened and um, seeing the type of fall you would expect further injuries' (A04- staff in intervention site)

'I've seen a few patients on floor in there and they've got back up and they've been fine, no bruising, no injuries, so... but comparing like one fall in there to one fall elsewhere it seems a little bit better in there than, you usually get some kind of bruising or something from the regular rooms, coz it's just that hard underfoot... if it feels safer for a patient, or from a patient point of view like if they did have a serious fall they wouldn't get as bad an injury as if they were to fall on the regular floors' (D05- staff in intervention site)

'They (patients) think it's a good idea, yeah, and I know a lot of relatives do, as well... I think from a nursing staff point of view that you know, that we have found it beneficial, like I say we have had patients fall in there, and we haven't had, unless they've hit the head on something else falling down, the nasty head injuries that we've had before in the past so yeah. Can we have it in all the bays?... I was actually looking forward to it (new floor) because unfortunately I have been on duty when, at night, when a patient fell in that bay (before intervention floor laid) and um, they actually died as a result of the fall... before my eyes yeah, so I was very um, sort of keen to see how the hip hop floor would make a difference basically... I quite like it, yeah. I do think it makes a difference' (C03- staff in intervention site)

'*if for any reason we are engaged somewhere else, like we were with the emergency the other night, and there was no staffing near that bay at the time because of the priority and that patient fell, having at the back of my mind on a day to day basis that that flooring is in there, to save lives and injury, is a comfort, so it's a conscious comfort coz you can't be everywhere at once and having that there knowing that you know they're not going to come in, fall and then get worse, um is definitely, yeah it is a relief... people who have slipped, fallen in that room, it's, yeah, it has made a difference to injuries or potential injuries that people can sustain from sliding or falling, um, so in that way its saved lives, I think… A recent one (example) for me was last week, quite a big guy, little bit wobbly on his feet...considering how big he was and his risk of internal bleeding because of his disease um, luckily after his fall... there wasn't even any bruising where he could of, you know, there could have been serious consequences had he fallen on to hard flooring like in here'* (C07- staff in intervention site)

There were some participants in the intervention sites that were unsure as to if the floor is beneficial

for the patients or not:

> *'I find it hard to judge how beneficial it is, coz I've never, I know it happens and I'm not disputing the fact that it's a good idea at all, um, but I've never known a patient break a bone or anything and obviously if you fall on that floor you're still getting the bumps that you would have anyway, it's not you know, it's not stopping you from getting hurt so I don't know how beneficial it is'* (D07- staff in intervention site)

6.6.2.3.3 Perceived benefits and negatives for patients: Walking and the use of walking aids by patients

One aspect of the floor described mainly by participants in control sites was the ease of use of walking aids by patients on the standard hospital floor:

> '*obviously it's much easier to push it on this floor than what they've got at home'* (E01- staff in control site)

> *'anecdotally I can't think of any occasion when a patient has or anyone has blamed a problem on the floor, I can't do that because of the way the floor is, I can't get over there, I can't do this, because of the floor, I can't recall any incident or moment when I've had a conversation or its been brought to my attention so no'* (F10- staff in control site)

> *'Yes, walking frames, um, with wheels and ones with the static and they seem to run nice and smoothly as well'* (H03- staff in control site)

And another participant thought that patients encountered difficulties with their walking frames on the control floor:

> *'often the patient will say um if they feel that it's difficult to push a frame over the floor, so that can make them more wary of walking, if they're finding it difficult to push the frame across the floor… it happen there, yeah, but again that could be them getting used to using a new piece of equipment'* (H07- staff in control site)

However, some participants from control sites thought that problems associated with walking frames may not be solely attributed to flooring characteristics:

> *'I think sometimes the types of frames they've got, I think they sometimes where they've got the rubbers um, on the bottom of their walking frames they tend to get stuck sometimes, if they don't sort of lift when they move them, and sort of push them along the floor then they get stuck but I guess they might get stuck on any type of floor really, I think it's just the way that the frames are used more than an issue with the floor'* (H05- staff in control site)

> *'if a patient puts too much weight through the zimmer frame, it will naturally scuffle the floor, anyway, but that's not anything the floor can help with'* (H06- staff in control site)

Some participants from intervention sites thought that patients used their walking aids with no apparent difficulty, whereas others highlighted problems:

> *'They just get up, they just get up and use their frames as normal, I don't think they'd realise it was, it was a different textured floor'* (A06- staff in intervention site)

'I don't think it (new floor) seems to affect the frames like it does pushing everything else, because I suppose you're not putting so much weight on them, but they (patients) don't report an increased affect' (D07- staff in intervention site)

'coz it's kind of obviously cushioney, it's a bit more difficult for patients to actually push the wheeled walking frames over, so they're having to use a lot more effort to push the walking frame on that type of flooring than what they would on other type of flooring, so they need a bit more strength really and stamina to get through it... I mean patients that we tend to get in obviously they're here for rehab, their gait pattern's never that great anyway and they do find it difficult to lift their feet up properly so, it does cause a little bit of a problem if they're trying to concentrate on moving the frame in the right direction and giving that a push and trying to concentrate on their gait pattern that we're telling them how to walk properly at the same time' (A07- staff in intervention site)

'some patients complain that their frames don't work properly, like the wheeled frames, they find it harder to push them on that floor... Yeah, frames, I think at first they sort of struggle but then they sort of get used to it themselves and sometimes it's just them, it's the first time they've a frame, um so it's harder to push it really... But it's never prevented them from like, they can still get up and go by themselves to the toilet when they're ready to do that' (D01- staff in intervention site)

'No, I don't think it (new floor) affects their mobility or the way they walk' (C02- staff in intervention site)

Another important element mentioned by staff is the role that the floor may play in gait and mobility assessment for patients. However, there appeared to be inconsistencies, for example, staff from control sites noted:

'being a flat surface we can get a more accurate gait assessment, if you start to do them on carpets and things it throws in a completely different dimension for balance and poor perceptions so they're much better for us being just a flat, smooth surface' (F05- staff in control site)

'another negative is sometimes there are frames that roll too easily on this, so it's not realistic for the patients surroundings, I'm not suggesting that we have carpet but it's so different to carpet at home, you get many people using a frame really well here, and so that may be a bit of negative in that sense in whether we could create something with a little bit more um, maybe not so smooth with a slightly bit of, not, friction or grip... they'll get more realistic to other homes and things like that… sometimes being a little bit more realistic to what patients have in their own homes' (H03- staff in control site)

'*if we can assess them on this flooring and they can control that, then we know they're gonna be fine at home on carpet'* (E02- staff in control site)

'if they're walking with the wheelie ones, they do tend to go a little bit quick...they do tend to push it a little but quick and they can lose their footing because the frame goes too far in front of them when they're walking' (E04- staff in control site)

Respondents working on the intervention floor described different scenarios illustrating how the intervention floor may have an effect on the rehabilitation process of the patients:

> *'I definitely think it (new floor) probably does affect the rehab process quite a bit, I think it's probably one of the main concerns really for the rehab therapist, um, because we're having to take the patient out of that environment ... we take them off that floor and they're actually managing quite well and they do a lot of mobility really outside of the bay, on the floor outside, rather than in the bay now coz, so we get more of a true reflection of how they're actually managing'* (A07- staff in intervention site)

> *'they're struggling to get their independence back so if they're not managing to mobilise as quickly as they would do, then that's really difficult... I have been concerned that it's (the new floor) slowed them down... I think sometimes it's a bit frustrating if they can't their frames moving and they can see its hard for us ... they quite often have the gutter frames where they have to lean on, with the little wheels, so they're pushing along but there's a sort of downward force as well'* (D13- staff in intervention site)

Other participants from intervention bays offered a different perception highlighting that the new floor may actually be beneficial for rehabilitating patients because it slows the zimmer frames down, better replicates carpet, and offers better slip resistance, for example:

> *'the zimmer frames don't run away with them and they tend, they can't go as fast as what they can on ordinary floors, which a lot of them tend to do, pick up and up and go'* (B15- staff in intervention site)

> *'the patients don't find it a problem generally with their frames... they find it goes slower, so the run of it is slower than it is on the ordinary lino floors, they have to put in more effort but that probably replicates a carpet better and most of our patients have carpets at home. So what I do is I generally take our patients to a carpeted area and actually they find it relatively similar to that of the flooring... that sort of surface because it replicates carpet (is) a little better just in my opinion'* (B10- staff in intervention site)

> *'it's very good because it just gives it extra grip, the ones with wheels (zimmer frames), I can't imagine there's any more resistance on there, than on their carpet at home, I should think... actually when it comes to mobilising, seeing people have that extra grip and it is comfortable under foot, it is nice to walk in there, um, I can imagine actually I would feel safer being on that, knowing that there was more grip with a stick or a zimmer frame ... It just sort of has a bit more resistance so when they move round if they're a little bit doddery it's not gonna, you know, Parkinson's or something, they're not gonna sort of wobble all over the place, so in that way it's a positive' (*C07- staff in intervention site)

6.6.2.4 Theme 4: Floor perceived as a part of a wider safety system

Staff in both intervention and control sites believed that safety may not necessary have to do with the floor alone but there may be other factors influencing patients' and staff's safety on the ward, such as size of wheels, patients' condition, footwear, contaminated floors, condition of equipment, etc:

6.6.2.4.1 Floor perceived as a part of a system: Patient's condition

'obviously it depends on the patient, it's very patient based... so if we've got somebody who backward leans quite a lot then you're gonna get that movement anyway of feet sliding along the floor, so we would automatically block somebody's feet anyway (F05- staff in control site)

'it depends on the condition of the patient, on the physical condition, because some they will complain it's slippy but it depends as well if they can bend their joints, like their knees and they can be able, but if somebody's like stiff as well they're gonna slip' (D14- staff in intervention site)

6.6.2.4.2 Floor perceived as a part of a system: Suitable footwear

'Providing you've got suitable footwear it's quite safe... we're very much aware of their footwear and that there's potential that if they don't have their footwear on they're more likely to slip on the floor... it's really looking at the floor surface in accordance with the footwear' (F03- staff in control site)

'I mean these shoes, they don't slip, so I think if I was an elderly patient I think I would feel alright on it, but some of our elderly patients walk without shoes on... Bare foot as well so... or they just have them foam slippers on which don't, you know, which aren't really quite good' (B15- staff in intervention site)

6.6.2.4.3 Floor perceived as a part of a system: Cleaning regimes

'if you're washing the floor obviously you've got to have the right solution otherwise you're gonna slip, aren't you?' (F02- staff in control site)

'if the domestic staff have put too much detergent in the water then it becomes extremely slippery and if they've put excess water on the surface then it tends to just lie on the top and it makes it even worse' (F03- staff in control site)

'I think that was more down to the cleaning product that was used, I think we had some bank domestics on the ward and they had used something on it which did make it very, very slipp... but otherwise that's the only time' (C03- staff in intervention site)

Contaminants on floor:

'If there's talc or anything like that it's really slippy… Yeah, it's really slippery with talcum powder, I've noticed… I have noticed that it's slippery if you bath somebody or wash somebody in the chair or if there's any talc on the floor you can tell it's there' (D06- staff in intervention site)

'obviously it's very slippery if there's anything on the floor… Water, possibly body matter… one (fall) was due to the floor being wet, the patient had tried to pour out a glass and had missed and went on the floor, and not long after we found out, sort of slipped on it so, it's not necessarily the fault of the floor itself' (H08- staff in control site)

'where the floor's been polished I suppose, so you've got polish and you've got fluid on top of that, it's gonna be quite slippery isn't it, so you've got two things I suppose, polish and fluids' (H05- staff in control site)

'Talcum powder can make even a no slip floor slippery, it can! Talcum powder can even make a non-slip, if it's a screed floor even worse, and then of course you've got where they rub themselves with oils or creams and what have you if that gets on the floor that can make it slippery, so that's why you've got to keep on top of it' (G02- staff in control site)

6.6.2.4.4 Floor perceived as a part of a system: Clutter on the floor

'move away all the hazards out the way, like if there's any equipment or tables or anything that's gonna be in their way to go round' (H07- staff in control site)

6.6.2.4.5 Floor perceived as a part of a system: Unfamiliar environment

'...coz at home they're more likely to fall on a carpet or they know which piece of furniture to reach for coz they're in their own environment, but in hospital if they're the slightest bit confused and you've put them into a strange environment um, I think that's when they're more likely to fall' (F06- staff in control site)

6.6.2.4.6 Floor perceived as a part of a system: Patients' and equipment's weight

'I don't know whether it's the floor, it's probably a combination of the floor and the chairs and possibly the weight of the patients, you know, you tend to have to really push quite hard' (F02- staff in control site)

'*any sort of wheeled trolleys, zimmers, things like that um, they're not as bad because the wheels tend to be a bit bigger and they're quite light items, but um, it's just not smooth, but I'll say the frames and zimmers are easier to use on the floor, coz they're quite light'* (D02- staff in intervention site)

'The beds are harder than the trolleys, definitely, and then obviously the trolleys are harder than the chairs, the chairs are a lot easier than the trolleys, but saying that you could have a slight person on a trolley and a big person on a chair and it could be the chair that's more of the problem. It really does depend also on the size of the patient as to how hard it's gonna be to get them across the floor' (D09- staff in intervention site)

'it is (hard) on here because the furniture's larger, the chairs are bigger and normally a bedside cabinet is about so big, we've got the wardrobes on the end of ours so it's all awkward furniture, it does make it, I mean it's all on wheels but it's still awkward to move… I mean some of the chairs, I can't see any in here, oh yeah, those two, they've got the wheels at the back but you've got to tip them so that you can wheel them along… You can see what I mean by the large furniture here, don't you? These chairs are quite big… They're not too bad unless they get stuck and then you've got to give it a good kick (G02- staff in control site)

6.6.2.4.7 Floor perceived as a part of a system: Size of equipment wheels

'it's not so much the floor surface, it's probably the integrity of the wheels of the object that I'm using so whether it's the bed um, the toilet chair, commode, um, the tables, it's normally the castors that are a problem, not the floor so much' (F10- staff in control site)

'it's mostly the bedside tables more than the zimmer frames I'd say, it's the smaller castor wheels that are the problem…I'd say it's the smaller sort of caster wheels that are the more difficult ones, I don't think the zimmer frames are too bad, um, but it's almost, it's the caster wheels that change direction I'd say than the ones that just go in one direction that we've had more problems with' (B09- staff in intervention site)

'I think the very small wheels... I wonder if it's the smaller wheels make it harder, because it's easier to move the bed than it is to move the tray tables and the wheels are bigger, but that's my opinion on it' (B10- staff in intervention site)

'I think larger wheels on anything are good, but if it's a big heavy object, the larger wheels don't seem to make a lot of difference. Things like bedside tables, the newer ones have larger wheels and they are better but we don't have all the large, all our tables are, you know, the older style' (D02- staff in intervention site)

6.6.2.4.8 Floor perceived as a part a system: Condition of equipment

'I think the main thing is just pushing with the trolleys but I think it could be because of old trolleys as well, wheels don't work as well and… It could be the equipment needs changing as well' (B15 – staff in intervention site)

'I think rather than the floor in that instance, I think the tables would assist more if we could actually move them without actually struggling … I think it must be the wheels and the dust and um, rust and wear and tear so they're not turning as they should' (G01- staff in control site)

'...the general makeup of a tray table, okay, coz they're not easy even on lino so I'm not trying to suggest that it's, I think generally the makeup of those type of tables is poor anyway' (B10 – staff in intervention site)

6.7 Discussion

The interviews aimed to explore with patients, visitors and staff their perceptions and experiences of using and working on the study bay floors. It was thought important to do so as interviewees may have particularly pertinent insights into otherwise unmeasured impacts of the floors under study. It is clear from the information gathered from these interviews that an investigation of a hospital floor can generate a wealth of views on how the floor may, and if so, to what degree, impact on patient and staff well-being and working practises. Additionally, interviewing people from across the included sites provided an insight into the possible (cultural) differences between ward environments, in attitudes and opinions towards the floors in use.

Installing a new type of floor in a health care environment had the potential to introduce changes on the ward and the daily interaction of staff, patients and visitors. It was clear that participants, even

within the same ward and even with the same role, held different views on the floor's qualities. It is fair to suggest that people's opinions were often varied and contradictory and this may show the different perceptions and experiences people have on any one specific aspect of the floor. These could be associated with factors that are intrinsic to individual patients and for staff, variants such as the frequency of the tasks undertaken on the floor, their professional role, staffing levels and individual experiences and expectations. An example of this was the frequently raised issue of moving equipment across the intervention floor.

A clear message was that staff indentified that moving equipment across the intervention floor required greater effort and was perceived by many as being a deficit of the intervention floor. However, whilst acknowledging this was a widely held view, it appears that this view was influenced by the role the staff member had and the tasks that they routinely undertook. For example, staff who did not routinely work on the floor may have found this attribute of the floor problematic, as they had not yet developed strategies to overcome the problem on a daily basis. Conversely, it may be suggested that for such staff members the problem was less because as they do not need to routinely work on the floor. Staff with roles which did not require much movement of equipment (e.g. doctors, consultants), although they may work on the floor daily, did not notice much difference in the floor; clearly this issue was more prevalent for staff who had to move equipment as part of their routine role. In addition to this, individual experience may also have influenced staff perceptions. For example, staff who had noted that they had previously witnessed patients' falling and injuring themselves noted that whilst the movement of equipment did create a problem, the possible benefits to patient safety outweighed these difficulties.

In addition, staff perceptions about the floor appear to influence staff attitudes towards specific health care processes. For example, there were differing opinions as to how 'slippery' the floors were (it is worth noting that mechanical testing of the floors only indicated that the intervention floor was slightly less slippery when wet, but according to guidelines this was negligible). These individual perceptions around slipperiness then led to comments on the relative positives and negatives of the floors slipperiness in relation to the mobilisation of patients. Comments were received that indicated that a 'slippery' floor made for easier patient mobilisation (e.g. being able to slide feet across the floor), whilst others noted that a less 'slippery' floor helped patients mobilise quicker (e.g. going from sit to stand, without having the patients' feet slip away from them). Similarly, staff conceptualised the 'thickness' attributes of the floor differently with regard to mobilising patients; some felt that the thicker floor better replicated carpet (like a home environment), whereas others felt that the thicker floor did not give a true reflection of how the patient was managing with their rehabilitation. In future, these issues may be better resolved in a focus group setting, which would have enable participants to discuss the relative merits and detriments of the perceived flooring attributes and explore solutions. Future mixed-methods research (such as this study) may consider beginning the study with a qualitative component, in order to give staff the opportunity to explore issues and potential solutions and obtain more ownership over any changes which come into place as a result of a new floor. At the very least, the management of expectations over what to expect from a new floor is something which should be taken into consideration in future.

As with staff, the patients' and visitors' comments about the bay floor were also inconsistent in relation to the floor's perceived qualities. For example, for some the floor looked 'clean' whilst to others, the same floor looked 'dirty'. It was also apparent that for many people 'a floor's a floor'; it is an integral part of system (of environmental, social, and personal factors), which can often be taken for granted and not really thought about in much depth (apart from perhaps when it is changed to something quite different, or put under 'the microscope' of a research study). The

'system' may contain various confounding characteristics which may influence injuries, falls, and adverse events. These ideally will be evened out across groups given a large enough cluster randomised trial, but none-the-less may be of value to document (along with standard patient baseline characteristics), and address where appropriate. These system elements, as highlighted in the interviews, may include for example: provision of footwear, cleaning regimes (solutions used), maintenance of wheels on equipment, and staffing support.

Against this background of differing perceptions and personal interpretations, it can be difficult to draw conclusions around how best to take things forward. Here, we focus primarily on potential mitigating strategies for overcoming issues experienced by certain individuals. By far, the strongest and most consistent issue raised by staff was the movement of equipment on the intervention floor. For some individuals they found the increased effort required negligible (or less of an issue when balanced against the perceived benefit for patients), whilst for others serious concerns were raised around the risk of injury. Some staff had found resolution via various strategies (e.g. enlisting more help to move objects, organising work to minimise the necessity to move objects), yet concerns still remained around emergency situations (e.g. when a bed has to be pulled out quickly and there may not be time to enlist help), and some staff expressed concerns that there was not always the availability of extra assistance.

The interviews highlighted a range of practices with regard to manual handling (e.g. the usual number of people utilised to move a bed); therefore future studies (or indeed any hospital planning on integrating a shock-absorbing floor) should begin by establishing the recommended number of people to move equipment and ensure the appropriate manual handling training for different pieces of equipment has been implemented. Given the *potential* cost-effectiveness of the shock-absorbing floor, another consideration could be to increase staffing levels within the wards to ensure that there is always (or more likely) an extra person available to assist with moving equipment, and/or to invest in equipment that offers better rolling resistance (e.g. with larger wheels, or assistive technology). Given the variety of equipment used even within any one hospital, it may become logistically complex to limit use to specific designs of equipment within any one area; however this may be a strategy worth considering in part. Restricting the floor to a bay area also enabled staff to create strategies such as leaving the trolley outside the bay as a means to minimise its movement. Future studies should explore the potential of different shock-absorbing floors which enable easier movement of equipment (without compromising too much on the shock-absorbency). Some interviewees highlighted the difficulty of getting objects moving due to them sinking down into the floor whilst stationary; it could be hypothesised that having a harder surface under objects which are normally stationary (e.g. beds, cupboards), may help overcome some of the issues experienced (this may however limit the adaptability of the layout of the bay).

The colour of the floor was discussed during the interviews, and as would be expected a range of views were expressed. In this study, hospitals were given the choice of what colour they wished to select (to be in keeping with their décor and with the view that it was theirs to keep). Clearly colour and design makes a difference to the amount of dirt/dust it shows up (with opposing views as to whether this is a good or bad thing), and the general ambience/homeliness it creates. Future studies may consider the guidance provided to hospitals in advance of selecting a colour, and possibly the merits of standardising the colour/pattern across sites.

These interviews were highly valuable in alerting us to potential performance bias (placement of high risk fallers on the intervention floor), which would not have been apparent from the trial data (including the information we gathered on internal transfers). To this end, we recommend that future studies incorporate a qualitative component, as well as seek ways to address potential biases.

Introducing a qualitative component towards the beginning of the intervention period may help detect biases as they arise (to provide an opportunity for remedial action), as well as detect changes in attitudes as the study progresses.

Our interviews were conducted half way through the intervention period, and towards the very end of the study. Due to time and resource constraints, we had limited opportunity to analyse the data as it was collected; this, coupled with an eagerness to provide individuals across sites with an opportunity to express their views, meant that we undertook more interviews than initially planned during our scheduled site visits. Had we had the opportunity to undertake more analysis in parallel, it is likely we would have reached data saturation earlier and been able to justify the end of data collection.

6.8 References

[1] Thorne CG. Flooring for geriatric wards: report of an investigation at West Middlesex Hospital. *The Builder* 1963;March 15:557-9.

[2] Burnard P. A method of analysing interview transcripts in qualitative research. *Nurse Educ Today* 1991;11:461-6.

7. SECTION 7: OVERALL CONCLUSIONS AND FUTURE DIRECTIONS

7.1 Summary of findings

This pilot study has described the changes that occur in elderly care units when shock-absorbent flooring is utilised. We have described changes to injury and fall rates which may be related to the use of the new flooring, as well as explored the mechanical properties of the floor, maintenance issues, cost implications, and users' opinions.

The findings indicate that the flooring may reduce fall-related injuries (possibly by around 54% of that with a regular floor), but may also increase the rate of falls (possibly by as much as a third). Whilst a decrease in injuries aligns with the study hypothesis, an increase in falls was unexpected and therefore more difficult to explain. Whilst indicative, our findings on injuries and falls are highly uncertain (with confidence intervals incorporating no difference) and subject to random error. It is unclear whether the observed increase in falls was related to random error, performance bias, detection bias, characteristics of the floor, other contributing factors, or a combination of these factors. Interviews with staff indicated that performance bias (e.g. differential placement and observation of high risk fallers) may have been an influencing factor on the results. It was noted that falls at intervention sites were reported in a more timely manner (and with more frequency) than at control sites. However we do not know how many falls may have gone unreported; it could be the case that those falls that were retrospectively identified by two control sites at the end of the study (and reported late), completed the dataset, thus removing the risk of detection bias. Mechanical testing indicates that *if* the flooring characteristics *do* influence falls, this is *unlikely* to be related to the slip potential properties (and therefore would more likely be related to the feeling underfoot). None of the falls reports identified the floor as a contributing factor to the fall event. Patients who were interviewed either did not notice any difference when walking on the new flooring, or if they did, did not indicate that the floor was more difficult to walk on (apart from some perceptions around slipperiness which occurred in both control and intervention sites). It is possible that external factors (such as footwear) were more influential on the falls rates (there were more people with bare feet at the time of fall in the intervention group), and patients who were interviewed highlighted a number of other influences (e.g. intrinsic factors, staffing support, footwear) other than the floor which impact on their risk of falling.

Mechanical testing of the floor indicated that the new flooring was more shock absorbent, maintained this level of shock-absorbency over the duration of the study, and performed marginally better than comparison floors with regards to slip-resistance, particularly when wet. The flooring in the current study created difficulties for staff with regards to manual handling of wheeled equipment, and this issue poses the potential for occurrence of adverse events. Over the course of the study, one 'pulled back' was reported, which did not require medical attention. The new flooring was generally well received by patients and visitors. Staff could foresee the potential benefits of the new flooring for patients, and although they saw some benefits for themselves (with regards to performing tasks on the floor, such as kneeling to dress patients, or cleaning under beds) this needs to be weighed up against the potential adverse effects for staff (with regards to increased efforts to push/pull equipment, and demands on staffing time to manage this increased effort).

The findings also indicate that the flooring is cost-effective, however it needs to be determined whether this is due to a decrease in fall-related injuries (which would lead to increased quality of life, and a less burden on healthcare resources), or an increase in falls (which is unacceptable). These findings cannot be confirmed by the current study, and we would recommend that a full-scale

study be undertaken. A full-scale study could take a number of forms, one option could be to have approximately 10-12 sites per study arm, each with 2 bays and followed up for 2 years.

7.2 Undertaking the study: lessons learnt

Here we shall explore some of our experiences in undertaking the study, and any lessons that may be learnt from these. We shall explore ethical, governance, recruitment and procedural issues.

7.2.1 Ethical approval

Obtaining ethical approval for this study although time-consuming (72 days for the initial application, and a further 71 days for a major amendment following the change in flooring manufacturer), was not actually that difficult. The main ethical concerns revolved around appropriate management of data, obtaining consent for collection of personal data, or consultee advice where patients lack the capacity to consent. Having completed the study, it can also now be seen that as part of weighing up the benefits and harms, future research will need to more prominently address the risks revolving around the potential of a shock-absorbing floor to increase patient falls, and the potential adverse effects on staff working on the ward.

Our consent form incorporated an item whereby patients could consent to have the data collected about them in this study, utilised for future ethically approved research. Two participants withheld their consent on this item. We have demonstrated the feasibility of incorporating a distinct but generic statement in the consent form (in accordance with current guidance) to assist in future data sharing and access arrangements, in accordance with the Medical Research Councils principles of data access.[1]

Future research involving patient follow-ups may also consider incorporating a separate point on the consent form for people to agree to being followed up at 3 months (in the current study people were opting out of the entire study if they did not wish to be part of this element). It is noted that sometimes people do not wish to be reminded of the past or commit to something long-term, and so having the choice of which elements of the study participants wish to engage in may help facilitate recruitment (alternatively too many choices may make the consent process more cumbersome and thus be detrimental to recruitment; a primary reason for declining to participant in this study was not wanting the bother).

7.2.2 Governance approvals

As a multi-centre study, involving sites from across England, we sought governance approval via the National Institute of Health Research Coordinated System for gaining NHS Permission (NIHR CSP). At the time of application this system was being newly implemented, and we believe we were one of the first studies to be put forward from the University, and through our local Research & Development Office. It took approximately 80 days from the initial contact with our Comprehensive Local Research Network (CLRN) to confirmation of CSP approval. Part of the issues we encountered revolved around the use of checklists, in that with our initial contact we were sent a checklist of items required, which included additional items that were not listed on the checklist available to us on the Integrated Research Application System (IRAS – the system for submitting applications for approval), and through subsequent liaison with the CLRN additional items were requested of us, which again were not listed on the initial checklists. Part of the purpose of the NIHR CSP is to forego part of the process of having to approach individual organisations for

approvals. Individual Research and Development offices do have to be approached however for site-specific approvals, and we did find that some organisations were still operating with forms from the previous system, and with their own personalised checklists, which somewhat reversed the idea of having a co-ordinated process.

Other components of research governance approval involved the setting up of contracts between the NHS Trusts and University, and obtaining 'research passports' which provide the University researchers with approval to undertake research at the specified sites, with agreed levels of contact with patients. These tasks necessitated a staggered process, as we worked with individual sites, which were agreeing to participate at different paces. With regards to the establishment of contracts, although the NHS has developed National Model Agreement for Non-Commercial Research in the NHS, this did not suit the University contracts office and amendments were necessary, the process of getting all sites agreed contracts took 210 days (including weekends/holidays).

The Government's health research strategy, *Best Research for Best Health*,[2] announced the introduction of research passports, among several measures to improve the research environment, to make it quicker and easier to begin agreed studies. This was a new process and for all parties and, as the Government's guidance was open to interpretation with regard to 'Level of Clearance' required, this took time to resolve (approximately 150 days from start to finish). All local agencies were positive and facilitative throughout this procedure; however the time it takes to obtain governance approvals should not be underestimated. Whilst undoubtedly further amendments to the system have taken place over the duration of this study, these important processes are never going to be simple, and larger studies should certainly plan for staggered start of research sites.

7.2.3 Site recruitment

The site recruitment process provided a clear illustration of the complexities of implementing a novel environmental intervention into the wider NHS system. The intervention, although not 'complex' in the traditional research sense, did prove to add a level of complexity to the study as the intervention potentially impacted on a number of domains within the NHS. One major factor was the number of departments, professional groups, and individuals who needed to be 'on board' in order for the study to move forward, e.g. clinical, business & operational director(s), falls co-ordinators, estates and facilities, infection control, medical and nursing staff, research and development departments, clinical governance managers, and risk managers.

An example of the types of queries that required addressing prior to site approval included the proposed management of door thresholds and skirting; an assessment of the financial risk of replacing floor (if desired) after the study period; concerns over the use of equipment on the new floor; the anticipated level of disruption during the floor installation; the management and potential implications of temporary closure of beds (especially if this was during periods of winter pressure); infection control matters and; possible impact of the research on staffing workloads. Other potential factors that required acknowledgement and deliberation at the beginning of the recruitment process included: any planned reconfiguration of ward staffing; planned reconfiguration of wards or services; anticipated moving of proposed study wards to new locations and ward refurbishments; and any proposed organisational changes within the Trust that could impact on the approval process.

In addition to addressing the organisational and operational requirements to obtain Trusts' approval, the physical attributes of potential sites also required assessing. To be included in the study, prospective wards were screened for humidity levels in the sub-floor, investigation of the sub-floor

material and the current floors' slip resistance rating. Sites needed to have existing floors with a slip resistance rating of no more than "R9". The reasons for this was to ensure that the overlay materials across sites were comparable, and to ensure that a floor covering was not replaced with one of lower slip resistance (the intervention floor has a rating of R9). Several site surveys revealed unexpectedly high levels of moisture in the sub-floor, resulting in the need for further negotiation with the flooring company to establish viable cost and time-frame estimates which would enable the installation of a damp proof membrane.

Future research will therefore need to plan and cost in the necessity of multiple site visits as part of the recruitment process (including to sites which may not eventually participate in the study). In the current study, we took a multiple approaches to identifying sites (e.g. through being on the UK CRN Portfolio, nursing forums, mailing lists, and personal contacts). Initial contact was frequently through a nurse specialist or consultant who had an interest in falls/injury prevention. It is possible that a 'top-down' executive level recruitment may be more efficient in future, however we also feel that it is vital to obtain sign-up from the individuals working on the ward daily and to have a champion who will keep the enthusiasm of the study going.

7.2.4 Procedural issues

The study successfully collected a rich data set from the study sites and participants. However, in any future study the range of data collected may need reviewing. Collecting such a wealth of information may not only have been at times time consuming and added pressure to the site staff but also indicated inconsistencies in the reporting of data. For example, we collected general information on which bodily systems were affected by illness, but this, in many cases, did not correspond to the specific diseases or illnesses that were reportedly associated with that patient. Data collection forms were also improved over the course of the study in order to clarify any misinterpretations, or adhere to site-specific standard operating procedures (e.g. inserting a place for the data collector to sign the form).

In order to reduce the demands on each research site, a future study may wish to consider not collecting patient identifiable data (and perhaps simply rely on ward level falls reports, if collected in sufficient detail). This may also potentially, negate the need to obtain full ethical approval. This approach would make a cost-effectiveness analysis implausible (as no follow-up address would be known), and may also make it difficult to identify recurrent fallers, which would have implications for the analysis.

Based on the experience from this study, future research may also need to review how sites manage the research processes on the ward. This may involve costing into any future bids the need to recruit research nurses for each site or at least having the expectation that each site would have allocated research nurse time. The current study had sites where the additional workload of the research was apportioned to ward based staff. Whilst it was clear that these sites were committed and strove to provide a high quality research service, it was an additional expectation on an already busy ward team. In addition, as part of their career progression, ward based staff may change their role at some point over the duration of the study and therefore, there is an ongoing requirement to ensure that the current ward staff are familiar with the study protocol.

The three month post discharge follow-up procedure that involved contacting participants, consultees and General Practitioners prompted a high volume of administrative work for the co-ordinating centre. This procedure may be more efficiently managed and result in a richer yield of information if personnel within each study site's locality were responsible for its collection. A

knowledge of and more importantly, access to, local health and social care information technology systems would possibly enable a quicker and more accurate accessing of patients health and social care uptake post discharge.

The mixed-method approach of this study was clearly beneficial, as it has enabled us to elaborate and expand upon issues which otherwise would have involved much more speculation. We would recommend future research incorporate a qualitative component to address user views, and identify any potential sources of bias. It may be useful for future research to utilise interviews towards the beginning of the study, in order to identify changes in the personal practices of staff (e.g. in the placement of patients) and identify any further training issues.

7.3 Dissemination plan

The findings from the pilot study will be disseminated through reports, peer-reviewed publications, national and international conference presentations and patient group forums. We will follow the guidance of the CONSORT statement for reporting of cluster randomised controlled trials.[3] Institution staff, participants and their carers (where requested), will also receive debriefing and feedback on the findings. We have been maintaining a database of individuals (including from external enquiries) who would like to receive a copy of the results. We are working on the following strategy:

- The protocol has already been published in *Injury Prevention*, and registered on *ClinicalTrials.gov* and the *UK CRN Portfolio* trial registries.
- We have also presented the protocol at the *International Conference on Slips, Trips, and Falls* and the *UK Slip Resistance Group.*
- To submit the findings of the study to *The Lancet* in the first instance.
- To submit a paper on the experiences of undertaking research on the environment to the *BMJ* in the first instance.
- To submit a paper detailing the cost-effectiveness analysis
- To submit a paper elaborating on the qualitative analysis
- To submit a paper elaborating on the mechanical testing
- To submit a paper on dealing with multiplicity and calculating rates in falls/injury analysis to *Statistics in Medicine* or *BMC Medical Research Methodology*.

7.4 Future plans for taking the research forward

Future research should:

- Consider ways to minimise the potential for performance bias. This could be achieved by: a) covering all bays within a ward with the new flooring so that staff do not feel the need to move patients in particular bays by virtue of the floor in place; b) providing control sites with a 'sham' new floor (if an appropriate one can be found), to introduce an element of blinding; c) undertake further training of staff to highlight the uncertainty about the effectiveness of the new floor to discourage performance bias.

- Consider ways to minimise the potential for detection bias. This could be achieved by: a) more rigorous checks of falls reporting against the institutional reporting system; b) more intensive training of all staff at sites who may report falls; c) better aligning the study data collection processes with the institutional reporting system, possibly via technological solutions.

- Consider ways to minimise the burden on staff in the pushing and pulling of equipment. This could be achieved by: a) improvements to the flooring system with regards to its 'stiction' properties; b) identification of more appropriate equipment to use in bays with the flooring (e.g. with regard to wheel design, and automation); c) implementation of policies, and practices to better manage the increased effort required to move equipment; d) considering the cost-benefit of increasing staffing levels to manage a softer floor.

- Address the pertinent question of whether a shock-absorbing flooring is more likely to increase the risk of falling.

- Be aware of the level of dialogue and negotiations that are required with a number of NHS professionals and departments when engaging in innovative research which has a potential impact on the wider NHS system. This will require a realistic expectation of the time required from initial contact to final 'sign off' in the site recruitment process

- Consider the type, amount and process of data collection from sites. This could be achieved by: a) identify the most pertinent data required; b) streamlining the data collection process and making more use of electronic data transfer systems; c) cost into the proposal dedicated research nurse time per site; d) identify and recruit personnel on site to co-ordinate the post discharge follow-up process.

- Consider cost and resource use differences between people experiencing different types of fall severity, compared to people who do not fall.

- Consider utility scores and life expectancy by fall severity type.

7.5 References

[1] Personal Information in Medical Research, MRC Working Group, 2000. (http://www.mrc.ac.uk/Ourresearch/Ethicsresearchguidance/Dataaccess/index.htm)

[2] Department of Health (Research and Development Directorate). Best Research for Best Health: A new national health research strategy. London: DoH Publications 2006.

[3] Campbell MK, Elbourne DR, Altman DG. CONSORT statement: extension to cluster randomised trials. *BMJ* 2004;328:702-8.doi:10.1136/bmj.328.7441.702

8. ACKNOWLEDGEMENTS

With special thanks to the Steering Committee for approving this protocol and providing feedback and advice. Thank you to Reuben Ogollah and Rebecca Turner for additional statistical support. Thank you to Heather MacKenzie for initial work on the study and continued support.

We would like to express our gratitude to the NHS Trusts who kindly participated in this study, the staff on the research wards, the Principal Investigators and the associated Research and Development offices. The Hospitals involved were: Ellesmere Port Hospital; Diane Princess of Wales Hospital, Grimsby; Harrogate District Hospital; St Marys Hospital, Isle of Wight; Freeman Hospital, Newcastle upon Tyne; Queen Alexandra Hospital, Portsmouth; Weston General Hospital, Weston-Super-Mare; York Hospital.

9. COMPETING INTERESTS

None to declare.

10. FUNDING

The Dunhill Medical Trust and the National Osteoporosis Society.

Appendix 1: Ward Audit Checklist

WARD AUDIT FORM (V3)
To be completed by member of research team.

Content Guidance:

1. General Background Information
   - Name
   - Location

2. Hospital Building Characteristics
   - Type of building
   - Age of building

3. Ward Information
   - Plan of ward
   - Refurbishment history
   - Facilities present
   - Capacity (bed numbers)
   - Number of beds per room
   - Plan of all Bedrooms

4. Study Area Information

   Flooring
   - *Surface*
   - *Steps*
   - *Dips/slopes*
   - *Wear and tear*
   - *Slip Rating Score (pendulum test)*
   - *Micro-Roughness Rating Score*
   - *Stiction (sticking-friction)*
   - *Shock-absorbency*

   Flooring Density
   Composition of flooring
   Age of flooring
   Maintenance History
   Cleaning Process/Policy

Flooring Design
- *Patterns*
- *Colour*
- *Surface lustre*

Room Lighting
- *Aspect of windows*
- *Number of windows*
- *Area of windows*
- *Window coverings*
- *Levels of light (Lux)*
- *Number of lights in room*
- *Type of lighting*
- *Shadows*
- *Nocturnal lighting*
- *Light pollution*
- *Control of lighting*
- *Sensors*

Room Entrances and Thresholds
- *Number of doors*
- *Dimensions of doors*
- *Door construction*
- *Glass Panels*
- *Opening direction*
- *Opening/closing mechanism*
- *Type of threshold*

Room Layout
- *Plan*
- *Partitions*

Room Furniture
- *Inventory*
- *Storage*

Staff-Patient Observation
- *Nursing Station*
- *Line of sight*
- *Nurse call system*

WARD and STUDY AREA AUDIT FORM

Date of Audit:……..…… Time of Audit…….

Audit completed by:……
……..

1. General information:

1.1 Name of Ward: _____

1.2 Location: Hospital: _____

Town/City: _____

1.3 Would you describe the location as:

Rural ☐ Suburban ☐ Urban ☐

2. Hospital Building Characteristics

2.1 Is the Ward located in a:

Single storey building ☐ Two-storey building ☐ Multi-storey building ☐

2.2 If located in a multi-storey building, on what floor is the ward situated

2.3 When was the building in which the ward is located originally built

1800-1850 ☐ 1851-1900 ☐ 1901-50 ☐ 1951-2000 ☐ 2001-present ☐

3. Ward Information

(Plan of Ward to be attached to each audit)

3.1 When was the Ward last refurbished (please note whether full or partial):

3.2 Does the Ward have:

	Yes	No	Don't know
Separate patient day room	☐	☐	☐
Dining room/area	☐	☐	☐
Therapy room	☐	☐	☐

If yes, please state the type of therapy e.g. physiotherapy, occupational therapy.

Bathroom(s)	☐	☐	☐
Please state how many bathrooms ……			
Clinical treatment room	☐	☐	☐
Clinical equipment store room	☐	☐	☐
Clinical staff 'station'	☐	☐	☐
Senior staff office	☐	☐	☐
Administration office	☐	☐	☐
Cleaner's Store	☐	☐	☐
Relative's room	☐	☐	☐
Kitchen	☐	☐	☐
Sluice room/disposal room	☐	☐	☐
Access to outside area for patients	☐	☐	☐
Other (please list)	☐	☐	☐

3.3 What is the capacity of the ward (number of beds):

3.4 Please state how many of the bed areas are:

One bed	☐	Two beds	☐	Three beds	☐	Four beds	☐
Five beds	☐	Six beds	☐	7 or more beds	☐		

4. Study Area Information

(This section will need to be completed for each individual study area if there is more than one area included in study area e.g. bedroom and connecting corridor).

Flooring Surface

		Yes	No	Don't know
4.1	Are there any steps in the area	☐	☐	☐
4.2	If yes, how many			
4.3	Are there any observable dips/slopes	☐	☐	☐
4.4	Is there any visible wear and tear	☐	☐	☐

4.5 If yes, please describe

4.6 What is the current flooring material ……..

4.7 What is the current sub-floor material …….

Information for questions 4.8 – 4.11 will be obtained from HSL floor testing procedures

4.8 Slip Rating Scale score ……..

4.9 'Micro-Roughness' Rating Scale score ……..

4.10 Stiction score (sticking-friction) ……..

4.11 Shock-absorbency score (impact testing) …….

4.12 Length of time present flooring has been laid …….

	Yes	No	Don't know
4.13 Are there maintenance records available	☐	☐	☐
4.14 Are there any mats/rugs in the study area	☐	☐	☐

4.15 If yes, how many:

Where are they located

	Yes	No	Don't know
4.16 Are they secure to the floor:	☐	☐	☐

4.17 Please detail <u>daily</u> cleaning method, specifications and products used
(Hospital protocol may be attached to report if available)

4.18 Please detail <u>deep</u> cleaning frequency, method, specifications and products used
(Hospital protocol may be attached to report if available)

<u>Flooring Design</u>

4.19 Is the floor covering:

Plain ☐ Patterned ☐

4.20 If patterned please describe pattern (e.g. pebble-dash; tiled effect; marbled; geometric shapes; stripes)

4.21 Please detail colour(s) of flooring

	Yes	No	Don't know
4.22 Does the floor covering produce glare in daylight	☐	☐	☐
4.23 Does the floor covering produce glare under artificial light	☐	☐	☐

Room Lighting

4.24 What is the aspect of external windows:

North facing ☐ South facing ☐ East facing ☐ West facing ☐

4.25 Number of windows (external)

4.26 Area of total windows (external) sq metres.

4.27 Percentage of wall area that are windows (external) %

4.28 Number of windows (internal)

4.29 Total area windows (internal) sq metres.

4.30 Percentage of wall area that are windows (internal) %

4.31 Total Number of windows (internal & external)

4.32 Total area of windows (internal & external) sq metres.

4.33 Percentage of all wall area that are windows %

4.34 What are the window coverings:

Vertical blinds ☐ Horizontal blinds ☐ Curtains ☐

Other ☐ please detail

4.35 Level of natural light (Lux measurement)

Meter reading:……. (Please state time……)

4.36 Total Number of lights in room……..

4.37 Type of lighting provision

Ceiling mounted ☐ Please state number……..

Wall mounted ☐ Please state number……..

Movable lamps ☐ Please state number……

		Yes	No	DK
4.38	During daylight is lighting even throughout the area	☐	☐	☐
4.39	During daylight are there areas of prominent shadows	☐	☐	☐
4.40	Under artificial lighting is lighting even throughout the area	☐	☐	☐
4.41	Under artificial lighting are there areas of prominent shadows	☐	☐	☐

4.42 What is the type of lighting at night

None ☐ Dimmed ☐ Spot lights ☐

4.43 Level of light during night period (Lux measurement)

Meter readings…… (please state time……..)

		Yes	No	DK
4.44	Is there any light pollution from other areas during the night	☐	☐	☐
4.45	Can patients control level of artificial light in room	☐	☐	☐
4.46	Are there light sensors in the room	☐	☐	☐

<u>Study Area Entrances and Thresholds</u>

Doors:

4.47 Number of entrance/exit doors…….

4.48 Dimensions of door Door 1 Door 2

Door 3 Door 4

4.49 What is the door construction:

Door 1 Wood ☐ Plastic ☐ Other ☐ (please detail)

Door 2 Wood ☐ Plastic ☐ Other ☐ (please detail)

Door 3 Wood ☐ Plastic ☐ Other ☐ (please detail)

Door 4 Wood ☐ Plastic ☐ Other ☐ (please detail)

4.50 Do the doors have clear glass panels

	Yes	No		Yes	No
Door 1	☐	☐	Door 2	☐	☐
Door 3	☐	☐	Door 4	☐	☐

4.51 Do the doors have opaque glass panels

	Yes	No		Yes	No
Door 1	☐	☐	Door 2	☐	☐
Door 3	☐	☐	Door 4	☐	☐

4.52 Door opening direction when standing in bedroom

	Inwards	Outwards	Both
Door 1	☐	☐	☐
Door 2	☐	☐	☐
Door 3	☐	☐	☐
Door 4	☐	☐	☐

4.53 Door opening/closing mechanism

	Handle	Automatic	Push Plate
Door 1	☐	☐	☐
Door 2	☐	☐	☐
Door 3	☐	☐	☐
Door 4	☐	☐	☐

4.54 Do the doors remain open once opened

	Yes	No	Don't know		Yes	No	Don't know
Door 1	☐	☐	☐	Door 2	☐	☐	☐
Door 3	☐	☐	☐	Door 4	☐	☐	☐

4.55 Please give details of any physical/electrical devices for keeping doors open:

4.56 Is there an automatic closing device on the door: Yes No Don't know

Door 1	☐	☐	☐
Door 2	☐	☐	☐
Door 3	☐	☐	☐
Door 4	☐	☐	☐

4.57 Is there a difference in height when entering or exiting the study area

Yes	No	Don't know
☐	☐	☐

4.58 If yes, is this accommodated by a

Gradient ☐ Step ☐ Other ☐

If other, please provide details

4.59 Room Layout

Plan of room with location of and distances between furniture. Include placement of light sources and partitions (see ward map also).

4.60 Are there any room partitions Yes ☐ No ☐ Don't know ☐

4.61 If so, describe their location

4.62 Are there fixed handrails in the area Yes ☐ No ☐ Don't know ☐

Furniture

4.63 Please detail the following in the study area:

Number of beds Number of wardrobes

Number of dining chairs Number of easy chairs Number of tables.

Number of bedside cabinets Number of bed trolleys

Number of chest drawers Number of floor lamps Number of tables

Other (please list)

4.64 Type of beds

Low bed ☐ High bed ☐ Adjustable bed ☐

4.65 Are the following routinely stored in the area (not in a dedicated secure cupboard or area)

	Yes	No		Yes	No
Hoists	☐	☐	Wheelchairs	☐	☐
Trolleys	☐	☐	Drip stands	☐	☐
Laundry trolleys	☐	☐	Portable screens	☐	☐
Oxygen cylinders	☐	☐	Commodes	☐	☐
Other (please detail)	☐	☐			

4.66 Is there dedicated storage for personal equipment (e.g. walking sticks, walking aides)

Yes	No
☐	☐

Staff- Patient Observation

	Yes	No
4.67 Is there a nursing station in the study area	☐	☐
4.68 If yes, is there a clear line of sight for staff observing patients	☐	☐

4.69 If no, what is the distance from the study area to the nursing station

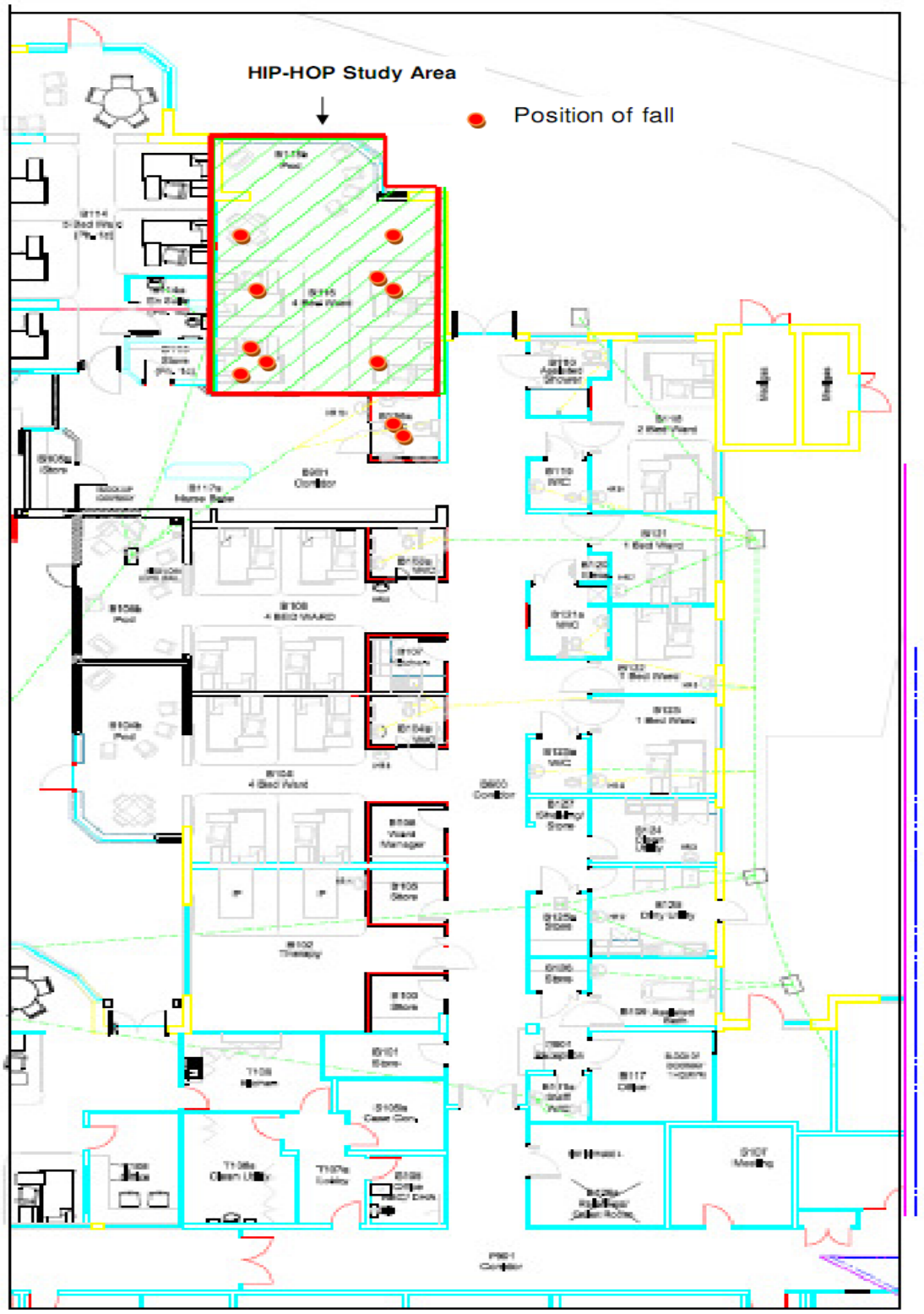
metres

	Yes	No
4.70 If no, is there a clear line of sight for staff observing patients	☐	☐
4.71 Is there a Nurse call system	☐	☐

Please note any other information that may be of interest:
(e.g. presence of movement sensors; positioning of wall sockets; presence of television in study area; views from windows)

Appendix 2: Ward Maps.

Intervention site A

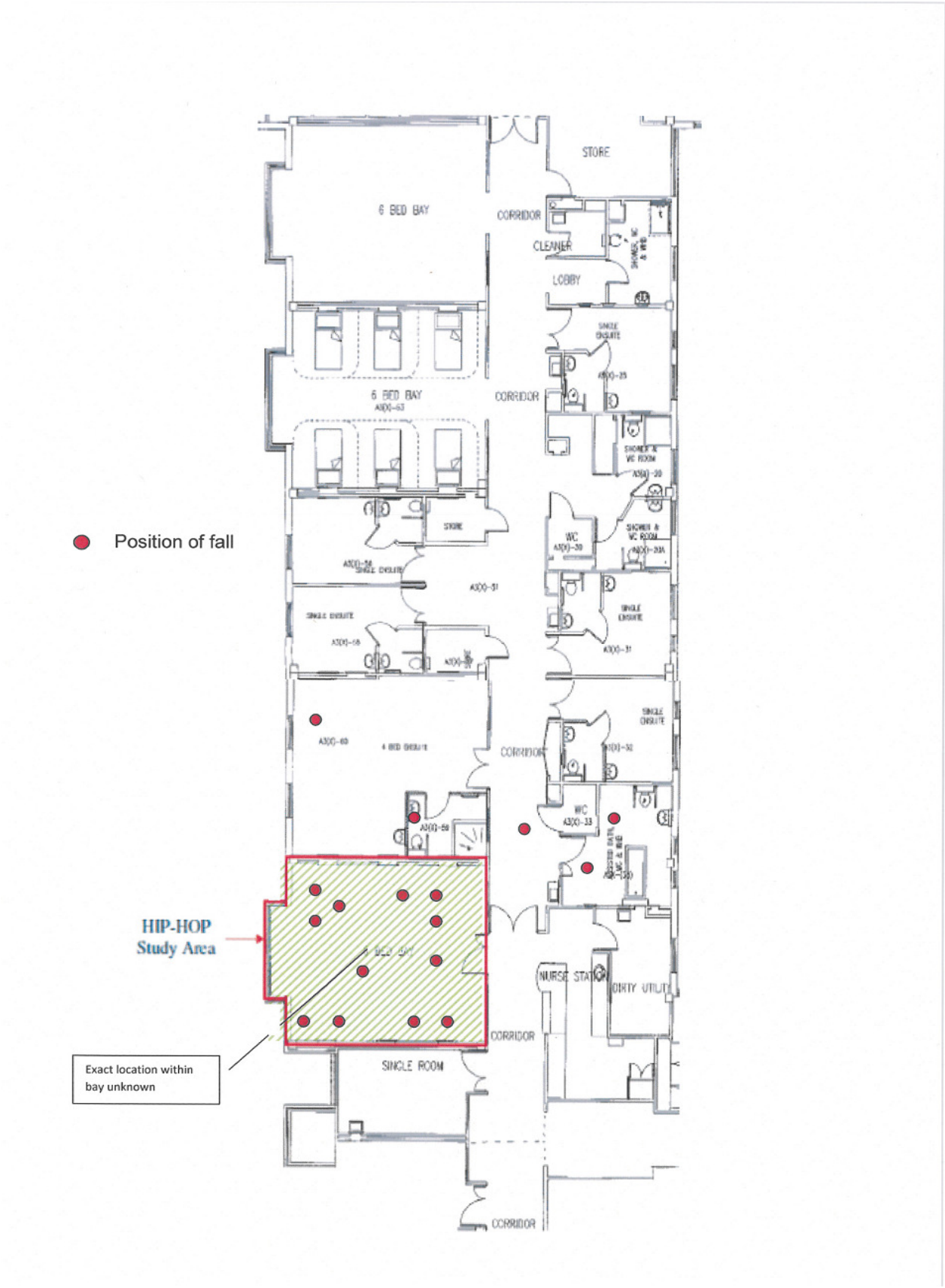


Appendix 2: Ward Maps. Intervention site B

Appendix 2: Ward Maps. Intervention site C

Appendix 2: Ward Maps. Intervention site D

Appendix 2: Ward Maps. Control site E

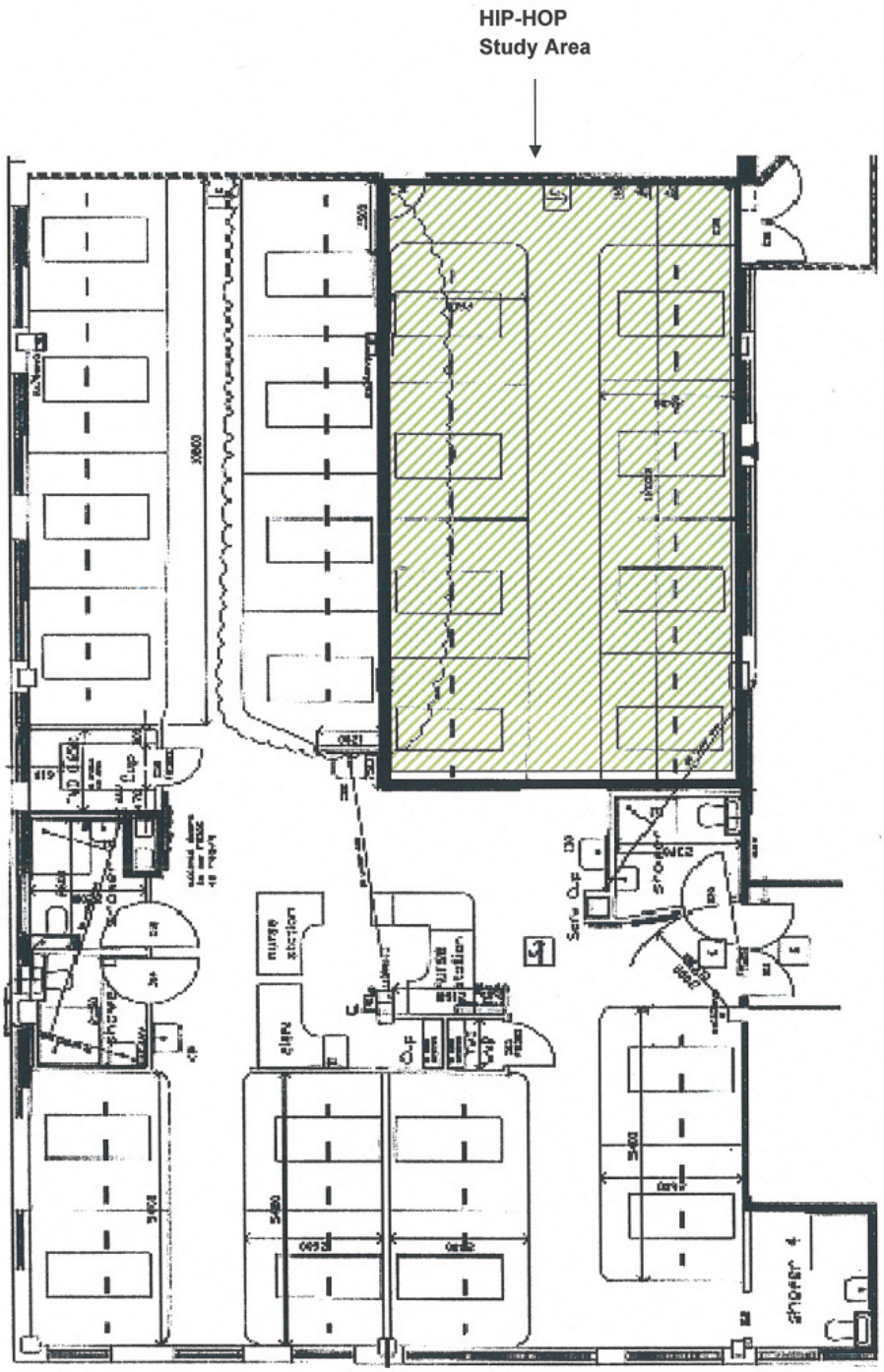


Appendix 2: Ward Maps. Control site F


HIP-HOP
Study area
Position of fall
Unknown fall location within study bay

Appendix 2: Ward Maps. Control site G

Appendix 2: Ward Maps. Control site H



COMMERCIAL PRODUCTS

Tarkett COMMERCIAL

STAND ON EXCELLENCE

DISINFECTANT STAINING

It is widely accepted that when highly concentrated disinfectants are applied to the surface of a vinyl floorcovering, permanent staining can occur.

Due to the possible inconsistencies in the dilution rates, application and period of "contact time" of these solutions it is impossible to say exactly which disinfectant liquids will cause a discolouration and develop further staining.
We have observed the products below with regard to their use, and find them to be acceptable when our guidelines are followed correctly.

ACTI-CHLOR DISINFECTANT TABLETS

We have no reason to believe that this product would damage vinyl floors, providing it is diluted correctly and applied in-accordance with manufacturer's instructions; however, it is important and therefore viewed as "best practice" if the disinfectant is rinsed off the floorcovering at the earliest opportunity after application.

Therefore, we do advise that after a disinfectant has been applied, the Tarkett floorcovering should be rinsed clean using a neutral detergent (pH 6-7) correctly diluted with clean water and allowed to dry.

We have previously tested a similar product called Chlor-Clean and have issued the statement below.
Being of a very similar nature to Acti-chlor Disinfectant we feel there would be no real difference in the use of the product or results from its testing as long as our guide-lines are followed.

CHLOR-CLEAN DISINFECTANT TABLETS

Tests have been performed on the above product in accordance with Tarkett's internal test method; *T 6003 Chemical resistance.*

The short summary of the test method is as follows:

· The actual solution is applied on the surface of material
· The areas are covered with watch glass, preventing the solution from drying or evaporating.
· Three intervals 2 min / 1 h / 24 h
· Cleaning with neutral detergent
· Final visual inspection

No negative influence was visible after realisation of the test.

Further data on this product can be sought at the web address below:

http://www.guest-medical.co.uk/environment/chlor_clean_environ/chlor_clean_environ.html

Technical Services
Tarkett Limited

(31/07/09)

OMNISPORT EXCEL MAINTENANCE INSTRUCTIONS

(HIP-HOP FLOORING STUDY)

To help protect your floorcovering from varying levels of traffic and also as the first defence against the weather, we strongly recommend that barrier mats be installed at entry points to the building to limit the amount of wet and dry soiling. If maintained correctly, these barrier mats should limit the transfer of foot borne contamination and make the daily cleaning and maintenance programme even easier.

Polish or maintainers should not to be applied to the surface of Tarkett products, as the unique PUR factory applied surface treatment removes their necessity.

Initial Treatment

1. The installation of the floorcovering must be fully completed, prior to carrying out any wet cleaning.

2. Ensure that all trace of adhesive is removed from the surface of the floorcovering.

3. Clean floor area with a vacuum, soft broom or preferably a dust control mop.

4. Depending on the level of site soiling after the installation is complete, it may be necessary to scrub the floor dean, prior to adopting the daily maintenance regime. Please find the following options.

   a) Mop the floor clean using a diluted low foaming neutral detergent (pH 6-7) specifically recommended for deaning of vinyl floorcoverings. The dilution rates must be in-accordance with manufactures instructions.

   b) Scrub floor clean with neutral detergent using a standard-speed rotary machine (150 – 250rpm) fitted with a **tan pad** or scrub with a scrubber dryer (combination machine) fitted with a **tan pad**.

   c) Scrub floor clean with neutral detergent using a standard-speed rotary machine (150 – 250rpm) fitted with a **red pad** or scrub with a scrubber dryer (combination machine) fitted with a **red pad.** If the surface is dull, dry burnish with an ultra high-speed rotary machine (best results 1000rpm) fitted with a **white pad**.

Daily Cleaning

Non-Mechanical Method

1. Clean floor area with a broom or preferably a dust control mop.

2. **If soiled:** Damp mop the area clean with diluted neutral detergent. Use a hand held **white pad** or an edging pad to remove heavier soiling.

It is important to ensure that only the smallest amount of moisture is deposited onto the floorcovering when cleaning, so that the floorcovering surface will dry within 15 – 20 seconds.

Mechanical Method

1. Clean floor area with a vacuum, broom or preferably a dust control mop.

2. **If soiled:** Spray clean with diluted neutral detergent using an ultra high - speed rotary machine fitted with a **white pad.**

Interim Cleaning

Non-Mechanical Method

1. Clean floor area with a broom or preferably a dust control mop.

2. Wet mop the area clean with diluted neutral detergent using a double bucket system. Use a hand held **white pad** or an edging pad to remove heavier soiled areas.

It is important to ensure that only the smallest amount of moisture is deposited onto the floorcovering when cleaning, so that the floorcovering surface will dry within 15 – 20 seconds.

Mechanical Method

1. Clean floor area with a vacuum, broom or preferably a dust control mop.

2. Spray clean with diluted neutral detergent using an ultra high – speed rotary machine (1,000rpm) fitted with a **white pad.**

Periodic Cleaning & Maintenance

1. Clean floor area with a vacuum, broom or preferably a dust control mop

2. Scrub floor clean with diluted neutral detergent using a standard-speed rotary machine (150 – 250rpm) fitted with a **tan pad** or scrub with a scrubber dryer (combination machine) fitted with a **tan pad.** If the surface is dull, dry burnish with an ultra high-speed rotary machine (best results 1000rpm) fitted with a **white pad.**

3. Depending on the location, it may necessary to occasionally scrub the floor clean with diluted neutral detergent using a standard-speed rotary machine (150 – 250rpm) fitted with a soft to medium brush followed by a **red pad** or scrub with a scrubber dryer (combination machine) fitted with a soft to medium brush followed by a **red pad.** Finally dry burnish with an ultra high-speed rotary machine (best results 1000rpm) fitted with a **white pad.**

Dry burnishing is an efficient method for limiting scuffmarks and also restores the floors surface (if light scratching has become visible). It is best to dry burnish immediately after the floorcovering has been machine scrubbed with a **red pad**. Dry burnishing greatly reduces renewed soiling. Use an ultra high-speed rotary machine (best results 1000rpm) fitted with a **white pad.**

Cleaning & Maintenance of Stairs

1. Clean risers with a broom or dust control cloth.

2. Clean treads by vacuuming or use a soft broom to sweep across the width of the stair.

3. Damp mop the area clean with diluted neutral detergent using a double bucket system. Use a hand held **white pad** or an edging pad to remove heavier soiled areas.

Appendix 4: Incident rates for falls and injuries broken down by sites (Intervention period)

Site	Incident Rate: All areas				Incident Rate: Study areas			
	Falls	All injuries	Moderate-Major injuries	Major injuries	Falls	All injuries	Moderate-Major injuries	Major injuries
Intervention Group (overall incident rate of injury per 1000 patient bed-days = 1.82)								
A	6.4	0.6	-	-	5.7	0.6	-	-
B	5.2	-	-	-	3.0	-	-	-
C	9.4	3.8	-	-	9.4	3.8	-	-
D	11.1	4.1	-	-	6.2	2.0	-	-
Control Group (overall incident rate of injury per 1000 patient bed-days = 2.74)								
E	10.3	4.5	2.6	1.7	7.2	3.5	1.7	0.8
F	3.6	3.0	1.8	-	3.6	2.4	1.2	-
G	3.8	1.4	-	-	2.2	1.4	-	-
H	-	-	-	-	-	-	-	-

Incident rates per 1000 patient bed-days.

Site	Rate per 100 fallers: All areas				Rate per 100 fallers: Study areas			
	Fallers (N)	All injuries	Moderate-Major injuries	Major injuries	Fallers (N)	All injuries	Moderate-Major injuries	Major injuries
Intervention Group (overall injury rate per 100 fallers = 25.8)								
A	9	11.1	-	-	8	12.5	-	-
B	5	-	-	-	3	-	-	-
C	7	42.9	-	-	7	42.9	-	-
D	10	40.0	-	-	6	33.3	-	-
Control Group (overall injury rate per 100 fallers = 54.5)								
E	11	45.5	27.3	18.2	8	50.0	25	12.5
F	6	83.3	50.0	-	6	66.7	33.3	-
G	5	40.0	-	-	3	66.7	-	-
H	-	-	-	-	-	-	-	-

Appendix 5: How falls were discovered

		Study Group		
		Intervention	Control	Total
How was the fall discovered?	Controlled Fall	1	5	6
	Observed fall	6	6	12
	Heard fall	9	6	15
	Found on floor	26	33	59
	missing	0	1	1
Total		42	51	93

Appendix 6: Location of falls

Period when fall occurred			Study Group		
			Intervention	Control	Total
Baseline Period	Area	Outside study area	0	6	6
		Inside study area	7	12	19
	Total		7	18	25
Intervention Period	Area	Outside study area	8	9	17
		Inside study area	27	24	51
	Total		35	33	68

Appendix 7: Description of footwear at time of fall

		Study Group	
		Intervention	Control
Baseline Period	bare foot	4	5
	normal socks or stockings	0	0
	anti-embolism/compression stockings	1	0
	slippers	1	6
	shoes	0	0
	appropriate footwear	0	0
	sandals/flip-flops	0	1
	bare foot (bandage on one)	0	0
	don't know	1	4
	missing	0	2
Intervention Period	bare foot	16	12
	normal socks or stockings	0	1
	anti-embolism/compression stockings	0	0
	slippers	9	13
	shoes	0	0
	appropriate footwear	1	2
	sandals/flip-flops	0	0
	bare foot (bandage on one)	1	0
	don't know	1	1
	missing	7	4

Appendix 8: Briefing paper circulated to study sites March 2011

Potential and Actual Adverse Events concerning the

HIPHOP Flooring Study

Introduction

Research studies have a duty to seek, document, assess and if necessary act upon adverse incident reports. This would include actual and potential adverse events. Normally these adverse events affect the research subject, but it is possible when the intervention is environmental that the adverse event may include individuals outside the research for example staffs or visitors.

The researchers have a duty to weigh these actual and potential adverse events and the injuries they cause or might cause in the context of the research outcomes and against unexpected positive events, which have also been reported and/or collected as part of qualitative studies. So for an early drug trial with a class of drugs called beta blockers in heart failure the unexpected finding of impotence in some men needed to be weighed against the drugs ability to improve the outcomes of heart failure and the unexpected finding that many subjects felt more relaxed and less anxious.

This study has had unexpected positive events reported and one type of adverse event reported. These and other factors will be systematically investigated in the qualitative part of the trial. The rest of this report focuses on the one adverse event that has been reported to date.

Reported Adverse Event (1)

The adverse event in question is the reported difficulty pushing or pulling hospital equipment over the intervention [cushioned] flooring.

The severity of this reported event is such that:

- It only seriously effects staff and not patients or visitors
- It appears to be of more concern the heavier the object is that needs to be moved
- It has not resulted in any serious injury

There are 4 intervention sites and 4 control sites of which 2/4 intervention sites and 0/4 control sites have raised this in their adverse event feedback.

One intervention site has undertaken detailed investigation and risk assessment

Process for Issue Resolution

The HIPHOP Steering Committee reviewed the adverse incident event (1) reports and came to the following conclusions:

1. The reported incidents were a significant issue and were in need of resolution

2. The reported incidents were not severe enough to halt the trial and there were a number of risk mitigation strategies which could be pursued in both the short and long term. In addition the true effect of the floor on patient outcome needed to be established in order that the appropriate risk mitigation strategy including not laying the floor could be determined. For example potentially very dangerous drugs that can cause death eg Thrombolytics for stroke are still given even though there is an increased serious intracranial haemorrhage [bleed] rate because even accounting for this many more people live and fully recover than with no treatment. If the trial had been stopped because of the bleeding the true benefit could never have been ascertained.

3. The actual degree of risk and the risk mitigation options need to be set down by an authoritative independent source such that individual sites [control and intervention]

    a. Are aware of the issues and their quantification

    b. Have a series of options and processes to mitigate the risks of those issues

    c. The research project is being seen to act ethically, morally and professionally

4. The Steering Committee have commissioned an independent report from the Health and Safety Laboratory, which will quantify the staff risks from pushing or pulling hospital equipment over the intervention [cushioned] flooring compared to standard vinyl flooring AND set down options for risk mitigation for individual sites to use in order to help them make their own decisions

5. The Steering Committee have recommended this report and the future Health and Safety Lab Report, when completed, be shared immediately with the research sites and be on the agenda of the next Steering Committee.

6. The Steering Committee also want to be appraised of the qualitative research findings on the floor from staff and patients

Appendix 9: Potential and actual adverse events covering letter March 2011

The HIP HOP Flooring Study
Helping Injury Prevention in Hospitalised Older People

University of Portsmouth
School of Health Sciences and Social Work

1st March 2011

Dear Colleague

I have just left the HIP-HOP Flooring Study Steering Committee, where potential and actual adverse events arising in the study were discussed.

There has been one class of adverse event reported, which is the difficulty initiating movement of heavy ward based equipment, especially when associated with small floor contact points for example small wheels. There have been no injuries reported.

The attached brief has been produced by the Steering Committee and can be shared freely with managerial, clinical and research staff involved directly and indirectly with the study.

I will be finalising the details of the independent [trusted third party] study with the Health and Safety Laboratory in the next few days. The study will take place in one of the intervention sites. The study will be funded through my personal research account at the University as there is no spare funding within the research grant. Details of which site and the timing of the study will be circulated later by Amy Drahota or Derek Ward. The finalised study will be shared directly with each study site and the Steering Committee at the same time.

Thank you for your continued support of the study and I hope you find the February 2011 Newsletter as exciting and informative as I did.

Kind regards

Professor Martin Severs FRCP. FFPHM, OBE
Chief Investigator

Appendix 10: HSL ergonomic appraisal cover letter to sites from Chief Investigator

University of Portsmouth

James Watson Hall (West)
2 King Richard 1st Road
Portsmouth
PO1 2FR

17th June 2011

Dear Colleague

Re: Potential and Actual Adverse Events concerning the floor in HIPHOP Study

Following the report of an adverse incident and local investigation, whilst moving a heavy object across the intervention arm flooring, the research group escalated the issue to the Steering Group. The Steering Group confirmed a number of actions, one of which was to commission an independent assessment and for this to be shared as soon as complete.

The report which was completed by the independent Health and Safety Laboratory is attached to this letter. The report is thorough and exhaustive and I believe very helpful, both for this study, and future studies but most importantly it is helpful to sites and staff now.

Clearly each site must make its own assessment armed with the evidence of the report, but for me the risk is related to forces and the hierarchy of controls. This is best shown in the diagrams on page 41 when one person moves the equipment [with or without patients being carried upon or within it] and that on Page 50 when it assumes two people are moving the objects. In short, if your policy is that two or more people should move heavy objects, or you are prepared to institute such a policy for the trial flooring, then the risk is reduced to amber or below, depending on what your policy says. The Executive Summary of the HSL report makes exactly the same point, so I am not challenging any aspect of the report merely trying to help sites with a simple step to assess risk and have a basis for decisions.

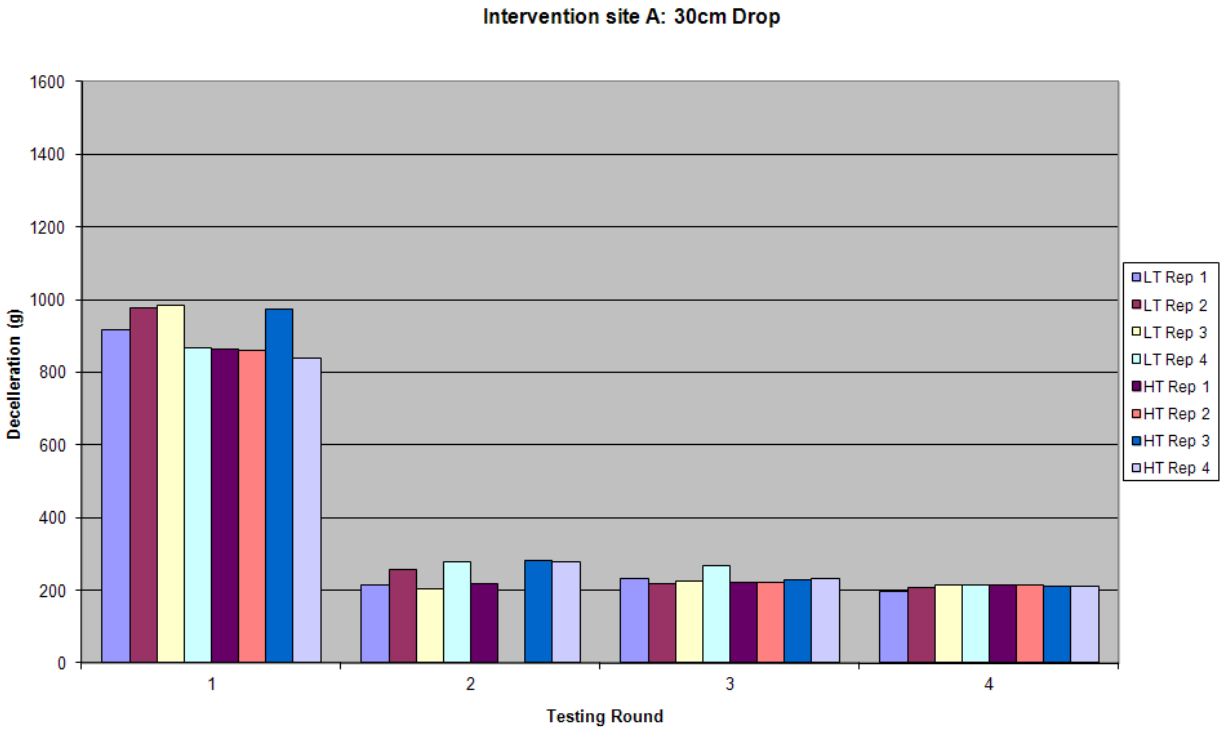
The study hopes to continue recruitment up until the end of August 2011, and we would like to support whatever decision sites wish to take. I have even checked the manual handling and patient transfer policy in my own Trust and was surprised but delighted to learn they recommend at least two people to move a heavy object like a bed occupied with a patient. If any of the research team can help you in any way please do not hesitate to get in touch.

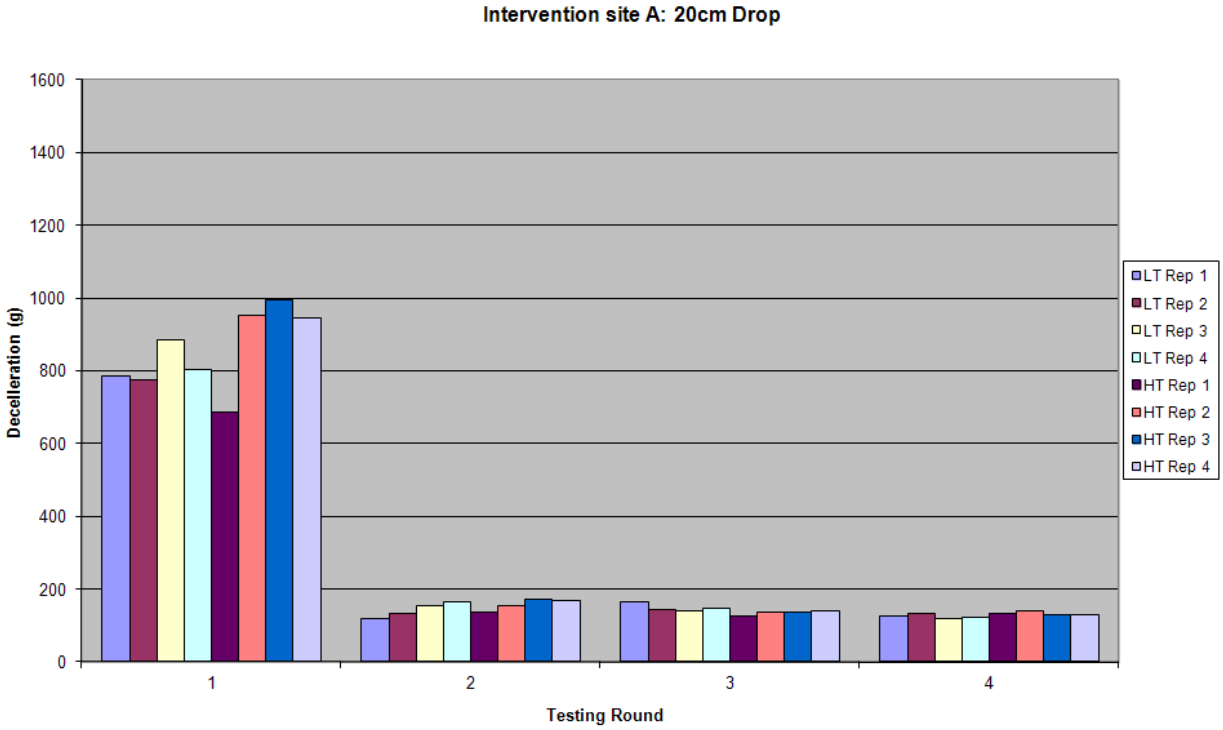
Kind regards,
Martin.

Professor Martin Severs OBE, FRCP, FFPHM

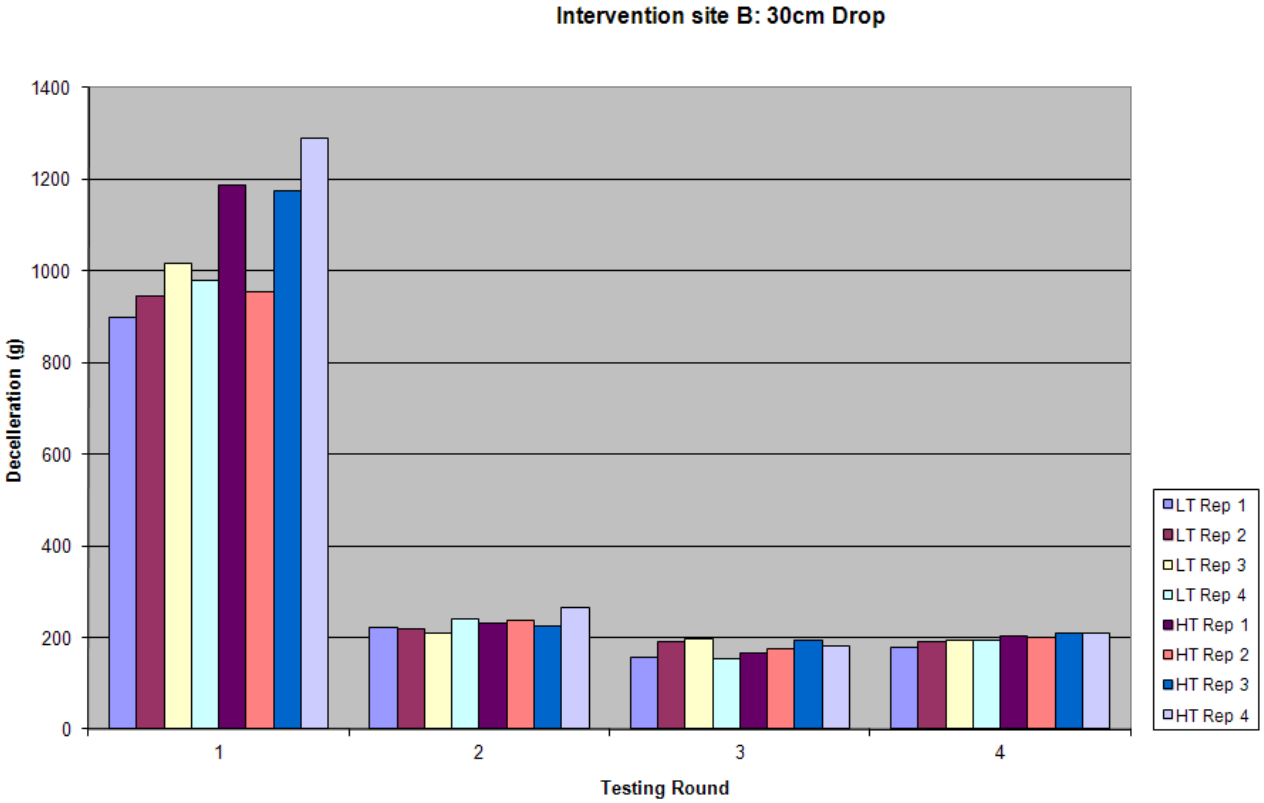
Appendix 11: Site summaries of mechanical testing

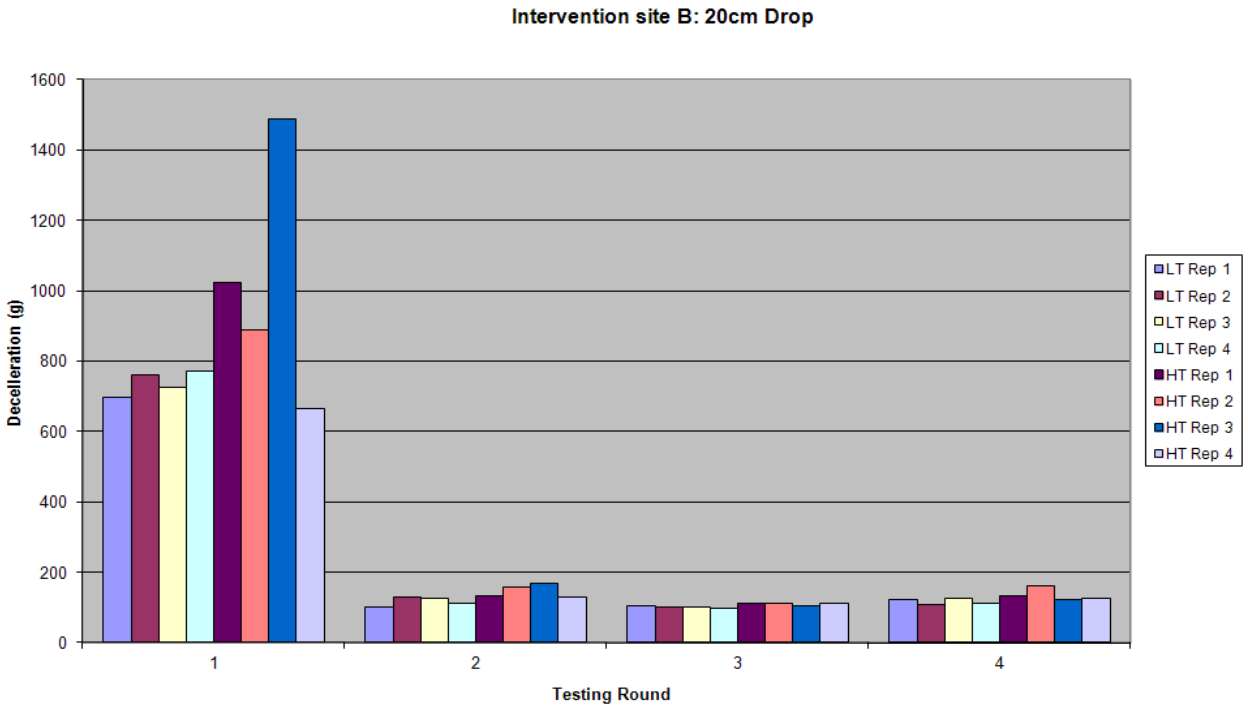
Impact Reduction – Intervention Site A



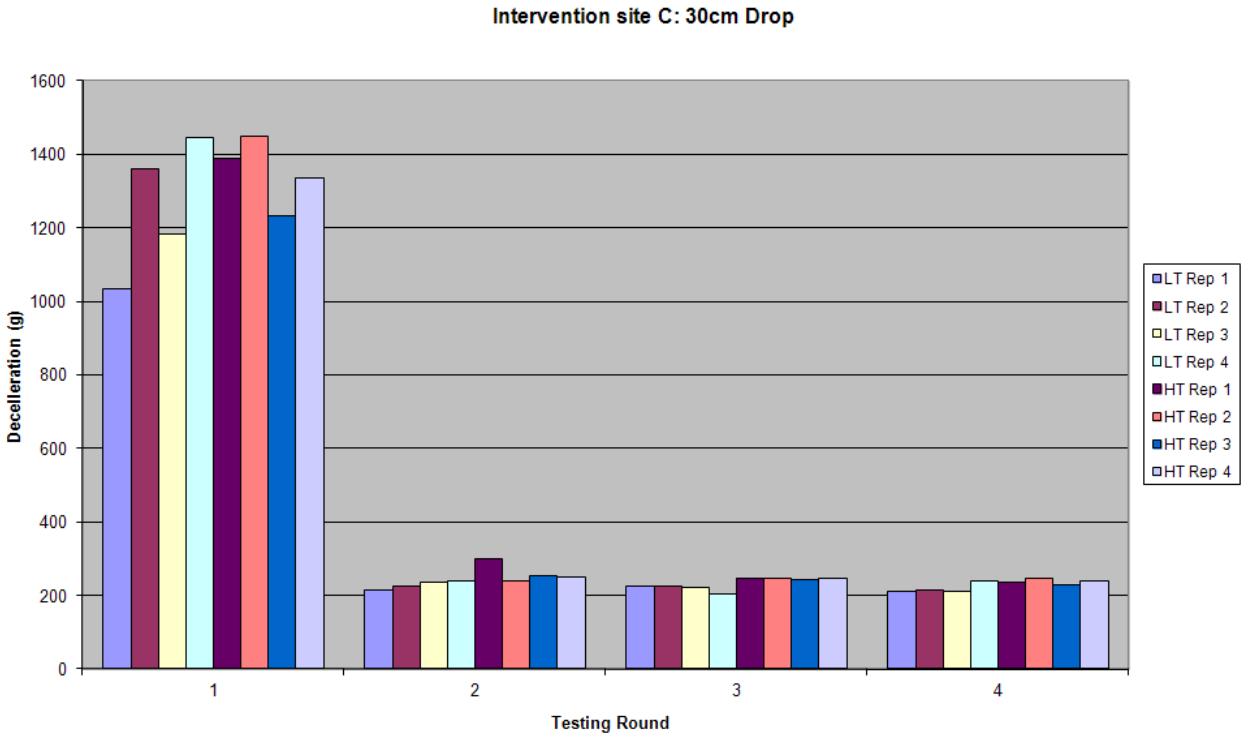


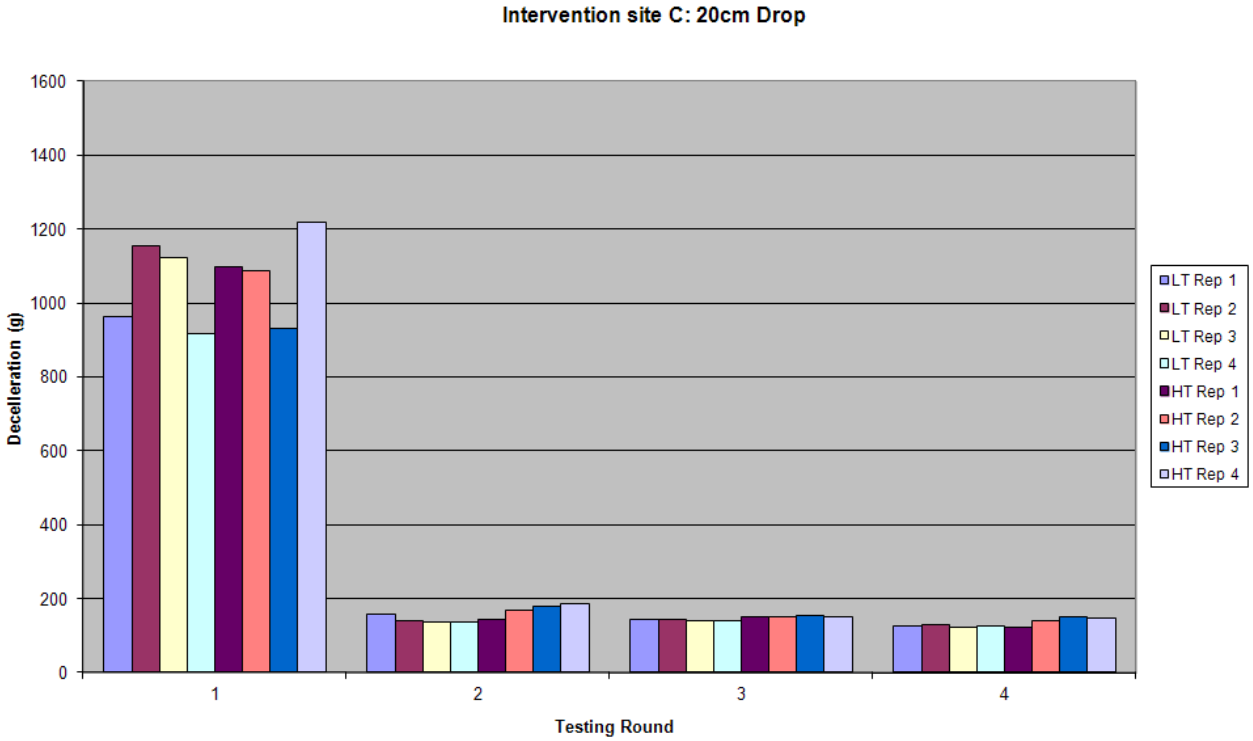
Impact Reduction – Intervention Site B



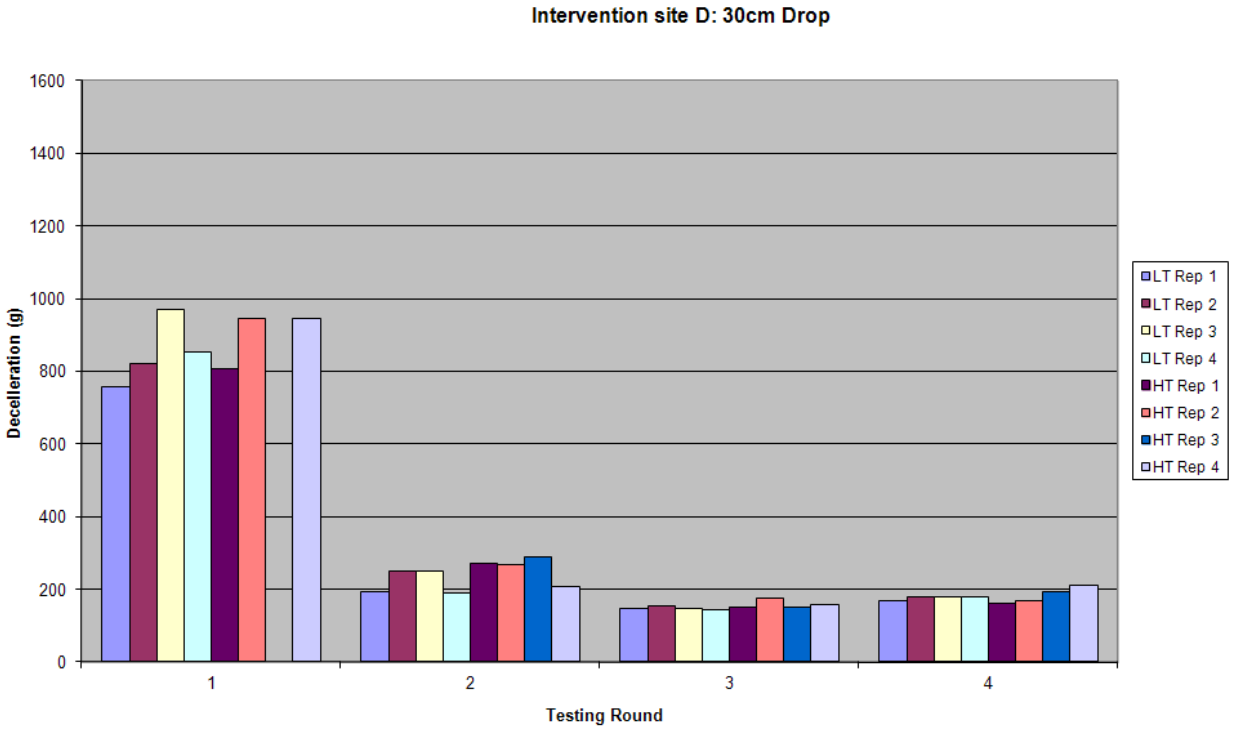


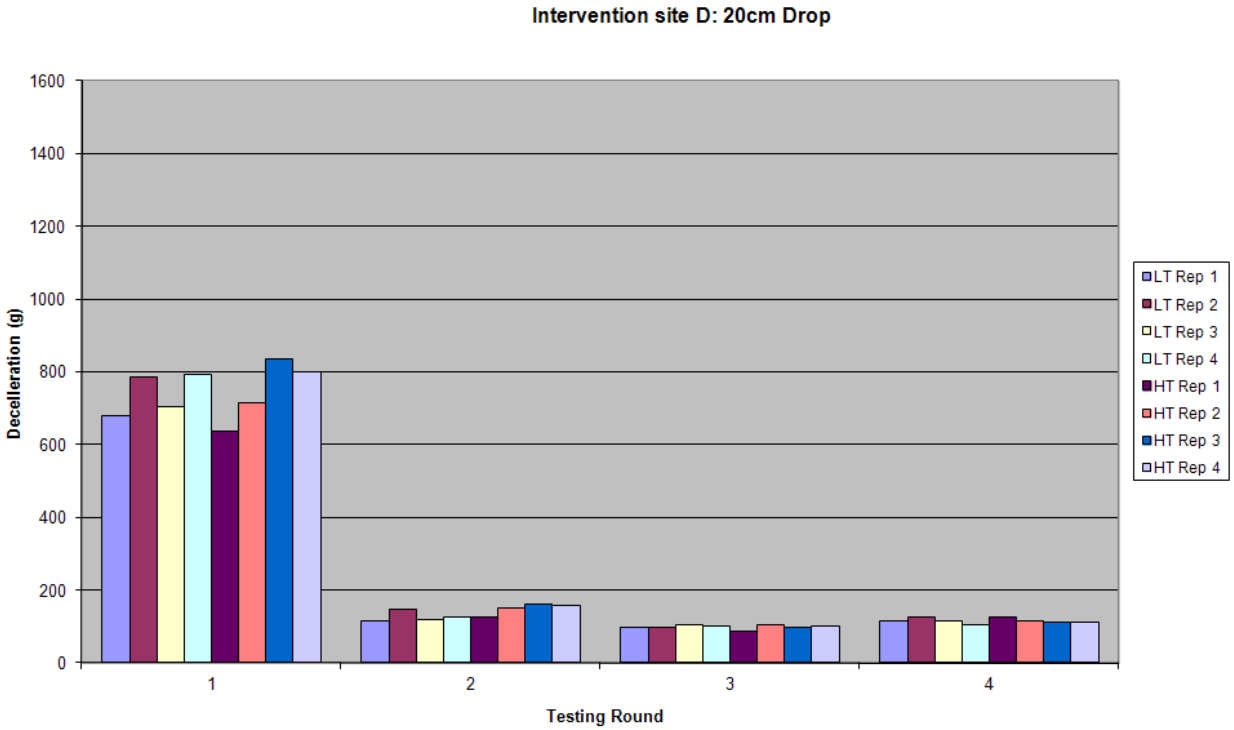
Impact Reduction –Intervention Site C



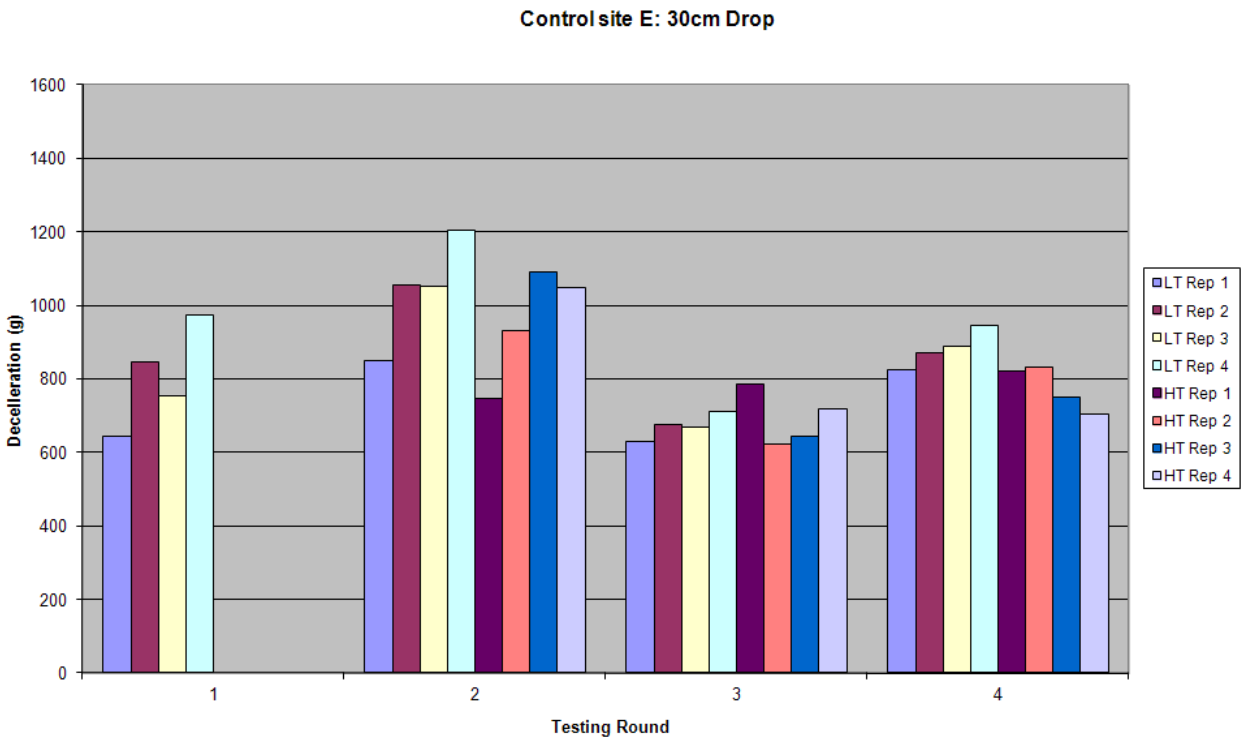


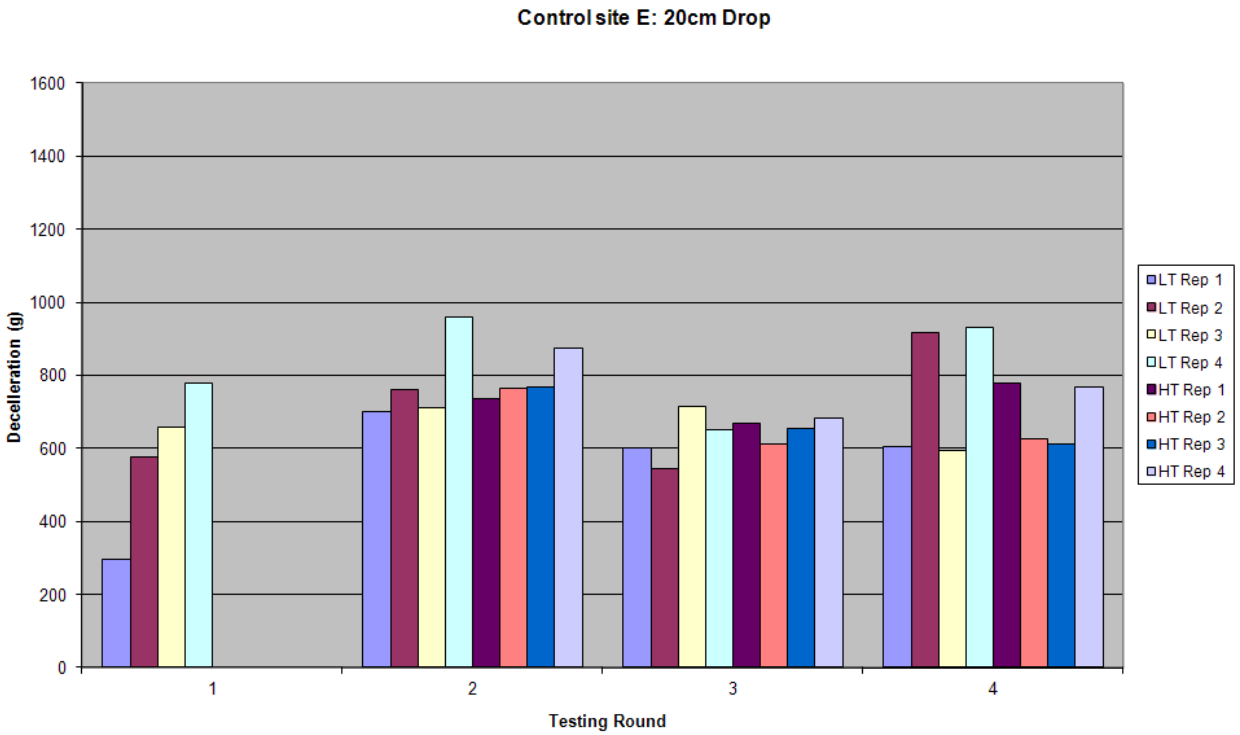
Impact Reduction –Intervention Site D





Impact Reduction – Control Site E





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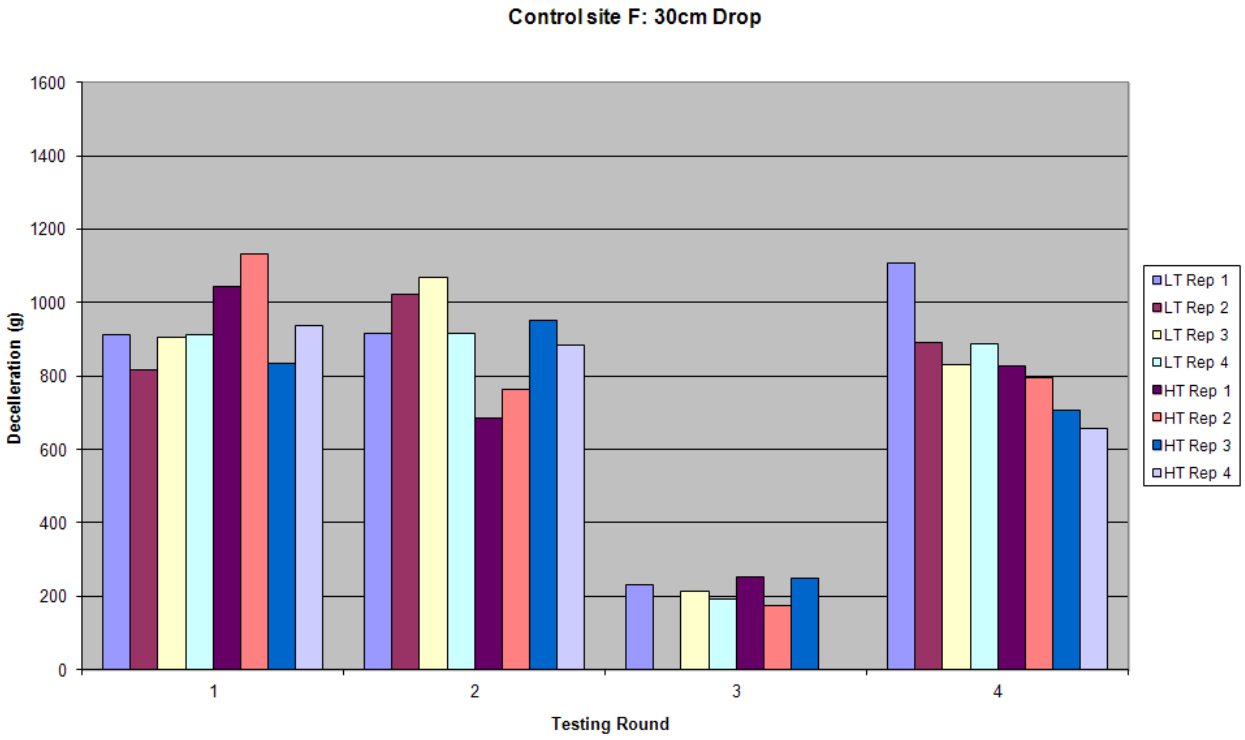

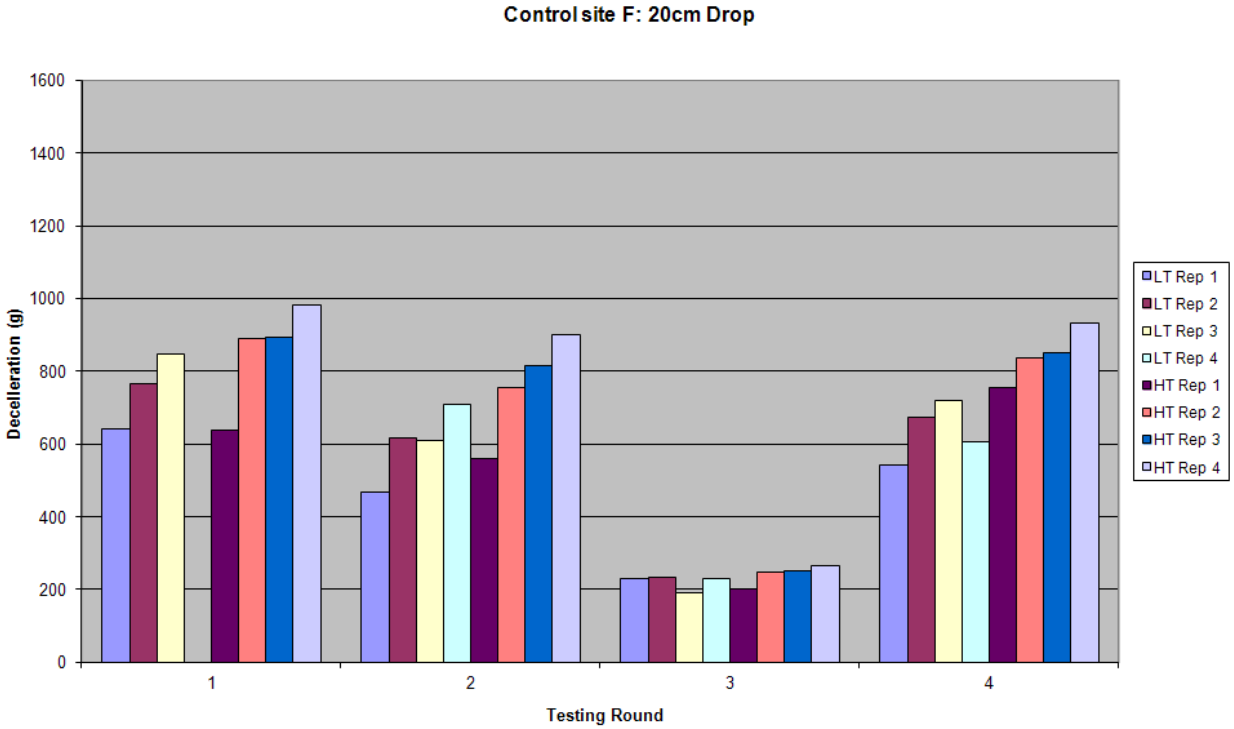

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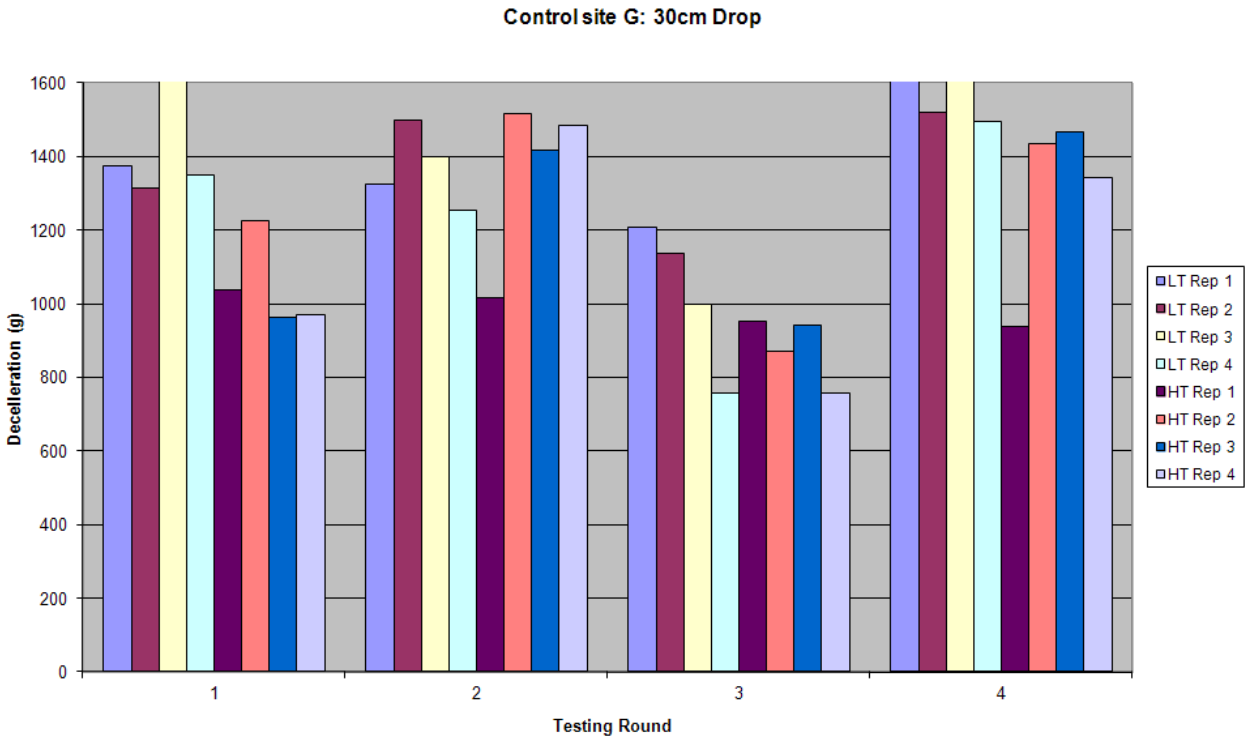

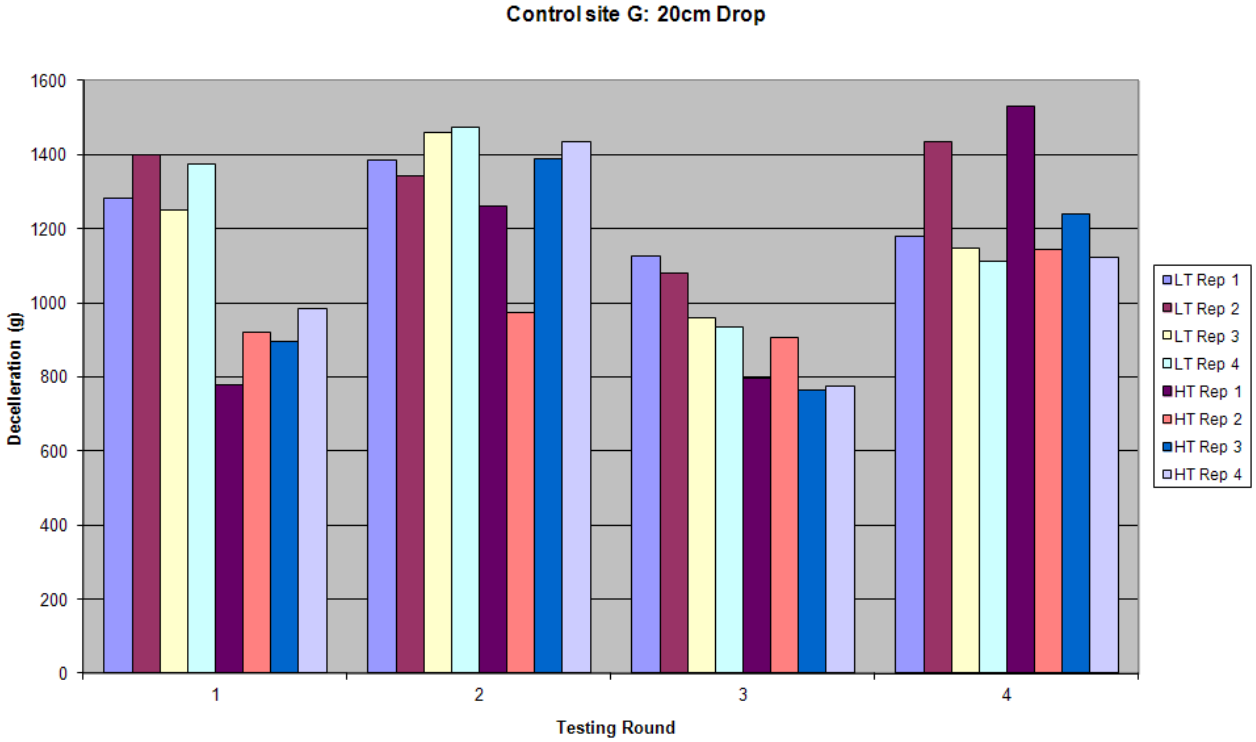

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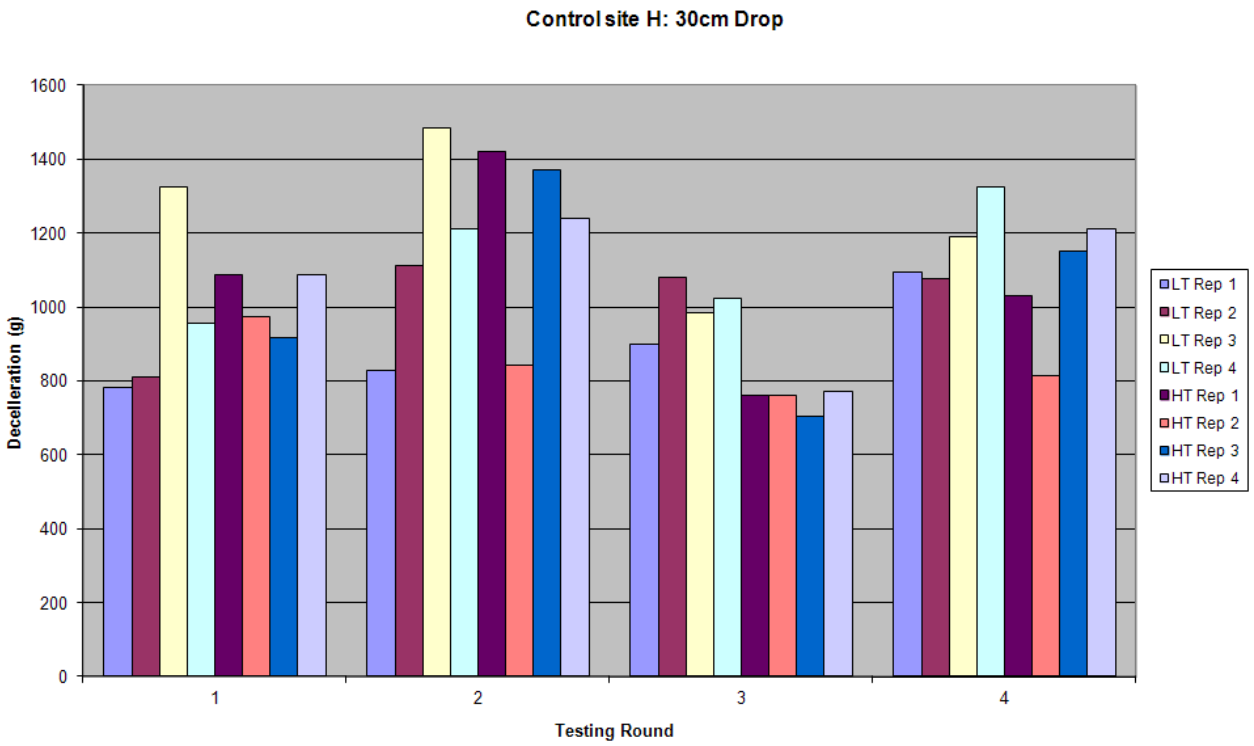
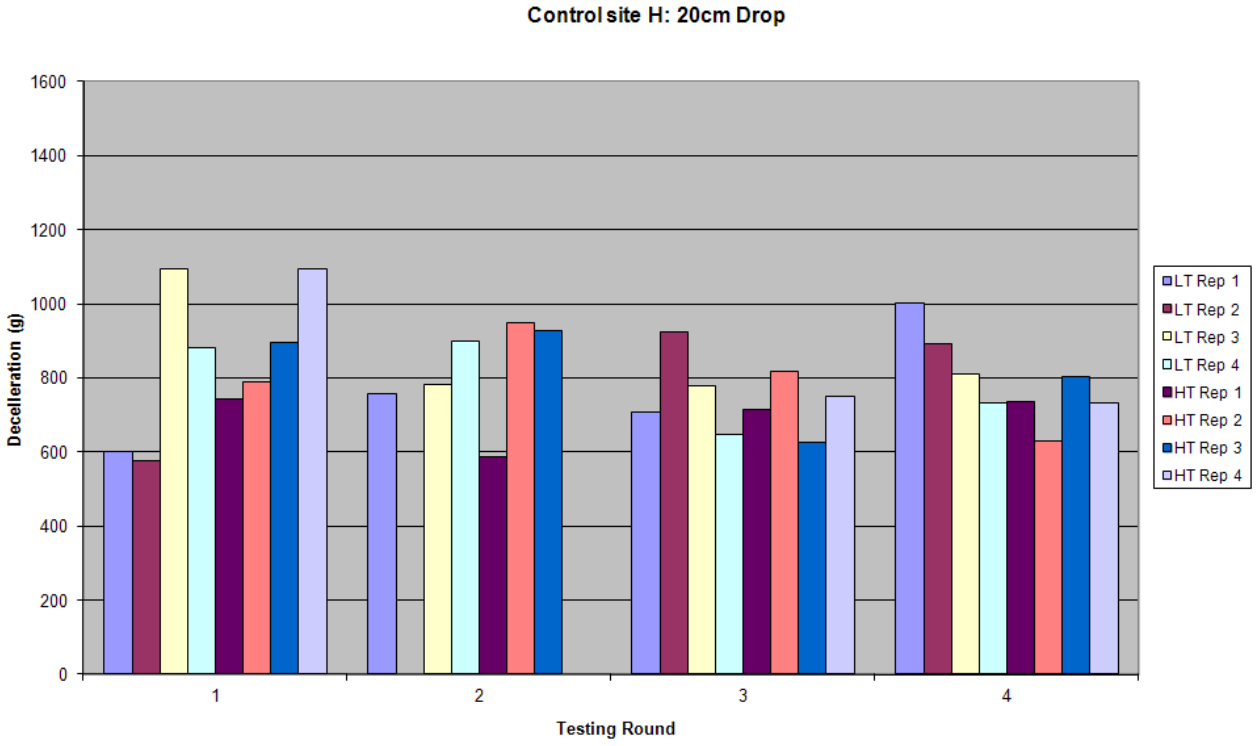
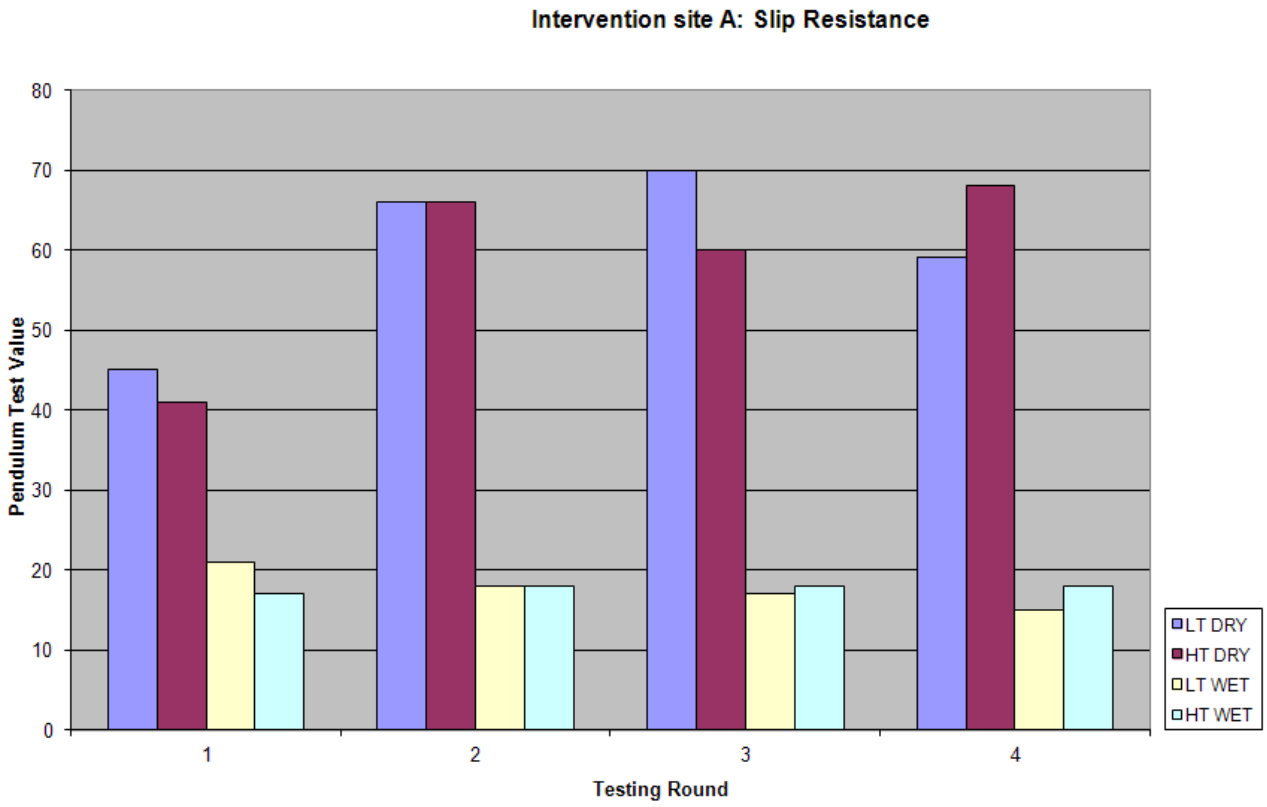
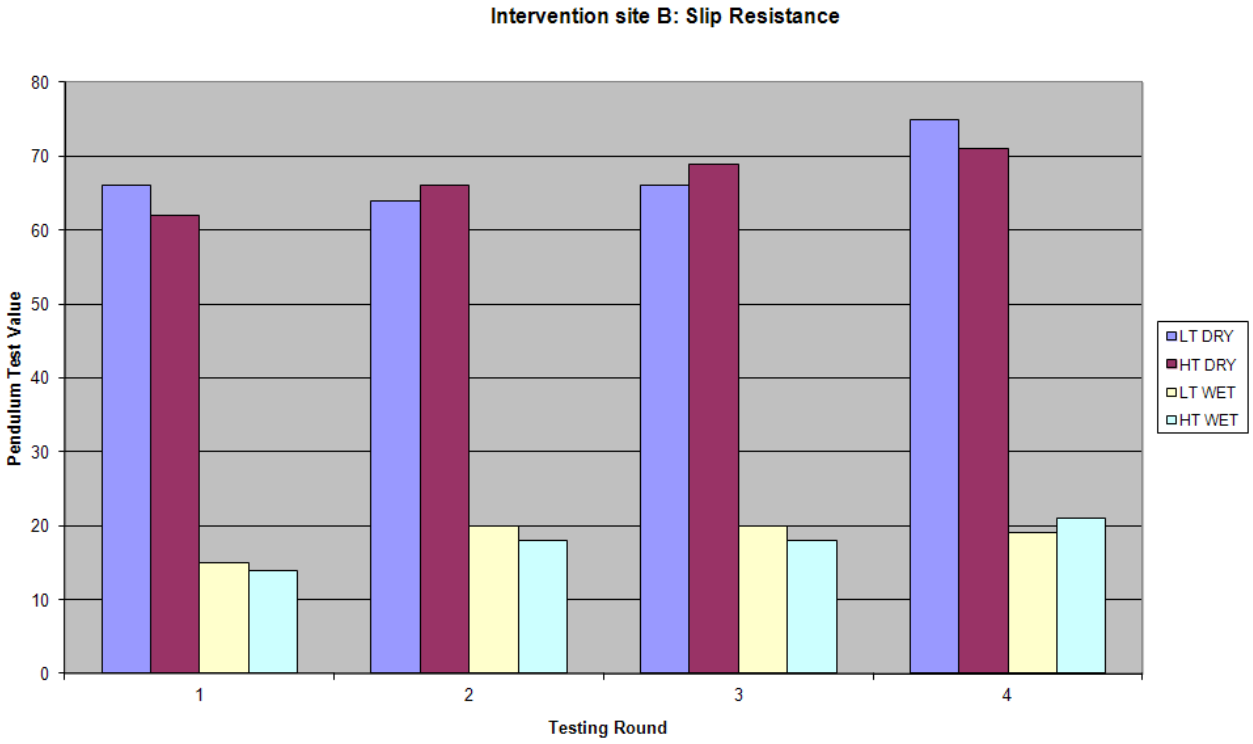


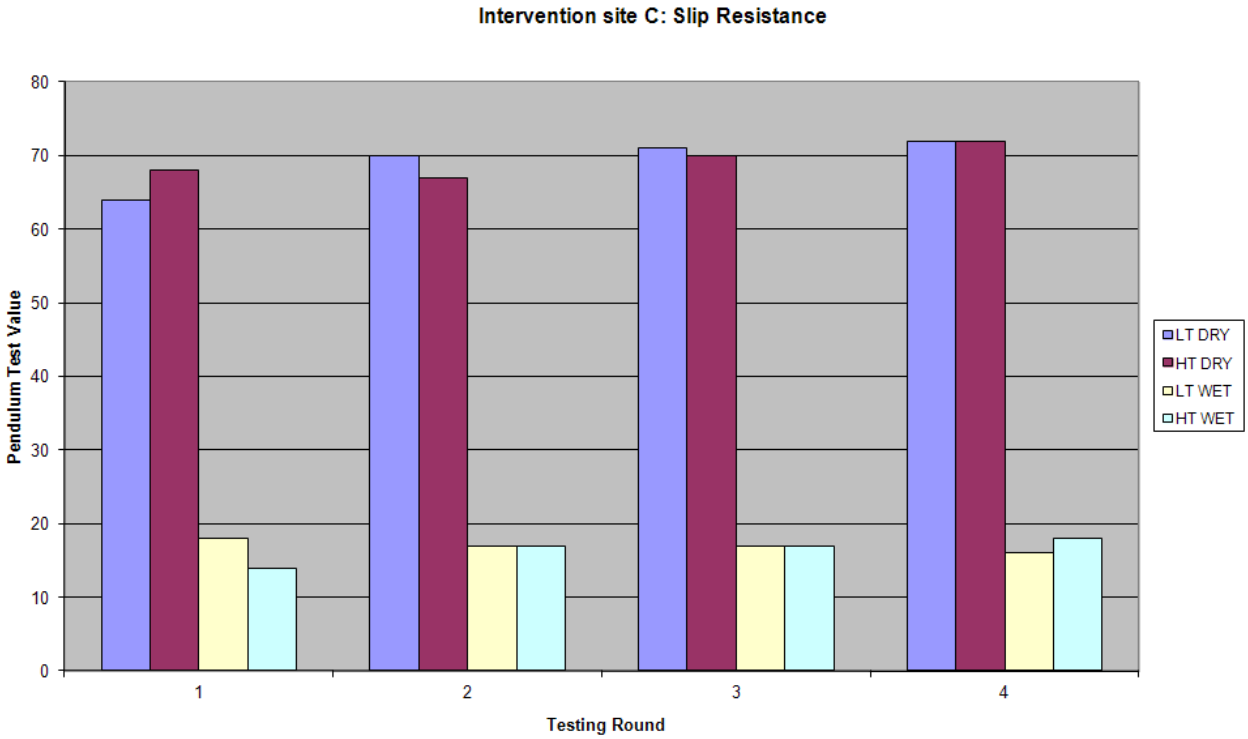


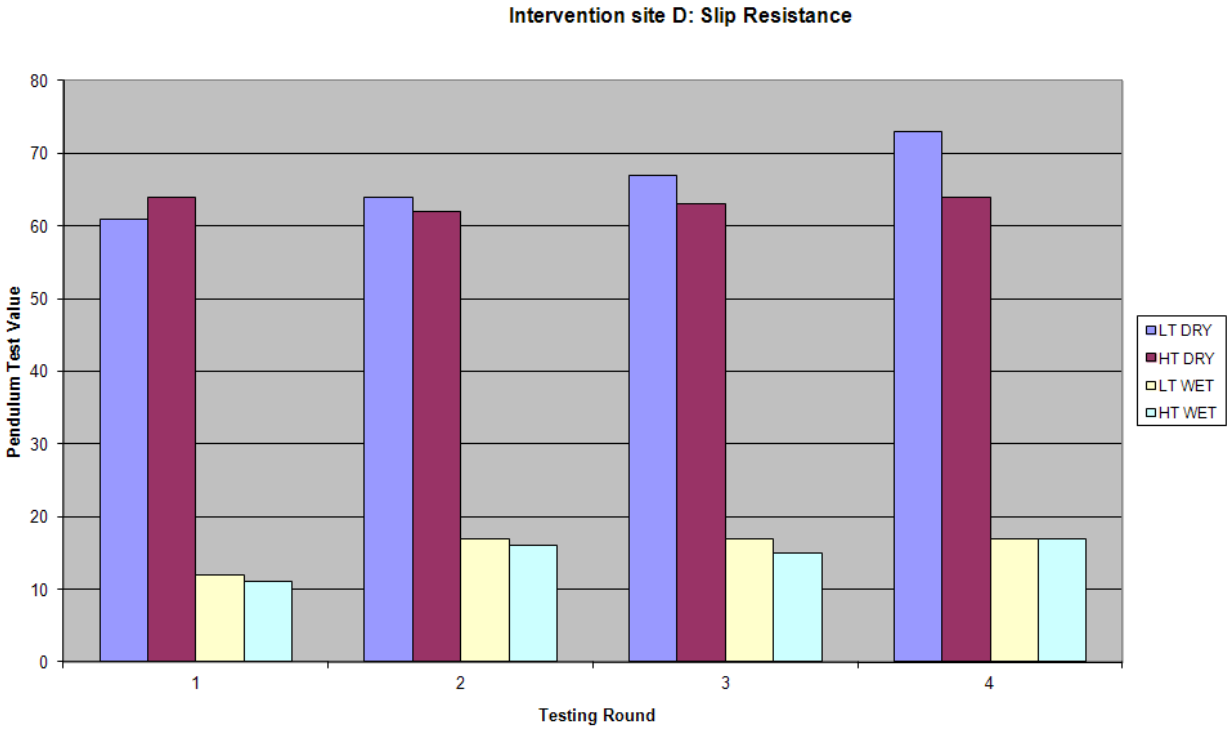
Slip resistance – Intervention Site A & B



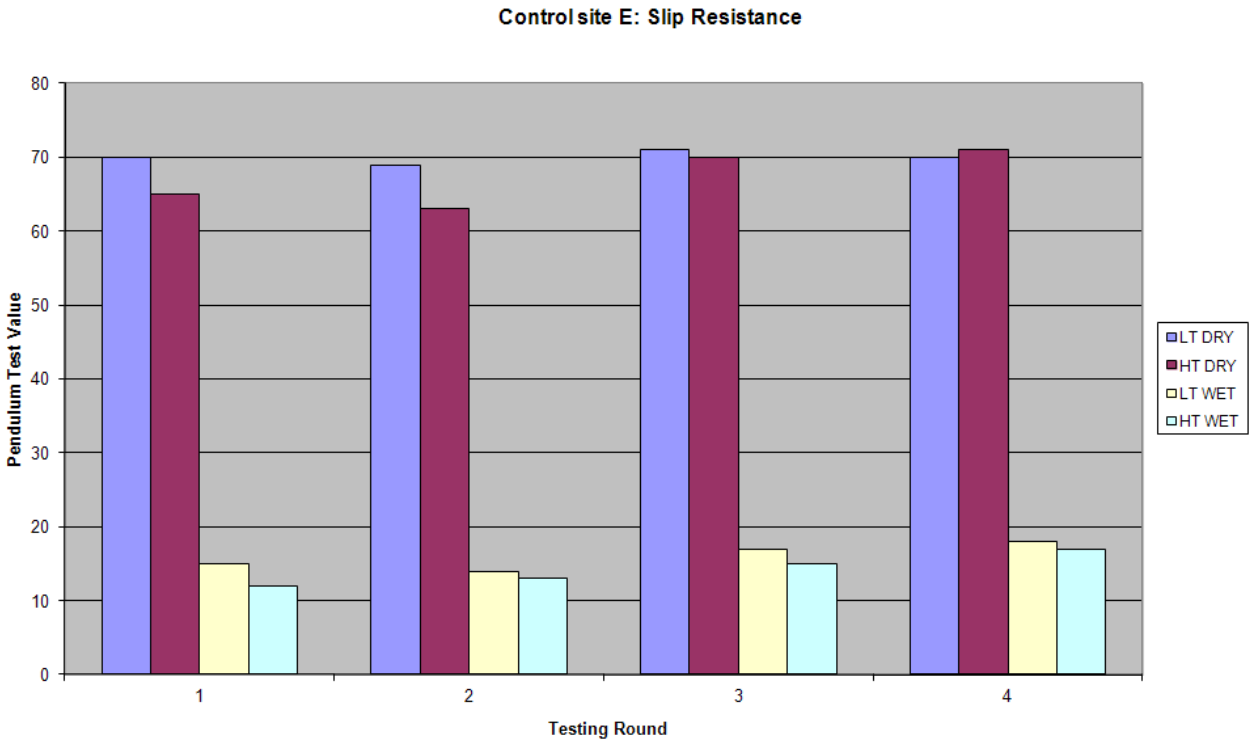


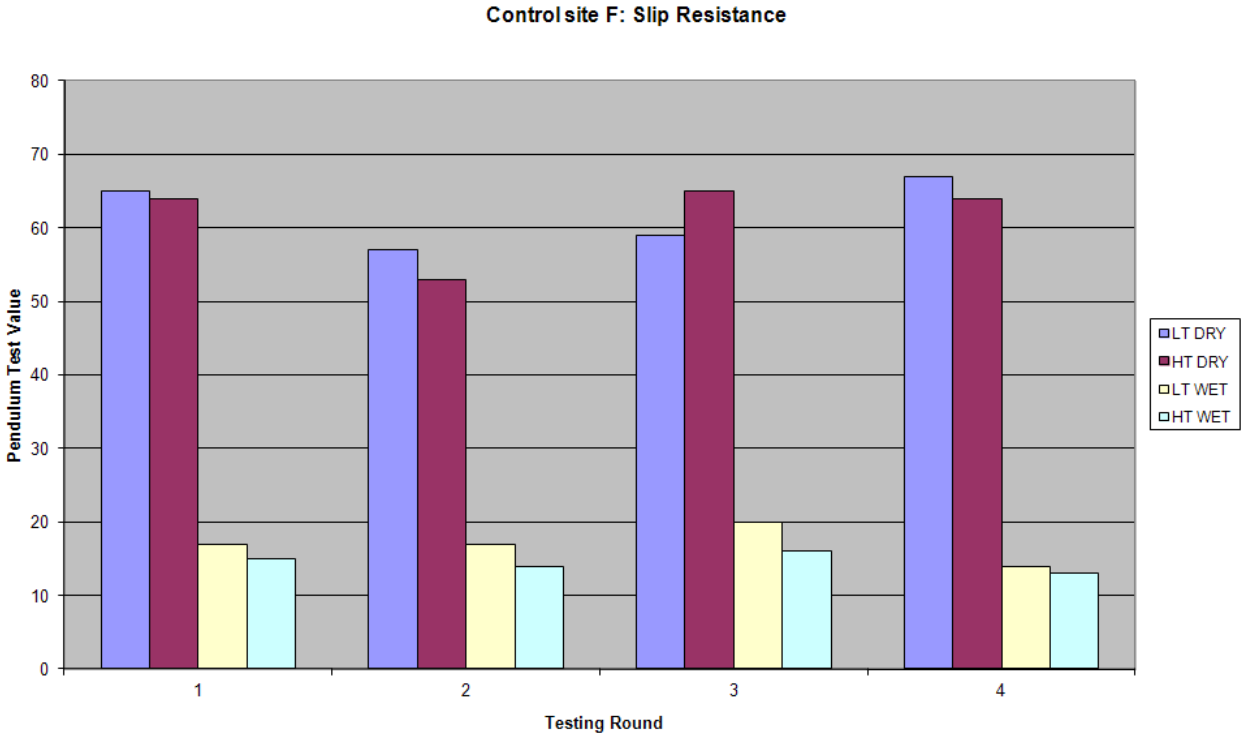
Slip resistance – Intervention Site C & D



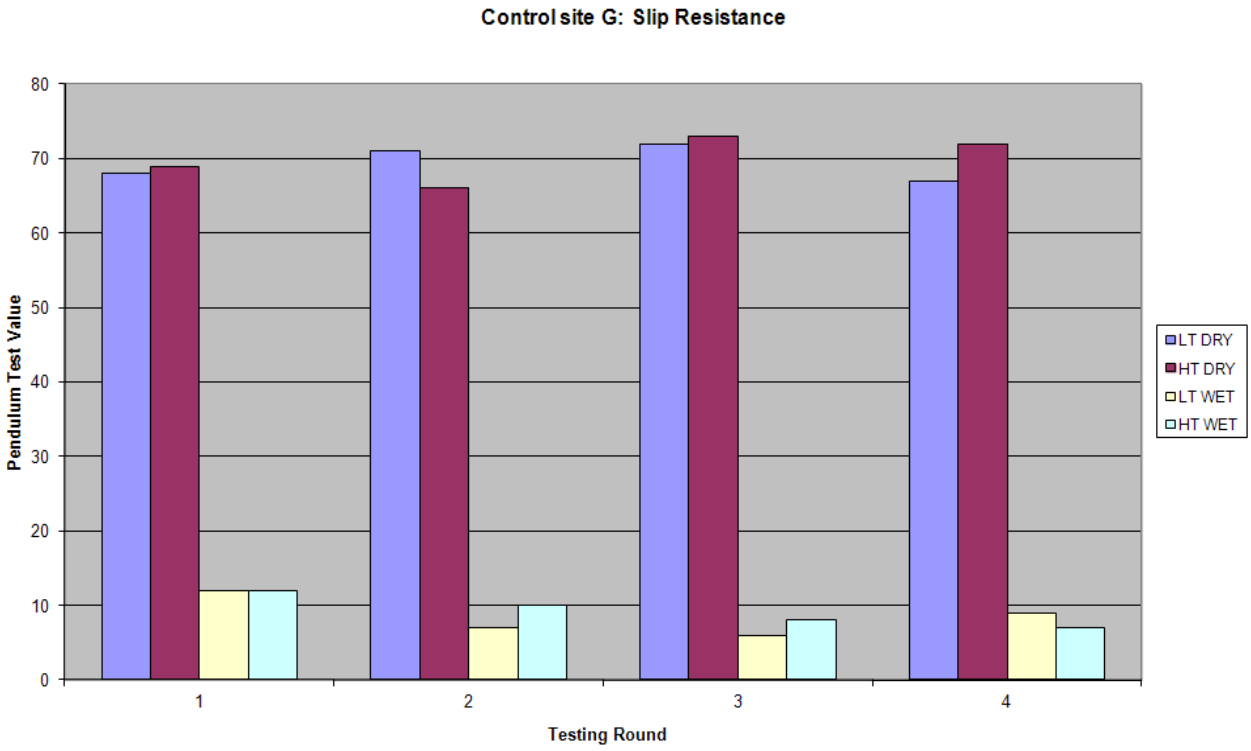


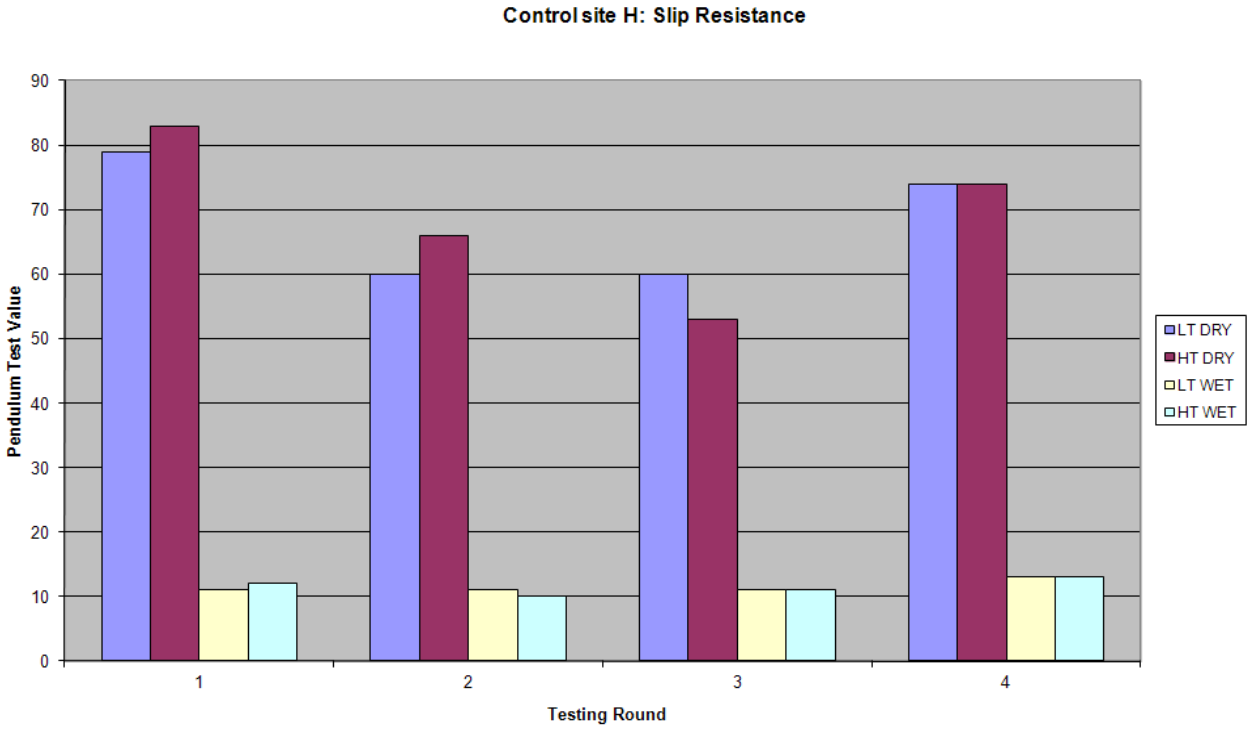
Slip resistance – Control Site E & F





Slip resistance – Control Site G & H





Appendix 12: Probabilities of events following falls – parameter values and justifications

Node	Probability Value				
	No Fall	Fall – No injury	Fall – Minor	Fall – Moderate	Fall – Major injury

			injury	injury	
Dead (during hospitalisation)	5.9%	13.5%	14.3%	14.3%	14.3%
Justification: Value for 'No Fall', 'Fall – No injury' and 'Fall – Minor injury' taken from the trial. Due to very few moderate and major falls data are sparse on these. Death rates were substantially raised for falls that caused no or minor injuries, and we assumed that death rates following a moderate or major fall would be similar to that observed after a minor fall.					
Discharged to another ward/ hospital	16.4%	22.9%	22.9%	22.9%	22.9%
Justification: Value for 'No Fall' taken from the trial. Data on transfers to another Ward or hospital were relatively rare even for minor fall patients and was seemingly contradictory (more fallers who experienced no injury were transferred than fallers who sustained minor injuries) and so the proportion that were discharged to another Ward or hospital was estimated for any *faller – not based on the severity of the fall.*					
Return to own house/previous residence	65.3%	33.9%	33.2%	0.0%	0.0%
Justification: These were calculated by calculating 1 - % discharged to another Ward/hospital - % who change residence to a nursing/residential home - % who die during hospitalisation					
Change residence to nursing/residential home	12.4%	29.7%	29.7%	62.9%	62.9%
Justification: For 'No Fall' the value was taken from the trial data. For falls that led to no injury and falls that led to minor injury similar proportions were discharged to a nursing or residential home rather than their usual place of residence (29% and 32% respectively) and so, assuming there were no differences between these we combined them to estimate that 29.7% of patients who had a fall and sustained no or minor injuries changed residence to a nursing or residential home. Data from Iglesias et al (2009) suggested that 1% of patients who had a fall and no fracture could be expected to change residence, compared to 8% of patients who had a fall and a fracture.[2] We therefore planned to use a relative risk of 8.0 to estimate the proportion of major fall patients who would change residence (as data from the HIP-HOP study was very sparse for these fallers). In the absence of other data, we planned to halve this relative risk for moderate fall patients. However, given the very high proportion of patients who experienced a minor fall and changed residence, applying this relative risk would lead to over 100% of moderate and major fallers changing residence to a nursing or residential home. Therefore, we capped this proportion such that all patients who experience a moderate or major fall who do not die in hospital, or are not discharged to another Ward or hospital, change residence to a nursing or residential home – therefore none return to their previous residence.					
Dead in hospital following transfer to another ward/hospital	5.9%	13.5%	14.3%	14.3%	14.3%
Justification: We assumed that patients who were transferred were effectively experiencing another 'hospitalisation' event and thus applied the same probability of death during that event as for the initial hospitalisation, based upon fall type.					
Return to own house/previous residence following transfer to another ward/hospital	81.6%	56.8%	56.0%	0.0%	0.0%
Justification: These were calculated by calculating 1 - % who change residence to a nursing/residential home - % who die during hospitalisation					
Change residence to nursing/ residential home following transfer to another ward/hospital	12.4%	29.7%	29.7%	85.7%	85.7%
Justification: The same probabilities were used for these as for the initial hospitalisation. We assume that all moderate and major fallers who did not die during the hospitalisation changed residence to a nursing or residential home based upon the relative risks obtained from the data presented in Iglesias et al (2009)[2], as discussed above.					

Table A1: Probabilities of events following falls

Appendix 13: Utility scores calculated based upon the Iglesias et al (2009) study

Iglesias et al (2009) used data on fear of falling, health related quality of life (HRQoL) (measured by the EQ5D) and a common set of baseline risk factors for fracture (smoking status, weight and age) to develop multilevel random effects models to estimate the long-term impact on HRQoL associated with falls, fractures

and fear of falling. The largest dataset used was from the Hip Protector trial which was an RCT of hip protectors for the prevention of hip fractures among women living in the community. Women aged 70 years and over with one or more risk factors for hip fracture were eligible. Baseline EQ5D data were available for 3223 of the 4196 recruited patients, and follow-up measurements were taken at 6, 12 and 18 months, at which follow-up rates were 89%, 83% and 82% respectively.[2] The utility model based upon the Hip Protector trial had the following components and coefficients:

Parameter	Coefficient	SE
Constant	0.2694	0.0114
Time	-0.0001	0.0004
Smoker	-0.0297	0.0101
Weight (kg)	-0.0001	0.0003
Age	-0.0017	0.0006
Fear of fall		
little of the time	-0.0308	0.0069
some of the time	-0.0670	0.0076
good bit of the time	-0.1035	0.0092
most of the time	-0.1521	0.0102
all the time	-0.1761	0.0116
Baseline EQ5D score	0.6566	0.0118
Interaction falls-time	-0.0002	0.0005
Interaction fractures-time	-0.0045	0.0009

Table A2: Utility model based on the Hip Protector Trial, from Iglesias et al (2009)[2]

The model demonstrated that along with the baseline EQ5D score, a patient's fear of falling had the biggest impact upon their utility score over time. The baseline mean age in the Hip Protector was 78 years, compared to 83 years in the HIP-HOP study, and the mean utility at baseline in the Hip Protector trial was 0.63. Using these figures we used the age parameter in Table A2 to estimate the mean expected utility score for patients aged 83. We then estimated relative risks for utility scores for patients who had experienced a fall or a fracture, with varying degrees of fear about falls. These are shown in the table below.

Fall Type	Utility score relative risk	Utility score used in economic model	Assumption
No fall	1.00	0.38	Estimated this utility score direct from HIP-HOP data. This is used as the base

			relative risk.
Fall – No injury	0.95	0.36	Assume that a fall with no injury leads to the fall decrement and the decrement associated with a little of the time fear of fall.
Fall – Minor injury	0.89	0.34	Assume that a minor fall leads to the fall decrement and the decrement associated with a some of the time fear of fall
Fall – Moderate injury	0.83	0.32	Assume that a moderate fall leads to the fall decrement and the decrement associated with a good bit of the time fear of fall
Fall – Major injury	0.71	0.27	Assume that a major fall leads to the fracture decrement and the decrement associated with an all of the time fear of fall

Table A3: Utility score multipliers

Appendix 14: Resource use and costs post discharge – parameter values and justifications

Resource Use (per 3 months)	Value				
	No Fall	Fall – No injury	Fall – Minor injury	Fall – Moderate injury	Fall – Major injury
Number of GP consultations if live in own home	1.57	1.57	1.57	1.75	1.93
Number of GP consultations if live in nursing/residential home	0.50	0.50	0.50	0.56	0.62
Justification: Value for No Fall was taken from the trial, and due to very low event and patient numbers for all fall types at 3 month follow-up we assumed that falls that did not cause injury, or caused only minor injury, did not impact upon the number of GP consultations. For moderate and major falls a relative risk was applied using the Iglesias et al (2009) paper.[2] Iglesias et al (2009) present 12 month data that showed that 85% of patients in the Vitamin D3 trial (in which the average age was 77 years, and data were available at 12 months from 237 fallers who did not sustain a fracture, and 62 fallers who sustained a fracture) who had a fall visited the GP in the 12 months following their fall, and those who did consult the GP on average 4 times. 84% of patients who had a fall and sustained a fracture consulted the GP an average of 5 times. Using these figures a relative risk of 1.23 between fall only and fall with fracture can be obtained. We used this RR, using fall with no fracture as a proxy for a minor fall, and fall with a fracture as a proxy for a major fall. For moderate falls, we 'halved' the RR, to 1.12. *We used the same approach for GP consultations for patients living in a residential or nursing home – data for no fall was taken from the trial, fall with no injury or minor injury were assumed to equal this, and RRs based upon Iglesias et al (2009) were applied for moderate and major falls.*					
Number of hospital readmissions if live in own home	0.45	0.45	0.45	0.54	0.64
Number of hospital readmissions if live in nursing/residential home	0.44	0.44	0.44	0.53	0.63
Justification: Value for No Fall was taken from the trial, and due to very low event and patient numbers for all fall types at 3 month follow-up we assumed that falls that did not cause injury, or caused only minor injury, did not impact upon the number of hospital readmissions. For moderate and major falls a relative risk was applied using the Iglesias et al (2009) paper.[2] Iglesias et al (2009) present 12 month data that showed that 23% of patients who had a fall were re-admitted to hospital in the 12 months following their fall. 33% of patients who had a fall and sustained a fracture were re-admitted. Using these figures a relative risk of 1.43 between fall only and fall with fracture can be obtained. We used this RR, using fall with no fracture as a proxy for a minor fall, and fall with a fracture as a proxy for a major fall. For moderate falls, we 'halved' the RR, to 1.22. Based on the 3-month follow-up HIP-HOP trial data, we estimated that those who were re-admitted spent 23.69 days in hospital – this figure was not adjusted for different initial fall types as data were too sparse. *We used the same approach for re-admissions for patients living in a residential or nursing home – data for no fall was taken from the trial, fall with no injury or minor injury were assumed to equal this, and RRs based upon Iglesias et al (2009) were applied for moderate and major falls.*					
Number of outpatient appointments if live in own home	1.32	1.32	1.32	1.63	1.94
Number of outpatient appointments if live in nursing/residential home	0.51	0.51	0.51	0.64	0.76

Justification: Value for No Fall was taken from the trial, and due to very low event and patient numbers for all fall types at 3 month follow-up we assumed that falls that did not cause injury, or caused only minor injury, did not impact upon the number of outpatient appointments. For moderate and major falls a relative risk was applied using the Iglesias et al (2009) paper.[2] Iglesias et al (2009) present 12 month data that showed that 53% of patients who had a fall had an outpatient appointment in the 12 months following their fall, and of those that did have such an appointment, the average number of appointments was 3. 78% of patients who had a fall and sustained a fracture had an average of 3 outpatient appointments. Using these figures a relative risk of 1.47 between fall only and fall with fracture can be obtained. We used this RR, using fall with no fracture as a proxy for a minor fall, and fall with a fracture as a proxy for a major fall. For moderate falls, we 'halved' the RR, to 1.24. *We used the same approach outpatient appointments for patients living in a residential or nursing home – data for no fall was taken from the trial, fall with no injury or minor injury were assumed to equal this, and RRs based upon Iglesias et al (2009) were applied for moderate and major falls.*					
Number of community nurse visits if live in own home	13.70	13.70	13.70	33.79	53.88
Number of community nurse visits if live in nursing/residential home	8.56	8.56	8.56	21.11	33.66
Justification: Value for No Fall was taken from the trial, and due to very low event and patient numbers for all fall types at 3 month follow-up we assumed that falls that did not cause injury, or caused only minor injury, did not impact upon the number of nurse visits. For moderate and major falls a relative risk was applied using the Iglesias et al (2009) paper.[2] Iglesias et al (2009) present 12 month data that showed that 11% of patients who had a fall had help at home in the 12 months following their fall, and of those that did have such help, the average number of help sessions was 2.8 per week. 29% of patients who had a fall and sustained a fracture had an average of 4.2 help sessions per week. Using these figures a relative risk of 3.93 between fall only and fall with fracture can be obtained. We used this RR, using fall with no fracture as a proxy for a minor fall, and fall with a fracture as a proxy for a major fall. For moderate falls, we 'halved' the RR, to 2.466. *We used the same approach for patients living in a residential or nursing home – data for no fall was taken from the trial, fall with no injury or minor injury were assumed to equal this, and RRs based upon Iglesias et al (2009) were applied for moderate and major falls.*					

Table A4: Post-Discharge health care resource use

Resource Use Costs	Value

	No Fall	Fall – No injury	Fall – Minor injury	Fall – Moderate injury	Fall – Major injury
GP consultations if live in own home	£278.67	£187.49	£187.49	£209.55	£231.61
GP consultations if live in nursing/residential home	£193.24	£102.07	£102.07	£114.08	£114.08
Justification: GP unit costs are estimated to be £36 per consultation, taken from PSSRU.[7] Where applicable, these are discounted by 3.5% for future years.					
Hospital readmissions if live in own home	£33,172	£22,319	£22,319	£27,171	£32,023
Hospital readmissions if live in nursing/residential home	£32,819	£21,967	£21,967	£26,742	£31,517
Justification: The cost per day associated with a readmission was estimated to be £635 per day, estimated using weighted DH Ref Costs for Trusts, 2009/10 (elective and non-elective inpatients, long stay (greater than 1 day).[6] Where applicable, these are discounted by 3.5% for future years.					
Outpatient appointments if live in own home	£610.92	£411.04	£411.04	£507.99	£604.93
Outpatient appointments if live in nursing/residential home	£442.92	£243.05	£243.05	£300.37	£357.69
Justification: The cost per outpatient appointment was estimated to be £93.58 per appointment, estimated using weighted DH Ref Costs for Trusts, 2009/10 (all follow-up outpatient apts).[6] Where applicable, these are discounted by 3.5% for future years.					
Community nurse visits if live in own home	£1,828	£1,230	£1,230	£3,033	£4,837
Community nurse visits if live in nursing/residential home	£1,519	£921	£921	£2,272	£3622
Justification: The cost per community nurse visit was estimated to be £27.00 per visit, based on PSSRU unit costs.[7] Where applicable, these are discounted by 3.5% for future years.					

Table A5: Post-Discharge total costs of health care resource use