An exploration of the use of devices for the prevention of heel pressure ulcers in secondary care: A realist evaluation

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Intellectual property and publication statements

The candidate confirms that the work submitted is her own, except work which has formed part of jointly authored publications. The contribution of the candidate and the supervisors to this work has been explicitly indicated below. The candidate confirms that appropriate credit has been given within the thesis where reference has been made to the work of others.

Chapter 3

GREENWOOD, C. E., NELSON, E. A., NIXON, J. & MCGINNIS, E. 2014. Pressure-relieving devices for preventing heel pressure ulcers. *The Cochrane Library*. (Withdrawn 2017 https://doi.org/10.1002/14651858.CD011013.pub2)

GREENWOOD, C., NIXON, J., NELSON, E. & MCGINNIS, E. 2019. Comparative effectiveness of medical devices for the prevention of heel pressure ulcers: a systematic review CRD42019152949. *PROSPERO: International prospective register of systematic reviews* [Online].

GREENWOOD, C. E., NELSON, E. A., NIXON, J., VARGAS-PALACIOSM, A., & MCGINNIS, E. 2020 Comparative effectiveness of heel-specific medical devices for the prevention of heel pressure ulcers: a systematic review. *Submitted to BMC Systematic Reviews*

My own contributions, fully and explicitly indicated in the thesis, have been conception of the systematic review, lead on protocol development, wrote the protocol, developed the search strategy, screened the studies from the list of titles and abstracts, assessed each study for inclusion according to the selection criteria, produced the data extraction form, data extraction, contacted manufacturers and experts in the field, and authors of retrieved studies for details of study data specific to heel pressure ulcers and missing data, identification of the included study, analysis including the assessment of bias, wrote the review and is the guarantor of the review.

All co-authors contributed by proof reading and approving the protocol and review and collaborating on the development of the search strategy. Dr Elizabeth McGinnis additionally contributed as second reviewer in line with good research practice in the screening of the studies from the list of titles and abstracts, the assessment of each study for inclusion according to the selection criteria, data extraction and assessment of risk of bias.

The Cochrane Wounds Group staff also contributed to the development of the search strategy. The strategy was run and updated by a member of the Cochrane Wounds Group.

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Abstract

Background

The heel is a particularly high risk and problematic area for pressure ulcers (PU) to develop. The effectiveness of devices and the factors that lead to their use for the prevention of heel PUs is poorly understood.

Aims

1. To assess the effectiveness of devices used for the prevention of heel PUs.
2. Explore what factors influence the implementation, and how heel-specific devices are used (or not used) in secondary care.

Methods

To address aim 1: Systematic review of the evidence of effectiveness for devices in the prevention of heel PU.

Aim 2: Realist evaluation, including Phase 1 - theory elicitation through stakeholder interviews with Tissue Viability Nurse Specialists (TVNS) from across the UK and Phase 2 - testing theories using ethnography in three orthopaedic wards in the North of England.

Results

Systematic review: identified 29 trials with fifteen comparisons and eight meta-analyses conducted. Offloading devices were found to be effective in prevention of ≥Category 1 and ≥Category 2 heel PUs when compared to standard care, but this is based on low to moderate quality evidence and intervention compliance was found to be an issue.

Realist evaluation Phase 1: Interviews with eight TVNS elicited thirteen candidate theories into three programme theories, regarding the proactive and reactive use of offloading devices, along with patient factors that influenced their use.

Phase 2: Ethnography found that heel-specific devices are used in practice. Leadership, protocols, identification of high-risk patient groups and access to devices influenced staff knowledge but did not necessarily increase device use.

Conclusion

Exploring the perceptions and realities of how offloading and heel-specific devices are used in practice can not only influence their use, but also inform how future device trials are designed and conducted to improve protocol compliance and reduce withdrawals and attritions.

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Abbreviations

AP	Alternating pressure	NPIAP	National Pressure Injury Advisory Panel
ABPI	Ankle brachial pressure index	NHS	National Health Service
C	Context	O	Outcome
CI	Confidence interval	PAD	Peripheral arterial disease
CLP	Constant low pressure	PPPIA	Pan Pacific Pressure Injury Alliance
CMO	Context mechanism outcome	PU	Pressure ulcer
EPUAP	European Pressure Ulcer Advisory Panel	PVD	Peripheral vascular disease
HCA	Health Care Assistant	QN	Qualified Nurse
HSF	High specification foam	RCA	Root cause analysis
ITT	Intention to treat	RR	Relative Risk
M	Mechanism	RCT	Randomised controlled trial
MDT	Multi-disciplinary team	SMD	Standard mean difference
MRI	Magnetic resonance imaging	TVNS	Tissue Viability Nurse Specialist

Chapter 1 Background

1.1 Introduction

This chapter describes what pressure ulcers are, how they develop, why they are a problem and the extent of the problem. It then goes on to describe the anatomy and physiology of the heel and why the heel is a particularly high risk and problematic area for pressure ulcers to develop. It will finally discuss who is at risk of developing a heel pressure ulcer, especially amongst patients being cared for in an acute care environment. Methods that can be used to reduce heel pressure ulcer risk will be discussed in the following chapter.

1.2 What are pressure ulcers?

is presented in Table 1-1. In 2009 two additional categories were defined; 'unstageable/unclassified' and 'suspected deep tissue injury' (EPUAP et al., 2019), initially for use in the US, but more recently implemented across England (NHS Improvement, 2018). As pressure ulcers are categorised according to depth of the wound, these categories are used when the depth of the wound is unknown. Unstageable describes wounds in which slough or necrosis (loose or dead tissue) obscures the wound bed. 'Suspected deep tissue injury' describes wounds in which it is suspected that there is deeper damage, such as when bruising or a blood blister is present (Table 1-1).

1.3 Why are pressure ulcers a problem?

Pressure ulcers are globally a significant problem that have the potential to affect any person with reduced mobility, in a wide range of care settings. Pressure ulcers have been found to have a massive impact upon health-related quality of life; their presence and treatment have been found to affect people's lives emotionally, mentally, physically, and socially (Gorecki et al., 2009, Spilsbury et al., 2007). Health related quality of life is a multidimensional concept which describes the physical, role functioning, social, and psychological aspects of well-being and functioning related to disease and health (de Wit and Hajos, 2013). It is something that differs between individuals and is therefore both objective and subjective. Along with affecting quality of life, pressure ulcers can be painful (Briggs et al., 2013, McGinnis et al., 2014a) and can cause infections such as osteomyelitis, cellulitis and sepsis which can lead to renal

failure, myocardial infarction, multiple organ failure, amputation and can be fatal (Black, 2004, Fowler et al., 2008, Gorecki et al., 2009).

Pressure ulcers also have a massive financial burden, with estimated mean costs of treating a pressure ulcer varying from £1,214 (Category 1) to £14,108 (Category 4) (Dealey et al., 2012b) and the estimated total cost in the UK is £1.4 to £2.1 billion annually (4% of total NHS expenditure) (Bennett et al., 2004). The latter study created a costing model based on data from prevalence and incidence studies in acute and long-term care. Costs for community nursing following discharge from hospitals were not considered which, along with inflation, means the true costs could be higher. A more recent estimate of the annual costs in the United States is USD 9.1 to 11.6 billion (Berlowitz et al., 2011). Most costs are due to nursing time, and more severe pressure ulcers have higher costs that relate to complication rates (e.g., infections or longer hospital stay) and litigation.

1.3.1 What is the extent of the problem?

There are several different methods through which pressure ulcer frequency have been reported; predominantly through prevalence, incidence and facility acquired rates.

Prevalence reports the proportion of individuals with a pressure ulcer within a defined population (e.g., within a ward, hospital, or geographical region). This can be measured as either a point prevalence which is a specific point in time (usually on a specific day), or a period prevalence which is over a specified period (usually days or weeks). Prevalence data therefore provides an indication of the extent of pressure ulcers within a given population (Baharestani et al., 2009, Berlowitz, 2012).

Incidence relates to the proportion of individuals who develop a new pressure ulcer within a population. Cumulative incidence refers to the proportion of a population that develops a new pressure ulcer over a specified time period (usually weeks or months) (Baharestani et al., 2009, Berlowitz, 2012). One of the problems with incidence reporting is that patients with existing pressure ulcers may or may not be excluded.

Facility acquired pressure ulcer rates measure incidence within that facility (also referred to as hospital acquired, nosocomial or healthcare acquired) at a specific point in time. However, this requires accurate documentation of skin assessments on admission to the facility in order to exclude pre-existing pressure ulcers (EPUAP et al., 2019). If reported accurately, these provide the best estimate of the adequacy of pressure ulcer preventative care within a facility.

Table 1-1 Pressure ulcer classification system (EPUAP et al., 2019)

Category	Description
Category I (1): Non blanching erythema	Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its colour may differ from the surrounding area. The area may be painful, firm, soft, warmer, or cooler as compared to adjacent tissue. Category I may be difficult to detect in individuals with dark skin tones. May indicate "at risk" persons.
Category II (2): Partial thickness skin loss	Partial thickness loss of dermis presenting as a shallow open ulcer with a red, pink wound bed, without slough. May also present as an intact or open/ruptured serum-filled or serosanguinous filled blister. Presents as a shiny or dry shallow ulcer without slough or bruising*. This category should not be used to describe skin tears, tape burns, incontinence associated dermatitis, maceration, or excoriation. *Bruising indicates deep tissue injury.
Category III (3): Full thickness skin loss	Full thickness tissue loss. Subcutaneous fat may be visible, but bone, tendon or muscle are not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunnelling. The depth varies by anatomical location. The bridge of the nose, ear, occiput, and malleolus do not have subcutaneous (adipose) tissue and can therefore be shallow. In contrast, areas of significant adiposity can develop extremely deep Category III pressure ulcers. Bone/tendon is not visible or directly palpable
Category IV (4): Full thickness tissue loss	Full thickness tissue loss with exposed bone, tendon, or muscle. Slough or eschar may be present. Often includes undermining and tunnelling. The depth of a Category IV pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput, and malleolus do not have subcutaneous (adipose) tissue and these ulcers can be shallow. Category/Stage IV ulcers can extend into muscle and/or supporting structures (e.g., fascia, tendon, or joint capsule) making osteomyelitis or osteitis likely to occur. Exposed bone/muscle is visible or directly palpable.
Unstageable/ Unclassified: Full thickness skin or tissue loss – depth unknown	Full thickness tissue loss in which actual depth of the ulcer is completely obscured by slough (yellow, tan, grey, green, or brown) and/or eschar (tan, brown or black) in the wound bed. Until enough slough and/or eschar are removed to expose the base of the wound, the true depth cannot be determined; but it will be either a Category/Stage III or IV. Stable (dry, adherent, intact without erythema or fluctuance) eschar on the heels serves as "the body's natural (biological) cover" and should not be removed.
Suspected deep tissue injury: Depth unknown	Purple or maroon localized area of discoloured intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer, or cooler as compared to adjacent tissue. Deep tissue injury may be difficult to detect in individuals with dark skin tones. Evolution may include a thin blister over a dark wound bed. The wound may further evolve and become covered by thin eschar. Evolution may be rapid exposing additional layers of tissue even with optimal treatment.

Reported prevalence rates can differ massively depending on the methodological design, settings, and rigor; from 0% to 54%. These two figures come from small studies; the 0% prevalence was in a single acute care unit following the implementation of a pressure ulcer prevention programme (Hiser et al., 2006), whilst the 54% prevalence was in a single urban acute care setting that had no structured risk assessment process (Moore et al., 2015b).

Some prevalence studies have been conducted as a survey or questionnaire which allows for a larger sample size (up to 85,838 participants) across a wider geographical area (VanGilder et al., 2008), but might not be as accurate as there is a reliance on the ability of the person completing the survey (Barrois et al., 2008, VanGilder et al., 2008). Other prevalence studies have an inclusion and exclusion criteria or require informed consent so do not include the whole patient population. As demonstrated, due to the variability in methods used, results of prevalence studies are not always comparable, but they can be used to demonstrate the significance of pressure ulcers as a worldwide healthcare problem; of the prevalence studies presented in Table 1-2, the median prevalence is 13.5% (range 7.8-54%), although this is a subset of the evidence on prevalence, based upon studies that reported individual body sites. Most prevalence studies concentrate on acute or long-term care (e.g., care homes) populations.

Pressure ulcer prevention is part of the national patient safety agenda, with several different monitoring systems being introduced including reporting monthly prevalence through the NHS Safety Thermometer, incident reporting systems and the Strategic Executive Information System (StEIS) for reporting Serious Incidents. Use of these systems is inconsistent between organisations in the UK, along with a variance in pressure ulcer classification systems being used, different methods of investigating how severe (Category 3, 4 and unstageable) pressure ulcers develop and if they were caused by lapses in care, means results are not comparable between organisations (Dealey et al., 2012a, Smith et al., 2016), therefore the true extent of the pressure ulcer problem between different healthcare settings and organisations remains uncertain.

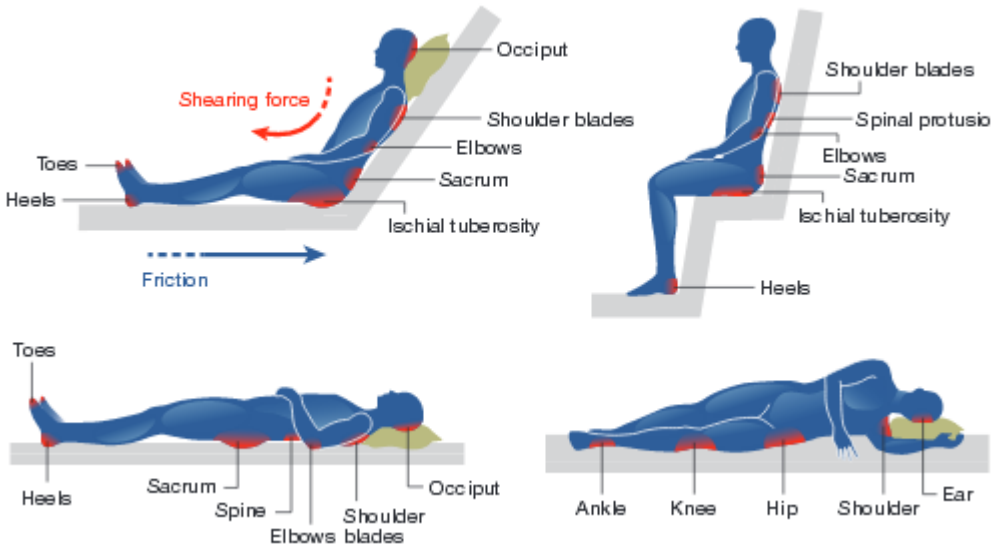
1.4 How do pressure ulcers develop?

Pressure ulcers are primarily caused when sustained pressure (including pressure associated with shearing forces) is applied to soft tissue, generally over a bony prominence (EPUAP et al., 2019). The most common locations for a pressure ulcer to develop are illustrated in Figure 1-1.

Pressure is a continuous physical force exerted on or against an object by something in contact with it. Shearing is when unaligned forces move in opposite directions, but

shear forces cannot exist in the absence of pressure. Shearing forces cause tissue damage when the skeleton and deep fascia slide downwards with gravity whilst the skin stays in contact with the surface, for example when a patient is in a semi-recumbent position in bed (Figure 1-1).

Figure 1-1 Common body sites for pressure ulcers to develop (Wounds UK, 2012)



There are several different theories with regards to how pressure and shearing forces affect the soft tissues and lead to pressure ulceration. Pressure ulcer conceptual frameworks attempt to address this through creating theoretical models of the critical determinants of pressure ulcer development (Coleman et al., 2014).

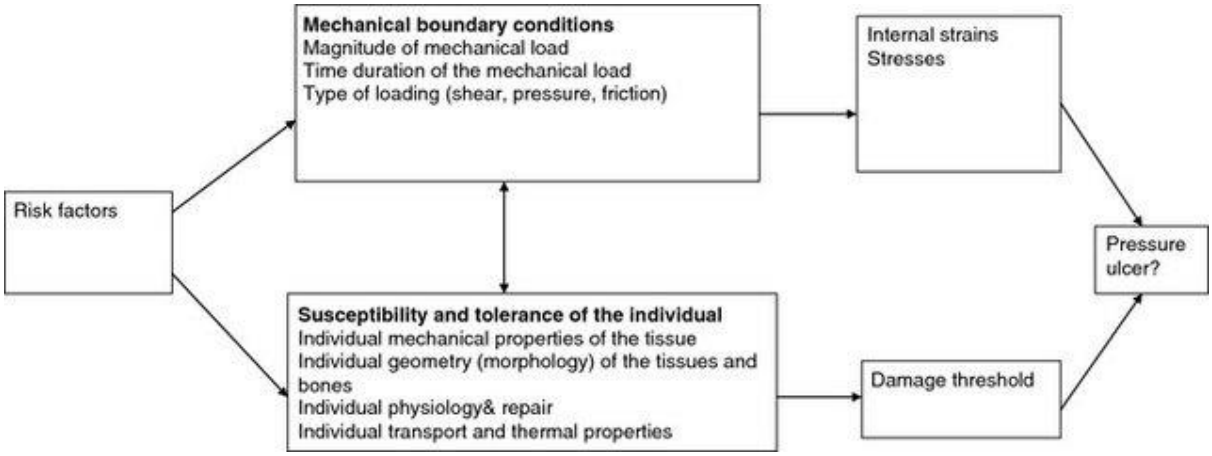
It is well established that the magnitude and duration of pressure are causal factors for pressure ulceration, but the relative contribution of magnitude and duration of pressure in the development of pressure ulcers is difficult to determine (Figure 1-2). However Defloor (1999) proposes that when sufficient shearing forces are present, half the pressure can lead to vascular occlusion. The tolerance of soft tissues to the effects of pressure had previously been thought to be an important variable in pressure ulcer development (Braden and Bergstrom, 1987, Defloor, 1999). More recently immobility, skin and pressure ulcer status, and perfusion have been identified as direct causal factors (Coleman et al., 2014).

Table 1-2 Prevalence studies since 2000 that also reported heel pressure ulcer prevalence

Author	Country	Setting	Year(s) prevalence took place	Total number of participants	Overall PU ulcer prevalence	Proportion of PUs on the heel (% of total PU population)
Amir et al. (2017)	Indonesia	Acute	Not reported	1,132	91 (8.0%)	16.9%
Barrois et al. (2008)	France	Acute	October 2004	37,307	3314 (8.9%)	46%
Davis and Caseby (2001)	Canada	Long term care	Not reported	187	84 (44.9%)	29%
Gunningberg et al. (2011)	Sweden	Acute	September 2009	1,192	14.9%	37%
Gunningberg et al. (2013)	Sweden	Acute	March 2011	16,466	2737 (16.6%)	29.7%
Gunningberg et al. (2013)	Sweden	Nursing homes	March 2011	18,592	2693 (15.5%)	32.4%
Jenkins and O'Neal (2010)	USA	Acute	4 surveys conducted quarterly in 2009	310	49 (15.8%)	26%
McGinnis and Stubbs (2014)	UK	Acute	5 surveys between 2006 and 2010			Range 19-26%
Mehta et al. (2015)	India	Acute	31st August 2013	258	28 (7.8%)	21.4%
Moore et al. (2015a)	Norway	Acute	Not reported	59	32 (54%)	10%
Moore et al. (2015b)	Ireland	Acute	Not reported	121	14 (12%)	29%
Stevenson et al. (2013)	UK	Community	2010	1782	185 (10.4%)	25.9%
Tubaishat et al. (2011)	Jordan	Acute	Not reported	302	36 (12%)	25%
Tubaishat and Aljezawi (2013)	Jordan	Acute	Not reported	295	48 (16%)	49%
VanGilder et al. (2008)	USA, Canada, Saudi Arabia, Australia	Acute & Long-term care	Using just 2005 survey data	85,838	3176 (15.2%)	23.6%
Vanderwee et al. (2011)	Belgium	Acute	April 2008	19,968	2419 (12.1%)	38.4%

There have been multiple laboratory and animal studies investigating the potential aetiological mechanisms by which stress and internal strain within the tissues lead to pressure ulcer development. These include lack of blood supply (ischaemia), tissue deformation, impaired interstitial flow, impaired lymphatic drainage, and reperfusion injury (Bouten et al., 2003, Coleman et al., 2014).

Figure 1-2 Factors that influence the susceptibility of an individual for developing pressure ulcers taken from NPUAP and EPUAP (2009), adapted by Coleman et al. (2014)



1.4.1 Tissue deformation

One of the more recent developments in our knowledge about mechanical forces and response of the body is in respect of tissue deformation. It is thought that pressure leading to reduced circulation reduces viability of muscle tissue over longer periods, whereas shear strains leading to cell deformation had a more immediate effect (Gawlitta et al., 2007b, Bader and Hawken, 1986). Without ischaemia, deformation causes cell membranes to rupture, damaging muscle tissue. Due to its stiffness, skin has been found to deform to a lesser degree than fat and skeletal muscle, with skeletal muscle the most susceptible to both deformation and ischaemia (EPUAP et al., 2019, Gawlitta et al., 2007a, Gawlitta et al., 2007b). The direct cause of the deformation damage remains unclear, but theories include direct rupture of the cytoskeleton, stretching of the plasma membrane or other factors leading to cell death (Breuls et al., 2003, Ceelen et al., 2008, Stekelenburg et al., 2007).

1.4.2 Ischaemia

Ischaemia occurs when there is a restriction in blood supply to tissues, causing a shortage of oxygen. Ischaemia has traditionally been viewed as the predominant aetiological factor for pressure ulcer development (Gawlitta et al., 2007b) Applying

pressure to a tissue that is higher than capillary pressure slows down flow in the capillaries and lymph nodes, resulting in an insufficient oxygen and nutrient supply, and reduced removal of metabolic waste, eventually leading to tissue damage (Defloor, 1999).

When there is an acute reduction in the circulating volume of blood, subcutaneous tissue is one of the first tissues in which vasoconstriction (muscular narrowing of blood vessels) occurs, and the last to regain normal perfusion once the circulating volume has been restored (Gottrup et al., 1987).

It has been theorised that following a period of prolonged ischaemia, once the tissue becomes re-perfused harmful oxygen free radicals can be released, causing a cytotoxic effect on the tissue, and exacerbating the existing damage (EPUAP et al., 2019, Jiang et al., 2011, Peirce et al., 2000). A number of different studies have looked at the magnitude and duration of pressure in animal models, finding an increase in tissue damage with an increasing number of total ischemia-reperfusion cycles (pressure being cyclically being applied and removed), duration of ischemia, and frequency of ischemia-reperfusion cycles (Tsuji et al., 2005, Peirce et al., 2000).

1.4.3 Impaired interstitial flow

The interstitial space surrounds tissue cells contain interstitial fluid, which is essential for healthy tissue homeostasis through the movement of nutrients and waste products across the cell barrier. Mechanical loading of muscle tissue has been found to hinder diffusion of nutrients, waste products and hormones that regulate muscle metabolism (Gefen et al., 2008), with the plasma membrane becoming more permeable when it is highly stretched (Slomka and Gefen, 2012).

1.4.4 Impaired lymphatic drainage

Occlusion of lymph vessels in soft tissues caused by external loading is associated with an accumulation of waste products, an increase in interstitial fluid, inflammation, fibrosis, and localised cell death contributing to pressure ulcer development (Gray et al., 2016, Reddy et al., 1981).

1.4.5 Microclimate

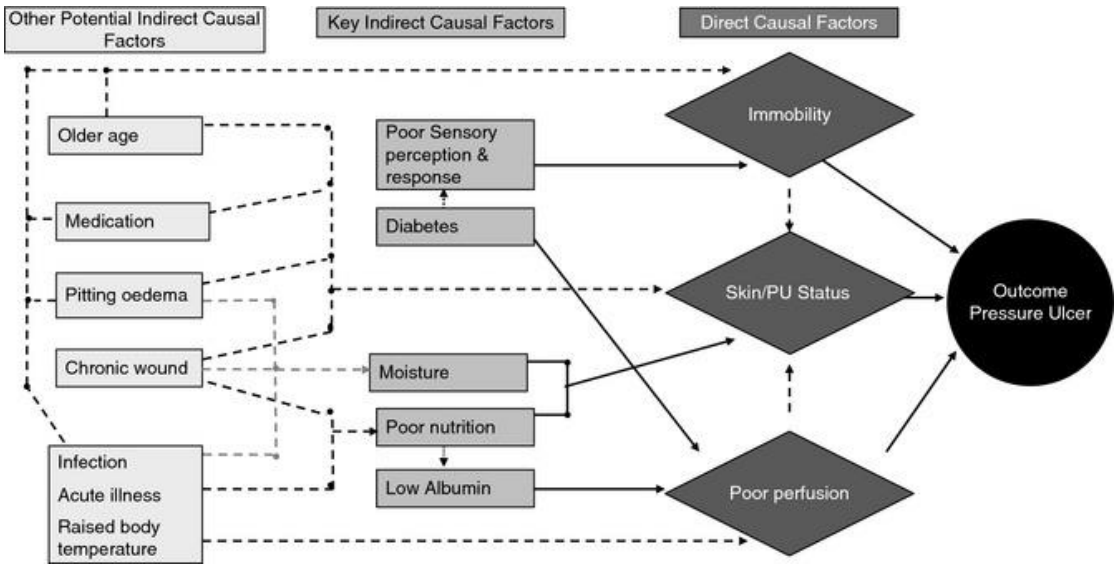
Microclimate refers to the temperature and humidity of the skin, especially between the skin and covering surfaces. As temperature and humidity increases, the skin becomes weaker and less stiff, whilst excessively dry skin becomes more brittle and liable to break. There is an increasing body of evidence to suggest that microclimate plays a

role in the development of superficial (Category 1 or 2) pressure ulcers (Gefen, 2011), but the characteristics and extent to which microclimate plays a role remains a matter of debate and ongoing research (EPUAP et al., 2014).

1.5 Conceptual framework

Although there have been a number of different conceptual frameworks for pressure ulcer development, Coleman et al. (2014) is the only to link evidence from a systematic review of epidemiological evidence and a consensus study including international clinical and bioengineering experts group meeting, therefore making it the most evidence based and up to date. It was used to explore the causal factors for pressure ulcer development and created into a theoretical causal pathway highlighting direct, key indirect and other potential indirect causal factors (Figure 1-3).

Figure 1-3 Theoretical schema of proposed causal pathway for pressure ulcer development (Coleman et al., 2014)



1.5.1 Direct causal factors

The risk factors for pressure ulcer development that were identified during a systematic review by Coleman et al. (2013), and which have been subsequently updated as part of the international guidelines (EPUAP et al., 2019), will be presented here.

1.5.1.1 Immobility

As previously discussed, pressure ulcers develop following sustained pressure, or pressure associated with shear. It is therefore logical to assume that having limited mobility will have a direct impact upon an individual's exposure to pressure and shear. However, not all immobile patients develop a pressure ulcer, therefore it is likely that

immobility in combination with other causal factors leads to a pressure ulcer developing.

1.5.1.2 Skin/pressure ulcer status

The presence of Category 1 pressure ulcers have been found to increase the probability of Category 2 pressure ulcer development by two to three times (Nixon et al., 2006a, Reed et al., 2003). General skin status is an important consideration because it is likely that the physiology, transport properties and ability of the skin to repair can become impaired (Coleman et al., 2013, EPUAP et al., 2014, EPUAP et al., 2019).

1.5.1.3 Poor perfusion

Factors that impair circulation, thus altering the perfusion and oxygenation of tissues increase the probability of pressure ulcer development. As can be seen in Figure 1-3 there are several indirect causal factors that influence perfusion such as diabetes, infection, and albumin. Other examples of conditions that can affect perfusion that were identified in the systematic review include cardiac disease, peripheral vascular disease (PVD), renal disease, cerebral vascular attack, inotropes, cigarette smoking and blood pressure (Coleman et al., 2014, EPUAP et al., 2019).

1.5.2 Indirect causal factors

As illustrated in Figure 1-3, indirect causal factors change the direct causal factors affecting the impact on the outcome or likelihood of pressure ulcer occurrence. These include nutritional deficit, skin moisture, temperature, advanced age, sensory perception, medication, and general health status including acute illness.

1.6 Why are heel pressure ulcers important?

The heel is the second most common site for pressure ulcers to develop, after the sacrum, accounting for between 10-49% of all pressure ulcers (Table 1-2). Along with being a common site for pressure ulcers to develop, the most severe pressure ulcers often develop to the heel (Clark et al., 2004).

Heel pressure ulcers can lead to pain, reduced mobility, and in extreme cases can result in a major amputation (Fowler et al., 2008). A study of heel pressure ulcer healing saw that only 42% of Category 2 or more severe heel ulcers healed over an 18 month period, with a median time to healing of 121 days (range 8–440) (McGinnis et al., 2014b). This section will go on to discuss how the anatomy of the heel makes it

high risk for pressure ulcers to develop and why they need to be managed differently to other body sites.

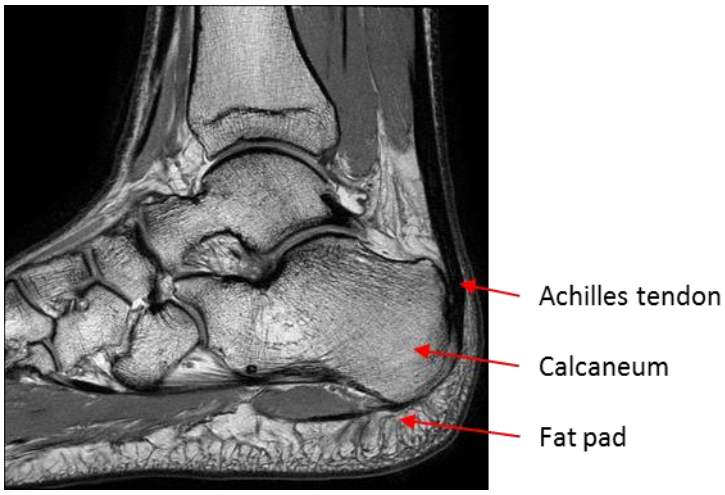
1.6.1 Anatomy and physiology of the heel

The heel is defined as the posterior aspect of the foot that covers the calcaneal tuberosity. The plantar aspect of the heel has a thickened dermis with the superficial fascia bound to the deep fascia, with fat contained in the interstices to create a large, tough but elastic fat pad (Figure 1-4), which is well adapted to absorb shock, pressure, and shear from the skeletal system during standing and locomotion.

In contrast the posterior heel has a smaller surface area, thin subcutaneous tissue volume, and no muscle (approximately 3.8mm between the skin and bone), providing little cushioning over the calcaneal tuberosity. The skin to the posterior heel is tightly bound to the underlying deep fascia and fibres of the Achilles tendon.

The Achilles tendon (also known as the calcaneal tendon) is the largest and strongest tendon in the body that connects the gastrocnemius and soleus muscles (calf muscles) to the calcaneum. Despite its strength, the Achilles tendon has a poor vascular supply, which along with the high tensions placed on it leaves it susceptible to injury.

Figure 1-4 MRI of the heel, adapted from radiopaedia.org



1.6.2 Who is at risk of developing a heel ulcer?

Due to the anatomy of the heel, there are clinical situations that make the heel an area more susceptible than other body sites to the effects of pressure and/or shear. Linking to the conceptual framework and causal factors discussed in 1.5, the risk factors and hypothesised mechanisms for heel pressure ulcer development are as follows:

1.6.2.1 Immobility

The small surface area and lack of muscle to cushion and distribute pressure to the posterior heel, leads to higher pressures being exerted directly over the bone when a person is in a supine position, semi-recumbent position or seated with the heels in direct contact with a foot stool (Tong et al., 2016). A person with reduced mobility might spend longer periods in a recumbent position in bed, where the foot tends to externally rotate (abduct) so pressure is going through the lateral posterior aspect of the heel where the surface of the calcaneus is irregular, and the covering fat pad is thinner (Tenenbaum et al., 2013). A computer modelling study has demonstrated that during bed rest an abducted foot posture leads to a greater load through the tissues (Sopher et al., 2011) along with skin strains (Tenenbaum et al., 2013), although Tong et al. (2016) found higher interface pressures in elderly participants when the foot was in an upright position.

Immobility can affect the heel in specific ways as there are conditions that can immobilise the lower limb, but not the rest of the body. A large proportion of the surgical patient population, where long periods of immobility alongside decreased sensation related to analgesia and anaesthesia increases pressure ulcer risk (Lindgren et al., 2005, Edwards et al., 2006).

Shear forces are a common problem in the acute and long-term care population due to poor positioning in beds or chairs, which can lead to the patient sliding downwards. Shear forces are also exerted when patients use their heel as a pivot point to reposition themselves. Friction can also cause an increased risk in heel pressure ulceration during poorly conducted moving and handling of patients, or when patients are agitated or have tremors that can lead to their heels rubbing against bed sheets. Patients that spend extended periods in bed can also have higher loads going through the heel due to the weight of blankets.

1.6.2.2 Poor perfusion

Conditions that reduce the circulation of the lower limb, such as peripheral arterial disease (PAD), increases the heels' susceptibility to ischaemia. In a study of heel pressure ulcer healing, 62% of all patients with a heel pressure ulcer had evidence of inadequate arterial blood supply to the lower limb (McGinnis et al., 2014b). In a smaller study 50% of patients with a heel pressure ulcer had evidence inadequate blood supply to the lower limb, of which 45% were considered to have a severe obstruction (Meaume and Faucher, 2007).

Circulatory conditions that reduce the blood flow to the lower limb such as PAD are commonly associated with older age. However, they can be present in younger people such as those with diabetes, hypertension, or smokers (Tendera et al., 2011).

During an acute illness, the sympathetic nervous system, and some medications (e.g., inotropes) preserve the body's organs, especially the heart and brain, through increasing the central circulating volume available to them, while decreasing the peripheral circulating volume. Making the feet and heels of patients in intensive care settings at risk of developing heel pressure ulcers (EPUAP et al., 2019, Coleman et al., 2014).

1.6.2.2.1 Diabetes

Diabetes is commonly associated with ulceration to the feet, primarily affecting the plantar aspect of the foot or the toes and tend to be caused by accidental trauma, especially from ill-fitting footwear (Jeffcoate and Harding, 2003, Macfarlane and Jeffcoate, 1997). Prolonged periods of hyperglycemia (high levels of glucose in the blood) can induce thickening and interlinking of collagen fibers in connective tissues, which in turn leads to progressive stiffening of the tissues (Gefen et al., 2001). Displacement of the soft tissues and atrophy can potentially lead to tissues that, along with being pathologically stiffer, could also be thinner over the calcaneus; thus decreasing the ability of the tissues to deform and spread the mechanical load transmitted from the bone (Gefen, 2010).

Peripheral neuropathy (reduced or altered ability to sense, in this case in the feet) is one of many complications of diabetes, resulting in significant morbidity and mortality (Callaghan et al., 2012). Although neuropathy is most common amongst diabetics, it is also associated with other conditions such as alcoholism, stroke, demyelinating diseases such as multiple sclerosis, and conditions such as Guillain-Barré syndrome, which can have quite a rapid onset (White et al., 2004). Peripheral neuropathy can lead to an increased risk of heel pressure ulcers, as individuals are unaware of pain and pressure, and so do not respond accordingly through repositioning the foot.

1.6.2.3 Skin Status

The presence of a pre-existing pressure ulcer, along with other conditions that affect structure and integrity of the skin increases the risk of an individual developing a heel pressure ulcer.

1.6.2.3.1 Oedema

Alongside reducing the blood flow to the lower limb, circulatory problems such as chronic venous disease and heart failure, can lead to an increase in pedal oedema

(swelling of the feet due to fluid accumulation), which impairs the delivery of oxygen and nutrients to the tissues, and also the disposal of metabolic waste products (Ryan and Byrne, 1989) along with a potential stiffening of tissues (Gefen, 2010). Oedema also increases the weight of the limb, which in turn, increases normal resting pressures.

1.6.2.3.2 Age related skin changes

A number of studies have found a significant association between pressure ulcer incidence and increasing age (Baumgarten et al., 2006, Nixon et al., 2006a, Perneger et al., 2002) and has been identified as an indirect causal factor (Coleman et al., 2013) (Figure 1-3).

With aging, the epidermis (outer layer of the skin) thins, is dry, dehydrated and lacks sebum (Tong et al., 2016). The strength and elasticity of connective tissues reduce, and blood vessels to the dermis also become more fragile (Defloor, 1999). The subcutaneous tissue thins which reduces the padding over bony prominences and can also reduce the shock absorbency capacity of the heel pad (Alcántara et al., 2002).

1.7 Summary

This chapter has presented what pressure ulcers are and how they develop and why they are a significant health care problem. Due to the unique anatomy of the heel and medical conditions such as PVD, PAD and diabetes the heel is an at-risk area for pressure ulcers to develop. However, acute illness can lead to a reduction in the peripheral circulation or a reduction in mobility levels which in turn increases the risk, making the acute care population at high risk.

There are various models that attempt to determine how the magnitude and duration of pressure affect the soft tissues and lead to pressure ulcer development, but factors affecting tissue tolerance are multi-factorial. Pressure ulcer prevention strategies therefore involve attempting to identify which patients are at risk of developing a pressure ulcer and implementing a plan of care that attempts to reduce the magnitude of pressure through the use of support surfaces and devices, and the duration of pressure through repositioning. These will be explored further in Chapter 2.

Chapter 2 Heel pressure ulcer prevention strategies

2.1 Introduction

This chapter provides a general overview of heel pressure ulcer prevention strategies including risk assessment, care planning and prevention strategies that address the direct and indirect causal factors discussed in Chapter 1. It will go on to demonstrate the number of different types of devices available for the prevention of heel pressure ulcers, along with the merits of each and recommendations based on international consensus. It will finally highlight the need for a systematic review of the evidence due to the wide range of device types available with different mechanisms of action along with the sparsity of good quality research.

2.2 How do we prevent pressure ulcers?

As illustrated in Chapter 1, pressure ulcers rarely occur due to a singular factor, therefore prevention strategies require an understanding of the different risk factors individual to each patient, and the implementation of a multifaceted plan of care.

Pressure ulcer prevention strategies in nursing tend to focus on identifying which patients will be at risk of developing a pressure ulcer, and for these patients implementing a plan of care aimed at modifying the direct and indirect causal factors identified in Figure 1-3. The primary focus is on factors that will affect the status of the skin along with decreasing the intensity and duration of pressure through increasing mobility and repositioning. The third direct causal factor is poor perfusion which nursing interventions alone will have little impact upon, but the focus should be on recognising this risk and modifying the other risk factors accordingly.

2.2.1 Recognising risk/risk assessment

Risk assessment is a central component of nursing practice aimed at identifying hazards and risk factors that have the potential to cause harm to vulnerable patients. It is a requirement that all patients being admitted to secondary or long term care provided by the NHS have a pressure ulcer risk assessment completed, (NICE, 2014b) to help identify at risk individuals and thereby target appropriate interventions. Pressure ulcer prevention interventions are not appropriate for all patients as they can be costly (e.g., medical devices), resource intensive (e.g., nursing time taken to reposition patients) and can impact upon quality of life for patients (e.g., frequent repositioning can disturb sleep).

There are numerous different risk assessment tools available, including Braden (Bergstrom et al., 1987), Norton (Norton et al., 1962), Waterlow (Waterlow, 2005) scales and more recently PURPOSE T (Coleman et al., 2018). There is insufficient evidence to state whether risk assessments have a better predictive capacity than clinical judgement alone (Diaz-Valenzuela et al., 2014). There is also very low certainty evidence regarding the effectiveness of risk assessment tools at reducing pressure ulcer incidence (Moore and Patton, 2019), they can be time consuming and provide false assurances of lack of risk. However, they can be advantageous as they can provide a structured framework, provide a clinical reminder which is beneficial for novice nurses and define relevant risk factors that are useful and measurable, allow for monitoring and audit, and should therefore be used in combination with clinical judgement (NICE, 2014b, EPUAP et al., 2019).

Risk assessments tend to assess the patients' risk, rather than identifying individual body sites, such as the heels. Table 2-1 explores which of the most used risk assessment tools identify risk factors specific to the heel explored in Chapter 1.

Table 2-1 Commonly used risk assessment tools and their ability to identify heel pressure ulcer risk factors

Heel ulcer risk factors	Braden	Norton	Waterlow	Purpose T
Perfusion	×	×	✓	✓
Skin status	×	×	✓	✓
Diabetes	×	×	✓	✓
Neuropathy	✓	×	✓	✓
Age	×	×	✓	×
Mobility	✓	✓	✓	✓

Regardless of which risk assessment is used, to be effective there is a requirement that the nurse understands, can interpret the results, and prescribe preventative interventions as deemed appropriate.

2.2.2 Care Planning

The concept of caring has long been a prominent aspect of the nursing role. A care plan is a written document designed to guide practice specific to each individual patients' needs. The Royal College of Nursing (2016) states the purpose of care planning is to:

- Ensure that the patient/client gets the same care regardless of which members of staff are on duty.
- Ensure that the care given is recorded.
- Support the patient/client to identify, manage and, hopefully, solve his or her problems.

If a patient has been identified as being at risk of developing a pressure ulcer, then it is recommended practice that they should have a preventative care plan initiated. There is no universal care plan used, but often each organisation will have their own template. A commonly used care plan bundle that is being adopted in a number of NHS hospitals is the SSKIN bundle (Gibbons et al., 2006), an acronym used to help nursing staff prescribe care:

Surface: make sure your patients have the right support

Skin inspection: early inspection means early detection - show patients and carers what to look for

Keep your patients moving

Incontinence/moisture: your patients need to be clean and dry

Nutrition/hydration: help patients have the right diet and plenty of fluids

2.2.3 Skin/pressure ulcer status

Skin assessment involves a healthcare worker observing at risk skin sites to identify if there are signs of early pressure damage or to assess the severity of pressure damage if present. Skin assessment is also a useful indication of the effectiveness of a preventative intervention (EPUAP et al., 2019).

The EPUAP et al. (2019) pressure ulcer classification system presented in Chapter 1 offers a structured tool for the assessment of pressure ulcers, but is reliant on the healthcare workers' skill and experience at undertaking this.

Skin assessment should also identify skin vulnerability such as moisture (e.g. from perspiration, wound exudate and incontinence) which is important as moist skin increases the coefficient of friction (Yusuf et al., 2015), and dryness reduces tensile

strength and flexibility (Baharestani et al., 2010). An appropriate skin care regime to the heels should be implemented that includes keeping the skin clean and hydrated, without the use of alkaline soaps (Ananthapadmanabhan et al., 2004). Nutrition and hydration is important in pressure ulcer prevention as macro and micronutrients are required to grow, develop, maintain and repair body tissues (EPUAP et al., 2019).

2.2.4 Immobility

Extended periods in one position would normally result in pain and discomfort which would stimulate an individual to change position. However, if the individual is unable to reposition themselves, or has impaired sensation or reduced levels of consciousness and will not experience the discomfort, then assistance will be required. Theoretically, by repositioning, the duration of pressure to the tissues is reduced which in turn reduces the levels of deformation and hypoxia (Defloor, 2000, Gillespie et al., 2014).

2.2.4.1 Repositioning

Frequent repositioning has long been a recommendation as a means of preventing pressure ulcers (EPUAP et al., 2019, NICE, 2014b), although there is still debate in the literature about how frequently a patient should be repositioned, and if repositioning techniques such as the 30 degree tilt are sufficient to prevent pressure ulcers, especially at the heel and will be explored further here.

Repositioning can be done using a variety of repositioning aids but is mostly done using pillows as this is something that is readily available in most clinical areas. For repositioning to be effective there is a requirement for the patient to maintain the position that they are turned to, along with the ability of the carers to repositioning the patient effectively. From personal experience in clinical practice it is sometimes seen that the patient is turned at the torso, relieving the pressure at the sacrum and buttocks, but the heels often remain in the same or similar position, or that patients will be turned but will return to a position that is comfortable to them, as reported in 34% of subjects by Vanderwee et al. (2007b).

There is a published systematic review looking at repositioning for the prevention of pressure ulcers in terms of both the degree of repositioning (30º versus 90º tilt) and the frequency (Gillespie et al., 2014). Only three randomised controlled trials (RCTs) were included, all of which were underpowered and at high risk of bias, and no evidence of a reduction in pressure ulcer incidence was seen with either the frequency or degree of repositioning (Defloor et al., 2005, Moore et al., 2011, Young, 2004). Further research is required here in the form of good quality RCTs (Gillespie et al., 2014).

Young (2004) compared the 30^0 tilt with 90^0 lateral rotation, although they do not state how frequently the patient was repositioned, and it was a very short study only lasting for one night. No difference was seen between the two groups.

Defloor et al. (2005) compared four different combinations of repositioning schedules in combination with standard or high specification foam mattresses using cluster randomisation. Significantly fewer pressure ulcers developed in the four hourly repositioning group on a high specification foam mattress.

A trials by Vanderwee et al. (2007b) and Bergstrom et al. (2013) were not included in the systematic review. Vanderwee et al. (2007b) compared frequencies of repositioning (two versus four hourly) for patients with Category 1 pressure ulcers on a pressure relieving support surface and saw no significant difference in frequency and number of pressure ulcers that developed and both groups had their heels elevated using a wedge-shaped cushion. Bergstrom et al. (2013) compared two, three and four hourly repositioning and reported no difference between the three groups.

Moore et al. (2011) compared the 30^0 tilt three-hourly versus six-hourly repositioning using the 90^0 lateral rotation. They saw significantly fewer pressure ulcers in the three-hourly 30^0 tilt group and was the only study to compare pressure ulcer incidence by body site. No heel pressure ulcers were seen, therefore the effect of repositioning on heel pressure ulcers remains uncertain.

2.2.5 Devices

For the purpose of this thesis, a device is any instrument, apparatus, implement, appliance, material or other similar or related article, intended to be used, alone or in combination, in human beings, for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease (World Health Organization, 2020).

Where effective repositioning is not possible or is insufficient to meet the patients' perceived need, medical devices can help to help minimise the risk. It has been identified that there is limited evidence on whether pressure redistributing devices reduce pressure ulcer risk at specific body sites, and have therefore been identified as a research priority (James Lind Alliance, 2013, NICE, 2014b).

Support surfaces such as mattresses and overlays, and dressings can be used for the prevention of pressure ulcers. In addition, for the prevention of heel pressure ulcers there are heel-specific devices. Current recommendations according to EPUAP et al. (2019, p147) are:

> *"For individuals at risk of heel pressure ulcers and/or with Category 1 or 2 pressure ulcers, elevate the heels using a specifically designed heel suspension device or a pillow/foam cushion. Offload the heel completely in such a way as to distribute the weight of the leg along the calf without placing pressure on the Achilles tendon and the popliteal vein".*

This is a strong recommendation meaning this should be carried out in practice, but the strength of the evidence that these recommendations were made is mainly based on either low to moderate quality RCTs or moderate to high quality quasi-experimental trials. Alongside RCTs, the biomechanical properties of a devices can be investigating through measuring interface pressures, perfusion of the tissues, usually through measuring blood flow or transcutaneous oxygen and carbon dioxide levels or using MRIs to measure tissue deformation. There is no consensus on which method is best, their comparability, and are often conducted in laboratory settings using healthy participants. Tissue Viability Society (2010) recommend that support surfaces should include human subject interface pressure tests as part of a wider investigation into their physiological effects, but as they cannot be standardised this should not form part of the basic product information. It is also acknowledged that other factors such as shearing forces and microclimate need to be considered (Tissue Viability Society, 2010).

2.2.5.1 Support surfaces

Support surfaces are specialist devices designed to redistribute the pressure exerted on the individual's body when in contact with the device. The term support surface can apply to specialist beds, mattresses, and mattress overlays, and to chair and wheelchair cushions. Chair and wheelchair cushions will not be explored as these do not have any impact upon the heels.

Support surfaces are not included in the EPUAP et al. (2019) recommendations for the prevention of heel pressure ulcers, due to the lack of evidence in their effectiveness. There is a Cochrane systematic review that looks at the evidence of effectiveness of support surfaces for the prevention of pressure ulcers, but does not look at individual body sites (McInnes et al., 2015). Support surfaces are part of standard care, and therefore how they might reduce the risk of heel pressure ulcers needs to be understood.

Mattresses and overlays aim to reduce the risk of pressure ulcer development to all parts of the body, and generally fall into one of two categories: constant low pressure (CLP) or alternating pressure (AP). CLP devices reduce the magnitude of the applied pressure by distributing the body weight over a larger surface area (as pressure is

related both to the force applied, and to the area over which it is spread; mathematically, Pressure = Force/Area). CLP mattresses (Figure 2-1) include foam mattresses and overlays, low air-loss mattresses, air-fluidised-bead beds and air overlays (McInnes et al., 2015).

Tong et al. (2016) saw significantly reduced interface pressures to the heels of elderly participants on a pressure relieving foam CLP mattress when compared to a standard hospital mattress, although the average pressures were only slightly below 32mmHg which is thought to be the average arteriolar flow and the pressure required to close capillaries and cause ischaemia (Landis, 1930).

Figure 2-1 Examples of CLP mattresses from top left clockwise low air-loss, foam mattress (Arjo) and air overlay (Repose® mattress from Frontier Medical)

AP devices (Figure 2-2) reduce the duration of pressure by alternately inflating and deflating air-filled cells in a mattress over a set cyclical period (usually every 5 minutes), thereby redistributing the pressure regularly for the whole body. These can differ by the depth and size of the cells, and the frequency of the inflation and deflation cycles. Some AP mattresses also have special heel zones where the cells can be partially deflated to help offload the heel. Despite this there is little evidence about the effects of AP mattresses on the prevention of heel pressure ulcers. Numerous studies have been identified looking at the properties and interface pressures of AP devices, (Vanderwee et al., 2008) only two were identified that reported separate heel interface pressures (Sideranko et al., 1992, Rithalia, 2004), however they used different methods to record and report the results. Sideranko et al. (1992) reported mean interface pressures at the heels of 22-22.8mmHg depending on position on the AP

mattress, whilst Rithalia (2004) compared four different AP mattresses and reported a range of interface pressures from a minimum of 39.4mmHg to a maximum of 186.9mmHg. The relationship between interface pressure measurements and pressure ulcer risk is almost completely unknown, therefore the utility of these proxy measures and the significance of these results on the prevention of heel pressure ulcers is unclear.

More recently hybrid mattresses (Figure 2-2) have been introduced which uses combines two technologies such as foam and alternating air so the mattress can be upgraded through the addition of a pump without the whole mattress needing to be replaced.

Figure 2-2 Examples of AP mattresses, from left to right: heel zone of an AP mattress with the heels floating and a hybrid mattress (Arjo)

2.2.5.2 Heel-specific devices

There are numerous heel-specific devices available on the market to prevent heel pressure ulcers that tend to fall into one of three categories:

- Devices that offload or float the heel
- Heel-specific CLP devices
- Heel-specific low friction devices

Recommendations by Huber et al. (2008) state that heel devices should increase the tissue blood flow, prevent shear forces, be effective in all positions, allow mobilisation, be easy to use, cost-effective and comfortable. They should also prevent hyperextension of the knee as this could lead to compression of the popliteal vein, which is a possible association with deep venous thrombosis (Leon et al., 1992, Huber and Huber, 2009).

2.2.5.2.1 Devices that offload or float the heel

The general consensus for preventing heel pressure ulcers is that the only effective method is through alleviating the pressure by elevating (offloading) the lower leg and calf from the mattress (Fowler et al., 2008, EPUAP et al., 2019). Offloading the heels so they are completely free of pressure can be achieved using a pillow, cushion, or wedge under the lower legs, or by using an offloading device that floats the heel. These will aim to distribute the pressure to the lower legs over a larger surface area whilst floating the heel, so it is free from pressure.

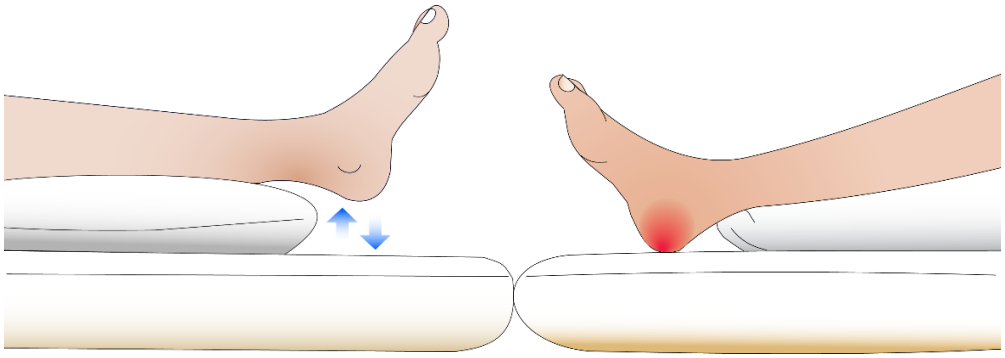
Pinzur et al. (1991) reported zero pressure to the heels when effectively elevated using a device. Huber et al. (2008) used a laser Doppler to measure flux at the heel (concentration and speed of the red blood cells with respect to time) as a method of assessing perfusion, although this was a study of non-hospitalised volunteers with and without PVD. They found that flux was significantly higher when using an offloading device compared with laying the heel on pressure reduction devices; illustrating the importance of elevation. Guin et al. (1991) compared the heel interface pressures for six different heel devices, including a combination of offloading and cushioning devices. The lowest pressures were reported with an offloading splint, although they came in a variety of sizes which complicates purchasing and application. The offloading splint was difficult to apply and would take several adjustments to ensure proper positioning, but this could be addressed through effective training of the staff and patients/carers. Guin et al. (1991) also found that products which were secured by straps to the foot or leg could lead to higher pressures at the heel if applied tightly. This could also cause a problem in patients with ischaemia if the straps are secured too tightly.

Pillows

Pillows can be effective at offloading the heel by being placed lengthways under the full length of the calf with a slight flexion to the knee, allowing the heel to be suspended above the mattress. Pillows are the most accessible method of elevating the heel as they are cheap and available to all clinical areas and are suitable for short term use in alert and co-operative individuals who can maintain the leg in the same position (EPUAP et al., 2019). Pillows can however be placed incorrectly leading to the heel still being in contact with the bed, or patient movement can cause the pillow to move (Figure 2-3), making pillows less suitable for more mobile patients, those who are agitated or where there is increased movement to the lower limb. The thickness of the pillow can differ, with thinner pillows or a heavier lower limb can cause ‘pancaking’ of the pillow leaving the heel in contact with the bed.

De Keyser et al. (1994) and Smith (1984) looked at the interface pressures of the heel when using a variety of different heel protection devices and found the lowest pressures in the standard pillow group. Pillows do not protect from footdrop, where extended periods of bedrest can lead to weakness and overstretching of the muscles and nerves to the lower leg.

Figure 2-3 Correct heel elevation using a pillow



Wedges

The heels can be elevated in a similar manner to pillows using a wedge (Figure 2-4). Wedges are thicker and larger than pillows minimising the chance of the wedge moving and the heel being in contact with the bed, but the leg can still move out of the correct position illustrate. Wedges such as the one in Figure 2-4 can also lead to an increase in pressure to the Achilles tendon. Beeckman et al. (2009) performed a non-randomised comparative study looking at pillows versus wedges and reported fewer heel pressure ulcers in the wedge-shaped cushion group, although two ankle pressure ulcers were reported, but it is unclear if this was attributed to the wedge.

Figure 2-4 Heel elevation using a wedge (Repose® Wedge, Frontier Medical)

Heel offloading devices

Heel offloading, also referred to as heel suspension devices, solve most of the problems associated with pillows and wedges as they; float the heel so it is free from pressure, are designed to stay in intimate contact with the foot and lower leg, can reduce friction & shear and can remain in place for up to 24 hours a day. Some can also help to minimise foot drop.

Heel offloading devices can vary in both design and materials as illustrated in Figure 2-5; such as foam or air-filled boots and Pressure Relief Ankle Foot Orthosis (PRAFO® boots). Recommendations, based on expert opinion, state that the device should be selected taking into consideration mobility, skin integrity, oedema, anatomical appearance and/or alignment of the foot and leg (e.g. contractures or deformities), manufacturers guidelines along with comfort and the patients' ability to tolerate the device (EPUAP et al., 2019).

Figure 2-5 Heel offloading devices from top left clockwise Pressure Relief Ankle Foot Orthosis (PRAFO by Anatomical Concepts UK Ltd), foam (Heelift reproduced by permission of Walgreen Health Solutions, LLC), padded (Prevalon™ Heel Protector III, Stryker) and air filled (Repose®, Frontier Medical)

2.2.5.2.2 Heel-specific CLP devices

CLP heel devices are designed either to reduce the magnitude of the applied pressure increasing the contact area through padding the heel or reduce the effects of the forces of friction or shear, or both. They can include gel, foam or sheepskin materials made into either a heel cup, bootie or overlays that only sit under the heels (Figure 2-6). They are useful in certain situations, for example patients where friction or shear is more of an issue than pressure (such as agitated or mobile legs), the more mobile patient if they can

be used under prostheses or shoes, or in certain situations such as surgery or vascular radiology where the limb cannot be elevated and needs to be kept stable.

Synthetic sheepskin has been found not to reduce heel pressures compared to no device (De Keyser et al., 1994). Pinzur et al. (1991) saw higher relative heel pressures in CLP devices when compared to devices that completely offload the heel. CLP devices might not reduce interface pressures but might reduce friction and shear. These studies also do not consider confounding factors such as comfort, patient preferences which can affect concordance with wearing the devices, whether the devices stay in place as well as the influence of friction and shear.

Figure 2-6 Heel-specific CLP devices, from top clockwise: gel heel pad, Sheepskin Heel Protector (by James Thornton, Thorpe Mill Ltd, licensed under CC BY-NC-ND 4.0) and egg-crate foam heel protector and sheet (© 2018 courtesy of Cardinal Health UK Ltd)

2.2.5.2.3 Heel-specific low friction devices

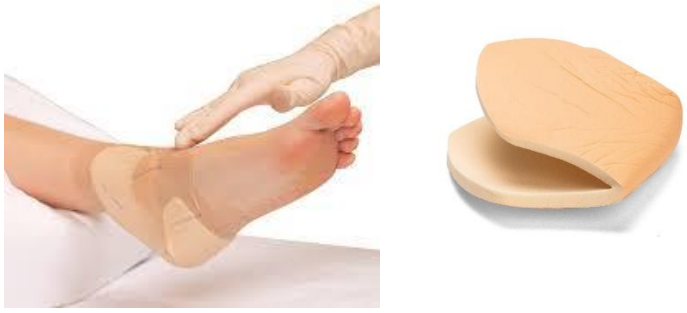
These can include dressings or booties that are designed to reduce the risk of pressure ulcer development through reducing the forces of friction and shear. Although it has been identified that complete offloading of the heel is the most preferential method for preventing heel pressure ulcers, this will not be suitable for all patients. Low friction devices could be more suitable for the more mobile patient or those with tremors or agitation that leads to frequent movement of the lower limb which could make the heels more susceptible to the effects of friction and shear rather than pressure. They could also be beneficial by protecting the skin of persons with frail skin.

2.2.5.2.4 Prophylactic dressings

Dressings, such as polyurethane or silicone foam can help to reduce heel pressure ulcer risk by cushioning the heel and reducing friction, and a simple film dressing can help reduce friction (Figure 2-7). In a laboratory setting a range of dressings including hydrocolloids, silicone and foam dressings have been found to reduce pressure, although this was to the sacrum (Matsuzaki and Kishi, 2015). Other laboratory studies have shown foam dressings to reduce pressure, shear and friction (Levy et al., 2015, Levy and Gefen, 2016) and can improve the microclimate of the skin (Call et al., 2013). Film dressings do not reduce interface pressures, but can reduce the effects of shearing forces (Nakagami et al., 2006) and allow for the skin to be monitored without tampering with the dressing.

A systematic review has shown that silicone dressings may reduce pressure ulcer incidence, however the evidence included was of a low level of certainty, and this review was looking at all body sites and not specifically at the heel (Moore and Webster, 2018). Therefore current recommendations are that prophylactic dressings should be used only as an adjunct to elevation (EPUAP et al., 2019).

Figure 2-7 Dressings for heel pressure ulcer prevention. From left to right multi-layered silicone foam dressing (Mölnlycke Health Care), polyurethane foam dressing, film dressing



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2.2.5.2.5 Low-friction garments

Textiles with low friction coefficient can be used as either bed linen or clothing such as undergarments and booties (Figure 2-8). The textiles work by reducing the effects of friction and shear as well as influencing the microclimate of the skin by absorbing moisture away from the skin and reducing heat. They have non-slip areas to help patient positioning and reduce the risk of slips and falls.

Medical technologies guidance from NICE (2014c), which was based on four multiple patient case series reports, shows that low friction booties have the potential to reduce the development and progression of skin damage caused by friction and shear in

patients at risk of developing a pressure ulcer, although there is insufficient evidence of effectiveness to support them being adopted into routine practice.

Figure 2-8 Low friction booties (APA Parafricta Ltd)

2.2.5.2.6 "Homemade" Devices

There are a variety of "homemade" devices reported in the literature as being used to reduce pressure at the heel, such as water-filled gloves (Figure 2-9) or intravenous fluid bags. Water-filled gloves were a more traditional nursing intervention for reducing pressure at the heel, however a small study measuring the interface pressures on the heels of healthy volunteers saw equivalent pressures between the water-filled gloves and a standard mattress, regardless of the size of the glove and amount of water in the glove (Lockyer-Stevens, 1993). Williams (1993) saw higher interface pressures when the heel rested on a water-filled glove compared to the bed in 40 inpatients. It is also a small area for the heel to be resting on so would be difficult to maintain it in the correct position. It has therefore been recommended that water-filled gloves should not be used as a pressure relieving aid (EPUAP et al., 2014).

Figure 2-9 Water-filled glove used for heel pressure ulcer prevention

Intravenous bags have been used to lift the heel from the bed by placing the bag under the Achilles. Bales (2012) performed a quasi-experimental trial comparing intravenous fluid bags and a heel offloading device for the prevention of heel pressure ulcers. Although they saw no pressure ulcers in either group, it could be assumed that

intravenous fluid bags can cause similar problems as the water-filled glove; the foot or bag could move and there is the potential that they could increase interface pressures in a similar manner to the water-filled gloves, and therefore increase risk of pressure ulcers developing over the Achilles.

2.3 Knowledge theories

Nurses knowledge of risk assessments, prevention practice and device use for the prevention of heel pressure ulcers could be of potential relevance to this thesis. How nursing knowledge is established, understood, transmitted, and used could be important when levels of formal knowledge might be limited and differ amongst staff.

Teaching, learning, and knowledge are interrelated, although learning and knowledge are separate and individual processes to teaching. An important component of teaching is imparting and sharing knowledge, but this alone is seldom enough to elicit a change in thinking or behaviours (Wills and McEwen, 2011). Knowledge is always in a state of flux, changing with experiences. Therefore as work changes, so does our knowledge (McKenna and Slevin, 2011).

There are numerous theories about knowledge and practice, how we learn complex skills, as well as theories specific to how nurses gain and use their knowledge. There are too many theories to consider them all within the remit of this thesis. Therefore, an overview will be given of two nursing theories that were deemed to be potentially relevant as they explore how knowledge influences practice.

Kerlinger and Lee (1986) theorise a hierarchy to knowledge with a positivist view that empirical evidence is required to provide certainty on whether something is true, but knowledge is also gained through tenacity, authority and *a priori*. Knowing through tenacity is knowing something because it has always been believed to be true, for example, regardless of the research evidence, nursing staff may consider that repositioning is the best way to prevent pressure ulcers. Knowing through authority is because an authoritative person, such as the Ward Manager or the TVNS, has said you must offload the heels to prevent heel pressure ulcers. Knowing through *a priori* is knowing something because reason tells you it is true, for example it is reasonable to assume that floating the heels will reduce the pressure ulcer risk as pressure has been removed.

By way of contrast, as most nurses work amongst teams whether it is on a ward, department, or a service, factors that influence nursing knowledge as part of a team, or ‘community’ also needs to be considered. A community of practice is a model of situational learning where learning is located in the relationship between the person

and the world (Wenger, 2010). In this theory nurses collaborate amongst their peers, with individuals working to a common purpose, defined by knowledge rather than the task (Andrew et al., 2008). Central to this theory is the belief that individuals are motivated to join a community of practice to develop a sense of identity and belonging. In an acute setting, through this act of engagement and collaboration, learning occurs and evolves over time to gain the knowledge and skills to become a proficient member of the nursing team (Ellingson, 2003, Andrew et al., 2008).

2.4 Discussion

This chapter has given an overview of the different devices and methods that can be used with the aim of preventing heel pressure ulcers, as well as considering how nurses knowledge of pressure ulcer prevention might influence practice. The gaps in knowledge illustrated in this chapter led to the aim of this thesis; to explore the use of devices in the prevention of heel pressure ulcers, both in terms of their clinical effectiveness but also how they are used and perceived in clinical practice.

When a new product is brought out, evidence for their use tend to be clinical evaluations led by the developers, which are often small in scale, underpowered with no comparator group or adequate allocation concealment which can lead to misleading results. Currently there is a lack of good quality evidence for robust recommendations to be made.

International guidelines state the heel should be free from pressure where possible (EPUAP et al., 2019), therefore it could be argued that any device that completely offloads the heel should be best practice; especially when experimental studies like Pinzur et al. (1991) demonstrate that offloading devices can lead to no pressure at the heel. Unfortunately, studies like these do not account for confounding factors such as whether the device is applied correctly, that it stays in place, length of time being worn, and whether there are any adverse events from their use such as increase in pressure to other body sites. This chapter has also demonstrated that there are numerous different types of devices, made of different materials and which will fit differently. A lot of the trials are more than 20 years old, and therefore the design of the devices could have changed over this period. They also often use healthy volunteers so there is no risk factor analysis, and they only look at one aspect of the products effectiveness over a short period. Therefore, clinical trials are necessary to evaluate a product, as this will aim to consider confounding factors, reflecting the effectiveness of a device in a real-world situation.

A systematic review is a method of secondary research that aims to identify, appraise and synthesise research-based evidence related to a specific research question and present it in a systematic manner that allows it to be accessible to all (Green et al., 2011). Pawson et al. (2005) criticises systematic reviews stating that they provide little evidence on how and why an intervention works in different contexts or circumstances. However, it was felt that the most comprehensive and objective way to appraise the current evidence base with regards to the relative effects of the different device types available for the prevention of heel pressure ulcers is by performing a systematic review (Liberati et al., 2009).

2.5 Summary

This chapter has presented the different strategies available to help identify whether an individual is at risk of developing a pressure ulcer, and the preventative care including devices that can be used to prevent heel pressure ulcers. When repositioning is insufficient or cannot be achieved, additional interventions are often sought in the form of a device, which can vary from a mattress to a dressing. However, the evidence with regards to which device is the most effective is sparse.

The following chapter will present a systematic review that will present the current evidence with regards to the different devices presented in this chapter in their effectiveness of preventing heel pressure ulcers.

Chapter 3 Devices for the prevention of heel pressure ulcers: a systematic review

3.1 Introduction

Chapter 2 presented the different devices available aimed at preventing heel pressure ulcers from developing, however there is a lack of evidence with regards to their effectiveness. A systematic review of the evidence of effectiveness of devices used for the prevention of heel pressure ulcers will be presented in this chapter. The chapter will begin with a rationale for carrying out a systematic review and why this was done utilising the Cochrane format. It will then go on to describe the research design, how studies were identified and appraised with regards to their quality and risk of bias using the GRADE approach. The findings are then summarised and based on these, recommendations for clinical practice and future research are presented.

This chapter is presented using The Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) format, a universally recognised quality standard for reporting systematic reviews (Liberati et al., 2009).

3.1.1 Research Question

What are the relative effects of different pressure-relieving devices in the prevention of heel pressure ulcers?

3.1.2 Rationale

It has been established in Chapter 2 that there are numerous approaches to reducing heel pressure ulcer risk. When a new device is brought out, the evidence provided tends to be clinical evaluations, led, or funded by the developers. These are often small, underpowered and with no comparator group or adequate allocation concealment, which can lead to misleading results. Therefore, by evaluating the existing evidence base for devices that aim to prevent heel pressure ulcers, and where possible combine in a meta-analysis to address low power, will answer the research question.

It is also important to consider whether heel-specific devices increase the risk of developing pressure ulcers to other body sites, as it has been shown that by elevating the leg there pressures to the sacral region increase (Al-Majid et al., 2017). Devices applied to the feet could also affect independent movement of the patient which could lead to an increase in friction and shear to other body sites. Therefore, for heel-specific

devices both heel and non-heel body sites should be evaluated separately to see if harm and effectiveness are related.

3.1.2.1 Existing evidence base

As discussed in Chapter 1, there is a small surface area to the posterior heel, along with the small volume of subcutaneous tissue, meaning that mechanical loads are transmitted directly angular to the bone; making it more challenging for pressure redistributing devices to redistribute the load (EPUAP et al., 2019), and therefore support surfaces could be less effective at preventing heel pressure ulcers in comparison to other body sites.

A previous Cochrane systematic review was looking at evidence for support surfaces (mattresses, mattress overlays, limb protectors and cushions) for the prevention of pressure ulcers (McInnes et al., 2015). The data analyses were not specific by body site and so it remains unclear if these devices are effective in specifically preventing heel pressure ulcers. Mattress trials tend to focus on whether they reduce the incidence of all pressure ulcers, but it is also important to know if they are effective at preventing heel pressure ulcers, or if additional interventions are also required. It is therefore necessary to do a systematic review focusing on devices for the prevention of heel pressure ulcers and update the searches following the McInnes et al. (2015) review.

McInnes et al. (2015) identified three studies that looked at heel-specific devices (Donnelly et al., 2011, Gilcreast et al., 2005, Tymec et al., 1997) but due to risk of bias and unclear reporting a meta-analysis could not be performed. A review by Nicosia et al. (2007) looking at pressure relieving surfaces on the prevention of heel pressure ulcers did include a robust search strategy and performed a meta-analysis. They found 14 randomised controlled trials (RCTs); 2 heel protection device trials and 12 mattress or overlay trials. Methodological quality of the included RCTs were assessed using PEDro (Maher et al., 2003) and Jadad scales (Clark et al., 1999), but these results were not considered when performing the meta-analyses. They found that foam mattresses were associated with a lower risk of heel pressure ulcer development compared with a standard hospital mattress, but no evidence of a difference was found with air mattresses compared with a standard hospital mattress. No meta-analysis was performed for the heel protection devices and no explanation is provided, but it is assumed that this is because there was no standard comparator. Due to the age of this review, it was assumed that further RCTs may now be available.

Two reviews described as systematic were also found; the first looking at pressure redistributing support surfaces and heel protection devices for the prevention of heel pressure ulcers (Junkin and Gray, 2009) and the second looked just at heel elevation devices (Clegg and Palfreyman, 2014). Neither of these studies used a robust search strategy, performed a meta-analysis, or a quality appraisal of the evidence, therefore all recommendations are made based on the results presented by the RCT authors.

Newer devices also need to be considered, such as Parafricta® Booties which work through reducing the development and progression of skin damage caused by friction and shear, however there is insufficient evidence of effectiveness (Meads et al., 2016). Dressings could also be viewed as a device that can potentially reduce the effects of friction and shear at the heel. In a systematic review by Moore and Webster (2018) it was found that silicone foam dressings may reduce the incidence of pressure ulcers, although there was a low level of evidence certainty due to included trials being imprecise or at risk of bias. This review did not report body site of pressure ulcer development so the effectiveness of dressings for the prevention of heel pressure ulcers remains unknown, therefore further research is required.

3.1.3 Objectives

To determine the relative effects of different pressure relieving devices for the prevention of heel pressure ulcers. All randomised controlled trials that assessed efficacy of devices for the prevention of heel pressure ulcers compared to other devices, no intervention, or standard care, in participants of any age in any care setting were included.

3.2 Methods

3.2.1 Protocol

The protocol was written using guidance from the Cochrane Handbook (Higgins and Green, 2011a) and peer reviewed, approved and published through the Cochrane Library (Greenwood et al., 2014).

A protocol ensures that a systematic review is carefully planned and documented before the review starts (Moher et al., 2015). The benefits of publishing a protocol prior to the systematic review being performed is that it increases the integrity and transparency of the research and there is greater consistency and accountability across the research team. Full details of the published protocol are outlined in the following sections.

3.2.2 Eligibility Criteria

3.2.2.1 Types of studies

Because this review addresses the effectiveness of an intervention, it was decided to only include randomised controlled trials (RCTs) that compared the effects of different pressure relieving or reducing devices on the incidence of new heel pressure ulcers. Provided that trials are of sufficient size, randomisation should ensure that participants in each group are similar with respect to both known and unknown prognostic factors. Therefore any difference found between the groups can, in principle, be ascribed to the causal effect of the intervention (Higgins et al., 2011a). Non-randomised trials have been seen to produce effect estimates that indicate more extreme benefits of an intervention compared with randomised trials, although it is difficult to predict the extent or direction of the bias (O'Connor et al., 2011).

RCTs focusing specifically on pressure-relieving or reducing devices in the prevention of diabetic foot ulcers were included if heel pressure ulcer data could be identified separately. Similarly, RCTs that compared the effects of pressure-relieving or reducing devices non-specific to the heel (e.g., mattresses) were included as long as they intended to redistribute or reduce pressure at the heel, and heel pressure ulcer data could be identified separately.

Cluster randomised trials were allowed, but in order to minimise the risk of a unit-of-analysis error (Whiting-O'Keefe et al., 1984) the participant would be adjusted for in the cluster as the unit of analysis (Higgins et al., 2011b). Cross-over randomised trials were also included.

3.2.2.2 Types of participants

People of any age in any care setting without a pre-existing Category 2 (or worse) heel pressure ulcer who were at any level of risk for developing a pressure ulcer were included.

3.2.2.3 Types of interventions

Any device or intervention designed either to offload or reduce pressure, friction and shear, or all at the heel were considered. These could be used alone or in combination.

The following interventions, as described in more detail in Chapter 2, were included and could be compared with each other, with no intervention, or with standard care. Treatment arms differed only in the pressure-relief intervention used.

- Total body AP devices
- Total body CLP devices
- Heel-specific offloading devices
- Heel-specific CLP devices
- Heel-specific low friction devices

3.2.3 Outcome measures

There are several different grading systems used to determine the severity of a pressure ulcer. For the purpose of this review, all outcomes were converted to the EPUAP/NPIAP grading system as this is internationally recognised (EPUAP et al., 2019) (Table 3-1).

Table 3-1 Conversion chart for different pressure ulcer categorisation scales used

EPUAP/ NPIAP/ PPPIA	Modified Shea Scale	Exton-Smith Scale	Torrance Scale	Dutch consensus meeting	AHCPR[1]	GNEAUPP[2]	AWMA	5 point scale used by Cadue et al. (2008)
0	0	0	0/1	0	0	0	0	0/1
1	1	1	2a	1	1	1	1	2
2	2	2	2b/3	2	2	2	2	3
3	3	3	4	-	3	3	3	4
4	-	4 /5	5	-	4	4	4	5
Unstageable	4	-	-	3/4	-	-	-	-
DTI	-	-	-	-	-	-	-	4
Granulating wound	5	-	-	-	-	-	-	-

3.2.3.1 Primary outcomes

In pressure ulcer prevention trials, the main outcome of interest is both the presence of any pressure ulcer and the severity, identified by the grade/category of the ulcer. Ideally, any measurements taken in a clinical trial should be precise and reproducible to eliminate observer variation (Pocock, 2013) however, pressure ulcer prevention trials

[1] Operational definitions recommended by the Agency for Health Care Policy and Research (AHCPR)

[2] Grupo nacional para el estudio y asesoramiento en Úlceras por Presión y Heridas Crónicas.

rely on the knowledge and experience of the practitioner to accurately classify the wound. Category 1 pressure ulcers (non-blanching erythema) can get confused with hyperaemia, be difficult to assess in individuals with dark skin tones or hyperpigmentation and can also be difficult to differentiate between moisture associated skin damage (Defloor and Grypdonck, 2004, Defloor et al., 2006, Vanderwee et al., 2007a). The main methods to diagnose a Category 1 pressure ulcer are either through the 'finger method'; using a finger to press on an area and check if the skin blanches, or the 'disc method'; using a clear plastic disc that can be pressed over the area to see if the skin blanches, which has been seen to be a more reliable method (Defloor et al., 2006, Vanderwee et al., 2006). Unfortunately, it is rarely reported which method was used.

Category 1 pressure ulcers are the most common and including any Category will increase power and therefore impact the sample size required for a trial. Category 1 pressure ulcers are associated with an increased risk of subsequent pressure ulcer development (Nixon et al., 2007); therefore are a clinically relevant outcome.

The primary outcomes for this review were:

- Heel pressure ulcer incidence, defined as the number of people who developed a new heel pressure ulcer of any category
- The number of new heel pressure ulcers that developed
- Category of any new pressure ulcer (grading system should be specified)
- Deterioration of pre-existing Category 1 pressure ulcer

3.2.3.2 Secondary outcomes

It is unknown how long it takes for a pressure ulcer to develop as there are several different factors that can influence an individual's tissue tolerance to the effects of pressure (Gefen, 2008, Coleman et al., 2013). Time to the development of a heel pressure ulcer (including time-to-development of each grade) is a relevant outcome, as if one group has a significantly longer time to pressure ulcer development then this is a risk reduction.

Other relevant outcomes that can influence how the devices are used in practice were included:

- Cost of the intervention
- Durability/longevity of the devices (e.g., single-patient use/frequency of replacement)

- Acceptability of the intervention with respect to comfort (from the perspective of the participant, or caregiver)
- Quality of life as measured by a validated scale (e.g. SF-36, PUQoL) (Gorecki et al., 2013, Ware, 2000)

3.2.3.3 Adverse events

Adverse events were recorded as it is important to know about any potential harms that could occur from the devices. For the heel-specific devices, where information was provided regarding development of new pressure ulcers at sites adjacent to the device, or to the sacrum, this would be reported as a potential adverse event.

3.2.4 Search

It is essential when performing a systematic review to develop an explicit and meticulous search strategy in order that all relevant papers are identified. The search strategy was developed by amalgamating strategies used in other systematic reviews of pressure relieving devices alongside terms identified by the researcher, minimising the likelihood of leaving out relevant terms.

For the heel-specific devices, terms used by manufacturers or found in the literature were included. Terms used to identify RCTs were those used by the Cochrane Wounds Group (Cochrane Work, 2019). The strategy was developed by the researcher in collaboration with the supervisory team (JN/EM/EAN) and was approved by Cochrane as part of the protocol submission (Appendix A Search Strategy). It was run by a member of the Cochrane Wounds Group; the most recent updated search was performed on 25th April 2016. No restrictions were placed in terms of language or year of publication.

3.2.4.1 Databases

The following databases were searched: The Cochrane Wounds Specialised Register; The Cochrane Central Register of Controlled Trials (CENTRAL); Ovid MEDLINE (1946 to 25 April 2016); Ovid MEDLINE (In-Process & Other Non-Indexed Citations); Ovid EMBASE (1974 to 25 April 2016); EBSCO CINAHL Plus (1937 to 25 April 2016). The following clinical trials registries were also searched to identify ongoing and unpublished studies that related to "pressure ulcer " using a full text search:

- ClinicalTrials.gov (http://www.clinicaltrials.gov/)
- WHO International Clinical Trials Registry Platform (ICTRP) (http://www.who.int/ictrp/en/)

- EU Clinical Trials Register (https://www.clinicaltrialsregister.eu/index.html)

3.2.4.2 Other resources

The bibliographies of all retrieved and relevant publications identified by these strategies were searched for further studies. Experts in the field were contacted and asked if they were involved in or knew of any studies relevant to this review. Manufacturers of devices used in the prevention of heel pressure ulcers were contacted and asked for information relevant to this review (Frontier Medical Group, DM Systems, Posey, Covidien, Sundance Solutions, Smith & Nephew, Spenco).

3.2.4.3 Study selection

There is the potential for bias to be introduced during the study selection process. Even with a protocol that contains clear and precise inclusion criteria, there is the potential for human error and subjectivity; where the reviewers knowledge and understanding (or lack of) of the area being reviewed can influence the selection process (McDonagh et al., 2013). It is not possible to completely remove this bias, as it is a subjective process, but to minimise this it was done independently by the researcher and supervisor (EM) in two phases. First the titles and abstracts of studies identified by the search strategy were assessed against the eligibility criteria for inclusion in the review. Full versions of potentially relevant studies were then screened against the inclusion criteria. Any differences in opinion were discussed with JN/EAN until consensus was met.

3.2.5 Data collection process

A data extraction form was developed and piloted prior to the screening process. The researcher and supervisor (EM) extracted data from eligible studies independently. If there was any disagreement during the extraction process, this was resolved by consensus during supervision meetings. Where possible study authors were contacted to obtain any missing data.

3.2.5.1 Data Items

The following information was collected:

- author, title, date of study and source
- participant inclusion/exclusion criteria
- participant characteristics (e.g., age, sex, diagnosis, comorbidity, baseline risk, details of existing ulcers)
- care setting
- study design details

- description of interventions
- description of any co-interventions
- duration of intervention (e.g., mean length of time on the support surface or wearing a heel-specific device over a 24-hour period) and length of time intervention took place (e.g., 2 weeks or until discharge)
- sample size calculation and sample size
- method of randomisation
- number of participants randomised into each arm
- allocation concealment
- blinding (of the participant/outcome assessor)
- outcome measures
- length of follow-up
- dropout rates and loss to follow-up
- results
- length of hospital stay
- intention-to-treat (ITT) analysis
- conclusions, as reported by the study authors.

3.2.6 Risk of bias assessment of individual studies

Bias is defined as a ‘systematic error or deviation from the truth in results’, meaning that multiple replications of the same study, on average, would reach the wrong answer (Boutron et al., 2019). Biases can occur in the design, conduct, analysis or reporting of a trial and can lead to under-estimation or over-estimation of the true intervention effect. The magnitude of the bias can also vary from small and trivial, compared with the observed effect, to substantial where an apparent finding may be entirely due to bias (Boutron et al., 2019).

Independently the researcher and supervisor (EM) assessed each included study using the Cochrane Collaboration tool for assessing risk of bias (Higgins et al., 2011a) and a 'Risk of bias' table were completed for each eligible study which addresses seven specific domains; sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessors, incomplete outcome data, selective outcome reporting and other issues (e.g. extreme baseline imbalance) (Appendix B Risk of bias tables). Blinding and completeness of outcome data were assessed for each outcome separately using the criteria set out in the Cochrane handbook (Higgins et al., 2011a). Trials were classified as being at high risk of bias if they were rated ’high’ for any of three key criteria, namely, randomisation sequence, allocation concealment

and blinded outcome assessment. Where there was a high risk of bias in any of these key domains, an attempt was made to contact the trial authors. Where contact details were available, open-ended questions were asked about the design and conduct of the study. However, not enough information was gained from any of the authors contacted to change the initial assessment of bias.

3.2.7 Summary measures

Where possible, all outcomes were reported using 95% confidence intervals (CI). For dichotomous outcomes risk ratios were calculated. For continuous outcomes, where the outcome measures were measured using the same scale, mean difference was calculated. Standardised mean difference (SMD) was used as a summary statistic in meta-analysis when studies assessed the same outcome, but measured it in a variety of ways (Deeks et al., 2011). Time-to-event outcomes (i.e. time-to-ulceration) were measured using the appropriate analytical method, as long as the individual time points were known for all participants (Deeks et al., 2011). If hazard ratios were reported, we had planned to extract and include in a forest plot or meta-analysis.

As this review is looking at heel pressure ulcer prevention, the unit of analysis could have been at the heel (i.e., the number of heel pressure ulcers that developed) or the trial participant (i.e., the number of trial participants who developed a heel pressure ulcer). Both are valid outcome measures; however, the unit of analysis needs to be the same as the unit of randomisation to avoid unit of analysis error, therefore the unit of analysis was the trial participant.

3.2.8 Synthesis of results

Studies were combined using a narrative overview and where appropriate a meta-analysis performed. The method used to synthesise studies depended on the quality, design, and degree of heterogeneity of the studies. If there had been high variability in the clinical characteristics, methodology, treatment effect or statistical heterogeneity, it would be inappropriate to perform a meta-analysis. Where studies were clinically similar and the outcome measures comparable, quantitative data, as presented in the study, were entered into RevMan 5.3 (Nordic Cochrane Centre, 2014), for analysis. Where there was no ITT, a best-case and worst-case scenario was performed to assess the impact of the missing data. For dichotomous outcomes, a relative risk (RR) plus 95% confidence intervals (CI) would be calculated. For three-armed trials where there were two interventions and one control, the members of the control group were divided equally for the meta-analysis to avoid double counting (Higgins et al., 2011b).

3.2.8.1 Risk of bias across studies

If ten or more studies were included for meta-analysis, visual asymmetry of funnel plots would have been used to assess for any potential reporting or publication bias (Sterne et al., 2011). The study protocols, where available, were consulted in order to identify outcome reporting bias.

3.2.8.2 Additional analyses

The following subgroup analyses had been planned if sufficient data were available:

- type of setting (community, inpatient, outpatient, operating room)
- participants with/without diabetes
- presence/absence of peripheral vascular disease
- presence of Category 1 pressure ulcer at baseline

When I^2 was greater than 0, the analysis was repeated using random effects model and sources of heterogeneity investigated using a sensitivity analysis in order to assess whether the findings were robust to the method used to obtain them (Higgins and Green, 2011b).

3.2.9 Assessing certainty using the GRADE approach

For systematic reviews the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach offers a system for rating quality of evidence and grading strength of recommendations (Guyatt et al., 2011). The certainty of a body of evidence is ‘the extent to which one can be confident that an estimate of effect or association is close to the quantity of specific interest’ (Schünemann et al., 2019). The GRADE approach considers:

- Within and across-study risk of bias (limitations in study design and execution or methodological quality)
- Inconsistency (or heterogeneity)
- Indirectness of evidence
- Imprecision of the effect estimates
- Risk of publication bias

Following each meta-analysis of primary outcome measures, the GRADE assessment is presented and used to assess the quality and certainty of the findings.

3.3 Results

3.3.1 Study selection

A PRISMA flowchart (Figure 3-1) was completed to demonstrate the number of citations retrieved through each search method and the number excluded at each stage (Liberati et al., 2009, Moher et al., 2009). One hundred and four citations were retrieved in full for detailed assessment and thirty-five citations were found that related to twenty-nine eligible studies for inclusion in the review. Published protocols were found for only three of the included studies (Bååth et al., 2016, Nixon et al., 1998, Nixon et al., 2006b). No eligible studies were obtained from the 12 companies that were contacted. Thirteen authors were contacted to see if they had further information and three responded with sufficient data for inclusion (Nixon et al., 1998, Santamaria et al., 2013, Torra i Bou et al., 2002). In total 69 citations relating to 63 studies were excluded from the review (Figure 3-1).

Where there were multiple citations for a single study these were grouped together and presented under the reference for the citation that has most of the results.

3.3.2 Study Characteristics

Table 3-2 illustrates the characteristics of the 29 studies (8770 participants) that met the inclusion criteria. The median sample size was 140 (range 32 to 1971) and only 15 of the studies included an *a priori* sample size estimate. The standard of reporting varied amongst the studies.

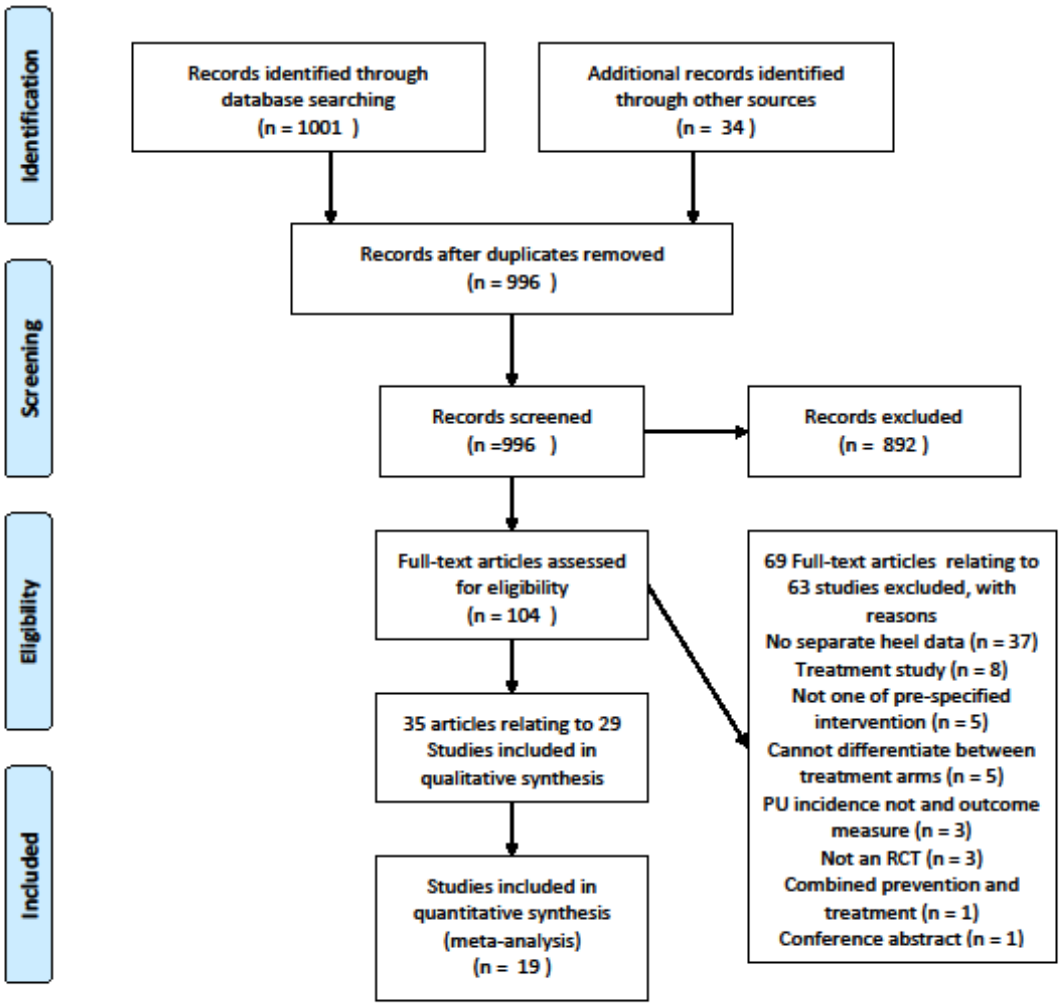
3.3.2.1 Participants

All participants were included in the trials because they had been assessed as at risk for developing a pressure ulcer. Twenty four studies had a mean age >60 compared with three studies <60 (Table 3-2), two of which had a mean age <41 years, the population consisted of people with a chronic neurological disease (Conine et al., 1990, Daechsel and Conine, 1985). The mean age for ten studies was >80 years; in keeping with age being a known risk factor for pressure ulcer development (Coleman et al., 2013).

3.3.2.2 Interventions

Nineteen studies evaluated total body devices, four heel-specific offloading devices, and four heel-specific CLP devices (three of which were dressings trials), one trial that compared different offloading devices and one compared heel offloading and CLP devices.

Figure 3-1 PRISMA flowchart (adapted from Moher et al. (2009))



3.3.2.3 Primary outcomes

Nine different pressure ulcer classification scales were used across the included studies (Table 3-1). For the purpose of the meta-analysis, where possible all results were converted to the EPUAP/NPIAP/PPPIA classification scale (EPUAP et al., 2019). Different outcomes were used with some studies reporting Category 1 or above and others reporting Category 2 or above pressure ulcers (Table 3-2).

3.3.2.4 Secondary outcomes

None of the trials reported quality of life. Ten studies reported time-to-pressure ulcer development, of which two studies reported median days (Berthe et al., 2007, Demarre et al., 2012), three studies reported mean days (Cadue et al., 2008, Takala et al., 1996, Tymec et al., 1997) and five studies reported Kaplan-Meier survival analysis (Donnelly et al., 2011, McGowan et al., 2000, Nixon et al., 2006b, Santamaria et al., 2013, Vanderwee et al., 2005), meaning that meta-analysis was not possible.

Table 3-2 Characteristics of included studies

Study	Care setting	Sample Size	Population	Intervention (int.)	Comparison (comp.)	Reported heel PU incidence ≥Category 1		Reported heel PU incidence ≥Category 2		Follow up period
						Int.	Comp.	Int.	Comp.	
Bååth et al. (2016)	Acute care Sweden	405 participants randomised but only N = 183 were admitted	Neurological symptoms or reduced general condition Mean age 86.3 (range 70 -100) 114 F 63 M	Heel suspension device boot (Heelift) (n = 103)	Standard care (n = 80)	15/103 (14.6%)	24/80 (30%)	0/103 (0%)	1/80 (1.25%)	Until discharge
Berthe et al. (2007)	Medical or surgical wards in Belgium	N = 1729	unknown	Kliniplot foamy block structure mattress (n = 657)	Standard hospital mattress (n = 1072)	2/657 (1.5%)	3/1072 (0.43%)	Did not report PU grade	Did not report PU grade	unknown
Cadue et al. (2008)	Intensive care in France	N = 70	Mean age 62.6 26F 44M	Foam body heel support (n= 35)	Standard care (n = 35)	3/35 (8.6%)	19/35 (54.3%)	Did not report PU grade	Did not report PU grade	Maximum 30 days
Campbell et al. (2010)	Orthopaedics ward in Canada	N = 72	unknown	Repose heel offloading boot (n=27) Custom made wedge (n = 23)	Standard hospital pillow (n = 22)	Repose: 0/27 (0%) Wedge: 0/23 (0%)	0/22 (0%)	Did not report PU grade	Did not report PU grade	Until discharge

Study	Care setting	Sample Size	Population	Intervention (int.)	Comparison (comp.)	Reported heel PU incidence ≥Category 1		Reported heel PU incidence ≥Category 2		Follow up period
						Int.	Comp.	Int.	Comp.	
Cavicchioli and Carella (2007)	Acute, post-acute and long-term care settings in Italy	N = 140	Mean age 77 100F 40M	Alternating low pressure (n = 86, only 69 included in analysis)	Continuous low pressure (n = 84, only 71 included in analysis)	1/69 (1.4%)	0/71 (0%)	1/69	0/71	2 weeks
Conine et al. (1990)	Extended care facility in Canada	N = 187	Neurological conditions Mean age 37.2 (range 19 - 55) 88 F 60 M	Alternating air overlay (n = 93)	Silcore overlay (n = 94)	19/72 (26.4%)	18/76 (23.7%)	Did not report PU grade	Did not report PU grade	3 months
Daechsel and Conine (1985)	Long term care hospital in Canada	N = 32	Neurological conditions Mean age 40.5 (range 19 - 60) 16 F 16 M	Alternating-pressure mattress (n = 16)	Silicore overlay (n = 16)	1/16 (6.3%)	0/16 (0%)	Did not report PU grade	Did not report PU grade	3 months
Demarre et al. (2012)	Belgian hospital	N = 610	Mean age 76.3 369 F 241 M	Alternating low pressure air mattress with multi-stage inflation and deflation of the air cells (n = 298)	Standard alternating low-pressure air mattress with a single stage steep inflation and deflation of the air cells (n = 312)	Not an outcome measure	Not an outcome measure	4/298 (1.3%)	6/312 (1.9%)	14 days

Study	Care setting	Sample Size	Population	Intervention (int.)	Comparison (comp.)	Reported heel PU incidence ≥Category 1		Reported heel PU incidence ≥Category 2		Follow up period
						Int.	Comp.	Int.	Comp.	
Donnelly et al. (2011)	Fracture trauma centre UK	N = 239	Mean age 81 (range 65 - 100) 184 F 55 M	Heelift offloading boot (n = 120)	Standard care (n = 119)	0/120 (0%)	17/119 (14.3%)	0/120 (0%)	9/119 (7.6%)	12 days
Ferrer Sola et al. (2013)	Medium-long stay hospital in Spain	N = 409	Mean age 81 240 F 163 M	Poly-urethane heel dressing (n = 208)	Classic padded bandage (n = 201)	7/208 (3.4%)	5/201 (2.5%)	5/208 (2.4%)	1/201 (0.5%)	Unknown
Gilcreast et al. (2005)	Military tertiary-care medical centres in Texas, USA	N = 338	Mean age 63.9 (range 18 - 97) 77 F 87 M	Bunny Boot (fleece) high cushion heel protector (n = 77) Egg crate heel lift positioner (n = 87)	Foot waffle air cushion (n = 76)	Bunny boot: 3/77 (3.9%) Egg crate: 4/87 (4.6%)	Foot waffle: 5/76 (6.6%)	Did not report PU grade	Did not report PU grade	Until discharge
Gray and Smith (2000)	District general hospital in UK	N = 100	Medical or orthopaedic patients. Mean age 65 39 F 61 M	New pressure reducing foam mattress (n = 50)	3-year-old pressure reducing foam mattress (n = 50)	Not an outcome measure	Not an outcome measure	0/50 (0%)	1/50 (2.0%)	10 days

Study	Care setting	Sample Size	Population	Intervention (int.)	Comparison (comp.)	Reported heel PU incidence ≥Category 1		Reported heel PU incidence ≥Category 2		Follow up period
						Int.	Comp.	Int.	Comp.	
Gunningberg et al. (2000)	Acute care in Sweden	N = 101	Suspected hip fracture. Mean age 84.5 (range 66 - 102) 81 F 20 M	10cm thick visco-elastic foam mattress in A&E and a 7cm visco-elastic foam overlay on top of the standard mattress on the ward (n = 48)	Standard trolley (5cm thick) in A&E and standard hospital mattress on the ward (n = 53)	Total number of heel PUs 1	Total number of PUs 1	Total number of heel PUs 2	Total number of heel PUs 3	Maximum 2 weeks
Hofman et al. (1994)	Acute care in Holland	N = 44	Femoral fracture. Mean age 84 38 F 6 M	Cubed foam mattress (n = 21, only 17 included in analysis)	Standard hospital mattress (n = 23, only 19 included in analysis)	Not an outcome measure	Not an outcome measure	3/17 (17.6%)	6/19 (31.6%)	2 weeks
Matsui et al. (2001)	Acute hospital in Japan	N = 107	Mean age 71.1 50 F 55 M	Two-layer alternating air (n=35) Single layer alternating air overlay (n=35)	Standard hospital mattress (n=35)	Two-layer: 0/35 (0%) Single layer: 4/35 (11.4%)	Standard care: 3/35 (8.6%)	Did not report PU grade	Did not report PU grade	Unknown

Study	Care setting	Sample Size	Population	Intervention (int.)	Comparison (comp.)	Reported heel PU incidence ≥Category 1		Reported heel PU incidence ≥Category 2		Follow up period
						Int.	Comp.	Int.	Comp.	
McGowan et al. (2000)	Orthopaedic wards in Australia	N = 297	Mean age 73.8 (range 60 - 97) 170 F 127 M	Australian Medical Sheepskin overlay, sheepskin heel and elbow protectors as required (n = 155)	Standard care (n = 142)	14/155 developed a total of 21 PUs, 2 of which were on the heels	43/142 developed a total of 72 PUs, 28 of which were on the heels	Did not report PU grade	Did not report PU grade	Until discharge or transfer
Nixon et al. (1998)	Surgical wards in UK	N = 446	Elective surgical patients, 55 – 69 years 56.5%, 70+ years 43.5% 208 F 235 M	Dry visco-elastic polymer pad to the torso and heels (n = 220)	Standard operating table mattress, both heels supported using Gamgee pad (n = 224)	7/220 (3.2%) developed a total of 8 heel PUs	13/224 (5.8%) developed a total of 16 heel PUs	2/220 (0.9%)	2/224 (0.9%)	8 days
Nixon et al. (2006b)	Acute care hospitals in UK	N = 1972	Mean age 75.2 (range 55 - 100) 1260 F 711 M	Alternating pressure replacement mattress (n = 982)	Alternating pressure overlay mattress (n = 990)	Not an outcome measure	Not an outcome measure	19/982 (1.9%) developed a PU, total of 21 heel PUs	18/989 (1.8%) developed a PU, total of 21 heel PUs	60 days
Ozyurek and Yavuz (2015)	Intensive care in Turkey	N = 105	Mean age 65 50 F 55 M	Viscoelastic foam 1 (n = 53)	Viscoelastic foam 2 (n =52)	22/53 developed a total of 34 PUs, 3 at the heel	23/52 developed a total of 27 PUs, 3 at the heel	Did not report PU grade	Did not report PU grade	Unknown

Study	Care setting	Sample Size	Population	Intervention (int.)	Comparison (comp.)	Reported heel PU incidence ≥Category 1		Reported heel PU incidence ≥Category 2		Follow up period
						Int.	Comp.	Int.	Comp.	
Ricci et al. (2013)	Long term care facilities in Italy	N = 50	Mean age 81.5 42 F 8 M	Aiartex 3D mattress overlay (n = 25)	Akton viscoelastic mattress overlay (n = 25)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)	28 days
Russell and Lichtenstein (2000)	Cardiovascular surgery patients in Canada	N = 198	Mean age 65.2 48 F 150 M	Multi-cell pulsating dynamic mattress (n = 98)	Standard care (n = 100)	0/98 (0%)	1/100 (1.0%)	0/98 (0%)	1/100 (1.0%)	7 days
Sanada et al. (2003)	Acute care unit in Japan	N = 108	Mean age 71.3	Double-layer air cell overlay (n = 29) Single-layer air cell overlay (n = 26)	Standard hospital mattress (n = 27)	Double layer: 0/29 (0%) Single layer: 2/26 (7.7%)	Standard care: 2/27 (7.4%)	Double layer: 0/29 (0%) Single layer: 1/26 (3.8%)	Standard care: 2/27 (7.4%)	10 days
Santamaria et al. (2013)	Intensive care unit in Australia	N = 440	Mean age 55	Mepilex® Border dressing (n = 219)	Standard care (n = 221)	3/219 (1.4%)	12/221 (5.4%)	Did not report PU grade	Did not report PU grade	24 days
Takala et al. (1996)	Intensive care patients in Finland	N = 40	Mean age 61.5 15 F 25 M	Constant low-pressure air mattress (n= 21)	Standard hospital foam mattress (n = 19)	0/21 (0%)	7/19 developed total of 13 PUs, 2 on the heels	Did not report PU grade	Did not report PU grade	14 days

Study	Care setting	Sample Size	Population	Intervention (int.)	Comparison (comp.)	Reported heel PU incidence ≥Category 1		Reported heel PU incidence ≥Category 2		Follow up period
						Int.	Comp.	Int.	Comp.	
Torra i Bou et al. (2002)	Hospital or home care patients in Spain	N = 130	Mean age 84.8 94 F 36 M	Allevyn Heel (n = 61)	Protective bandage (n = 50)	2/61 (3.3%)	22/50 (44.0%)	Did not report PU grade	Did not report PU grade	8 weeks
Tymec et al. (1997)	Acute care in USA	N = 52	Mean age 66.6 (range 27 - 90) 23 F 29 M	Foot Waffle (assumed n = 26)	Hospital pillow (assumed n = 26)	6 PUs, 0 to the heel	2 PUs, 1 to the heel	Did not report PU grade	Did not report PU grade	14 days
Van Leen et al. (2011)	Care home in Holland	N = 83	Mean age 82.6 67 F 16M	Static air mattress (n = 42)	Cold foam mattress (n = 41)	Not included	Not included	1/42 (2.4%)	3/41 (7.3%)	6 months
Van Leen et al. (2013)	Care homes in Holland	N = 41	Mean age 80.0 32 F 9 M	Viscoelastic Foam with static air overlay (n =20)	Viscoelastic Foam alone (n = 21)	Not included	Not included	1/20 (5.0%)	3/21 (14.3%)	6 months
Vanderwee et al. (2005)	Hospitals in Belgium	N = 447	Mean age 81.5 (range 76 -88) 282 F 165 M	Alternating pressure overlay (n = 222)	Standard care (n = 225)	Not included	Not included	5/222 (2.3%)	16/225 (7.1%)	Unknown

Figure 3-2 Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

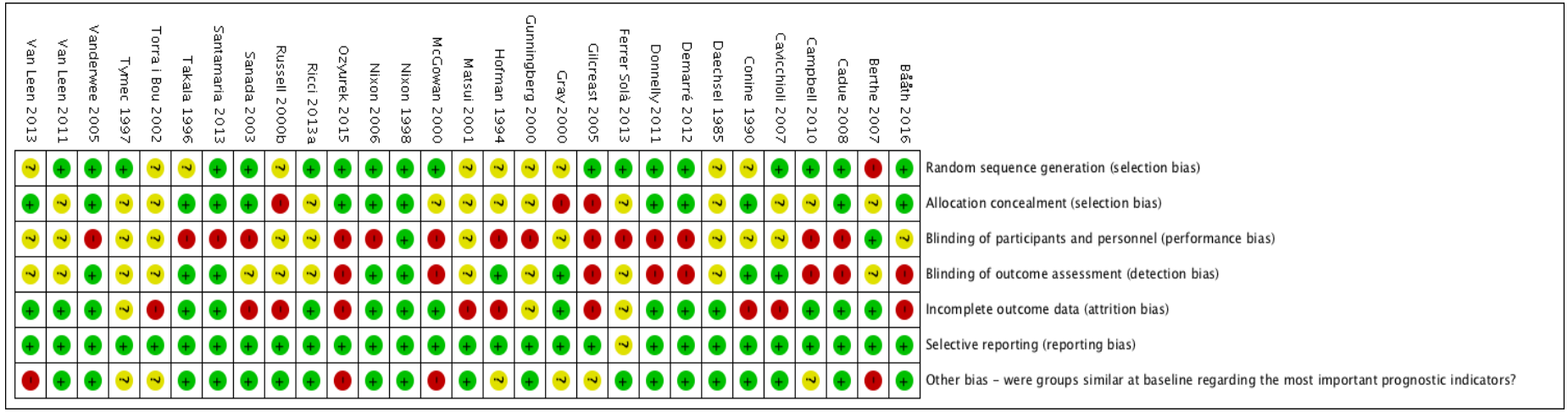
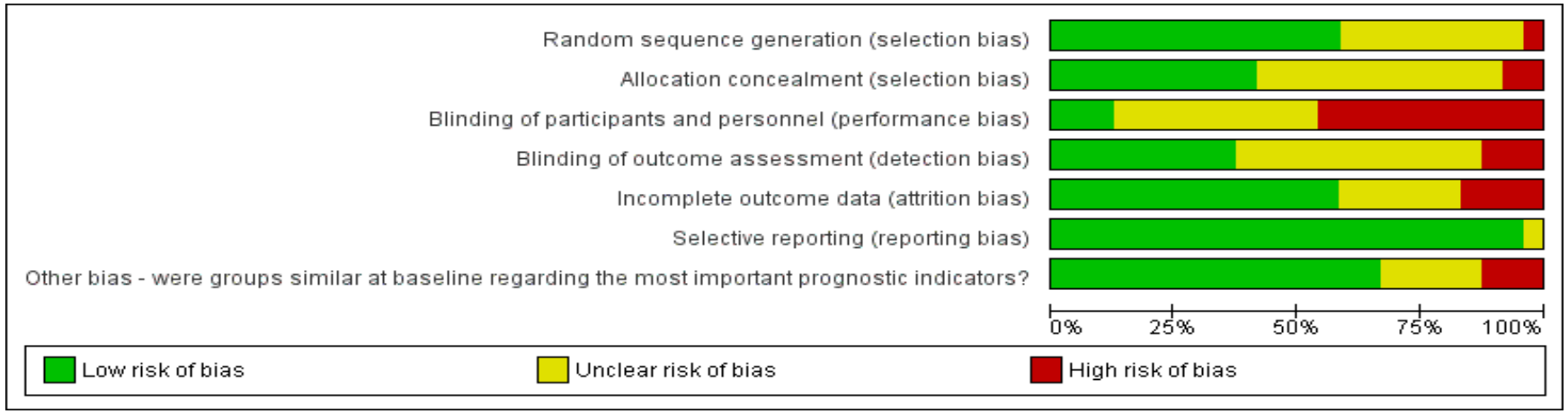


Figure 3-3 Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included



3.3.3 Risk of bias within studies

Risk of bias for each study was considered using the Cochrane tool for assessing risk of bias (Higgins et al., 2016) and the tables for the individual studies are presented in Appendix B Risk of bias tables with the summary and graph presented in Figure 3-2 and Figure 3-3. The risk of bias tables were used to help judge the GRADE assessments that follows each comparison (Guyatt et al., 2011).

Where there were high or unclear risk of bias in any of the domains, or missing outcome data, the study authors were contacted for clarification about the design and conduct of their study. Contact details were found for 18 studies, and 11 authors responded providing additional information about the conduct of their studies (Bååth et al., 2016, Cadue et al., 2008, Campbell et al., 2010, Cavicchioli and Carella, 2007, Nixon et al., 1998, Santamaria et al., 2013, Takala et al., 1996, Torra i Bou et al., 2002, Van Leen et al., 2013, Van Leen et al., 2011, Vanderwee et al., 2005). Only one of the studies was deemed to be at low risk of bias for all areas (Nixon et al., 1998).

One study was assessed as high risk of bias as it did not state the method of randomisation, and changed the randomisation ratio following an interim analysis which found that high risk participants were more often assigned to one arm so modified the randomisation in favour of the other arm (Berthe et al., 2007). Seven studies were classed as having an unclear risk of bias as they did not describe randomisation method (Conine et al., 1990, Daechsel and Conine, 1985, Gray and Smith, 2000, Gunningberg et al., 2000, Hofman et al., 1994, Russell and Lichtenstein, 2000, Torra i Bou et al., 2002). The remaining 21 studies were assessed as low risk of bias for randomisation. Only 12 of the 29 included studies gave information that indicated that participants were allocated with concealment.

3.3.3.1 Incomplete outcome data (attrition bias)

The completeness of outcome data for each main outcome in each study was examined, including whether reasons for attrition or exclusion were reported; whether there was re-inclusion of participants; and if the numbers in each intervention group were reported compared with total number of randomised participants. Ten studies were assessed as high risk of bias as they did not adequately address incomplete outcome data or include an ITT analysis, and one study stated that they conducted an ITT, however it is not a true ITT (Russell and Lichtenstein, 2000). Three studies were assessed as unclear risk of bias as they did not report this or it was unclear if there were any drop outs or withdrawals (Ferrer Sola et al., 2013, Gunningberg et al., 2000,

Tymec et al., 1997). The remaining 16 studies were assessed as at low risk of attrition bias.

3.3.3.2 Selective reporting (reporting bias)

Whilst all studies were assessed as low risk, this was not based upon inspection of study protocols for all studies, but on the study reports. The study protocols were only available for three of the studies (Bååth et al., 2016, Nixon et al., 1998, Nixon et al., 2006b). Judgement for the remaining studies were made based on the reporting of outcomes in the results that were described in the methods. Funnel plots could not be performed to assess for publication bias as fewer than 10 studies were included in each meta-analysis (Higgins et al., 2019).

3.3.3.3 Other potential sources of bias

Baseline characteristics of the included studies were assessed for risk of bias. Two studies were assessed as unknown risk as minimal baseline demographics were provided (Campbell et al., 2010, Gilcreast et al., 2005). Hofman et al. (1994) was assessed as unknown risk of bias because although age and length of hospital stay were similar, sex and fracture type were not similar at baseline, although sex is not a risk factor for pressure ulcer development (Coleman et al., 2013), it is not known if patients with different fracture types are more at risk. Torra i Bou et al. (2002) was also at unknown risk of bias because the two groups were comparable at baseline "once the inclusion of patients with diabetes was rejected", when diabetes is a known risk factor (Coleman et al., 2013).

Due to most of the studies being at unknown or high risk of bias for at least one factor, it was not possible to perform a sensitivity analysis. Risk of bias was not used to weight the studies in the comparisons; all included studies were used in the analysis regardless of methodological flaws. However, methodological quality is discussed in relation to the interpretation of the results.

3.3.4 Results of individual studies

Details of the individual studies and results are presented in Table 3-2. The main outcome of interest for this review was heel pressure ulcer incidence, however some trials reported this as the number of participants who developed a heel pressure ulcer, and some reported it as the total number of heel pressure ulcers that developed. This is problematic for meta-analysis as it cannot be assumed that each participant has two heels, or that only one ulcer developed on each heel. This risks a unit of analysis error

(Hirji and Fagerland, 2009) as it is the person that is randomised, but multiple body sites are at risk.

3.3.5 Synthesis of results

3.3.5.1 Total body AP devices (9 trials)

There is a wide variety of AP devices available including replacement mattresses and mattress overlays. The devices can vary by the number and size of the cells, layers of cells and cell cycle time, which is not always reported in RCTs. The control used for some of the total body device trials was the "standard hospital mattress". There is no international definition of what constitutes a standard hospital mattress, which can change between countries, hospitals and over time as technologies change. Therefore, in this review a standard hospital mattress is assumed to be a low-tech foam mattress that is used as part of standard care practices.

Comparison 1: AP compared with standard hospital mattress (3 trials; 413 participants)

This comparison included three studies (Matsui et al., 2001, Russell and Lichtenstein, 2000, Sanada et al., 2003) which compared any type of AP mattress, with a variety of cell depths and cell-cycle times with a standard hospital mattress for the prevention of pressure ulcers in a mixture of acute and extended care settings.

Primary outcome: heel pressure ulcer incidence, Category 1 (or equivalent) or above

Russell and Lichtenstein (2000) compared a multi-cell pulsating dynamic mattress with a standard hospital mattress. No participants in the AP group developed a heel pressure ulcer, and one participant in the standard hospital mattress group developed a Category 3 heel pressure ulcer. However, this person was randomised to the AP group, but due to a change in the operating room schedule was placed on conventional treatment, therefore was reassigned to the standard hospital mattress group in the original publication’s analysis. Only participants with a minimum of three days observation were included in their ITT. The results presented in the meta-analysis are as per the results presented in the study, but Two three-armed RCTs compared a double layered air-cell overlay, a single layer air-cell overlay and a standard hospital mattress (Matsui et al., 2001, Sanada et al., 2003). It was felt that the air overlays were homogenous enough to be pooled into a single AP group.

Table 3-3 shows that the missing data and reporting as per ITT makes a substantial difference on the direction of effect.

Two three-armed RCTs compared a double layered air-cell overlay, a single layer air-cell overlay and a standard hospital mattress (Matsui et al., 2001, Sanada et al., 2003). It was felt that the air overlays were homogenous enough to be pooled into a single AP group.

Table 3-3 Results for Russell and Lichtenstein (2000) including best-case and worst-case scenarios

	AP Group (n)	Standard Hospital mattress (n)	RR, Fixed 95% CI
Presented results	0/89	1/96	RR 0.36, 95% CI 0.01 to 8.71
Intention to treat	1/98	0/100	RR 3.06, 95% CI 0.13 to 74.23
Best-case scenario	1/98	4/100	RR 0.26, 95% CI 0.03 to 2.24
Worst-case scenario	10/98	0/100	RR 21.42, 95% CI 1.27 to 360.68

In the protocol for both trials, it states that if participants on the standard hospital mattress developed any pressure ulcer, they would be transferred onto an air mattress. There was no ITT analysis in either of these studies, therefore the denominators are the numbers presented by the authors after withdrawals and attrition. Best and worst-case scenarios were conducted to determine the impact of missing data. The use of best-case and worst-case scenarios had no effect on the direction of effect for the Matsui et al. (2001) study (Table 3-4).

Table 3-4 Results for (Matsui et al., 2001) including best-case and worst-case scenarios

	AP Group (n)	Standard Hospital mattress (n)	RR, Fixed 95% CI
Presented results	4/70	3/35	RR 0.67, 95% CI 0.16 to 2.82
Best-case scenario	8/72	13/35	RR 0.65, 95% CI 0.15 to 2.74
Worst-case scenario	10/72	13/35	RR 0.97, 95% CI 0.26 to 3.66

For the Sanada et al. (2003) study the overall pooled analysis was substantially altered, with the best-case scenario moving the direction of the pooled estimate to favour the AP overlay, and the worst-case scenario moving the pooled estimate to favour the standard hospital mattress; demonstrating a potential impact of the missing data on the results of this study (Table 3-5).

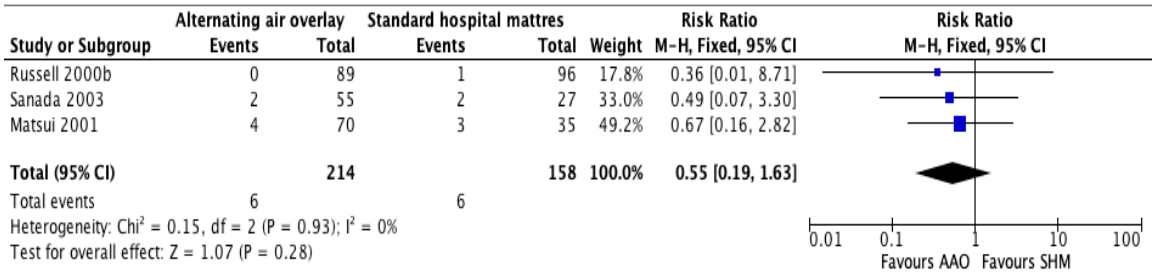
For the meta-analysis, the studies were pooled using a fixed-effects model and the single layer and double layer mattress groups were pooled into an AP group. A total of

385 participants were pooled from the three studies. There was no clear difference between the two groups in terms of the number of participants who developed a Category 1 or above heel pressure ulcer (RR 0.55, 95% CI 0.19 to 1.63; I^2 = 0%) (Figure 3-4).

Table 3-5 Results for Sanada et al. (2003) including best-case and worst-case scenarios

	AP Group (n)	Standard Hospital mattress (n)	RR, Fixed 95% CI
Presented results	2/55	2/27	RR 0.42, 95% CI 0.06 to 2.80
Best-case scenario	2/73	10/35	RR 0.10, 95% CI 0.02 to 0.41
Worst-case scenario	20/73	2/35	RR 4.79, 95% CI 1.19 to 19.38

Figure 3-4 Forest plot for AP versus standard hospital mattress for prevention of Category 1 or above heel pressure ulcers

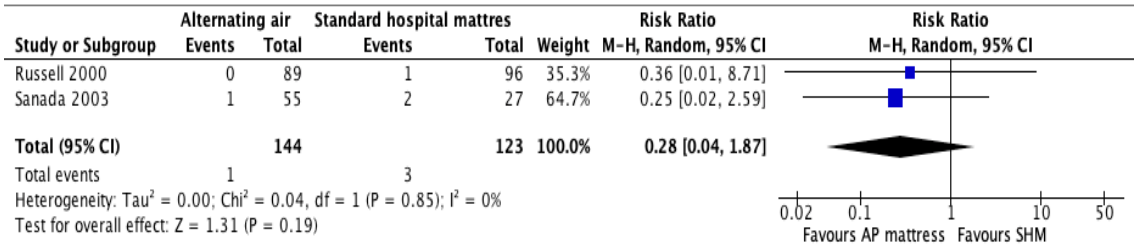


GRADE assessment: Very low certainty evidence; downgraded once for design & execution due to high risk of attrition bias for all studies and poor reporting for all studies; downgraded once for imprecision due to small sample size and wide 95% CI that crossed the line of no effect.

Primary outcome: heel pressure ulcer incidence, Category 2 (or equivalent) or above

A total of 306 participants were pooled from the two different AP groups (Russell and Lichtenstein, 2000, Sanada et al., 2003). No clear difference was seen between AP and standard hospital mattresses in the prevention of Category 2 or above heel pressure ulcers (RR 0.28, 95% CI 0.04 to 1.87; I^2 = 0%) (Figure 3-5).

Figure 3-5 Forest plot for AP versus standard hospital mattress for prevention of Category 2 or above heel pressure ulcers



GRADE assessment: Very low certainty evidence; downgraded once for design & execution due to high risk of attrition bias for all studies and poor reporting for all studies; downgraded once for imprecision due to small sample size and wide 95% CI that crossed no effect.

Secondary outcome: Adverse events

Russell and Lichtenstein (2000) reported that approximately half of all participants experienced adverse events (no difference between groups), but all were related to the participant's condition and none were attributable to the surface.

Comparison 2: AP compared with CLP mattress (4 trials; 806 participants)

This comparison includes four studies which compared any type of AP mattress, with any type of CLP mattress (Cavicchioli and Carella, 2007, Conine et al., 1990, Daechsel and Conine, 1985, Vanderwee et al., 2005). These studies took place in a mixture of acute and extended care settings.

Primary outcome: heel pressure ulcer incidence: Category 1 (or equivalent) or above

Two trials compared AP air overlays with CLP static overlays (Conine et al., 1990, Daechsel and Conine, 1985). It has not been possible to pool the results as the Conine et al. (1990) trial as it gives the total number of heel pressure ulcers: In the AP group 39/72 participants developed a total of 133 pressure ulcers, 19 of which were on the heel, and in the CLP group 45/76 developed a total of 148 pressure ulcers, 18 of which were on the heel. It is unclear if participants experienced more than one heel pressure ulcer, and if this were the case then a unit of analysis error would occur as the unit of randomisation, the person, should be the unit of analysis, unless adjusted analyses are prepared to take account of clustering. There was no ITT analysis performed in this trial, with the results for the 39 randomised participants who dropped out not included in the presented results. A best and worst-case analysis was not possible.

Daechsel and Conine (1985) reported no clear difference between the AP and CLP groups; RR 3.00, 95% CI 0.13 to 68.57.

GRADE assessment: Low certainty evidence: downgraded once for design & execution due to poor reporting for all studies; downgraded once for imprecision due to small sample size and wide 95% CI that crossed the line of no effect.

Primary outcome: heel pressure ulcer incidence Category 2 (or equivalent) or above

Vanderwee et al. (2005) compared an AP overlay with no turning protocol against a visco-elastic foam mattress with a four hourly turning protocol. We are moderately certain that there is a difference in the incidence of Category 2 or above heel pressure ulcers in favour of AP overlays when compared to visco-elastic foam mattresses, but there is a possibility that it is substantially different (RR 0.32, 95% CI 0.12 to 0.85).

GRADE assessment: Moderate certainty evidence; downgraded once for design and execution due to lack of blinding of participants and personnel.

Cavicchioli and Carella (2007) is a three-armed trial but the high specification foam mattress arm was excluded from the analysis as participants were not randomised to this intervention. The analysis is therefore only concerned with the two randomised arms that compare an air mattress in either AP or low air loss (CLP air) mode. There was no ITT analysis in this study, therefore the denominators presented in Table 3-6 are the numbers presented by the authors after withdrawals and attrition. Best and worst-case scenarios were performed to determine the impact of missing data from this study and found that the overall pooled analysis results were substantially altered, with the best-case scenario moving the direction of the pooled estimate significantly and substantially favour the AP intervention, and the worst-case scenario moving the pooled estimate to significantly favour the CLP intervention; demonstrating a potential impact of the missing data on the results of this trial (Table 3-6). No clear difference was seen between AP or CLP mattresses for prevent Category 2 or above heel pressure ulcers (RR 3.09, 95% CI 0.13 to 74.47).

GRADE assessment: Very-low certainty evidence; downgraded once for design & execution due to high risk of attrition bias and poor reporting; downgraded once for imprecision due to small sample size and wide 95% CI that crossed the line of no effect.

Table 3-6 Results for Cavicchioli and Carella (2007) including best-case and worst-case scenarios

	AP Group (n)	CLP Air Group (n)	RR, Fixed 95% CI
Presented results	1/69	0/71	RR 3.09, 95% CI 0.13 to 74.47
Best-case scenario	1/86	13/84	RR 0.08, 95% CI 0.01 to 0.56
Worst-case scenario	18/86	0/84	RR 36.15, 95% CI 2.21 to 590.36

These trials were put in the same comparison, but as the CLP groups differ due to being a CLP foam and a CLP air mattress, it was decided that they were clinically heterogeneous and therefore not pooled.

Secondary outcome: Acceptability of the intervention

Daechsel and Conine (1985) reported that participants did not indicate a particular preference to either type of mattress that they were assigned, although there is a lack of evidence of a systematic approach to this data being collected and is potentially subject to reporting bias. Conine et al. (1990) recorded the number of participants who dropped out of the trial due to discomfort, with no clear difference between the two groups (RR 1.18, 95% CI 0.67 to 2.08).

GRADE assessment: Low certainty evidence: downgraded once for design & execution due to poor reporting for all studies; downgraded once for imprecision due to small sample size and wide 95% CI that crossed the line of no effect.

Comparison 3: AP mattresses with different alternation cycles (1 trial; 610 participants)

This comparison includes one study which compared two different AP mattresses with single and multi-stage alternation cycles in an acute care setting (Demarre et al., 2012).

Primary outcome: heel pressure ulcer incidence Category 2 (or equivalent) or above

No clear difference was found between the two groups: RR with multistage 0.64, 95% CI 0.18 to 2.23, versus single stage.

GRADE assessment: Low-certainty evidence; downgraded once for design & execution due to high risk of performance and detection bias and poor reporting; downgraded once for imprecision due to wide 95% CI that crossed the line of no effect.

Comparison 4: AP replacement mattress and AP overlay mattress (1 trial; 1972 participants)

This comparison includes one study which compared an AP replacement mattress with an AP overlay mattress in an acute care setting (Nixon et al., 2006b).

Primary outcome: heel pressure ulcer incidence, Category 2 (or equivalent) or above

No clear difference was found between the two groups: RR with AP mattress 1.05, 95% CI 0.55 to 1.98 versus AP overlay.

GRADE assessment: Moderate certainty evidence; downgraded once for design and execution due to lack of blinding of participants and personnel.

Secondary outcome: Acceptability of the intervention

The acceptability of the mattresses was assessed by recording the numbers of participants who requested to change mattresses due to comfort (Nixon et al., 2006b). We are moderately certain that there is a clear difference in favour of the AP replacement for the number of patient requested mattress changes (used as a proxy measure for comfort). (RR 0.81, 95% CI 0.69 to 0.97).

Secondary outcome: Adverse events

Nixon et al. (2006b) reported 399 adverse events for 308 participants: nine adverse events in eight participants were attributable to the mattress. This included four falls (all on the replacement mattress), four bed rails incidents for three participants (two on replacement mattress and one on the overlay), one case of contact dermatitis from the replacement mattress. Twelve adverse events were reported unrelated to the mattresses.

Summary: Total body AP devices

One meta-analysis was performed on two of the nine trials found evaluating total body AP devices. No clear difference was found between the AP and standard hospital mattresses in the prevention of heel pressure ulcers. GRADE assessment showed very low-quality evidence amongst these trials. We are moderately certain that AP overlays reduce the incidence of Category 2 or above heel pressure ulcers, but there is a possibility that it is substantially different, and this is based on one trial with moderate certainty evidence. More evidence is required to strengthen this recommendation. None of the trials included time-to-heel pressure ulcer development. In terms of acceptability of the intervention Nixon et al. (2006b) found that fewer participants requested a change in mattress in the AP replacement mattress compared with the AP

overlay group, although the reasons why changes in mattresses were requested is not known. Only Nixon et al. (2006b) reported adverse events; attributing nine adverse events to the surface that the participant was on. No trials included quality of life as an outcome measure. There are not enough studies to show a difference, more trials are needed that look at mattresses for the prevention of heel pressure ulcers.

3.3.5.2 Total body constant low pressure (CLP) devices (11 trials)

There are several different products which were considered as total body CLP devices as described in 3.2.2.3. These were differentiated into CLP air and CLP foam mattresses.

Comparison 5: High specification foam mattress compared with standard hospital mattress (3 trials; 1874 participants)

This comparison includes three studies (Berthe et al., 2007, Gunningberg et al., 2000, Hofman et al., 1994) which compared any type of high specification foam mattress with a standard hospital mattress in a variety of acute care settings.

Primary outcome: heel pressure ulcer incidence Category 1 (or equivalent) or above

One trial compared a foam block mattress with a standard hospital mattress (Berthe et al., 2007). There was no clear difference in the heel pressure ulcer incidence between the mattresses; RR 1.09, 95% CI 0.18 to 6.49.

GRADE assessment: Low certainty evidence; downgraded once for design & execution due to high risk of selection bias and poor reporting; downgraded once for imprecision due to wide 95% CI that crossed the line of no effect.

Primary outcome: heel pressure ulcer incidence Category 2 (or equivalent) or above

There was no ITT analysis for Hofman et al. (1994), therefore the denominators are the numbers presented by the authors after withdrawals and attrition. The Hofman et al. (1994) trial gives the total number of heel pressure ulcers: In the foam block mattress group after 2 weeks 4/17 participants developed a total of 8 pressure ulcers, 3 of which were on the heel, and in the standard hospital mattress group 13/19 participants developed a total of 18 pressure ulcers, 6 of which were on the heel. It is uncertain whether foam block mattresses are more effective at preventing Category 2 or above heel pressure ulcers than a standard hospital mattress as the certainty of the evidence has been assessed as very low.

GRADE assessment: Very low certainty evidence; downgraded twice for design & execution due to high risk of attrition and performance bias and poor reporting; downgraded once for imprecision due to small sample size.

Gunningberg et al. (2000) compared a visco-elastic foam trolley mattress and then subsequent overlay to a standard trolley and standard hospital mattress. 18/119 participants were excluded but it was unclear if this was before or after randomisation, therefore only complete case data are presented. The total number of heel pressure ulcers, rather than total number of participants that developed a heel pressure ulcer were presented; in the viscoelastic group they reported three heel pressure ulcers out of 48 participants who developed pressure ulcers; one Category 1 and two Category 2. In the standard hospital mattress group, they reported five heel pressure ulcers in 53 participants: two Category 1 and three Category 2 It is uncertain whether viscoelastic mattress overlays are more effective at preventing Category 2 or above heel pressure ulcers than standard hospital mattresses as the certainty of the evidence has been assessed as low.

GRADE assessment: Low certainty evidence; downgraded twice for design & execution due to high risk of performance bias and poor reporting.

Due to there being a possible unit of analysis error pooling was not performed (Gunningberg et al., 2000, Hofman et al., 1994).

Secondary outcome: Cost

Only Berthe et al. (2007) reported the cost of the intervention (€70 for the foam block mattress), no cost comparison was provided.

Secondary outcome: Acceptability of the intervention

Gunningberg et al. (2000) reported no difference between the two groups for participants who reported that comfort was "good" or "very good" (RR 1.00, 95% CI 0.89 to 1.13).

Comparison 6: New versus old high specification foam mattress (1 trial; 100 participants)

This comparison includes one study (Gray and Smith, 2000) which compared a newer version of a high specification foam mattress with an older version in an acute care setting.

Primary outcome: heel pressure ulcer incidence Category 2 (or equivalent) or above

No clear difference was seen between the new and old mattresses; (RR 0.33, 95% CI 0.01 to 7.99).

GRADE assessment: Very low certainty evidence; downgraded twice for design & execution due to high risk of selection bias and poor reporting; downgraded once for imprecision due to small sample size and wide 95% CI that crossed the line of no effect.

Secondary outcome: Acceptability of the intervention

No difference was seen between the two groups for participants who reported the mattress as "comfortable" or "very comfortable" (RR 1.00, 95% CI 0.90 to 1.11).

Comparison 7: Different high specification foam mattresses (1 trial; 105 participants)

This comparison includes one study which compared two different types of high specification viscoelastic foam mattresses for the prevention of pressure ulcers in an acute care setting.

Primary outcome: heel pressure ulcer incidence, category 1 (or equivalent) or above

Ozyurek and Yavuz (2015) randomised 357 participants, but only participants with a length of stay >7days were included in the analysis (n=105). The total number of heel pressure ulcers that developed were reported, therefore only complete case data could be presented. 22/53 participants on the first high specification visco-elastic foam mattress developed a total of 34 ulcers, 3 of which were at the heel compared with 23/52 participants on the second high-specification viscoelastic foam mattress who developed a total of 33 ulcers, 3 of which were at the heel. RR calculations were not performed due to a potential unit of analysis error.

GRADE assessment: Very low-quality evidence; downgraded twice for design & execution due to high risk of detection, performance and attrition bias and poor reporting; downgraded once for imprecision due to small sample size.

Comparison 8: Sheepskin overlay compared with standard hospital mattress (1 trial; 297 participants)

This comparison includes one study which compared Australian medical sheepskin overlays with standard hospital mattresses for the prevention of pressure ulcers in an

acute care setting (McGowan et al., 2000). Some participants in the sheepskin arm would also receive sheepskin heel or elbow protectors depending upon the perceived need.

Primary outcome: heel pressure ulcer incidence Category 1 (or equivalent) or above

The total number of heel pressure ulcers that developed were reported, rather than the number of patients with ulcers. For the sheepskin overlay 14/155 participants developed a total of 21 ulcers, two of which were at the heel compared with 43/142 participants in the standard hospital mattress group who developed a total of 72 ulcers, 28 of which were at the heel. RR calculations were not performed due to a potential unit of analysis error.

GRADE assessment: Low-quality evidence; downgraded twice for design & execution due to high risk of performance and detection bias and poor reporting.

Comparison 9: Static air overlays compared with high specification foam mattresses (2 trials; 124 participants)

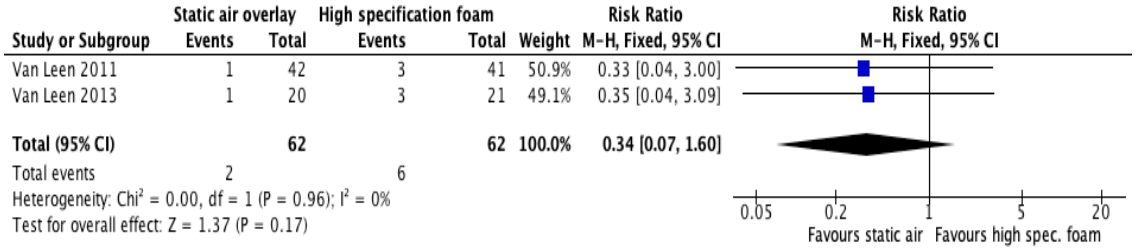
Two trials compared static air overlays with a high specification foam mattress for the prevention of pressure ulcers in nursing home residents (Van Leen et al., 2013, Van Leen et al., 2011).

Primary outcome: heel pressure ulcer incidence Category 2 (or equivalent) or above

Van Leen et al. (2013) is a crossover trial, so only data up until the point of crossover were included (Greenwood et al., 2014). Data from these two studies were pooled using a fixed-effects model; Heterogeneity: $Chi^2 = 0.00$, df = 1 (P = 0.96); $I^2 = 0\%$. There was no clear difference in the number of heel pressure ulcers that developed in the two groups (RR 0.34, 95% CI 0.07 to 1.60) (Figure 3-6).

GRADE assessment: Low certainty evidence; downgraded once for design & execution due to lack blinding, downgraded once for imprecision due to small sample size and wide 95% CI that crossed no effect.

Figure 3-6 Forest plot comparing static air overlay with high specification foam mattress for the prevention of Category 2 or above heel pressure ulcers



Comparison 10: Constant low-pressure air mattress compared with standard hospital mattress (1 trial; 40 participants)

One trial compared a powered CLP air mattress with a standard hospital mattress in an acute care setting (Takala et al., 1996).

Primary outcome: heel pressure ulcer incidence, Category 1 (or equivalent) or above

No clear difference was seen between the two groups: RR 0.18 with CLP air mattress, 95% CI 0.01 to 3.56 versus a standard hospital mattress.

GRADE assessment: Low certainty evidence; downgraded once for design & execution due to high risk of detection bias and poor reporting; downgraded once for imprecision due to small sample size and wide 95% CI that crossed the line of no effect.

Secondary outcome: Time-to-pressure ulcer development

The mean number of days to the development of heel pressure ulcers was 9.5 days in the standard hospital mattress group. Due to the event rate of 0 in the CLP air mattress group a fair comparison of time-to-heel pressure ulcer development cannot be performed.

Comparison 11: Specialist mattress overlay compared with visco-elastic overlay (1 trial; 50 participants)

One study compared a specialist mattress overlay with a visco-elastic overlay for the prevention of pressure ulcers in a long-term care setting (Ricci et al., 2013).

Primary outcome: heel pressure ulcer incidence Category 1 (or equivalent) or above

No difference was seen between the surfaces with 0/25 heel pressure ulcer developing in the specialist mattress overlay group and 0/25 in the visco-elastic overlay group.

GRADE assessment: Low certainty evidence; downgraded once for design & execution due to poor reporting; downgraded once for imprecision due to small sample size.

Secondary outcome: Acceptability of the intervention

No difference was found between the two arms in terms of acceptability of the interventions using Global safety and tolerability scores: with all participants in both arms rating the overlays as either "good" or "excellent".

Summary: Total body CLP devices

Due to the low numbers if trials that reported heel pressure ulcers, the low quality, and clinical heterogeneity of the trials included in this section, only two out of the ten trials identified were suitable for meta-analysis (Van Leen et al., 2013, Van Leen et al., 2011) and the GRADE assessment showed that this to be low certainty evidence and therefore our confidence in the effect estimate is limited. No clear difference was found in any of the studies for the prevention of heel pressure ulcers. Takala et al. (1996) reported time-to-pressure ulcer development at the heel, but no analysis was possible as they had an event rate of zero in the CLP air mattress group. Four trials reported acceptability of the intervention; however, these are not comparable as they all use different methods to measure this, and none were measured using a validated scale. No trials reported adverse events or quality of life.

3.3.5.3 Heel-specific devices

A total of nine trials compared heel offloading or CLP devices with other devices or with standard care.

Comparison 12: Heel-specific offloading device compared with standard care (3 trials; 492 participants)

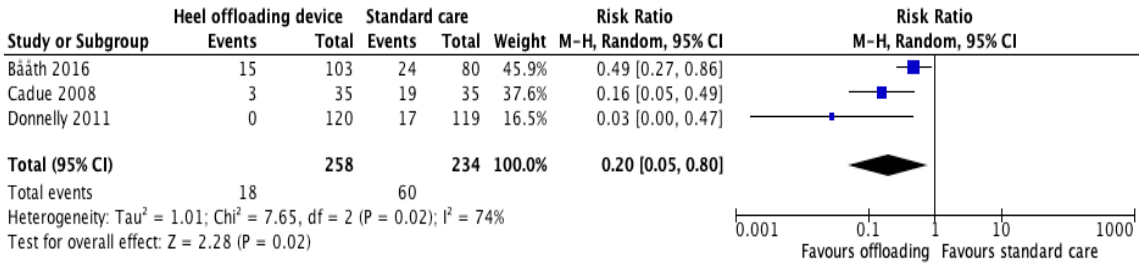
Three studies were included which looked at a variety of devices designed to offload pressure at the heel compared with standard care in a variety of acute care settings (Bååth et al., 2016, Cadue et al., 2008, Donnelly et al., 2011). Standard care often includes mattress according to clinical need, a repositioning schedule, and a skin care regimen.

Primary outcome: heel pressure ulcer incidence Category 1 (or equivalent) or above

Bååth et al. (2016) randomised 405 participants in the ambulance prior to consent, but only 183 participants were included in the analysis as a large proportion of participants were not admitted to hospital or one of the wards involved in the trial. This is unlikely to lead to bias as the intended effect of the intervention is dependent on the participant being admitted to hospital, which cannot be influenced by the randomised allocation.

The heel pressure ulcer incidence data was pooled for the three studies (Bååth et al., 2016, Cadue et al., 2008, Donnelly et al., 2011), with a total of 492 participants, using a random effects model due to statistical heterogeneity ($Chi^2 = 7.65$, df = 2 (P = 0.02); I^2 = 74%) (RR 0.20, 95% CI 0.05 to 0.80 (Figure 3-7). A difference was found in favour of the offloading device.

Figure 3-7 Forest plot for the comparison of offloading devices with standard care for the prevention of Category 1 or above heel pressure ulcers

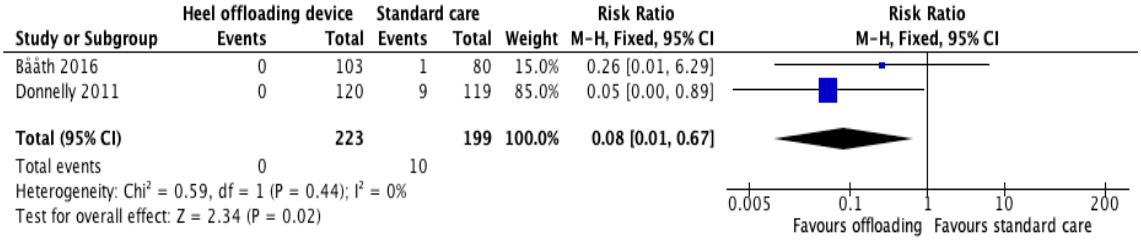


GRADE assessment: Low certainty evidence; downgraded once for design & execution due to lack of blinding, downgraded once for imprecision due to small sample size. The confidence in the effect estimate of whether offloading devices prevent Category 1 or above heel pressure ulcers is limited due to the quality of the evidence, the true effect may be substantially different from the estimate of effect.

Primary outcome: heel pressure ulcer incidence Category 2 (or equivalent) or above

Two trials included Category 2 or above outcome data (Bååth et al., 2016, Donnelly et al., 2011). The heel pressure ulcer incidence data were pooled, with a total of 422 participants, using a fixed-effect model ($Chi^2 = 0.59$, df = 1(p = 0.44); I^2 = 0%) (RR 0.08, 95% CI 0.01 to 0.67) (Figure 3-8). We are moderately confident in the effect estimate of offloading devices preventing more Category 2 or above heel pressure ulcers compared to standard care. The true effect is likely to be close to the estimate of effect, but it is possible that it is substantially different due to the quality of the evidence.

Figure 3-8 Forest plot for the comparison of offloading devices with standard care for the prevention of Category 2 or above heel pressure ulcers

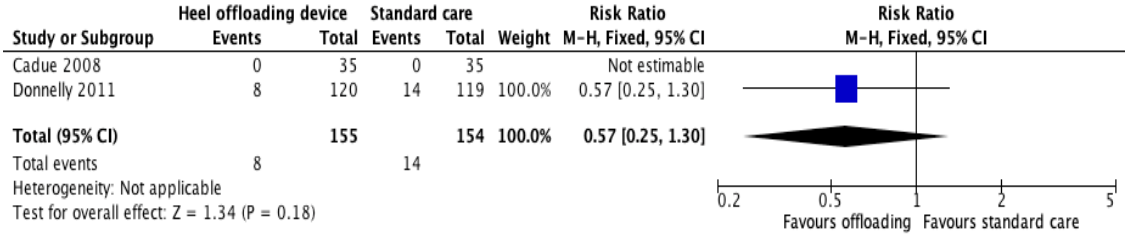


GRADE assessment: Moderate certainty evidence; downgraded once for design & execution due to lack of blinding.

Secondary outcome: pressure ulcer incidence to other body sites, Category 1 (or equivalent) or above

A meta-analysis was performed for the two studies that reported the number of participants that developed a pressure ulcer to body sites other than the heel, (Cadue et al., 2008, Donnelly et al., 2011) using fixed effects model. No evidence of a difference was seen for heel offloading devices being associated with pressure ulcers at other body sites (RR 0.57, 95% CI 0.25 to 1.30; I^2 = 0%) (Figure 3-9).

Figure 3-9 Forest plot for Category 1 or above pressure ulcer development at other body sites



GRADE assessment: Low certainty evidence; downgraded once for design & execution due to lack blinding, downgraded once for imprecision due to small sample size.

Secondary outcome: Time-to-heel pressure ulcer development

Cadue et al. (2008) recorded a mean time-to-development of Category 1 or above pressure ulcers of 5.6 days in the offloading group versus 2.8 days in the standard care group. They also reported an increase in the days that participants remained ulcer free in the heel-specific offloading device group; 8.7 days versus 2.8 days.

Donnelly 2011 plotted Kaplan-Meier survival function and found a significant difference in the number of days before the development of HPUs in favour of the offloading group.

GRADE assessment: Low certainty evidence; downgraded once for design & execution due to lack blinding, downgraded once for imprecision due to small sample size. The confidence in the effect estimate of whether offloading devices effect the time to development of Category 1 or above heel pressure ulcers is limited due to the quality of the evidence, the true effect may be substantially different from the estimate of effect.

Secondary outcome: Acceptability of the intervention

This outcome was reported in two studies (Bååth et al., 2016, Donnelly et al., 2011) but no comparison was possible as this was not recorded using comparable, validated scales. Donnelly et al. (2011) reported 88 protocol violations which were reported either from subjects' comments or clinical observations as being due to the offloading device hindering movement, being too warm, causing pain or discomfort, or issues with the application/removal. Baath reported perceptions of the device from the participants, of the patients that were questioned, 39% felt that it caused friction and one experienced blistering caused by the boot straps, 48% perceived the boot as comfortable when lying down and 25% perceived it as comfortable when lying on their side and 63% perceived it as 'okay to have on when I'm sleeping.

GRADE assessment: Moderate certainty evidence; downgraded once for design & execution due to lack of blinding.

Secondary outcome: Adverse events

Donnelly et al. (2011) reported 45 adverse events, but only one was potentially attributable to the offloading device; bruising was documented to the lower limb, which could have been caused by the offloading device, or from when the participants legs were bound together by the paramedics to immobilise a fracture.

Bååth et al. (2016) reported one adverse event in the intervention group where a participant "developed blistering due to the bootstraps".

Comparison 13: Different heel offloading devices (2 trials; 124 participants)

This comparison includes a three-armed trial comparing three different offloading devices; a standard pillow, an offloading boot and a wedge within an orthopaedic acute care setting (Campbell et al., 2010) and a two-armed trial comparing an offloading boot to a standard pillow in an acute care setting (Tymec et al., 1997).

Primary outcome: heel pressure ulcer incidence Category 1 (or equivalent) or above

Tymec et al. (1997) only specified that there were 52 participants, but not how many were in each group. They reported one patient in the pillow group developing a heel pressure ulcer and no patients in the offloading device group.

For Campbell et al. (2010), the trial took place over a 14 day period, participants were followed until discharge, but due to the nature of the condition this was over a short period (exact data unknown). These trials could not be pooled due to clinical heterogeneity of the controls and the number of participants in each group for Tymec et al. (1997) was not known.

Secondary outcome: pressure ulcers to other body sites

Tymec et al. (1997) reported six Category 1 or above pressure ulcers that developed to other body sites in the offloading device group and one in the pillow group. All the ulcers that were reported were to the lower limb.

Secondary outcome: Acceptability of the intervention

Campbell et al. (2010) collected feedback from both the participants and clinical staff in the form of both written and verbal feedback, 18 people gave positive feedback regarding the pillow, 19 for the Repose and 28 for the wedge, although denominators are not known.

Secondary outcome: Time to heel pressure ulcer development

Tymec et al. (1997) reported a mean time-to-development in favour of the pillow group; 10 days for the offloading device group compared with 13 days in the pillow group, although not enough data was provided to do a statistical analysis.

Secondary outcome: Adverse events

In the Campbell et al. (2010) trial, four participants had the hospital pillow removed as they had all undergone knee replacement surgery and had relatively short legs which led to the pillow bunching up beneath the knee which interfered with the newly replaced joint. One participant had the wedge removed as they had a fractured hip, and the wedge did not keep the leg high enough to keep the hip aligned when in traction. No adverse events were reported in the offloading device group.

Tymec et al. (1997) reported higher mean interface pressures to the Achilles tendon of 14.2mmHg (SD 15.6mmHg) in the offloading device group compared with 31.2mmHg (SD 15.6mmHg) when using a pillow to offload the heel.

Comparison 14: Heel-specific offloading devices compared with heel-specific CLP device (1 trial; 338 participants)

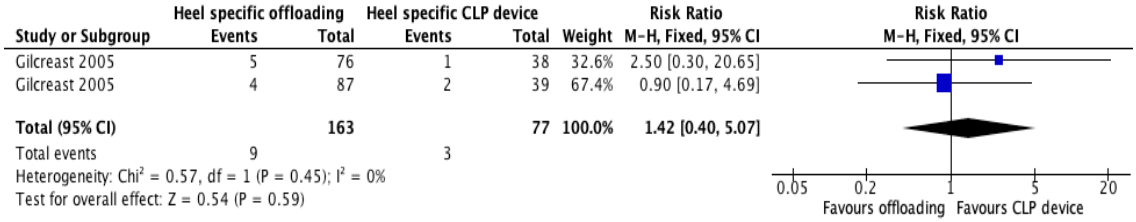
This comparison includes a single three-armed trial comparing three different heel-specific devices: a CLP device, an egg-crate offloading boot and an air filled offloading boot in an acute care setting (Gilcreast et al., 2005).

Primary outcome: heel pressure ulcer incidence Category 1 (or equivalent) or above

A total of 338 participants were randomised, but only 240 participants had complete data; because the trial did not specify the participant group prior to drop out only complete case data were presented. Double counting was avoided by members of the control group (CLP device) being divided for the meta-analysis. There was no clear difference between the CLP and offloading devices (RR 1.42, 95% CI 0.40 to 5.07) (Figure 3-10).

GRADE assessment: Very low certainty evidence; downgraded twice for design & execution due to high risk of selection, detection, performance, and attrition bias; downgraded once for imprecision due to wide 95% CI that crossed the line of no effect.

Figure 3-10 Forest plot for the comparison of offloading and heel CLP devices for the prevention of Category 1 or above heel pressure ulcers



Secondary outcome: Costs

Gilcreast et al. (2005) reported that the CLP device was significantly cheaper than the other interventions. This was just for the cost of the device, but they did include the cost of pillows as they were sometimes used with the CLP device, and the cost of replacement devices as they would sometimes be lost in the laundry.

Comparison 15: Heel-specific CLP devices compared with standard care (4 trials; 1425 participants)

This comparison includes four studies looking at CLP heel-specific devices such as dressings or gel pads that aim to reduce the peak pressure or friction and shearing forces at the heel; compared with standard care (Ferrer Sola et al., 2013, Nixon et al.,

1998, Santamaria et al., 2013, Torra i Bou et al., 2002). These studies took place in a variety of settings including acute care, operating rooms, and home care environments.

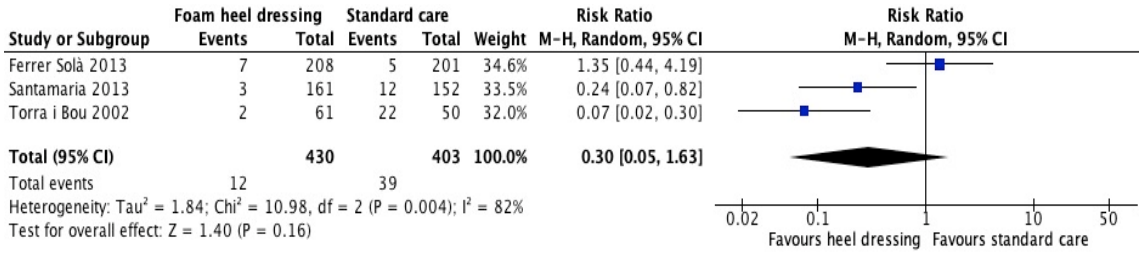
Primary outcome: heel pressure ulcer incidence Category 1 (or equivalent) or above

Nixon et al. (1998) compared a dry visco-elastic polymer pad under the torso and heel to a standard operative table foam mattress in the prevention of intra-operative pressure ulcers. It was therefore felt that due to the difference in the intervention type, and the setting being in an operating theatre this trial could not be included in the meta-analysis due to clinical heterogeneity. Additional study data were sought and obtained from the author as the published article does not include heel pressure ulcer incidence. It was therefore possible to report heel pressure ulcer incidence at the participant level and at the ulcer level. No clear difference was seen between the two groups (RR 0.45, 95% CI 0.14 to 1.43).

GRADE assessment: High certainty evidence

Three studies compared foam heel dressings to standard care; two compared a polyurethane heel dressing with a classic padded bandage (Ferrer Sola et al., 2013, Torra i Bou et al., 2002) and one compared a multi-layered silicone foam dressing with standard care (Santamaria et al., 2013). The presented data for these three studies were pooled with a total of 833 participants; using a random-effects model (Tau^2 = 1.84; Chi^2 = 10.98, df = 2 (P = 0.004); I^2 = 82%). There was no clear difference in the number of Category 1 or above heel pressure ulcers that developed (RR 0.30, 95% CI 0.05 to 1.63) (Figure 3-11).

Figure 3-11 Forest plot for the comparison of CLP heel devices with standard care for the prevention of Category 1 or above heel pressure ulcers



It is likely that the source of heterogeneity is Ferrer Sola et al. (2013) where the direction of effect is reverse of the other studies included in this meta-analysis. There was insufficient information about attrition, and it was unclear if an ITT analysis was performed.

A best- and worst-case scenario was performed to determine the impact of missing data for the Torra i Bou et al. (2002) study and Santamaria et al. (2013). This was found to have no effect on the direction of effect for Torra i Bou et al. (2002) (Table 3-7) but for Santamaria et al. (2013) the worst case scenario changed the direction of effect towards the control group (Table 3-8).

Table 3-7 Results for Torra i Bou et al. (2002) including best-case and worst-case scenarios

	Polyurethane heel group (n)	Standard care (n)	RR, Fixed 95% CI
Presented results	2/61	22/50	RR 0.07, 95% CI 0.02 to 0.30
Best-case scenario	2/65	37/65	RR 0.05, 95% CI 0.01 to 0.22
Worst-case scenario	6/65	22/65	RR 0.27, 95% CI 0.12 to 0.63

Table 3-8 Results for Santamaria et al. (2013) including best-case and worst-case scenarios

	Silicone foam dressing (n)	Standard care (n)	RR, Fixed 95% CI
Presented results	3/161	12/152	RR 0.24, 95% CI 0.07 to 0.82
Best-case scenario	3/219	81/221	RR 0.04, 95% CI 0.01 to 0.12
Worst-case scenario	61/219	12/221	RR 5.13, 95% CI 2.84 to 9.25

GRADE assessment: Very low certainty evidence; downgraded once for design & execution due to lack blinding, downgraded once for inconsistency due to high I^2 and $P<0.05$, downgraded once for imprecision due to small sample size and wide 95% CI that crossed no effect.

Primary outcome: heel pressure ulcer incidence Category 2 (or equivalent) or above

Ferrer Sola et al. (2013) was the only trial to report Category 2 or above heel pressure ulcers, no clear difference was seen, with 5/208 in the polyurethane heel cup group and 1/201 in the classic bandage group (RR 4.83, 95% CI 0.57 to 41.0).

GRADE assessment: Very low certainty evidence; downgraded once for design & execution due to high risk of performance bias and poor reporting; downgraded once for imprecision due wide 95% CI that crossed the line of no effect.

Secondary outcome: pressure ulcer incidence to other body sites, Category 1 (or equivalent) or above

Ferrer Sola et al. (2013) reported no clear difference, with 3/208 in the polyurethane heel cup and 0/201 in the classic padded bandage group (RR 0.14, 95% CI 0.01 to 2.66).

GRADE assessment: Very low certainty evidence; downgraded once for design & execution due to high risk of performance bias and poor reporting; downgraded once for imprecision due wide 95% CI that crossed the line of no effect.

Secondary outcome: Costs

Torra i Bou et al. (2002) reported a difference between the costs of the device plus nursing time over an eight week period in favour of the foam heel dressing when compared with the protective padded bandage, although we have very little confidence in the effect estimate due to very-poor quality evidence (SMD -0.46, 95% CI -0.81 to -0.11) (Torra I Bou et al., 2008).

GRADE assessment: Very low-quality evidence; downgraded once for design & execution due to high risk of attrition bias and poor reporting; downgraded once for imprecision due small sample size. Santamaria et al. (2013) published a cost benefit analysis which included costs for both sacrum and heel. When the costs were recalculated for heel pressure ulcers only, we are moderately certain that the average costs per group were $55.84 per patient for intervention and $137.94 for control, but no adjustment was made for severity of pressure ulcer or potential patient differences.

GRADE assessment: Moderate quality evidence; downgraded once for design & execution due to high risk of performance bias.

ITT was not considered for either study.

Secondary outcome: Relative acceptability of the intervention

Torra i Bou et al. (2002) saw a difference in favour of the foam heel dressing when using a five-point scale, where 1 was the lowest value and 5 was the highest value, to assess the comfort of the dressing application from the perspective of the patient (SMD 3.05, 95% CI 2.54 to 3.56) although we have very little confidence in the effect estimate due to very-poor quality evidence.

GRADE assessment: Very low certainty evidence; downgraded once for design & execution due to high risk of attrition bias and poor reporting; downgraded once for imprecision due small sample size.

Summary

Of the ten heel-specific trials identified, three trials compared heel offloading devices with standard care and were included in a meta-analysis, which showed that there is limited evidence that offloading devices reduce the risk of developing a Category 1 or above heel pressure ulcer due to the low quality of the evidence reducing the certainty of these results.

Two trials compared heel offloading devices with standard care and were included in a meta-analysis, which showed that we are moderately confident that offloading devices reduce the risk of developing a Category 2 or above heel pressure ulcers. The moderate quality of evidence means the true effect is probably close to the estimated effect.

Two of these studies included time-to-heel pressure ulcer development data, but they were reported differently hence they could not be pooled.

Only one trial, of low quality, compared offloading devices to CLP heel-specific devices and no clear difference was seen.

Four trials compared heel-specific CLP devices such as polyurethane foam heel dressings and gel pads with standard care; the three foam heel dressings were included in a meta-analysis. We are uncertain whether foam heel dressings reduce the incidence of Category 1 or above heel pressure ulcers as the certainty of the evidence has been assessed as very low due to high risk of bias, imprecision, and inconsistency.

There is no clear evidence that heel-specific CLP devices increase or decrease the risk of developing a pressure ulcer to other body sites. Only Santamaria et al. (2013) included time-to-pressure ulcer development as an outcome measure but this was combined for heel and sacral ulcers and could not be separated.

A single high-quality trial looked at the use of visco-elastic polymer pads to the heel in theatres, compared with a standard operating table mattress; no clear difference was seen in the prevention of heel pressure ulcers.

3.4 Discussion

Any device which could potentially be used for the prevention of heel pressure ulcers was included in this review, however it was rare that identical devices would be tested in different trials, and therefore devices had to be grouped together subjectively into comparisons that appeared to be homogenous based on their apparent mechanism of action. Since the systematic review was written, standards have been published to test methods for quantifying mattress characteristics by the Rehabilitation Engineering and

Assistive Technology Association of North America (RESNA) (2019), and EPUAP et al. (2019) have published terms and definitions associated with support surfaces which will aid in assessing comparability for support surfaces. A recent network meta-analysis of mattresses, overlays, and integrated bed systems for the prevention of all pressure ulcers, used these definitions and identified 65 studies with 14 different intervention groups (Shi et al., 2018), whereas this review identified 9 different mattress types, which were grouped in a similar manner to Shi et al. (2018).

There is no recognised definition or standardisation of heel-specific devices, with very little published early phase research into the mechanisms of action for individual devices. In order to obtain CE (Conformité Européene) marking, wound care products and devices are only required to demonstrate safety and performance. Brölmann et al. (2012) theorised that this leads to a reluctance from manufacturers to perform high-quality research in an already profitable and unrestricted market for new wound care products. In the absence of evidence this can lead to a reliance on case reports and personal opinions. Without knowing the exact mechanisms through which individual heel-specific devices work, they were subjectively grouped by reported function: offloading the heel by preferentially loading another part of the foot and lower leg better able to tolerate the pressure; reduce the intensity of pressure to the heel through increasing the contact surface area; or reducing intensity of pressure and friction. There are a multitude of characteristics of a device that would potentially impact its ability to translate a theoretical beneficial effect on heel interface pressure into a reduction in heel pressure ulcers that include:

- The physical characteristics of the fabric (moisture wicking performance, heat capacity, shear and friction, elasticity, density)
- Different fastenings to the limb to minimise movement of the foot within the device, and thereby the length of time the heel remains in the offloaded position. However tighter straps can cause trauma when there is poor circulation to the limb, and one study reported higher interface pressures to the heel in some devices when the straps were tightened (Guin et al., 1991)
- Positioning of the foot in the device. Some devices are designed to minimise foot drop or external rotation of the foot and maintain the foot in an upright position. The foot naturally eternally rotates when in a supine or semi-recumbent position (Sopher et al., 2011, Tong et al., 2016), although these studies found differing effects of foot posture on the tissues of the heel. Sopher et al. (2011) reported higher tissue strains when the foot was externally rotated

using computer modelling, whilst Tong et al. (2016) reported higher interface pressures when the heel foot was upright at a 90° angle to the bed

- The size of the device in relation to the size of the limb
- How the pressure is redistributed away from the heel to the rest of the lower limb

Along with the different mechanical properties of the devices, there are numerous variables that can influence how offloading devices are utilised in practice that did not appear to be considered in the included trials, which in turn will influence the effectiveness of the devices along with trial concordance. These potential confounding factors include:

- Ease of application of the device could influence if it is applied properly and whether the heel is offloaded, in the correct position in the device, and free from pressure
- The amount of time that the patient wears the device for, both in terms of hours during the day and number of days
- Frequency of device removal by the patient or healthcare worker
- If there are bandages, stockings or socks applied to the limb
- The position of the patient in bed. Most studies that look at interface pressures to the heel are done with healthy volunteers in a supine position (Aquila and Ferretti, 1997, Flemister, 1991, Sopher et al., 2011, Tenenbaum et al., 2013), but in reality patients are rarely nursed in this position as head elevation is believed to improve breathing and minimises risk of chest infections (Niël-Weise et al., 2011). Grap et al. (2016) found that backrest elevation and knee angle affect the pressures to the heel
- Masaki et al. (2013) measured heel blood flow during loading and offloading in individuals with a normal as well as low ankle brachial pressure index (ABPI)[3]. They found that offloading for longer than 60 minutes in patients with an ABPI <0.80 led to a decrease in heel capillary perfusion and excessive elevation of the heel may decrease heel capillary perfusion (Roeder et al., 2005). Devices that hyperextend the knee could also lead to an increase in DVT risk (Huber and Huber, 2009, Leon et al., 1992)

[3] The ratio of the patient's systolic blood pressure at their ankle to the systolic blood pressure in their arm. Those with an ABPI <0.80 are considered to have reduced blood flow to the lower limb and <0.5 have significant peripheral arterial disease.

- Movement of the patient, Grap et al. (2016) found that pressures at the heel increase with patient movement, which could be due to the heel being used as a pivot point to lift and move the rest of the body. This could also have an impact of how well the device stays in position
- Repositioning: does the limb move in the device during repositioning or does the device influence how the patient is positioned, the frequency the patient is repositioned or the patient's ability to reposition themselves
- Impact the device has on the shearing forces exerted on the heel during movement

3.4.1 Strengths of the systematic review

This is an original piece of research, furthering the knowledge about the use of devices for the prevention of heel pressure ulcers. Although there have been previous systematic reviews regarding the use of devices for the prevention of heel pressure ulcers (Clegg and Palfreyman, 2014, Junkin and Gray, 2009), neither used a robust search strategy or performed a meta-analysis, and this is the first to include all potential devices from mattresses to heel-specific devices and prophylactic dressings. The protocol for the review was written and published prior to being conducted (Greenwood et al., 2014) and the PRISMA guidelines (Moher et al., 2009) and GRADE (Guyatt et al., 2011) were followed during writing to ensure that the reporting of the systematic review was thorough, transparent and robust.

To thoroughly review the existing evidence-base the review included a broad search strategy to include all devices that could be used in the prevention of heel pressure ulcers. Twenty-nine RCTs were included with fifteen different comparisons and nine meta-analyses were performed. This was more than expected when compared to other systematic reviews in pressure ulcer prevention; Gillespie et al. (2014) looked at repositioning and identified three RCTs, two of which were pooled. No RCTs were found for the review by Zhang et al. (2015) looking at massage therapy and Moore and Webster (2018) identified 18 RCTs for their review on dressings and topical agents for the prevention of pressure ulcers and included 6 meta-analyses.

To minimise publication-bias this review was not restricted by language, however due to translation costs alternatives were sought to allow for inclusion. A Spanish paper was translated by a colleague (Ferrer Sola et al., 2013) and a Japanese paper was translated by a friend who was learning Japanese and took it to her study group (Matsui et al., 2001).

3.4.2 Limitations of the systematic review

To be able to answer the review question, it was necessary for trials to include heel-specific data. Several RCTs were excluded because they displayed their data in terms of "how many participants developed a pressure ulcer" but did not provide the body sites. It is likely that this information is not included because the aim of these trials is to see if there is an overall impact on pressure ulcer incidence. This can be illustrated by the systematic review looking at support surfaces for the prevention of pressure ulcers which included 59 trials, compared to only 29 in this review (McInnes et al., 2015). However, it is necessary to know if support surfaces affect the risk of developing a pressure ulcer to all body sites equally because interventions can reduce pressure at one site by changing the distribution of pressure, which is why it was felt this systematic review was necessary. It would be beneficial for future RCTs to include body site data by randomised group.

Heel pressure ulcer incidence could also be presented in different ways; the total number of participants that developed a heel pressure ulcer or the total number of heel pressure ulcers that developed. The problem with the latter is that it could lead to a unit of analysis error as it is unknown in how many participants these heel pressure ulcers occurred, the assumption would have to be made that all participants had both lower limbs and only one pressure ulcer developed per heel; meaning that pooling was not possible.

Several trials describe the control as being ‘standard care’, but this is frequently poorly described, and as practice moves on, so does standard care. In the RCT by Tymec et al. (1997) pressure ulcers develop significantly sooner in the intervention group, leading to the device being redesigned. Therefore, as the devices develop and technology moves on, it is difficult to assess the relevance of the existing research, which is an ongoing issue in medical device trials (Nixon et al., 2019). This is one of the reasons that generic device definitions were used, and similar products pooled rather than comparing specific products.

There is also a potential for publication bias, if studies of pressure relieving devices are sponsored by device manufacturers, results may not be published if they show no benefit or a negative effect. Product manufacturers and experts in the field were contacted to identify unpublished research; but no additional studies were identified. In the absence of widespread trial registration for device related trials, it is not possible to identify how many trials may have been completed but not reported.

Adverse events were rarely reported, this could be because pressure ulcer incidence is the outcome of interest, which itself is an adverse event. It is also a possibility that adverse event reporting in device trials is poor due to it not being valued or if sponsored by the manufacturers then not wanting them to be publicised.

3.4.2.1 Dated searches

This review was initially conducted in 2015, with an updated search included in April 2016. Therefore, between the review being initially conducted and this thesis being submitted additional papers have been published, but as the analyses had already been conducted it would not be feasible to re-run these. It was therefore decided to re-run the search strategy in December 2019 to determine if any additional studies had been published in the intervening time. Two AP versus CLP mattress trials were identified that also reported heel pressure ulcer rates, but the CLP devices differed; a static air overlay (Beeckman et al., 2019) and high risk foam (Nixon et al., 2019). These would have been added to comparison 2, which might have allowed for a meta-analysis to be performed, although the comparators for these two trials are heterogenous. An additional two dressings trials (Santamaria et al., 2018, Hahnel et al., 2019) along with two ongoing registered trials that are yet to be published were identified (Nct, 2018, Nct, 2017), although these were not found to change the results of comparison 15 (Greenwood et al. (2020), article in press).

Although these would not change the results of this review, it illustrates the importance of updating systematic reviews as the evidence base grows.

3.4.2.2 Quality of evidence

The overall quality of the included evidence according to GRADE was moderate to very low. The majority of the studies were at high risk or unknown risk of bias for one or more of the key areas; only one of the trials was at low risk of bias for all assessed areas (Nixon et al., 1998). Twenty-eight out of twenty-nine trials were at risk of bias for blinding of participants and personnel. In medical device trials the intervention can be difficult, but not impossible to blind the participants or personnel to, such as removing the device prior to data collection. However, participants are often too ill to be removed from a support surface prior to assessment of their pressure areas, and this could be inconvenient and time consuming for the patient and nursing staff. Assessment of the outcome of a pressure ulcer requires some judgement by the assessor, which could be influenced by knowledge of intervention. Some trials are trying to minimise this bias through the use of photography to verify skin assessments, where those who are assessing the photographs are blinded to the intervention (McGinnis et al., 2017).

However, it is still unknown how reliable photography is for differentiating between blanching and non-blanching erythema, especially on darker skin tones (Baumgarten et al., 2009). Nixon et al. (1998) were able to minimise performance bias by blinding participants and data collectors because their study was delivered in the operating theatre, an area where the data collector would not be involved, and the participant would be unaware of the intervention.

Overall, the included studies were assessed using the GRADE approach as imprecise; many of the included trials had a small sample size and were therefore underpowered due to the low event rates and had wide 95% CI. RCTs should be adequately powered to detect treatment effects of a specified size, should they exist. Therefore, sample size calculations should be used to help estimate the number of people recruited to a trial, however only fourteen trials (n = 14/29, 48.3%) include an *a priori* power calculation.

It is necessary to use a robust tool to assess the quality and certainty of the evidence in a systematic review, however for medical device trials, without exploring more ways to blind participants or personnel, they will all be automatically downgraded when using the GRADE approach, and therefore will never be ‘high quality evidence’ and a definitive conclusion could never be found. More research is needed into better methods to overcome the risk of bias due to lack of blinding, along with the GRADE approach taking these difficulties into account when assessing trial quality. If more studies followed the CONSORT statement for reporting of clinical trials (Begg et al., 1996), this would also improve trial reporting and reduce risk of bias.

3.5 Summary

Due to the poor quality of the included trials, the certainty of the results reduces. Comparisons between heel-specific offloading devices and standard care found a significant difference in favour of offloading for all Categories of heel pressure ulcer. While the quality of evidence was low according to GRADE, when looking at the prevention of Category 2 or above heel pressure ulcers, one of the studies was excluded making the evidence moderate quality.

This review has clearly identified the lack of evidence for both total body and heel-specific pressure relieving devices for the prevention of heel pressure ulcers. The systematic review has also identified some key issues with regards to the trial design of both heel-specific devices; as there were issues with trial compliance, withdrawals and protocol violations, and the consideration of the heel as a subgroup in total body device trials.

The mechanical properties of heel-specific devices and numerous variables that can influence how devices are utilised in practice do not appear to be considered in the included trials and are infrequently published as early phase research trials. The subsequent chapters will present a Realist Evaluation that will explore how heel-specific devices are used in clinical practice for the prevention of heel pressure ulcers, and how knowing this can inform future trial design.

Chapter 4 Identification of research question and methodological approach

4.1 Introduction

Following on from the systematic review presented in Chapter 3, although a significant difference was found in favour of offloading devices for all Categories of heel pressure ulcer, the quality of the evidence was low according to GRADE. It therefore remains uncertain whether any of the devices presented in Chapter 2 are effective in the prevention of heel pressure ulcers. This Chapter will provide a critique of the RCT design for the device related trials included in the systematic review. It will then go on to discuss how realist evaluation was selected as the methodological approach to explore how offloading devices are used in clinical practice, and how knowing this could influence and improve future trial design.

4.2 Research Problem

In Chapter 3, the systematic review demonstrated that there may be a benefit to offloading devices in the prevention of heel pressure ulcers (both Category 1 or above and Category 2 or above) in patients at risk of developing a pressure ulcer, but this lacked certainty due to the low volume and quality of evidence. Due to insufficient and low-quality evidence we do not know if total body support surfaces, heel-specific CLP devices or heel-specific low-friction devices have an impact on the rate of development, or severity of pressure ulcers; it is possible that they do prevent heel pressure ulcers but were evaluated in a way that masks their effectiveness, or they have no significant effect.

RCTs are widely regarded as the gold standard to evaluate the effectiveness of interventions, because of their unique study design with comparable groups which controls for unknown or unmeasured confounders (Lewin et al., 2009, Moore et al., 2015a). The next logical step would therefore be to increase the existing knowledge base through the addition of a further good quality RCT. However, this could be perceived as short-sighted without first considering the learning from the previous trials, taking into consideration the issues that some of the existing RCTs experienced. These included high rates of withdrawals (Bååth et al., 2016, Donnelly et al., 2011), protocol violations and attrition (Donnelly et al., 2011), and low event rates (Campbell et al., 2010, Gilcreast et al., 2005, Tymec et al., 1997). Any further RCTs would need to address these issues first.

Regardless of the evidence, from clinical experience it is known that these devices are already widely used in clinical practice (hence the window of opportunity to test them versus no device may have been missed due to adoptions prior to an evidence base); but we do not know how, when, and why they are implemented and used in the absence of a robust evidence base.

4.2.1 Withdrawals, protocol violations and attrition

Three of the included RCTs explored participants' perspectives of the heel devices; Donnelly et al. (2011) asked structured questions to gain opinions of the heel devices from the perspective of the patient, but reporting of these outcomes was problematic due to only presenting percentages, meaning the number of participants interviewed is unknown. Feedback included weight and bulk of the boot (36%), heat (particularly at night) (31%) and discomfort (24%). These, along with problems with the application and removal of the device, were associated with some of the protocol violations. Gilcreast et al. (2005) reported that some participants found the heel devices 'hot and bothersome' without reporting the data in any more detail, hence reporting issues precluded further analysis. Bååth et al. (2016) received feedback from only 28% (n=29/103) of participants assigned the offloading. Feedback about the devices included that they caused friction (n=9), were itchy (n=14), caused blistering from the bootstraps (n = 1), and some evaluated the boot as ugly (n=19). Due to the lack of full reporting and different denominators being reported for some of the outcomes, it was not possible to clearly determine whether the event rate was appropriately described.

None of these trials had sufficient evidence to associate the participants' perspectives with the high rates of withdrawals and attrition. No other research has been found about patient preferences with regards to the use of heel devices or the experience of the prevention of heel pressure ulcers.

4.2.2 Low event rates

Recently PRESSURE 2, the largest mattress RCT conducted worldwide with a sample size of 2029, reported lower than anticipated event rates of 7.9% of patients developing a Category 2 or above pressure ulcer to all body sites, compared to the predicted rate of 18%. Along with lower than anticipated recruitment, this led to the trial being underpowered under its original trial design (Nixon et al., 2019). It could therefore be anticipated that a trial looking at heel pressure ulcer prevention devices could anticipate an even lower event rate because, as demonstrated in Chapter 1, prevalence studies consistently report approximately 25% of all pressure ulcers develop at the heel. If sample size calculations were based on these event rates, it

would be anticipated that for a trial to have sufficient power to show a difference, a sample size similar to or larger than PRESSURE 2 would be required if conducted in the general population. This is why some of the trials focused on patient populations deemed to be at higher risk of developing a heel pressure ulcer such as orthopaedics (Donnelly et al., 2011, Campbell et al., 2010) or critical care (Santamaria et al., 2013, Cadue et al., 2008). One option would be to conduct a pilot study amongst high-risk populations to attempt to address the issues of attrition and withdrawals along with piloting recruitment and data collection.

4.2.3 Clinical practice

So far, this thesis has demonstrated that there is insufficient clinical evidence with regards to the effectiveness of any device for the prevention of heel pressure ulcers, however it is known from clinical practice that they are widely used. Little is also known about how and why nurses decide to use devices when there is little research evidence. In these circumstances personal preferences can be formed from the experience and influence of champions/leaders (Grebel and Wilfer, 2010, Institute of Health Economics, 2015).

A study by Teo et al. (2019) found that despite the availability of interventions, pressure ulcer prevention and management practices were suboptimal due to a poor understanding of the mechanisms behind the interventions. It is therefore important to understand how and why devices are used in practice in order to inform trial design, before seeking to address the lack of effectiveness evidence.

4.3 Research Objective and focus

The objective of this study was to explore how and why heel devices are used (or not used) and reasons behind how and why they might (or might not) be used for the prevention of heel pressure ulcers. Due to the large range of heel devices, and the range of environments in which a patient can be cared for with heel devices, to increase the depth of the research, the focus was limited to:

- Any device that works by offloading/floating the heel, because this is where there is limited evidence for heel pressure ulcer prevention
- Secondary care, because this is where the majority of the RCTs took place, where heel pressure ulcers are more likely to occur, and it is also the area of the researcher's clinical expertise.

The following research questions were developed:

1. What factors influence the implementation of offloading devices in a clinical area?
2. How are offloading devices used (or not used) in clinical practice?
3. How could this knowledge influence trial design and reduce attrition rates in future clinical trials?

4.4 Identification of methodology

To answer the research questions, the perspectives of those who use the heel devices in clinical practice need to be sought. There are numerous approaches that could be taken to answer the research question, therefore this chapter will consider how qualitative and mixed methods research can be used to inform trial design, before going on to justify the choice of realist evaluation as a methodology.

4.4.1 Qualitative and mixed methods research

From a philosophical view, positivism is the search for generalizable knowledge based on natural phenomena and their properties and relations (Comte, 1908). Empirical research such as early phase experiments are viewed as positivist and work by attempting to create a closed system by standardising conditions, minimising the effects of extraneous factors and reducing bias in order to assess the efficacy of a causal agent, based on notions of cause and effect (Maxwell, 2012). However, complex healthcare interventions take place in open systems in which many factors additional to the intervention itself will affect its effectiveness (Porter and O'Halloran, 2012).

When assessing the effectiveness of a device it is more than just whether the device works at preventing a heel pressure ulcer that needs addressing, but also factors such as the participants' experience, tolerability of the device, ease of delivery, usability, and cost effectiveness. A range of research designs and methods could be used to address this.

The current evidence from the systematic review is positivist, in that it only provides descriptions of outcome patterns, telling us about group differences to ascribe cause and effect. The other end of the spectrum from this positivist view point is constructivism, which is where qualitative research sits, aimed at understanding the lived experience through the individuals' interactions with the environment (Andrews, 2012). A qualitative approach could provide explanations of why the intervention works (or fails), along with the mechanisms through which they bring about change, and how

these might be replicated by similar interventions in the future (Moore et al., 2015a, Pawson and Tilley, 1997f). Qualitative and mixed methods approaches are therefore more frequently being undertaken before a clinical trial, as part of a feasibility study, or alongside or after an RCT, as part of a process evaluation; to find out not just if an intervention works, but how and why it works (or does not work), and for whom in what circumstances.

A process evaluation can be a separate study or conducted as part of an RCT to examine the implementation, receipt and setting of an intervention to aid in the interpretation of how the intervention brings about an outcome (Oakley et al., 2006). The Medical Research Council framework recommends that process evaluations should be mixed methods, although existing process evaluations are predominantly qualitative (Moore et al., 2015a, Craig et al., 2008). Using a mixed methods approach could inform factors that influence how and why these heel devices are used in practice in the absence of clinical evidence with the aim of improving compliance with trial protocols, but this would need to be done in a methodologically sound way that is relevant and informative for future clinical trials.

One hundred and four citations were reviewed for inclusion in Chapter 3, of which fourteen related to heel-specific devices and ten were included. Of the ten trials, only one reported a qualitative element; Campbell et al. (2010) used a nominal group process to identify seven priority items for a heel-specific device selection to be used in their orthopaedic department. Two trials included participants' opinions of the devices in the forms of surveys (Donnelly et al., 2011, Bååth et al., 2016). It is possible that more of the included trials addressed multiple aspects alongside the clinical trial but were missed as they were published separately to the RCT, although none were identified during the literature search or referenced in the studies.

O'Cathain et al. (2013) performed a systematic mapping review of RCTs in the field of health published in peer reviewed journals during 2008-2010 and identified 296 articles that reported a total of 356 examples of qualitative research undertaken alongside trials. In their appraisal, they reported that most of the qualitative studies were either poorly integrated into the clinical trials and/or methodologically weak. The framework described by O'Cathain et al. (2013) that explores qualitative research used alongside RCTs in the field of health research was used in Table 4-1, to highlight where there are gaps in the current knowledge with regards to the use of heel devices.

4.4.2 Offloading as a complex intervention

Table 4-1 highlights that the biggest knowledge gaps are regarding the intervention and content delivery. The use of offloading devices could be argued as being a fairly simple intervention; the device floats the heel, and in the absence of pressure a pressure ulcer is prevented, but in reality it is more complex than that, with various interconnecting components to the intervention, beyond just the offloading device itself, that act both independently and inter-dependently (Campbell et al., 2000, Craig et al., 2008, Lewin et al., 2009).

Table 4-1 Framework used by O'Cathain et al. (2013) to describe qualitative research performed alongside RCTs, and the extent to which they have been addressed in existing heel pressure ulcer studies, highlighting the gaps in current knowledge

Category	Subcategory	Existing literature on heel pressure ulcer prevention
Intervention content and delivery	Intervention development	Already numerous heel devices available on the market
	Intervention components	Is it more than just the heel devices that influence their use, but also how the patients and staff react to and use heel devices?
	Models, mechanisms, and underlying theory development	No data
	Perceived value and benefits of intervention	Limited data from the perspective of the participants and staff
	Acceptability of intervention in principle	Limited data from the perspective of participants (Donnelly et al., 2011) and staff (Campbell et al., 2010)
	Feasibility and acceptability of intervention in practice	Some data from the RCTs regarding acceptability of heel devices from the perspective of the participants, but little information from the perspective of nursing staff
	Fidelity, reach and dose of intervention	Little known about how long the heel devices are used for or in what clinical areas they are used
	Implementation of the intervention in the real world	Little known about how the heel devices are used (or not used) in practice
Trial design, conduct and processes	Recruitment and retention	RCTs included in the SR give some data on this, but there were some retention issues reported in some of the trials (Bååth et al., 2016, Donnelly et al., 2011)
	Diversity of participants	Incidence studies and risk factors research already inform this
	Trial participation	Addressed in some existing RCTs (Bååth et al., 2016, Donnelly et al., 2011)
	Acceptability of the trial in principle	No pilot or feasibility studies reported that address this

Category	Subcategory	Existing literature on heel pressure ulcer prevention
	Acceptability of the trial in practice	No pilot or feasibility studies reported that address this
	Ethical conduct of the trial	Addressed in existing RCTs (Bååth et al., 2016, Campbell et al., 2010, Donnelly et al., 2011, Gilcreast et al., 2005, Tymec et al., 1997)
	Adaptation of trial conduct to local context	Not reported
	Impact of trial on staff, researchers, or participants	Impact of trial on staff or researchers not reported
Outcomes	Breadth of outcomes	Outcomes concentrate on pressure ulcer incidence, not much data on patient reported outcome measures, OUTPUTs study will address this (Lechner et al., 2019) and PUQoL as part of the PRESSURE 2 trial (Nixon et al., 2019)
	Variation in outcomes	Outcomes concentrate on pressure ulcer incidence, little variation in outcomes since international grading systems started being used (NPUAP and EPUAP, 2009, EPUAP et al., 2014)
Measures of process and outcomes	Accuracy of measures	Studies exist that look at grading, reliability and validation of pressure ulcer outcomes (McGinnis et al., 2017)
	Completion of outcome measures	Studies exist that look at grading, reliability and validation of pressure ulcer outcomes (McGinnis et al., 2017)
	Development of outcome measures	OUTPUTs study addressing core outcomes for pressure ulcer trials (Lechner et al., 2019)
Target condition	Experience of the disease, behaviour, or beliefs	Patient reported health-related quality of life tool (PUQoL-P) has been developed to address this (Rutherford et al., 2018, Gorecki, 2011)

Complex interventions can be defined as being composed of multiple ‘components’, that interact and involve behaviours (either in those delivering or receiving the intervention) with the purpose of changing one or more outcomes (Moore et al., 2015a, Craig et al., 2008). Not all the components, particularly social and organisational, will have a specific purpose but instead influence the extent to which the purpose is achieved. For example, in a study of severe pressure ulcer development, it was found that prevailing cultural norms impacted on the decisions and actions of clinicians (Pinkney et al., 2014). Investigations into the development of severe pressure ulcers has found that they usually occur due to a sequence of events, rather than a singular causal factor (Greenwood and McGinnis, 2016).

When examining offloading as a complex intervention, the components and behaviours involved include, but are not limited to, the process through which the offloading device

is selected and adopted into clinical practice, patient preferences and values, along with how staff use (or do not use) the intervention. It is not just the offloading device that prevents the pressure ulcer, but the patient's response to it in terms of whether they will/are able to wear the device and keep it on, along with the interaction between the patient and healthcare worker to ensure that it is implemented. The extent to which the device changes the behaviour of the healthcare worker and/or the patient also needs to be considered.

It could also be argued that complexity is not just a characteristic of the intervention, but a feature of the dynamic health systems in which they are implemented (Shiell et al., 2008, Hawe et al., 2009). Regardless of whether the intervention is simple or complex, the healthcare system in which it is implemented will almost invariably need to adapt to accommodate it (Greenhalgh and Papoutsi, 2018). Due to the dynamic nature of healthcare systems, the conventional empirical quest for predictability, certainty, and linear causation can be supplemented and improved upon by addressing how we can best deal with unpredictability and uncertainty (Greenhalgh and Papoutsi, 2018).

4.5 Realism

To try and understand not just if offloading devices prevent heel pressure ulcers, but also how they might work and the reactions of the patients and staff to the intervention, we must acknowledge the complexity and the interplaying factors that could influence their use. Whilst the importance of both positivist and constructivist approaches have been acknowledged, a realist approach was taken as, broadly speaking, it sits between the two paradigms and acknowledges the importance of both. Realism asserts that the real world is an open system involving social structures and our knowledge of it is processed through human behaviour. It acknowledges that our understanding will always be partial and imperfect, but can be built on over time with evidence (Wong et al., 2013, Pawson and Tilley, 1997f).

Realism has many philosophical iterations including critical realism, constructive realism, philosophic realism, scientific realism, experiential realism, subtle realism and emergent realism to name a few, and debate continues regarding the nature of realism (Maxwell, 2012). The two most well-known philosophical approaches, critical and scientific realism will be explored further.

4.5.1 Critical realism

Critical realism is widely associated with, but not restricted to, the work of the British philosopher Roy Bhaskar (Bhaskar, 1973). Bhaskar describes three levels of reality, the empirical, the actual, and the real. The empirical domain describes the world we experience through our senses which are a critical part of the world, but alone cannot define the world. The actual domain describes actual events, whether or not we experience them, and the real domain describes the underlying mechanisms that produces the events.

Porter et al. (2017) describe critical realism as recognising two distinct sources of causation: social structures and human behaviour. As previously described in 4.4.1, RCTs are positivist and work by attempting to create closed systems to identify causation. From a critical realist perspective, when studying complex social systems, it is impossible to conduct the 'closed system' investigations available within the experimental science paradigm. Critical realist research methods instead focus on theoretical inquiry of social systems by exploring the real to establish how it relates to the empirical and actual domains.

In nursing research, critical realism aims to investigate complex phenomena by progressing beyond measuring outcomes, superficial causes or examining correlations, to identify the deeper and wider causes of outcomes (Clark et al., 2008). For example, Clark et al. (2005) explored why cardiac rehabilitation programmes are so variable in the longer term, through identifying participants' perceptions of the contexts and mechanisms that influence effectiveness of programmes.

4.5.2 Scientific realism

From an ontological point of view, scientific realism considers that the world is independent of our mind and science gives us knowledge of this world (Jagosh et al., 2019). Reality consists of both observable entities, things that can be seen, and unobservable entities. The outcome of interest is triggered by unobservable entities (mechanisms) acting in a physical, observable entity (context) through a process known as generative causation (Van Belle et al., 2016). A mechanism can be activated by a range of contexts and can be detected using a mixture of methods.

This is in contrast to Hume's (1739) successionist view that causation is unobservable and only through scientific testing can we differentiate between a spurious association and a causal relationship. Certain causal forces cannot be observed, for example we cannot witness the cognitive leap a person makes to stop smoking, but it is only once there is a net difference between the outcomes of an intervention and control that a

judgement can be made that a smoking cessation intervention has worked (Pawson and Tilley, 1997e).

In contrast to critical realism that says the closed systems used in experimental science cannot be used to explore social systems, scientific realism states that experimental investigations can only ever achieve partial closure (Pawson, 2013b). As science develops over time, theories are converging, becoming an approximate truth, but it is acknowledged that there can never be complete certainty.

Scientific realism has been used by social epidemiologists to gain a deeper understanding of how, why, and under what contexts macrosocial determinants could improve, or harm, population levels of health (Ng and Muntaner, 2014). For example, Muntaner (2013) generated theory and data driven statements about immeasurable mechanisms and causal powers that link race and health.

4.5.3 Realist Evaluation

Realist evaluation is more of a methodology than a philosophy, that uses realist principles based on the paradigm of scientific realism (Jagosh et al., 2019). Realist evaluation was developed in the 1990s by Pawson and Tilley, originating in social policy, evaluating social interventions, programmes of change for social betterment that involve righting wrongs, correcting deficient behaviours or alleviating inequality (Pawson and Tilley, 1997f). More recently realist evaluation has been developed and adapted as evaluators seek to answer process-orientated questions in order to contribute to evidence-based practice in healthcare (Porter and O'Halloran, 2012), and is now being widely used in many different areas for the evaluation of programmes, policies, services and interventions.

Realist evaluation is a theory driven approach that allows for an exploration of the effectiveness of a programme, policy, service or intervention, but also gives an understanding of how the causal mechanisms are influenced by both human decisions and actions; simply put what works for whom, in which situations (Pawson and Tilley, 1997f). This is done by looking beyond the empirical domain, unearthing generative causation through a process called retroduction. It has been suggested that retroduction overcomes the deficiencies of the logics of induction and deduction to offer causal explanations. Merely knowing whether A leads to B is insufficient, instead we need to gain an understanding of how A gave rise to B (Bhaskar, 1973). Gaining ontological depth through going back from, below or behind observed patterns of regularities to discover what produced them can lead to an understanding of the underlying mechanisms in order to explain outcomes (Houston, 2010).

Theory-based approaches provide a key to unlock complex processes between the intent and outcome of an intervention, by examining implementation, the causal processes that generate outcomes and contextual factors that influence them (Chen and Rossi, 1980; Weiss, 1998). There are other theory driven evaluation approaches that this research could have taken, such as theories of change (Blamey and Mackenzie, 2007). In comparison to realist evaluation, where the focus is on causation, theories of change focus on implementation, where the theory is ideally articulated, owned and approved by a wide range of stakeholders who are best placed to understand the intervention, and are developed through a process of 'backwards mapping' from the ultimate goals of the intervention towards the inputs and activities (Rolfe, 2019). The stakeholders have ownership of the theory of change generated and are involved in the key decisions behind the relative importance of the theory along with the actual evaluation research. In realist evaluation the theories are owned more by the researcher(s) based on their knowledge, experience, and the existing evidence base, and developed through a smaller and more purposive selection of stakeholders. It is more concerned in identifying potential causal triggers and the most promising theories then go on to be tested (Blamey and Mackenzie, 2007).

It is important to acknowledge the researcher's position as a clinician and how this will influence the research. Being a Tissue Viability Nurse Specialist (TVNS) with experience of using offloading devices in clinical practice meant that the researcher already had several theories about how and why offloading devices are used in practice, and it was this interest and experience that led to the topic of this PhD. A qualitative methodology such as grounded theory would not be suitable as this requires a neutrality in the data collection and analysis in order to assure that as new categories emerge they will not be contaminated (Glaser and Strauss, 1967); in contrast a methodology such as realist evaluation acknowledges and incorporates this knowledge.

Realists would argue that it is not the intervention that produces the outcome, but how people respond to and make use of the resources that the intervention provides that determines the outcome, and how people respond is highly dependent upon the context (Greenhalgh et al., 2011, Wong et al., 2012). The researcher has witnessed different offloading devices being used in different ways in different contexts, with differing responses to them from patients and staff using them. Realist evaluation is therefore best placed to answer the research question of 'how and why different offloading devices are used (or not used), and reasons behind how and why they might (or might not) be used in clinical practice for the prevention of heel pressure ulcers?'

Realist evaluation has been used in nursing and health research as a methodological approach that incorporates a mix of methods to allow for an exploration of contextual factors that influence the link between the intervention, the outcome, and the mechanisms involved; the role of both the human understanding and response to the intervention, along with the external reality need to be incorporated in order to fully understand the outcome (Greenhalgh et al., 2011). Realist evaluation has been used by McGaughey et al. (2017) to explore how early warning systems are used to recognise the deteriorating patient in hospitals, using mixed methods including interviews, focus groups, observations and case notes review. They found that organisational and cultural changes that facilitated staff empowerment, ongoing experiential learning and a flexible implementation of protocols led to successful implementation of rapid response systems.

Another example is Randell et al. (2017) who used realist evaluation to explore the integration of robotic assisted surgery into routine practice using a combination of literature review, interviews, observations, and questionnaires. They found that training and skills mix of the team was important, as well as effective team work requiring the surgeon to encourage communication within the team.

4.5.3.1 Programme theories

Realist evaluation starts with one or more programme theories; a hypothesis about how an intervention works and involves eliciting, testing, and refining these theories. It is believed that whenever a programme or intervention is designed and implemented, there are one or more underpinning theories regarding what 'might cause change', regardless of whether the theory(s) are explicit (Pawson and Tilley, 1997f). By developing clear hypotheses about how, and for whom, to what extent, and in what contexts a programme or intervention might 'work', the theories are made explicit.

The theories are expressed in terms of context, mechanism, and outcome configurations (CMOs) where a desired outcome (O) pattern is brought about by the mechanisms (M) triggered in certain contexts (C). It is understood that causal associations are rarely universal, but are adaptive 'demi-regularities', (frequently produced behaviours or patterns), in which settings and context triggers the mechanisms that bring about change (Dalkin et al., 2015). Summed up this contextual dependence of generative mechanisms are expressed as context-mechanism-outcome configurations; using the formula C + M = O, the analytical unit on which realist evaluation is built (Wong et al., 2016, Pawson and Tilley, 1997b).

In their realist evaluation of the use of early warning systems, McGaughey et al. (2017) developed CMOs following a realist review of the literature along with interviews with key stakeholders. Four CMOs were developed about how rapid response systems improve outcomes, lead to early recognition, early referral, and early recognition.

4.5.3.2 Contexts:

Context is often used synonymously with settings and environments which triggers the mechanism (Dalkin et al., 2015). One way of thinking about contexts is that they could be static (e.g. aspects of the physical environment) or dynamic (e.g. relationships, networks) (Pfadenhauer et al., 2017). Pawson (2013a) describes the layers that make up contexts as the four I's that are complicated, intertwined and in motion:

- *Individuals* – the characteristics and capacities of staff, patients or relatives who use the intervention
- *Interpersonal relations* – the relationships between the different staff (nurses, doctors, allied health professionals) as well as between the staff and patients
- *Institutional settings* – the rules, norms, and customs local to the intervention, for example differences between the ways different clinical areas or specialities work and the pressure ulcer prevention practices or programmes that are in place
- *Infrastructure* – the wider social, economic, and cultural setting which could include procurement processes or the influences of the wider organisation.

A context can also be described in terms of different levels (Pfadenhauer et al., 2017):

- *Macro level* – refers to everything surrounding a community or organisation, for example the policies and regulations across a whole health system or country.
- *Meso level* – looks at a specific community or organisation, for example the introduction of a new intervention or guidelines in a specific hospital or clinical area.
- *Micro level* – is interested in the direct level of an interaction e.g., where an intervention is delivered by a clinician or a team to a specific patient group.

A contextual factor should not be considered as an on/off switch, but the degree in which it 'fires' the mechanism (Dalkin et al., 2015). For example, it is not whether nurses are educated about offloading devices, or not, that affects how nurses use devices for the prevention of heel pressure ulcers; it could be how it is decided what is in an educational programme from the policy makers, the setting in which the education is delivered, who delivers the education, access to the devices, and the recipients' response to it. It could be argued that due to contextual factors, an intervention is never implemented in the same way twice, or under the same circumstances (Pawson, 2013a).

4.5.3.3 Mechanisms:

The mechanism by which an intervention works (or not) is through particular decisions or 'reasoning' made by 'actors' in response to the resources the intervention provides and are only triggered when the right contextual factors are present (Pawson and Tilley, 1997c, Dalkin et al., 2015). Interventions typically provide multiple resources and recipients of an intervention may have different responses to particular resources. Mechanisms are not variables, they are usually unobservable attributes that attempt to explain why variables are related (Astbury and Leeuw, 2010). By penetrating "beneath the surface of observable inputs and outputs the layers of individual reasoning" (Pawson and Tilley, 1997d) we can gain ontological depth and attempt to understand how the resources made available influence peoples' choices and capacities.

Astbury and Leeuw (2010) suggest that there are three interrelated types of mechanisms that work in the macro, meso and micro contextual levels:

- *Situational mechanisms* - operate at the macro-to-micro level and demonstrate how specific social structures, situations or events shape an individual's beliefs, desires, and opportunities. An example of this could be how culture on a ward and the influence of the manager can affect staff perceptions with regards to the effectiveness of an intervention.
- *Action-formation mechanisms* - operate at the micro-to-micro level and look at how individual choices and actions are influenced by specific combination of desires, beliefs, and opportunities. For example, regardless of the strong evidence that smoking reduces life expectancy, smokers rationalise to avoid quitting that 'it won't happen to them because they are not a heavy smoker'.
- *Transformational mechanisms* - operate at the micro-to-macro level, when individuals interact with one another, generating macro-level 'collective' outcomes which could be intended or unintended. One example of this is the 'bandwagon phenomena' such as bloodletting; where up until 200 years ago both physicians and patients had a shared belief that bloodletting was an effective treatment (Hagemoser, 2009).

4.5.3.4 Outcomes:

A programme of intervention is likely to have multiple mechanisms that can have different effects on different subjects in different situations, therefore leading to multiple outcomes (Pawson and Tilley, 1997d).

Realist evaluation seeks to understand both the intended and unintended outcomes of an intervention or programme. The outcomes are analysed in order to confirm whether

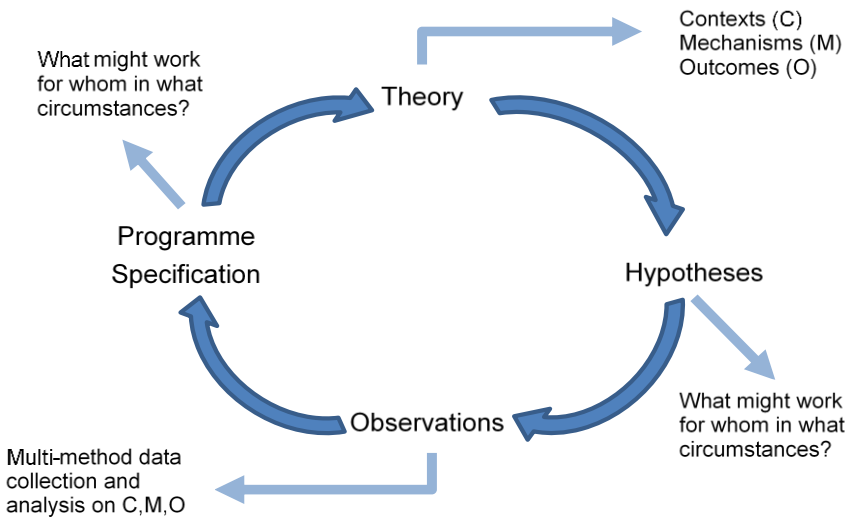
the conjectured theories, contexts and mechanism are present (Pawson and Tilley, 1997d), the aim being to identify demi-regularities or patterns of outcomes (Pawson, 2006b). The term ‘outcome’ could mean different things dependent on the type of evaluation. For example, a process evaluation might focus on ‘patterns of implementation’ or ‘patterns of efficiency or cost effectiveness’ in economic evaluations (Wong et al., 2016).

4.6 Methodology

Realist evaluation is seen as cyclical, starting with a set of initial programme theories that go on to be refined and tested by collecting data on implementation, impact, contextual factors that might affect the outcomes, and how these contexts shape the mechanisms that might bring about change (Figure 4-1). As the social world is an open system that is continually changing and evolving, the effectiveness of a programme or intervention could therefore be subverted or enhanced through the introduction or unanticipated new contexts and mechanisms (Pawson and Tilley, 1997d). Realism therefore tells us that nothing is absolute, and there is never certainty, the addition of further data will build on and lead to further refinement of the theory in different contexts and only stops once satisfied that there is sufficient evidence, at least for the time being.

In realist evaluation there is no hierarchy of evidence; to identify mechanisms and contextual features and explain how findings fit together, different data types along with the expertise of different people involved in the programme are required.

Figure 4-1 The Realist Evaluation cycle, source: (Pawson and Tilley, 1997b)



4.7 Summary

This chapter has presented the research problem identified following the systematic review presented in Chapter 3. It also provides a rationale for why realist evaluation was identified as an appropriate approach to explore how and why different offloading devices are used (or not used) and reasons behind how and why they might (or might not) be used in clinical practice for the prevention of heel pressure ulcers when there is an absence of clinical evidence. It has also presented the philosophical underpinnings behind realism and where realist evaluation sits.

The following chapter will describe the process of undertaking a realist evaluation, which will include how the research was designed and the methods used to address the research problem.

Chapter 5 Realist evaluation phase 1: Tissue Viability Nurse Specialist (TVNS) interview methods

5.1 Introduction

The realist evaluation of how and why different offloading devices are used in clinical practice for the prevention of heel pressure ulcers consists of two phases: phase 1 concerns theory elicitation and refinement, and phase 2 theory testing (Figure 5-1 The two phases of this realist evaluation.

This chapter will provide an overview of the methods for both phases, focusing on phase 1 of the realist evaluation; TVNS interviews. This will include how the research was designed and the methods used. The theories developed from the interviews will be presented in Chapters 6-8, and further detail of the methods of phase 2 will be provided in Chapter 9, and Chapter 10 will report the results of phase 2.

The Rameses II reporting standards for realist evaluation (Wong et al., 2016) were developed to improve the conduct and reporting of realist evaluation. These were developed using a Delphi panel of international experts in realist evaluation who identified twenty items that should be included when reporting a realist evaluation. The reporting standards have been followed, with adaptation to reflect the linear presentation of the two phases, in particular how the results of phase 1 influenced the design and methods of phase 2.

5.2 Methods

5.2.1 Phase 1: Theory elicitation

Realist evaluation aims to establish the viability of a using the best available evidence, through a process of theory elicitation, testing and refinement.

Theory elicitation can be carried out in several ways, such as interviewing stakeholders, reviewing the existing literature on the topic, identifying relevant theories from the literature, or some combination of these approaches. In this study theory elicitation involved presenting candidate theories to a range of stakeholders, to refine, develop and add to the theories, based on their direct experience of the intervention, combining this with evidence from the literature (Wong et al., 2016, Randell et al., 2017).

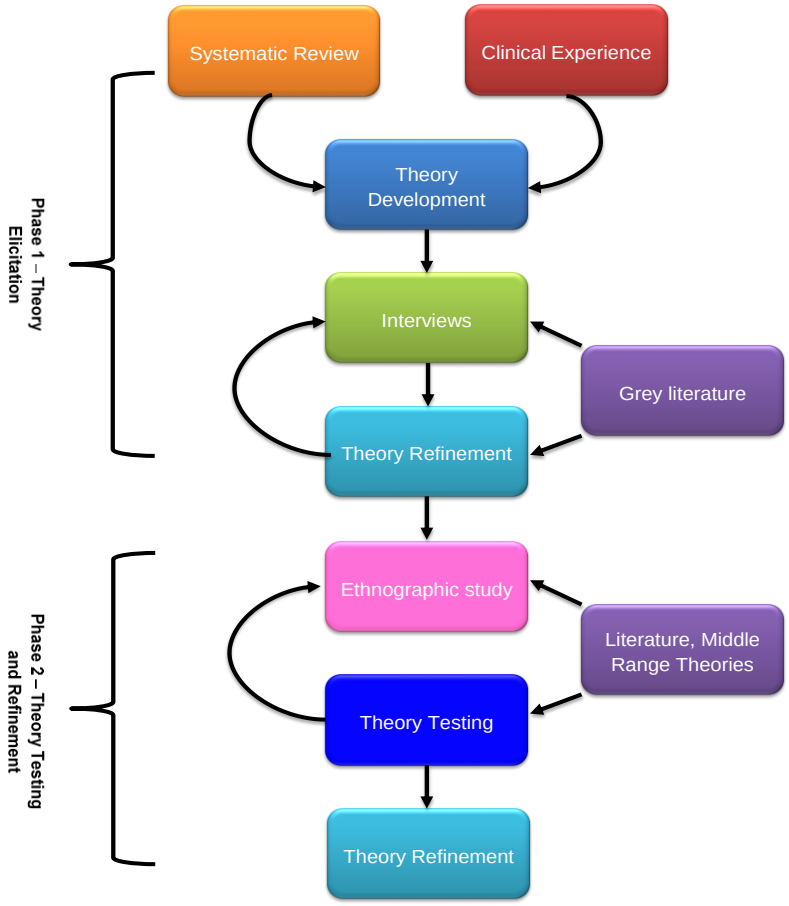
5.2.1.1 Initial theory development

As a Tissue Viability Nurse Specialist (TVNS) working in a large acute trust in the North of England, the researcher entered this PhD with substantial clinical experience of using offloading devices with the aim of preventing heel pressure ulcers. Realist evaluation makes the assumption that in the 'real world' programmes or interventions will only work in some contexts for some people, firing different mechanisms in different circumstances, generating different outcomes (Wong et al., 2016). Pre-existing or newly generated theories will need to be developed and refined by addressing contexts, mechanisms and outcomes, in order to become a realist programme theory (Pawson and Sridharan, 2010).

Thirteen initial 'candidate theories' were created from personal clinical experience and from the literature identified during the systematic review to answer the first two research questions presented in Chapter 4:

1. What factors influence the implementation of offloading devices in a clinical area?
2. How are offloading devices used (or not used) in clinical practice?

Figure 5-1 The two phases of this realist evaluation



Whilst developing the theories it became clear that they could be grouped into either factors that influence how nursing and healthcare professionals implement and use (or do not use) offloading devices in practice (theories 1-10; Table 5-1) or patient factors that influence their use (theories 11-13; Table 5-2). The theories are presented in the form of CMOs attempting to explicate the resources and reasoning that make up the mechanisms, to bring about the outcome in certain contexts. The theories about how nurses and healthcare professionals use offloading devices were mainly based on personal experiences of practice, due to the paucity of coverage of this aspect in the literature. Theory 12 was based on some of the findings from the RCTs included in Chapter 3 regarding patient comfort factors (Bååth et al., 2016, Campbell et al., 2010, Donnelly et al., 2011).

5.2.1.2 Identification of stakeholders and sampling strategy

Popper philosophises that what we see is our interpretation of the real, not the real itself (Popper, 1999). The realist approach assumes that the accounts of stakeholders have a direct relationship with experiences in the 'real world', therefore data gathered through interviews about how the candidate theories manifest in the 'real world' can provide evidence that has relevance beyond the interview situation (Manzano, 2016).

Purposeful sampling allows the researcher to select information rich cases that will provide greater insight into the research problem considered by the researcher to be of greatest importance (Emmel, 2013). Those sampled are deemed worthy of in-depth study due to their detailed insight into the topic, giving a different but potentially greater power to this type of research, compared with probability sampling (Emmel, 2013). A broad range of stakeholders should be purposively selected based on the researcher's hypotheses (Manzano, 2016).

Key stakeholders are more likely to have a wide range of experiences with regards to the successes and failures of an intervention, and therefore have specific ideas on the mechanisms that work or do not work, alongside an awareness of the people and places for whom and in which the intervention works (Pawson, 1996, Pawson and Tilley, 1997a). Manzano (2016) recommends that for the initial theory development and refinement phase, it is better to start interviewing key stakeholders such as practitioners who know the intervention well (e.g., nurses), rather than recipients of the intervention (e.g., patients).

It was identified that the key stakeholders should be clinical experts in pressure ulcer prevention, such as TVNSs, who will have experience of implementing offloading devices in a variety of contexts (different hospitals and ward settings) and will therefore

be aware of the processes by which the devices are implemented, utilised, and evaluated by nursing teams.

Within qualitative research there is no simple method for determining what sample size is sufficient. Sample size is dependent upon the purpose of the interviews, likelihood of data saturation, and the resources of the researcher (Mason, 2010). It has been suggested that expertise in the chosen topic can reduce the number of participants needed in a study (Jette et al., 2003), and a sample size of 6-8 may be adequate for homogenous groups (Holloway and Wheeler, 2010). The goal of this phase is to have enough participants to develop the initial theories and identify those which warrant further exploration. Therefore, a purposive sample of eight participants for this stage of the study was deemed likely to be sufficient to gain a range of perspectives to develop and refine the theories to a sufficient level, within the time and resource constraints of the research project.

5.2.1.3 Recruitment process

A purposive sample of TVNSs were identified through networks of TVNSs throughout the UK (such as the Tissue Viability Society, the North East of England, the Midlands and the East of England Tissue Viability groups) and through published literature found during the Cochrane systematic review/literature review, where contact details were provided or contact details could be identified through electronic sources (such as ResearchGate). The only stipulation was participants had to hold a clinical role as a TVNS of any band, within an acute care setting. Potential participants were approached by email with a participant information sheet (Appendix C Participant information sheet and consent form provided as attachments. The email and participant information sheet provided the name and contact details of the researcher for potential participants to contact should they wish to discuss the research prior to making their decision. Participants were asked to express their interest or to decline participation within 3 days. A reminder email was then sent on days seven and fourteen after the first email (timing of reminder emails was taken into consideration if an ‘out of office’ notification was received). If no response was received after three emails no further contact was made.

It was found that if a response was received from a potential participant, then their preference would be to have the interview within the following weeks as they often had busy schedules which could change if booked too far in advance. Recruitment was therefore performed in waves to accommodate for this, with either one network area or up to five individual nurses being contacted at a time.

Table 5-1 Nursing factors that might influence how offloading devices are implemented

Initial candidate Theory	Context	Mechanism	Outcome Pattern
1: Healthcare professionals with advanced knowledge of PU prevention are more likely to appropriately implement an offloading device as a preventative measure	The specialist has more dedicated time to review the patient. Also, PU prevention is a priority for the specialist as it is an area of expertise and something they do on a regular basis.	**Resource**: Specialist knowledge **Reasoning**: Specialist knowledge will lead to a more thorough and holistic risk assessment and will have more knowledge of the available resources	Patients are more likely to have a heel offloading device implemented when there is access to a specialist nurse with advanced knowledge
2: Nurses working in clinical areas that frequently care for patients at high risk of developing PUs are more likely to implement an offloading device as a preventative measure because PU prevention becomes more of a clinical priority and staff are more experienced at managing at risk patients and aware of the resources available to them	Culture and ethos of the healthcare setting (with high risk of PU development) makes PU prevention more of a focus	**Resource**: Staff knowledge **Reasoning**: Patients being cared for in an environment where there are high numbers of at-risk patients means that PU prevention is more of a priority and staff are more experienced in managing at risk patients and aware of the resources available to them / used to implementing them (i.e. – not just awareness).	Patients are more likely to have a heel offloading device implemented
3: Nurses are more likely to implement an offloading device if it is easily accessed within the care environment	Patients cared for in an environment where offloading devices are kept as ward stock or can be easily accessed	**Resource**: Offloading devices **Reasoning**: Nurses perceive that an intervention is needed immediately for patients at risk, and so respond by utilising offloading devices immediately following risk assessment	Increased utilisation of offloading devices in high-risk patients

Initial candidate Theory	Context	Mechanism	Outcome Pattern
4: If patients are moved frequently between different care environments then offloading devices are less likely to be utilised because of cost factors	Where it is anticipated that patients are going to be frequently moved between care environments	**Resource**: Offloading devices **Reasoning:** Nurses do not see it as a priority and something that can be left for the next person to deal with. If the offloading device is single patient use only, the nurses might see it as too much of a hassle to order or feel it should not come out of their budget and therefore the next ward can order the offloading device. If the offloading device is re-useable there is an ownership issue, and the ward are fearful that it will be sent with the patient and be lost.	Patients who frequently move between wards or who have a short-anticipated stay are less likely to have a heel offloading device.
5: Single patient use offloading devices, versus reusable devices, will be more desirable dependent on the care environment and priorities of the ward manager	Different patient groups in different care environments	**Resource**: Single use vs reusable offloading devices **Reasoning**: The financial priorities of the budget holder and patient types in their area will determine which offloading devices they will have available and how readily they will be available in that area	Implementing a plan of care appropriate to the patient becomes more about what is available and affordable rather than what is best for the patient, irrespective of cost
6: Offloading devices are more effective in patients with reduced consciousness	Patient with reduced consciousness (e.g., brain injury or sedated)	**Resource**: Offloading devices **Reasoning:** The patients will be unable to remove the offloading devices themselves/will not have an awareness of the offloading device	↑ compliance and effectiveness in care environments such as ICU

Initial candidate Theory	Context	Mechanism	Outcome Pattern
7: Nurses are more likely to utilise heel offloading devices as a response to pressure damage rather than as a preventative measure	Patients at risk of developing a heel PU	**Resource**: Offloading devices **Reasoning**: Nurses are more likely to risk assess the patient as a whole and implement a total body device such as a mattress, rather than to risk assess individual body sites. It is only once pressure damage has occurred that they implement an offloading device	Offloading devices utilised more in patients with heel PUs rather than at risk patients.
8: If a powered air mattress is already in use, additional preventative methods are less likely to be utilised	Patients at high risk of developing a heel PU	**Resource**: Powered air mattresses **Reasoning** Nurses knowledge, attitudes and opinions of mattresses will mean that they feel that this is sufficient to meet the patient's needs	↓ utilisation of offloading devices in settings or people with a powered mattress in place
9: Repositioning is a key component of PU prevention but is less likely to take place if offloading devices are being utilised.	Care environment where nurses lack capacity to reposition patients and/or knowledge of the need for repositioning	**Resource**: Pressure relieving equipment including mattresses, cushions, and offloading devices **Reasoning:** Nurses are outsourcing to devices to replace need for frequent repositioning	Patients are repositioned less frequently and could in turn increase risk of developing a PU. Care becomes focused on the device rather than the patient
10: Conversely, the offloading device is a physical reminder for nurses and the patients of their risk and therefore more attention is paid to this at-risk body site.	Patients at high risk of developing a heel PU	**Resource**: Offloading devices **Reasoning:** The presence of the offloading device reminds the patients and nurses that the heel is an at-risk area, so more attention is paid to the heel	↓ Heel PU incidence because of a reduction in pressure, but also raises awareness of risk which leads to better self-care from the patient and more effective care from the nurse/carer

Table 5-2 Patient factors that influence how offloading devices are used

Initial candidate Theory	Context	Mechanism	Outcome Pattern
11: Offloading devices are not suitable for use in patients who are at high risk of falls as they could become a fall hazard.	Patients at high risk developing a heel pressure ulcer and of falls, where falls prevention is more of a priority	**Resource**: Nurses knowledge and prioritisation **Reasoning**: Nurses perceive some offloading devices can be a fall hazard and so are reluctant to use them with patient at high risk of falls	↓ use of offloading devices in this patient group because falls prevention takes a priority over pressure ulcer prevention
12: Patients are not always compliant with the use of the offloading devices due to comfort factors	Patients at risk of developing a heel pressure ulcer with capacity to make decisions about their care.	**Resource**: Offloading devices **Reasoning**: Patients perceive the offloading device as bulky, hot, uncomfortable, or hindering self-movement and so are reluctant to use them	↓ compliance and usage of offloading devices
13: Risk assessments that involve the patient and/or carer are more likely to highlight specific risk factors/ high risk areas leading to plan of care that is more patient specific and the patient will comply with	Risk assessments that take place in the presence of the patient and or carer	**Resource**: Offloading devices **Reasoning:** When nurses involve the patient and/or carers when performing a risk assessment and planning the patients care they will have a more comprehensive risk assessment and ↑ knowledge about the patient's pressure ulcer risk	An increased awareness of risk leads to an increased utilisation of interventions specific to the patient's need. By involving the patient in the care planning process, they will be more likely to comply

5.2.1.4 Data collection methods

Standard research interviewing techniques tend to sit in one of three domains – structured, un-structured or semi-structured. Structured interviews tend to consist of fixed, closed questions and have more of a positivist experimental design with more objective outcomes (Pawson and Tilley, 1997a). To the other extreme, unstructured interviews involve a more constructivist approach and tend to be more of a conversational style of interviewing where the researcher starts with a broad range of 'themes' to be explored until a mutual understanding is achieved. Realism sits in-between positivism and constructivism and interviewing in realism uses a combination of methods, with elements of the two extremes in the form of semi-structured interviews (Pawson and Tilley, 1997a).

There is not a singular approach to realist research; therefore there is no one authoritative account of how a realist interview should be performed (Manzano, 2016). The realist interview is qualitative in nature, as it is conducted in a manner that explores the participants' views through conversations and is driven by the theory that requires refining. The conventional guidance for qualitative interviews is for an interviewer is to take on a neutral position when engaging with the participant so as not to influence their responses, thereby minimising bias. However, in realist research the researcher's theory is the subject matter that requires developing and refining, and the function of the interviewee is to confirm, falsify, and above all refine the theory (Pawson and Tilley, 1997f). Therefore the "teacher-learner cycle" of realist evaluation (Pawson and Tilley, 1997f) was adopted for this stage of the research; a technique whereby the theory is taught to the interviewee, having heard the theory the interviewee is then able to teach the researcher about their understanding in respect of components of the theory in an informed way.

Interviews were conducted over the telephone at a time convenient to the participant. Due to the geographical variation of participants, with TVNSs from across the UK being invited to participate, along with time constraints, face-to-face interviews were not feasible and telephone interviews were the most accessible method of enquiry. There is little evidence to suggest that telephone interviews differ to face-to-face interviews in the amount, quality or interpretation of the data (Novick, 2008).

The topic guide was developed from the 13 candidate theories presented in Table 5-1 and Table **5-2**, and was designed to utilise the clinical expertise and experiences of the participants by unpicking the CMO configurations of each of the theories, with the aim of developing and refining the theories alongside developing any potential new theories. As this research was an iterative process a preliminary analysis took place

prior to the next interview, as described in 5.2.1.7, and the topic guide was developed and amended prior to each interview. An example of the topic guide can be seen in Box 1.

The interviews were digitally audio-recorded and transcribed verbatim to create an authentic, accurate and permanent record of dialogue for analysis. The first interview was transcribed in full by the researcher as it was felt necessary to have experience of the transcription process, and then due to time factors the remaining interviews were transcribed by an external transcription agency.

Box 1 - Sample interview topic guide utilising the teacher-learner method

Theory 1: Do you feel that as a TVN, because pressure ulcer prevention is at the forefront of your clinical priorities, you are more likely to implement an offloading device as a preventative measure than a ward-based nurse?

Probes:

- **If yes**, could you explain more? Could you give any examples? Why do you think this is so? Is it due to your knowledge of the available offloading devices, or a more holistic assessment of the patient?
- **If no**, could you expand on this? Why do you think our experiences differ? Who do you feel is most likely to initiate a device?

Theory 2: Do you think nurse's utilisation of the device varies according to care environment? For example, clinical areas that care for a population that is at high risk of developing pressure ulcers are more likely to implement a preventative intervention because it is more of a key priority?

Probes:

- **If yes**, could you explain more? Could you give any examples? Why do you think this is so? Is it their knowledge or the resources available to them that influences this? Do you think the culture and ethos of the ward influences this?
- **If no**, could you expand on this? Why do you think our experiences differ?

5.2.1.5 Ethical Considerations

It is a requirement that research involving patients, service users, care professionals or volunteers is reviewed by a research ethics committee to ensure that the dignity, rights, safety and well-being of participants has been considered during the design of the research (Health Research Authority, 2017).

Ethical approval

The ethical implications for this phase of the research mainly related to the recruitment of TVNSs and the time taken to participate in a telephone interview. There was the

potential that poor or dangerous practice could have been disclosed due to the nature of the research questions, so this was considered during the ethics application, with the inclusion of methods that sought to address this. Ethical approval was gained through the School of Healthcare Research Ethics Committee (SHREC) in October 2015 (HREC15-014, Appendix D School of Healthcare ethics approval (November 2015)). NHS ethics was not required because holding an NHS post was not a requirement, recruitment was through external groups and the interviews would have no impact on their job role.

Confidentiality and data protection

All interview transcripts were anonymised and stored in a password protected section of the M: drive of the University computer system. As telephone interviews were conducted, oral consent was audio-recorded and a consent form signed on the participant's behalf, scanned, and saved on the M: drive, therefore keeping the research paperless and secure. A confidentiality agreement was signed by the transcriber and a secure file exchange programme was used to send the audio recordings.

5.2.1.6 Grey literature review

Due to the iterative nature of realist research along with its multi-method nature, simultaneous literature searches were performed alongside the interviews to help develop and refine the theories. This included searching a specific grey literature database (OpenGrey) and searching manufacturers' websites identified during Chapter 3. Secondary and tertiary literature identified in Chapter 3, that did not meet the inclusion criteria, were also included.

5.2.1.7 Data Analysis

Data analysis should be systematic, robust and comprehensive in order to instil confidence in the reader when considering the implementation of research findings (Spencer et al., 2014b). In realist evaluation the analysis process is not a defined separate stage of the research process; it is an ongoing iterative process seeking out nuggets of information that can be used to explain wider CMO configurations (Wong et al., 2016, Manzano, 2016, Pawson, 2006a).

Coding is a way of labelling sections of information compiled during a study, assigning it symbolic meaning along with creating a similarity-based ordering of the data (Miles et al., 2014b). The data are segmented into discrete units, labelled, and grouped by categories that can either be pre-determined prior to analysis or emergent. By doing

this the data are decontextualised and contextualised (Tesch, 1990). However, one critique of this method of data analysis is that the relationships developed between these categories and the data are based on similarity and not contiguity, which can lead to a neglect of context (Maxwell, 2012). Therefore, like a lot of aspects of realist methods a middle-ground approach is taken to data analysis, searching for similarities, relationships and meaning within the data.

Due to the methods employed in this stage of the research, time constraints became a constant issue. The iterative nature of the research required transcription and analysis between each interview, which was time consuming. Therefore, a simple and straight forward primary thematic analysis was required so the time between interviews could be shortened. Primary analysis involved an inductive process of listening back to the recordings and reading though the transcriptions and allowing themes and ideas to emerge. These would then be noted down and mapped against the candidate theories. Once all the interviews had been completed a more in-depth thematic analysis took place with open coding against categories and themes derived from the candidate theories.

Presentation of quotations

The results section (Chapters 6-8) presents quotes from the interview transcripts to illustrate and develop arguments about the candidate theories. In order to help the quotes make sense for the reader the text has been edited: pauses, repetitions and identification of places and people have been excluded, an ellipsis (…) indicates where some of the participant dialogue has been excluded or parentheses [ ] are used where the text has been altered.

Maxwell (2012) argues that although manipulation of the data in this manner could be seen as affecting the validity of the study through introducing subjectivity by the researcher, in realist research the identity and perspective of the researcher is a valuable resource in making sense of the data.

5.2.2 Phase 2: Theory testing and refinement

It was not possible to take all the theories forward for testing due to time and resource constraints, therefore the theories were prioritised, and one overarching programme theory was identified for testing (Chapter 9). There is a need for some theories to be held for confirmation at a later point, while focusing attention on the testing of other theories (Pawson, 2013c).

One of the key tenets of realism is the basic idea that mechanisms are not always observable because they are about peoples' reasoning. Rather, it is necessary through interviewing to explain why the relationships come about; to establish what goes on in the system that connects its various inputs and outputs (Dalkin et al., 2015).

To test the theory, it is necessary to observe what is happening in everyday clinical practice. Observations are a powerful way of studying peoples' actions and accounts in everyday contexts, rather than under experimental conditions set up by the researcher (Hammersley and Atkinson, 2007). It allows for a detailed investigation of the cultural norms, beliefs and behaviours that are characteristic to that setting or environment (Morgan-Trimmer and Wood, 2016, Nicholls et al., 2014). There are several different methods that the observations could have taken, with consideration given to action research and case study design before a multi-site ethnographic approach was chosen.

Action research involves the researcher collaborating with the participants in the research setting with the aim of enacting positive change through a series of interconnected cycles of analysis, goal-setting, planning, evaluation and change (Lewin, 1946). Action research has been used in realist studies as a method of evaluating a change in practice within a complex intervention or policy (Westhorp et al., 2016), but was not appropriate for this research as the aim was to observe how and why offloading devices are used in practice, not to make a change in practice.

Case study approach is a method that aims to make comparisons between multiple perspectives rooted in a specific context, or multiple contexts for the multiple case study approach (Simons, 2014). Case study design is structured around context(s), institution(s) or location(s) where the understanding of the research issue needs to be holistic, comprehensive and contextualised (Lewis and McNaughton Nicholls, 2014). Interventions are typically implemented simultaneously within different settings and at multiple levels. It is, however, not necessarily useful or meaningful to observe this happening at all levels, and the relevant level will depend on the assessed intervention and the system in which it exists (Pfadenhauer et al., 2017), so was not selected.

Ethnography is the study of people in their natural environment where the researcher participates in the setting in order to collect data and can use a mixture of qualitative and quantitative methods (Hammersley and Atkinson, 2007). Ethnographic research typically involves prolonged observation in the field, focusing on the language, behaviour and interactions between different parties (Brewer, 2000). Ethnographic observations have been found useful as part of other realist evaluations to explore

aspects of the context that cannot easily be measured, such as the culture of an organisation (Randell et al., 2014).

The role of the researcher is to immerse themselves in the lives of the people in the setting they are researching to understand their social meanings and ordinary activities. The data derived from an ethnographic study is gathered from a mixture of methods, in part from observations of naturally occurring phenomena as well as evidence generated from enquires and conversations with participants and sources, and documentary evidence of various kinds.

The key purpose of interviews in realist evaluation is to understand people's reasoning, but formal interviews or informal conversations with participants can also provide information that might be missed during observations, or that might have happened in the past, along with being used to check the researchers understanding of what has been observed.

Ethnography was adopted as triangulating both structured and unstructured observations including a review of documentation, along with interviews, across different wards, will provide a more complete and accurate account of what is happening in practice than they could singularly, deepening our understanding rather than just confirming it (Evers and Staa, 2010, Miles et al., 2014a, Greene, 2007). Ethnography allowed for testing of the theory alongside identifying new contexts, mechanisms, and outcomes through exploring the observable and the unobservable.

5.3 Summary

This chapter has presented the methods of data collection and data analysis for Phase 1: theory elicitation and refinement. Due to the iterative nature of realist evaluation, the results of Phase 1 informed the focus of the research and the methods used in Phase 2 (theory testing). Therefore, a linear presentation in this, and subsequent chapters has been used for the benefit of the reader to be able to comprehend the rationale behind the research design. The findings from Phase 1 and how the interview data were used to modify and refine the original 13 candidate theories into three programme theories are presented in Chapters 6-8. The selection of one of these theories for testing followed by the methods for the ethnography are presented in Chapter 9 and the ethnography findings in Chapter 10.

Chapter 6 Programme theory 1 – Proactive use of offloading devices

6.1 Introduction

This chapter begins with descriptive results of the TVNS interviews followed by the results of the interviews. During the analysis three programme theories emerged that encompassed all 13 initial candidate theories. Chapters 6-8 follow the analysis plan described in Chapter 5 for the theory elicitation and refinement phase of the realist evaluation, with each chapter focussing on one of the three programme theories.

This chapter will demonstrate how the interview data were used to modify and refine candidate theories 1-6 (Table 5-1) into programme theory 1 which examines how offloading devices are used proactively in the prevention of heel pressure ulcers. Each of the initial candidate theories are considered in turn, with the contexts presented as the subheadings. Then finally all six candidate theories will be summarised and refined together into programme theory one.

6.2 Descriptive results

6.2.1 Participant recruitment

Eight TVNSs were recruited and interviewed over a seven-month period between January and August 2016. They were all recruited via email through networks identified in 5.2.1.3. The average duration of the interviews was 55 minutes (range 42 - 74 minutes) giving a total of 437 minutes (7.3 hours) of interview data for analysis.

6.2.2 Participant demographics

The recruited TVNSs (Table 6-1) were all employed by the NHS and worked across the UK; six from England, one from Northern Ireland and one from Wales. Three worked solely in acute care, five worked across primary and secondary care settings. For those who worked in a combined role, they were asked to discuss experiences in acute care.

Agenda for Change was introduced into the NHS in 2004 as a statutory framework for pay and conditions, with the intention of modernising and replacing the existing Whitley scales and clinical grading schemes into a universal banding system. Staff are placed in one of nine pay bands, based on their knowledge, responsibility, skills, and effort needed for the job (NHS Staff Council, 2019). The TVNSs had a wide range of job roles, ranging from band 6 Clinical Nurse Specialists (CNS) to senior TVNS & Lead Nurse/Nurse Consultant with a wide range of experience ranging from 2.5 to >20

years. The banding of the more senior TVNSs were not recorded and there is no set band for the different job titles as this is set by the individual organisation and can range from band 7 to 8c. There was also a large variance in the size of the patient populations, with the larger trusts likely to be tertiary centres with more specialities and therefore a wider variety of patients including maternity and paediatrics. This could lead to different contextual factors with regards to experiences of caring for different patient types and complexities in different organisations.

Table 6-1 Participant demographics

Participant number	Current Role	Length in role (years)	Approx. Acute Patient Population	Acute or combined NHS Trust
P1	Band 6 CNS	3	1700 beds	Acute
P2	Lead nurse	20	1900 beds	Combined
P3	Band 6 CNS	5	250 beds	Combined
P4	Lead nurse	20	900 beds	Combined
P5	Lead nurse	16	1000 beds	Combined
P6	Band 7 CNS	5	500 beds	Acute
P7	Band 7 CNS	2.5	800 beds	Acute
P8	Nurse Consultant	17	400 beds	Combined

6.2.3 Heel pressure ulcer prevention

A variety of heel-specific devices and campaigns/training materials for education about the prevention of heel pressure ulcers were used by the TVNSs (Table 6-2). The “Heels Up” campaign is a catchphrase used amongst TVNSs that they utilise and adapt accordingly for use in their areas. The ThinkGlucose programme (NHS Institute for Innovation and Improvement, 2011) was designed to improve the management of people with diabetes on any hospital ward in the UK and P5 had utilised this to create a campaign for their Trust highlighting the risk of wounds including pressure ulcers to the feet of diabetic patients. The variety of different devices and methods utilised to promote heel pressure ulcer prevention by the TVNSs highlights that there is no general consensus on how and what devices should be used (if any) to prevent heel pressure ulcers in an acute care population.

Table 6-2 Heel pressure ulcer prevention strategies used by the TVNSs

Participant number	Offloading devices used	heel pressure ulcer prevention policy/strategy/campaign
P1	Repose®, PRAFO®, orthotic footwear	Nothing heels specific
P2	Pillows, Heelift®, Prevalon®	Heels up
P3	Repose wedge®, pillows, soft cast.	Nothing heels specific
P4	Pillows, foam heel lift devices.	Aide memoir (a flow sheet that they follow)
P5	Dependent on ward area, no agreed criteria for use of heel devices	ThinkGlucose campaign concentrating on the foot, intentional rounding
P6	Kerapro® and Aderma®, some offloading boots, but used on a single patient basis	Nothing heels specific
P7	Offload (Repose® style) and custom-made troughs	Heel protection flow chart
P8	Repose® boots and wedges, Heelpro	Nothing heels specific – moving over to new care plan

6.2.4 Grey literature review

The grey literature search was conducted on 18/08/2016 and yielded 50 potentially relevant articles (Table 6-3). Most of the articles gained from contacting manufacturers and searching their websites were conference posters of either case studies or product reviews of their offloading devices and did not add anything additional to the theories. Twenty-four papers potentially relevant papers were identified that had been previously excluded from the systematic review.

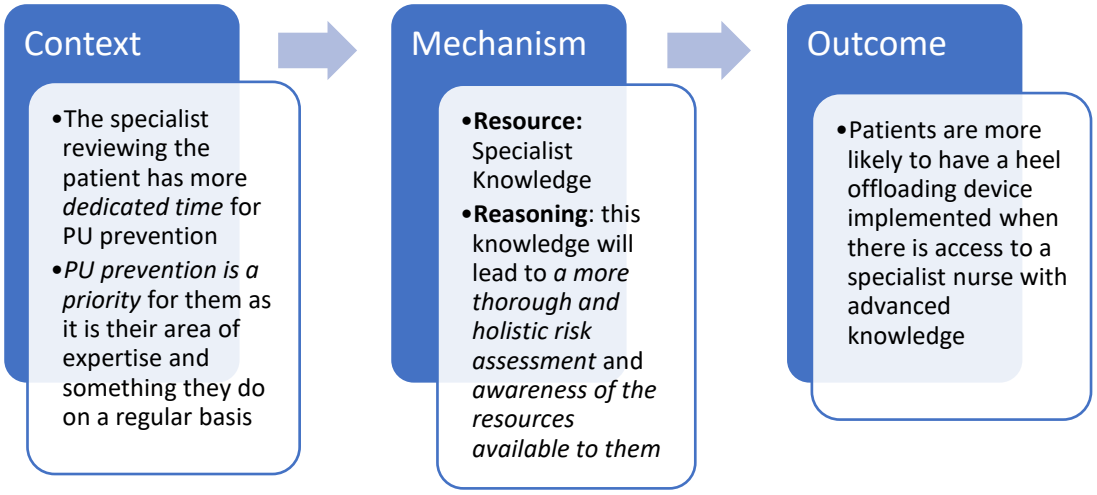
Table 6-3 Grey literature search results

Source	Number of papers retrieved
Open Grey	0
Systematic review search	24
Manufacturers	26

6.3 Candidate theory 1

Healthcare professionals with specialist knowledge of pressure ulcer prevention are more likely to appropriately implement an offloading device as a preventative measure

Figure 6-1 Initial theory 1



This theory was initially developed from my personal clinical experience and perceptions of how the devices are used and was originally broken down into the CMO in Figure 6-1. This theory started as “Healthcare Professionals with advanced knowledge of pressure ulcer prevention” as in practice this is not limited to just TVNSs, but also includes link nurses (nurses who act as a link between their own clinical area and the TVNS team to increase awareness of pressure ulcer prevention, wound care issues and motivate staff to improve practice), nurses with an interest and other professional groups who use offloading such as physiotherapists and podiatrists. In the interviews other healthcare professions were acknowledged and discussed (mainly podiatry and physiotherapy) but as the TVNSs largely reflected on their own first-hand experiences and specialist knowledge, there was little data about other professionals. The link nurses tend to be developed and trained by the TVNSs, so the specialist knowledge of the TVNS will have a direct impact upon the knowledge and practice of the link nurses, as described by this interviewee:

> *“We have link nurses and we have identified and trained them up to a certain level” (P4, lead nurse).*

6.3.1 Dedicated time

During the interviews, dedicated time was explored as a potential contextual factor. TVNSs perceived themselves, when compared to ward staff, to have more dedicated time to do a thorough assessment of the patient; being able to take into consideration all of the risk factors individual to that patient which could increase susceptibility to heel pressure ulcer development. P4 described the dedicated time that they have with patients to assess their pressure areas and pressure ulcer risk as a "privilege", because the ward nurses have so many other competing priorities. P1 discusses their job role being "focused" on pressure ulcer prevention, which means they are more likely to find out more information from patients in a short period of time, but this is likely to tie into the specialist knowledge as well as the job role of the TVNS, as demonstrated in this quote.

> *" when we go and chat to patients we can very often, and maybe that's because we're sort of slightly out of the situation, um, and that's what we're focusing on, that we can find out information from patients within a few minutes that is sometimes like, well, you know, why wasn't someone else able to find that out, but I think that it is because we are almost, not detached, but we've...that's our focus" (P1, Band 6 CNS).*

It could therefore be argued that having dedicated time and singular focus when assessing patients allows for a more thorough assessment of the patient's pressure ulcer risk, and therefore the patients' requirements in respect to heel offloading.

The context of dedicated time is not just limited to assessment of patients, but also in the investigation, sourcing, and evaluation of devices. P2 discussed working with podiatry to look at the different devices:

> *"…we really want to sit down [with podiatry] and, you know, get as many samples of all the products that are available to try and work out, you know, when we use what and where" (P2, lead nurse).*

P3, P4 and P6 discussed that it was their role as TVNSs to test and evaluate devices for trust or ward level implementation. Individual wards do not have the time and therefore develop a 'reliance' on the TVNSs to decide what devices should be used and to provide training on how to use them. As demonstrated in Chapter 2, there are numerous different devices available on the market for the prevention of heel pressure ulcers, with what is available continually changing as new products are introduced or old ones adapted. This information is usually gained directly from the supplying companies, either through meetings with sales representatives, attending conferences or literature from the companies; something that is more frequently targeted to TVNSs and that ward staff rarely have access to. The volume of devices can be problematic for specialists as demonstrated by P2, who has 20 years' experience in the role:

> *"I still think that even within my own mind, I do not feel that I know all of the devices that are out there, and I do not know, you know, which is best in which scenario" (P2, lead nurse).*

There is a potential that the sheer volume of choice could act to confound strategic, evidence-based decision making by the TVNS, meaning that the devices selected for use within an organisation are those with the best sales team.

The TVNSs interviewed tended to see it as their responsibility, either as the tissue viability service or in conjunction with another speciality like podiatry or procurement, to research the different devices available, how they work, figure out if they would be suitable for their patients, financial implications and any evidence base behind them, as this quote demonstrates:

> *"…I think, you know, [ward staff] do rely on us bringing them in and I think also finance rely on us bringing them in as well, and the matrons for the directorates" (P4, lead nurse).*

There is no set process for how this would take place and would differ between organisations. P5 reflected upon not having agreed criteria for the use of heel devices in their organisation and had taken it upon themselves as part of their role to develop this as this quote shows:

> *"At the moment there's nothing sort of… no agreed policy in place, so we [TVNSs] have just set up a heel working group of which there is mixed clinical area, procurement and podiatry, myself and practice development to look at the use of heel devices" (P5, lead nurse).*

Due to the context of dedicated time, the TVNS can become a resource to the patients, staff and the organisation in general. Their specialist knowledge, regardless of how they develop this, will influence which devices are used, how and where throughout their organisation. From personal experience, on occasion there could be a ward manager or link nurse with an interest in heel pressure ulcer prevention, who might source a device without the support of the TVNS, but this tends to be the minority rather than majority of clinical areas; none of the TVNSs interviewed gave examples of this happening in their organisations.

6.3.2 Pressure ulcer prevention is a priority

Along with the TVNSs having dedicated time to focus on pressure ulcer prevention, it is also seen as a key component of their job role with priorities from their organisation seen as an influencing factor. The NHS is a macro context that influences the organisation with pressure ulcer rates being monitored in some organisations in England through the Safety Thermometer (Harm Free Care, 2019) and Category 3, 4 and unstageable pressure ulcers requiring investigating and reporting as a serious incident (NHS Improvement, 2019).

The reduction of acquired pressure ulcers, (developed whilst the patient was an inpatient in a particular hospital or facility) is frequently seen as the responsibility of the TVNS, therefore if there is a high incidence of heel pressure ulcers in a clinical area, this might influence the implementation of an offloading device to help drive down pressure ulcer rates as demonstrated here by P4:

> *"When I started writing guidelines it was all about making sure to direct resources to where they're needed, and that's normal now that we need to do that because we [the TVNS team] are so performance managed. So yes, the devices can make a difference" (P4, lead nurse).*

Root cause analysis (RCA) is a systematic process for identifying "root causes" that led to a serious incident, and an approach for responding to them to minimise the chance of it occurring again. RCAs usually involving a structured documentation review and interviews with those involved (which can include the patient) and a meeting to discuss the findings and identify learning points. The investigation would normally be conducted by the clinical area where the incident occurred, but for pressure ulcer RCAs the TVNS would be involved in the meeting and aiding in identifying learning points. This could potentially be a method through which clinical environments that might need to prioritise pressure ulcer prevention, and where a device could be beneficial are identified, which P3 gives an example of:

> *"For example, elderly wards, as well trauma & orthopaedics, they're so twitchy, so they've got stock of offloading devices on their wards, so they're very mindful. They've learned the lessons as well from a few pressure ulcers that patients developed on their wards. They've done root cause analysis and that's another thing which basically increases their awareness" (P3, Band 6 CNS).*

Along with sharing the lessons learnt from the investigation with the ward staff, if a knowledge deficit was identified then this might be addressed through training and education or focused work with the ward to resolve this. All of the TVNSs mentioned training and education as being a key component of their job role, and felt it was a mechanism by which they could successfully implement an offloading device at a ward or organisational level to achieve a reduction in pressure ulcer rates.

6.3.3 Knowledge brokering

One of the mechanisms by which TVNSs gain their specialist knowledge is through networking. In the absence of robust evidence, TVNS utilise the knowledge and experiences of other TVNSs, as discussed by P3:

> *"…when I'm having to choose a device I basically go by the manufacturer's advice but then trial [evaluate] it, and again with colleagues, see what the rest of the organisations have used, to see if they have trialled [evaluated]*

> *it…no point if the device fails in another organisation, no point having a go in our Trust" (P3, Band 6 CNS).*

TVNSs are the experts in pressure ulcer prevention for their organisation, therefore when there is a lack in clinical evidence to make decisions on practice, the TVNSs either have to create their own evidence through 'trialling' the devices (a product evaluation[4] that is usually devised and carried out or led by the TVNS team) or search for an alternative evidence source to support their decisions. This could be from other specialities or from colleagues outside of their organisation, although this seemed to be related to experience, with the more junior TVNS (band 6 or under 5 years of experience) opting for this. It could be considered that this does require an element of trust by the TVNS though; trust in the rigor of the evaluation process by their colleagues along with trust that the context of their organisation is similar enough for the results of their evaluation to be transferable (e.g., if the evaluation were performed in a small cottage hospital, would it be equally as effective in a large teaching hospital).

The TVNS might also turn to the distributor of the device for support in implementation and training. Building up a good relationship with the distributor will affect usage which P8 gives an example of:

> *"our procurement actually monitors the usage of [offloading devices], and tells us how many we've got through, so if we feel that we're getting through too many we'll get the company in and get them to do training" (P8, Nurse Consultant).*

An interesting mechanism identified here by P8 is where an increase in usage of devices is assumed to be a sign of inappropriate use, something that is monitored as a method of keeping costs down. However, it could also be that an increase in usage is a sign of proactive use or that there is a change in the patient population with more patients who require offloading in that clinical area.

6.3.4 Summary

The TVNSs have specialist knowledge with regards to the use of offloading devices and the different devices available, which is a resource utilised on a meso level by the organisation they work in with regards to the reduction in pressure ulcer rates. This awareness and knowledge of the resources available is developed in part due to the dedicated time that they have to focus on pressure ulcer prevention, which in turn leads to a more proactive use of offloading devices. This can be through direct patient care,

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[4] Where the device is either provided to individual patients or a specific ward, and feedback is collected from ward staff and/or the patient about their judgement of the value, worth and effectiveness of the device.

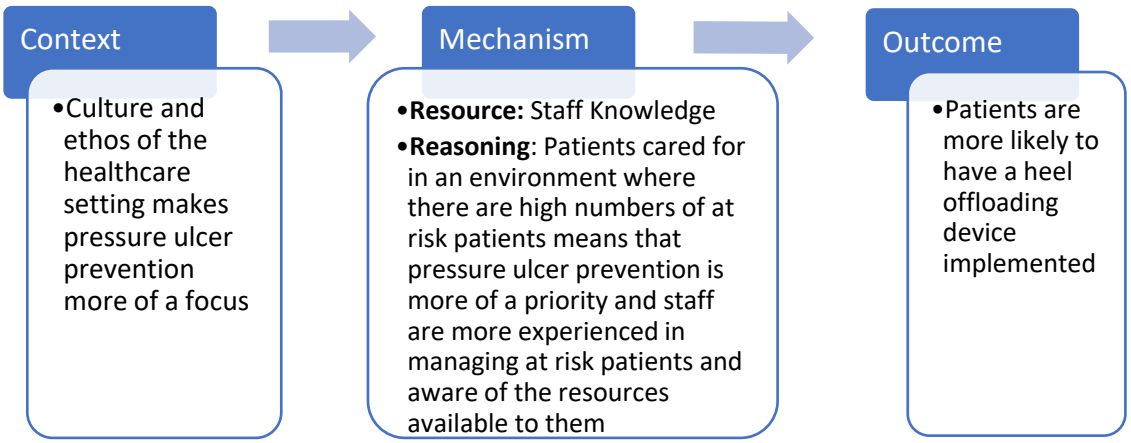
or through their influential role within their organisations. The TVNS feel they are perceived by both ward staff and the wider organisation as being a valuable resource for driving forward and influencing the initiation and use of offloading devices through training and education along with the development of guidelines and protocols.

6.4 Candidate theory 2

Staff working in care environments that frequently care for patients at high risk of developing pressure ulcers are more likely to implement an offloading device as a preventative measure

In Chapter 3 it was noted that the majority of RCTs took place in trauma, orthopaedics, elderly care, and critical care environments, because these areas are most likely to have the patients at highest risk of developing heel pressure ulcers. This candidate theory stated that nurses working in clinical areas that frequently care for patients at high risk of developing pressure ulcers are more likely to implement an offloading device as a preventative measure. Here, pressure ulcer prevention becomes more of a clinical priority and staff are more experienced at managing at risk patients, and aware of the resources available to them.

Figure 6-2 Initial theory 2



6.4.1 Culture and ethos of the healthcare setting

During the interviews, the TVNSs agreed that staff in healthcare settings that care for patients at high risk of developing pressure ulcers are more likely to implement an offloading device. Therefore, the factors that influence the culture and ethos of these care environments was explored.

The TVNSs often described viewing it as part of their role to identify these settings and to focus their resources to these areas. As discussed in 6.3 some of the TVNSs view their roles as being performance managed against the pressure ulcer rates for their

organisation, making pressure ulcer prevention a priority. If there are high rates of heel pressure ulcers in a clinical area, this might influence the TVNSs resources towards that area and therefore more likely to introduce a device to that clinical area as part of this.

P3 discussed how the RCA process increased awareness and the wards became mindful of their patient population's risk, which in turn led to an increase in the use of offloading devices, as discussed here:

> *"…they are very cautious about their population, for example elderly wards, as well trauma orthopaedics, they're so twitchy, so they've got stock of devices, offloading, Repose® wedges on their wards, so they're very mindful... They've learned the lessons as well from a few pressure ulcers that patients developed on their wards. They've done root cause analysis and that's another thing which basically increases their awareness"* (P3, Band 6 CNS).

The RCA process might act as a mechanism to identify the clinical areas at high risk and therefore more likely to require an intervention, subsequently influencing implementation. The TVNSs knowledge of their organisation and risk factors is also a mechanism through which high risk wards are identified as discussed here:

> *"So, for example the diabetic ward and the orthopaedic ward and ICU probably are the highest risk areas… but they absolutely get [use of offloading devices] drummed into them" (P8, Nurse Consultant).*

This TVNS's example focuses on the highest risk areas because they will have more patients with risk factors for developing a heel pressure ulcer and will therefore have a higher incidence of heel pressure ulcers. Using terms like "drummed in" gives the impression of repetition as a mechanism for learning.

If a knowledge deficit was identified during the RCA, then this might be addressed through training and education or focused work with the ward. It has been found, with regards to pressure ulcer prevention, that nurses with a sounder knowledge base make better clinical decisions than those with a poorer knowledge base (Lamond and Farnell, 1998). All of the TVNS discussed training and education being a large part of their role and used it to increase the knowledge of ward staff with regards to risk factors for pressure ulcer development, along with heel pressure ulcer prevention strategies.

Another mechanism to make a change in pressure ulcer rates and to get a device implemented, as well as influencing the culture and ethos of a healthcare setting, is through good leadership as this TVNS discusses:

> *"I think if you have not got good leadership you will not get your pressure ulcer rates down. Our fractured neck of femur ward has an absolutely fantastic ward manager. Obviously, they are an extremely high-risk area… [the fractured neck of femur ward] hadn't had an avoidable pressure ulcer*

for over a year, which I think is an amazing achievement being as it's such a high-risk area" (P6, Band 7 CNS).

Leadership is the ability to influence, inspire confidence and generate support among followers for the vision and direction of the leader (McEwen and Wills, 2011). There are numerous theories and models with regards to leadership but there is not enough evidence from the interviews to inform what it was about the ward manager that influenced the change to be able to map it against an existing theory.

6.4.2 Summary

The TVNSs discussed care environments such as orthopaedics, critical care, and care of the elderly as being areas that frequently care for patients at high risk of developing heel pressure ulcers. These were identified through the TVNS knowledge of risk factors, their organisation as well as through RCA investigations. This was reflected in Chapter 3 as they were the predominant care environments where the RCTs took place. The TVNSs would focus their resources, in the form of time, education, and devices towards those areas as this could make the biggest impact and change in pressure ulcer rates.

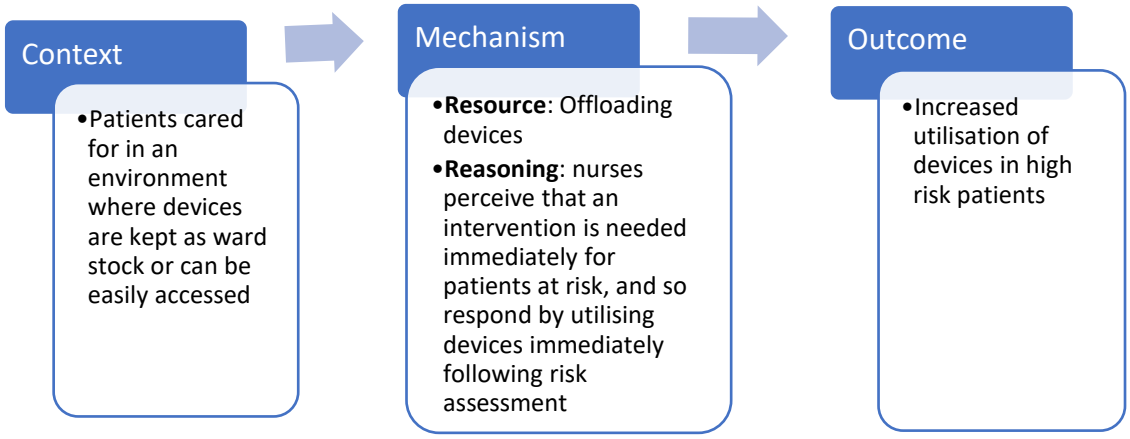
Following on from the identification of these areas, staff are made more knowledgeable of the risk factors for their patient group through shared learning from RCA investigations along with focused and repeated training and education. Spaced repetition theory is based on the work by Ebbinghaus (2015) that tells us that repeated learning over a period of time increases the likelihood of embedding knowledge into long term memory. This strategy of repeated teaching could be expected to increase the knowledge of heel pressure ulcer risk factors, and theorised that it acts as a mechanism to increase the likelihood of devices being implemented and used in their clinical area to prevent heel pressure ulcers from occurring. Leadership has also been identified as a potential mechanism for influencing pressure ulcer prevention strategies including device use and staff engagement.

6.5 Candidate theory 3

Nurses are more likely to implement an offloading device if it is easily accessible within the care environment

It was theorised that the easier it is to access a device, the more likely they are going to be used in practice, which is supported by Källman and Suserud (2009) who identified that nurses' perceived lack of access to equipment as being a barrier to effective pressure ulcer preventative care. This theory was broken down into the following CMO.

Figure 6-3 Initial theory 3



6.5.1 Care environments that stock offloading devices

Theory 3 does tie in with theory 2, as it is also assumed that care environments that are used to caring for patients at risk of developing a heel pressure ulcer are more likely to have a stock of offloading devices. This is because if they have identified their patient group as being at risk, they are more likely to source a device to reduce this risk. The TVNSs perceived that having a device as stock is necessary, but this alone will not to lead to a proactive use of devices. A recurring theme from the TVNSs to increase offloading device use was through 'raising awareness'. Mechanisms that raise awareness were identified as a robust protocol and/or educational package that includes specific risk factors for the heel and the use of offloading devices, which is demonstrated here:

> *"…obviously if they're [the offloading device] there and they know about them, they've been educated about them then they're more likely to use them" (P4, Lead Nurse).*

Another possible mechanism through which awareness is gained is through repeated use of the offloading devices, which leads to familiarity with the device and becomes part of routine practice, as this TVNS describes:

> *"…I think once there was more awareness and I think when more nurses see [offloading device] and they know what it does and how to use it, then they're more inclined to initiate it themselves" (P6, Band 7 CNS).*

P7 was part of a regional collective strategy which combined education and access to equipment, which they felt to be an effective strategy, as described in this quote.

> *"…we were part of the whole 2012 Ambition from the Midlands and East and there was a massive drive in education and equipment for the nurses, and that's had a huge impact on our numbers of pressure ulcers" (P7, Band 7 CNS).*

P7 did acknowledge that this initial drive was not followed up and they felt this subsequently led to device usage dropping and pressure ulcer rates increasing,

although it is not known whether it is the education, the high focused attention from the ambition or 'leadership buy-in' that was influential, but the TVNS supported repeated learning as discussed in 6.4.

6.5.2 Delays in access

From clinical experience, if it is decided that a patient requires an offloading device, if it is kept on the ward it can potentially be put on the patient immediately, whereas if it requires ordering in, regardless of how quick this process is, there will always be a delay from the identification of the need to implementation. This was explored during the interviews and it was found that this delay varies greatly between organisations depending upon how and where they are ordered from and what the ordering process entails. Some organisations have a centralised stock which can be accessed within a few hours, whilst others order the devices through the NHS supply chain which could take several days to be delivered.

Several of the TVNS discussed how having devices easily accessible does increase their usage. There are multiple factors that could affect the ordering of a device, which in turn would delay or altogether stop a patient from being given a device. These factors included problems with the order process, such as difficulties accessing the ordering system or requiring financial approval, or due to competing priorities for the ward staff, which P5 gives an example of:

> *"in a busy environment, [ordering offloading devices] is just one more thing that they [nurses] have to sort out" (P5, Lead Nurse).*

There can be a delay in ordering the device or they might not be ordered at all due to *"getting lost in transit in terms of communication"* (P1, Band 6 CNS)

This was also reflected in the literature; Campbell et al. (2010) and Spilsbury et al. (2008) identified availability of equipment as being a barrier to implementation and provision of pressure ulcer preventative care.

In P5's organisation, matron level approval was required before anything could be ordered which would cause a delay in accessing equipment or make them less likely to order due to the extra "hassle" of contacting the matron. This is likely a mechanism from managers to monitor and control spending on wards, which ties in with theory 4 (which follows).

Some of the TVNSs discussed using pillows to offload the heels in situations where wards do not have access to a device or are waiting for a device to be delivered. This is something that can in theory be used immediately and all wards should have access to pillows. However, this is not always the case as this example shows:

"the problem we've got is that we do not have many pillows, so finding a pillow is a real scrabble, so that's part of a massive problem when it comes to using them as a reliable offloading device" (P5, Lead Nurse).

6.5.3 Summary

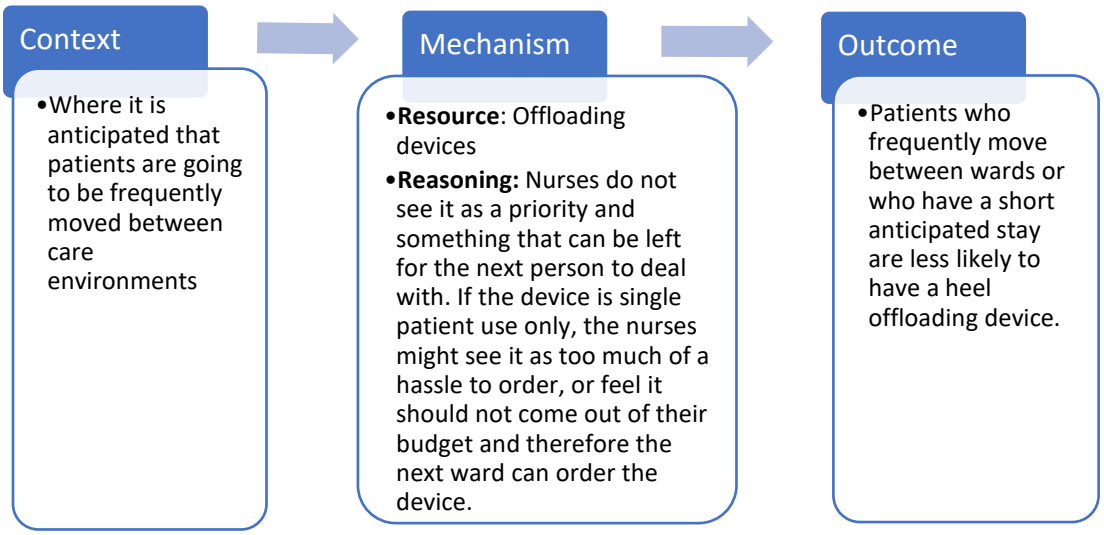
In a busy ward environment where nurses have multiple competing priorities, if the device is kept as a stock item it is more likely to be initiated in a timely manner. This could be because the offloading device is not kept as stock and therefore easily accessible, delays in the supply process and poor communication can lead to a delay in the device being initiated or be a barrier to it being used altogether. In the absence of devices, alternatives are sought such as pillows, because the need to offload the heels has been identified.

There is little evidence for the use of pillows as an offloading device, but in practice pillows are often used under the lower leg (not on the foot) to elevate the heels off the bed, as they are easy to access. Tymec et al. (1997) did report difficulties in maintaining offloading with a pillow as well as offloading devices over a 24-hour period, with the heel moving as the patient moved. Restlessness was reported as making heel elevation difficult, if not impossible to maintain, with a pillow.

6.6 Candidate theory 4

If patients are moved frequently between different care environments, then offloading devices are less likely to be utilised because of cost factors

Figure 6-4 Initial theory 4



The cost of offloading devices was discussed by most of the TVNS as something that does influence their use. There were differences between organisations in how the devices are ordered and who pays for them, but in most cases, they would be paid for

out of an individual ward's budget. For clinical areas that have a high turnover of patients, such as A&E or admissions wards, even if the devices could be re-used between patients, there could be a reluctance to use the devices in case they leave the clinical area with the patient, as this becomes a financial implication and their access to the device is lost:

> *"…if we were going to try and implement heel offloading devices at point of entry to hospital, if they're deemed to be at risk, then it means that it could be A&E or the medical admissions unit that were constantly buying them, even if they were using them for the rest of the stay in hospital" (P5, Lead Nurse).*

The TVNSs' responses suggest that the mechanism in which offloading devices are paid for does seem to be an influencing factor, as ward managers and matrons seem to be protective of their segment of the budget for their clinical area, therefore costs from an organisational context does appear to influence usage of offloading devices. If a benefit to the devices could be demonstrated on an organisational level and there was evidence that they reduce pressure ulcer incidence, then it would be likely that they would be funded.

P7 gives an example of how the costs influence the ownership of the devices at a ward level:

> *"...the ideal would be that the patient would come in and they would get given a pair of heel protectors and it would follow them through, but that's not how it works. We'd love to be able to do that, but there's just not the budget for those sorts of things. So, they are ward owned and the wards do, when they're not throwing them away because they think they're disposable, they do keep hold of them" (P7, Band 7 CNS).*

Although the financial implications of the devices appear to be a consideration for the TVNSs and managers when making recommendations on what type of devices they should use, it remains unclear whether this influences the ward staff, with some of the TVNSs thinking that wards became protective over their reusable devices and not letting them leave the ward with patients, but others felt that the ward staff would just think in terms of what is best for the patient. Some of this could be around the perceived "ownership" of the equipment as suggested by this TVNS:

> *"I think there's something there about… it's almost like the [ward's] ownership of the equipment really rather than, you know, it should be the patient's equipment" (P5, Lead Nurse).*

6.6.1 Summary

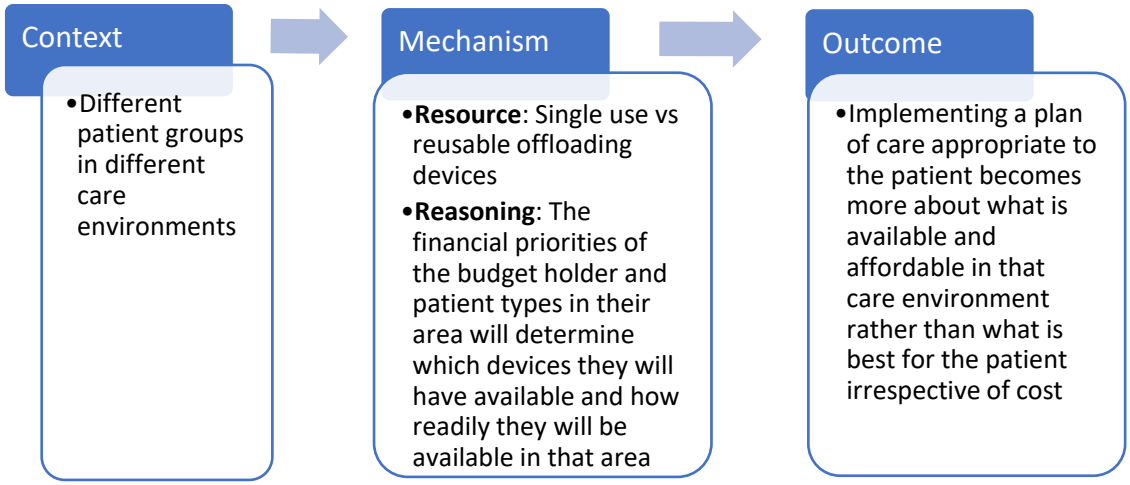
A combination of contextual factors become apparent. The frequency of patient movement between care environments becomes an issue when devices are paid for out of the ward budget, making ward managers' awareness of costs influential on their

usage, which in turn leads to ward staff becoming protective over the devices. This brings about a perceived ownership of the devices being by the ward rather than the patient. This closely links in with theory 5 (which follows in section 6.7) as the cost of the devices does seem to have an influence on the choice of reusable or single patient use devices (as described in Chapter 2). What was less clear was how much influence the cost of the devices had on usage at a micro level by the nursing team.

6.7 Candidate theory 5

Single patient use offloading devices, versus reusable devices, will be more desirable dependent on the care environment and priorities of the ward manager

Figure 6-5 Initial theory 5



This theory started by looking at whether re-usable (as opposed to single patient use) devices were more desirable in particular situations, but it links in with theory 4 with regards to the financial implications. As discussed in 6.6, a key mechanism appears to be the perceived 'ownership' of the devices being with the patient or the ward. Single patient use devices belong to the patient, so will stay with them throughout their inpatient journey whereas reusable devices are owned by the ward. The TVNSs described how wards become protective over 'their' devices and do not want them to be 'lost' with the patient during ward transfers, as this TVNS gives an example of:

> *" I think some of the issues with the reusable devices has been the fact that they have disappeared off with the patient, when the patient has left the area, so that can be a cost issue" (P2, Lead Nurse).*

However, if a patient is transferred to another ward without a device then there could be a delay until that patient's heels are offloaded again. Therefore, the financial constraints on a meso level and the ownership of the devices can lead to a clinical governance issue with wards only considering the requirements of the patient whilst

they are under their care, rather than for the whole of the patient's journey as this TVNS's example describes:

> *"You then have the problem where the ward does not want to transfer [the reusable offloading device with the patient] if they belong to the ward and they've paid for them. They may not transfer the patient with them, and then the patient may not have access to them in the next ward" (P5, Lead Nurse).*

However, there is a financial consideration for wards where there are a large proportion of patients who are at high risk of developing a heel pressure ulcer that may benefit from offloading. Reusable devices can be more desirable as 'what will benefit most of their patient population' is taken into consideration, as discussed in this TVNS's example:

> *"if they're in ITU for a week post op, they are on inotropes [medication that influence how effectively the heart pumps but can alter blood flow to peripheries] and everything else, then you know, they're going to be hugely at risk. So, you may want cheap and cheerful but not the long-term single patient device. So, it could be that you go down the wedge or something that you can re-use for someone else in exactly the same situation the following week" (P5, Lead Nurse).*

There is also an element of personal experience, expertise, and preferences of the nurse, with regards to the choice of device. The evidence based nursing model acknowledges that not only should the available research evidence be taken into account, but also clinical expertise allows nurses to be able to balance the benefits and risks of the different treatment options available to them for each patient, taking into account the patient's unique clinical circumstances including comorbidities and personal preferences (DiCenso et al., 1998). But when there is a lack of evidence and knowledge about the potential resources available then the nurse might choose a device based on familiarity, as P1 describes:

> *"unless staff recognise which device is suitable for which patient, they would still just go for the same one [staff] were comfortable with all of the time" (P1, Band 6 CNS)*

6.7.1 Summary

The type of offloading device available in a clinical area is influenced by the patient population and what will cater for their immediate needs. As discussed in candidate theory 4 (6.6), patient transfers are a consideration where clinical areas manage individual budgets. The perceived ownership of the devices is a key mechanism, with single patient use devices being owned by the patient whereas reusable devices are owned by the ward. This leads to wards being protective over their stock and not wanting them to leave with the patient, regardless of what is best for the patient in the

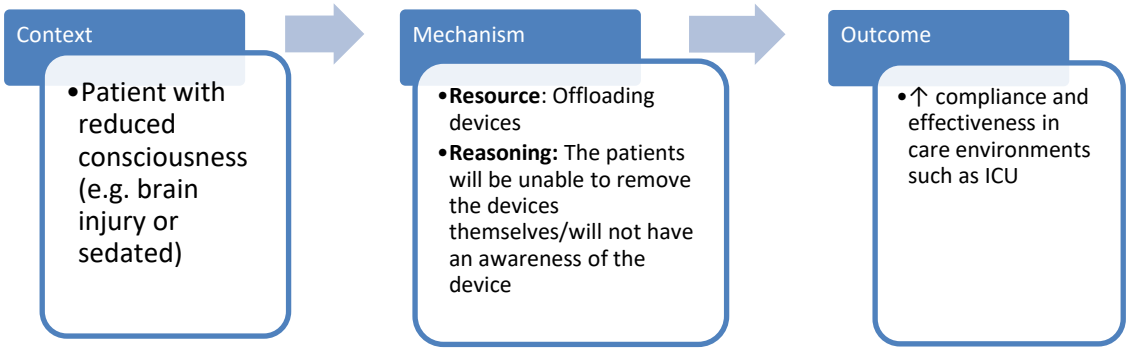
long term. There is also a question regarding how to provide the most cost-effective care for most patients within a clinical area. If wards regularly care for patients that might benefit from offloading, reusable devices could be more financially viable. It remains unknown what proportion of usage is single patient versus reusable for different clinical environments.

6.8 Candidate theory 6

Offloading devices are more effective in patients with reduced consciousness

Patients cared for in areas such as critical care or stroke wards could be at high risk of developing a pressure ulcer due to being bed bound, having reduced consciousness, or being sedated and ventilated, and therefore immobile and completely reliant on staff for all care including repositioning. These patients are therefore at high risk of developing a heel pressure ulcer, not only because of their immobility, but also their medical condition and/or medications that can lead to decreased perfusion to the lower limb. It was therefore theorised that this patient group would benefit from offloading because of their level of risk, but also it would be more effective because they would be less able to remove the device.

Figure 6-6 Initial theory 6



There was overall agreement with this theory from the TVNSs. There were views that this was because this patient group is 'more compliant' due to their immobility and inability to remove the device as this TVNS describes:

> *"Their patients [ICU] are pretty immobile and easier to manage from that respect. So, although they are at higher risk because of inotropes, in fact they're more compliant is probably what they are" (P4, Lead Nurse).*

These patients are more likely to require offloading because they will be higher risk and are less likely to remove the device. It could therefore be argued that this is a care environment that should offload on a routine basis as discussed by P5:

> *"They're not moving [the leg] off the pillow or whatever you're using, so it's easy to reposition them to keep the device in place. I'm not sure whether comfort is a case or just immobility and inability to remove it" (P5, Lead Nurse).*

Throughout the interviews there were differing opinions with regards to the use of pillows and wedges as an offloading device. However, most of the TVNs discussed that in this patient group, they would promote the use of a pillow or a wedge in preference to an offloading boot. This was because if the lower limb is immobile, then a device that is fixed to the foot is not required. This relates to theory 5 (6.7) with regards to reusable devices, including pillows, being more suitable and cost effective for a patient group that cannot remove the device or complain about it being uncomfortable, as described here by P8:

> *So, wherever the patients are very high risk, I mean, have really high-risk factors and there is a risk that their legs could come off the pillow, then I would go for the higher end device. But I do think even for your high-risk patients, if they offload satisfactorily on a pillow then there's a place for that" (P8, Nurse Consultant).*

Patients with reduced consciousness or an immobile limb were identified by all the TVNSs as being a patient group they consider to be at high risk of developing a heel pressure ulcer, so should be proactively offloaded. Generally, it was seen that this could be achieved as there are fewer patient factors that will affect device usage, and staff should know that all of their patients are at high risk of developing a heel pressure ulcer, and hence the importance of offloading for all of their patients. It is also possible that this is a patient group where reusable devices such as pillows and wedges could be more suitable, giving further evidence to candidate theory 3.

6.9 Candidate theories 1-6 summary

These six candidate theories were identified as being part of a larger programme theory regarding processes that would lead to a more 'proactive' use of offloading devices for the prevention of heel pressure ulcers. It was identified that there were three contextual levels that were influential. From a macro level the priorities of the NHS to reduce pressure ulcer rates influenced the TVNSs as they identified pressure ulcer prevention and reduction in pressure ulcer rates within the meso context of their organisation as being a significant part of their job role. This was done through identifying clinical areas that they knew had a high-risk population, or where patients had developed a severe pressure ulcer and shared learning points identified the need for offloading through the RCA process. Within an organisation the TVNSs viewed their role as influential in the use of offloading devices, not only by implementing them on the patients they see, but also through encouraging wards to proactively use them

through identifying the clinical need, sourcing the devices, raising staff awareness of what is available to them, and providing training and education on how to use them and risk factors for heel pressure ulcer development. The TVNSs viewed training and education as being a large component of their job role and that this was key for influencing the use of these devices.

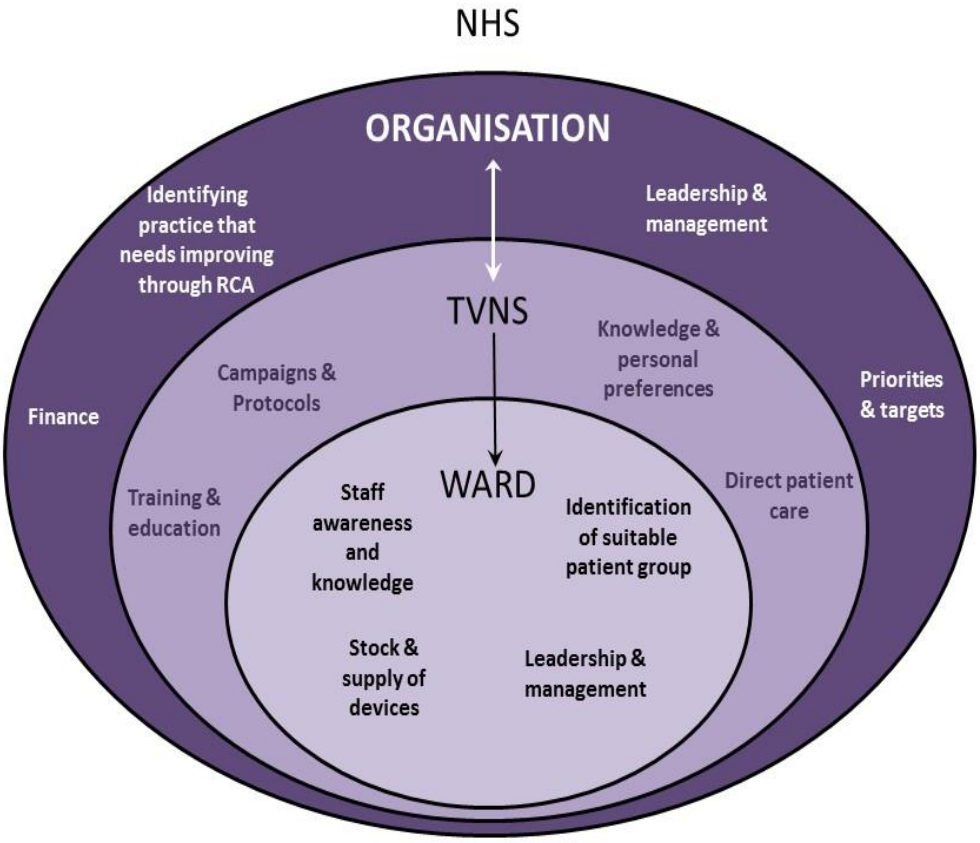
The TVNSs felt that they, along with senior nursing managers (ward managers and above), were conscious of the cost of devices. In most of the TVNSs organisations offloading devices are paid for out of individual ward budgets. In the micro context of individual wards, the choice of reusable or single patient use devices might be influenced by what is most cost effective for their patient group. It is unclear if the cost of the devices has any impact on how individual ward staff use the devices, or if ward staff were even aware of the costs, but it was felt that having offloading devices easily accessible to them will increase their usage when in combination with an increased awareness of pressure ulcer risk factors.

In clinical areas where there is a high turnover of patients, where patients are less mobile or where offloading devices are not immediately available to them pillows could be used as a desirable temporary offloading device. During the grey literature review this advice was reflected by Black (2004), but Campbell et al. (2010) stated the pillow should not be seen as a replacement for an offloading device as it does not always stay in place, and does not always effectively offload, depending on the thickness of the pillow and the weight of the limb. There is also the risk that because a pillow is not a device specific to offloading, it can be removed and used elsewhere on the patient or for another patient (Gilcreast et al., 2005).

6.10 Programme theory 1

NHS and organisational priorities with regards to reduction in pressure ulcer rates are influential towards the job role and focus of the TVNS. The TVNSs see themselves as central to heel pressure ulcer prevention at a macro, meso and micro level, which can be done through the proactive use of offloading devices, thereby acting as both a context and a mechanism. TVNSs identify the need for offloading, help to source the devices, promote their use through training and education and prescribe them to individual patients. Factors that influence their use on a micro level can be the patient group, staff knowledge, cost and having a stock of the devices. This is illustrated in Figure 6-7 with the macro context of the NHS and the wider organisation, and how this influences the context and mechanism of the role of the TVNS, and in turn how they influence the context of individual wards.

Figure 6-7 Schema for programme theory 1 illustrating the contexts and mechanisms that lead to a proactive use of offloading devices



6.11 Summary

This chapter has presented how candidate theories 1-6 have been refined into programme theory 1 regarding the proactive use of offloading devices for the prevention of heel pressure ulcers. Chapter 7 will go on to refine candidate theories 7-10 into a second programme theory.

Chapter 7 Programme theory 2: Reactive use of offloading devices

7.1 Introduction

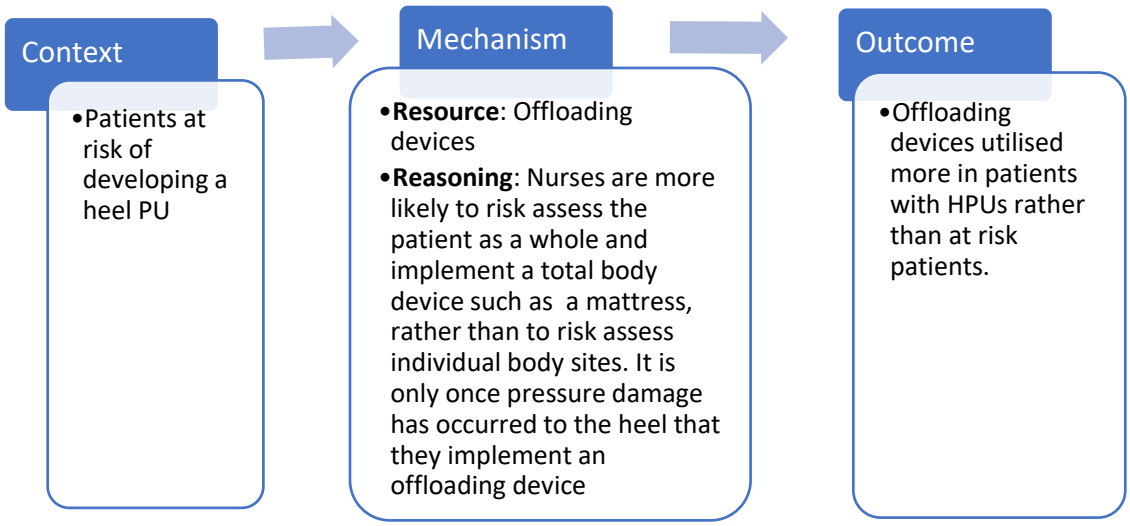
This chapter will demonstrate how the TVNS interview data were used to elicit and refine initial candidate theories 7-10 into a programme theory about how offloading devices are used 'reactively'. When a heel pressure ulcer is already present the desired outcome becomes the treatment of the heel pressure ulcer, prevention of a pressure ulcer developing on the other heel and prevention of deterioration through offloading.

This theory was developed from personal experience in clinical practice; where it had been observed that offloading devices tended to be initiated once there was blanching erythema or a heel pressure ulcer of any category had occurred, as a treatment and to prevent deterioration, rather than implementing the device in the first instance when there were no signs of skin damage. This was explored during the interviews to see if this was something that occurs more widely, to try and establish why this happens, and if this was viewed as an effective way of utilising offloading devices.

7.2 Candidate theory 7

Nurses are more likely to utilise heel offloading devices as a response to pressure damage rather than as a preventative measure

Figure 7-1 Initial theory 7



Offloading following a pressure ulcer developing was often described as a 'reactive response' and it could be that the skin damage is a visual mechanism that highlights the risk that the patient is to develop a heel pressure ulcer as this example illustrates.

> *"…even though they have got the [offloading device kept as stock], they wouldn't think to put it there as a preventative, again they would use it, but it would be a reactive response, so the advantage it furthers the staff on the ward in having the equipment there, is that from their perspective when the damage occurs they can put that offloader in place to stop any further deterioration, but they wouldn't think to pro-actively put it in place" (P1, Band 6 CNS).*

This reflects candidate theory 3, where it was felt that having a stock of offloading devices increases utilisation, although it is acknowledged that this does not happen every time and the reasons why are not known.

7.2.1 At risk patients

As discussed in Chapter 2, risk assessment is a key component of pressure ulcer prevention (NICE, 2014b) by helping the nurse to identify whether the patient is at risk, and implement appropriate preventative care. However, how the information from the risk assessment is utilised and interpreted is an issue as this TVNS discusses:

> *"risk assessment is I think undertaken but I do not think it's interpreted that well, certainly not in particular body sites" (P5, Lead Nurse).*

Rather than the context being patients at risk of developing heel pressure ulcers, it is the clinical areas without a clear protocol/pathway for heel offloading. In this context, nurses do not tend to think of individual body sites during the risk assessment. The focus might be primarily on the buttocks and sacrum, and the heel gets missed as washing and cleansing patients, especially if the patient is incontinent, will focus on this region. The need for heel offloading is only thought about when skin damage, either as erythema or a heel pressure ulcer, becomes a visual prompt that the current management strategy is not working, and therefore an additional intervention is required. P6 gives an example of this:

> *"I think when patients have deep tissue injury and it's left uncovered, you know, there's no reason to cover that over. I think that heightens nurses' awareness to think, oh that patient is at high risk, they've already got a deep tissue injury, we need to ensure that we are repositioning. It's almost in their face that they have to do something about it" (P6, Band 7 CNS).*

It could be rationalised that if the skin is assessed as normal, with no signs of pressure damage, that the patient is receiving sufficient pressure relief and therefore does not require an additional intervention. There is a balance of assessing the patient's risk and initiating the device as a preventative measure, but this could lead to additional financial costs if all patients are offloaded. Observing the skin for the first signs of a

pressure ulcer developing, in the form of blanching erythema, and initiating offloading at that point could be a viable option, but the danger with the latter is that these first signs could be missed, or there is a delay in accessing the device and the additional intervention is implemented too late to prevent a heel pressure ulcer.

There are nationwide campaigns such as React to Red Skin (2019) that aims to teach the importance of early recognition of deteriorating pressure areas, where there is either blanching or non-blanching erythema, and aims to teach staff to be reactive to early signs of pressure damage to prevent it deteriorating to more severe damage. This recognition of erythema as a precursor to a pressure ulcer developing is a mechanism to alert the nursing team that additional interventions such as offloading devices are required. The TVNSs all stated that skin inspection was key for identifying at risk heels, however when skin inspections are missed along with signs of deterioration, pressure damage more severe than erythema occurs before an offloading device is implemented.

Barriers to skin inspection of the heel were explored; one suggestion, which is reflected in clinical practice, is the difficulty in actually accessing and looking at the heel in patients that are difficult to reposition or have limited mobility in the lower limb as this example illustrates:

> *"The heels are difficult to visualise so to speak, I think sometimes the damage gets missed, so until that damage is staring them in the face...the minute they see that blistered area, then that would probably trigger [implementing an offloading device]" (P1, Band 6 CNS).*

Physical barriers to skin inspection were also discussed, such as bandages, socks, or casts, although it was not known why a skin inspection is not done if the physical barrier is removable as this TVNS discusses:

> *"If a patient's got a four-layer bandage on, of course you're not going to take that down and check the heels, but what we would expect and what we teach is that they document it… "patient has four-layer bandage and is not due for changing until this date, skin will be checked at that time" and that's absolutely fine. What's not okay is when, they've got socks or [venous thrombus embolism prevention] stockings and they don't check underneath them" (P6, Band 7 CNS).*

There were comments from those TVNSs who tended to work in areas with no heel-specific campaign, about the heels not being thoroughly inspected during routine skin assessments as this TVNS discusses:

> *"I'm not convinced that skin inspection is always undertaken thoroughly for the heels. I think sacral areas tend to get a big focus and I think people sometimes forget about the heels" (P5, Lead Nurse).*

It could therefore be that a successful campaign, protocol, or education about the heel being a high-risk area could be a mechanism that increases skin inspection at the heel which in turn leads to early recognition of deterioration.

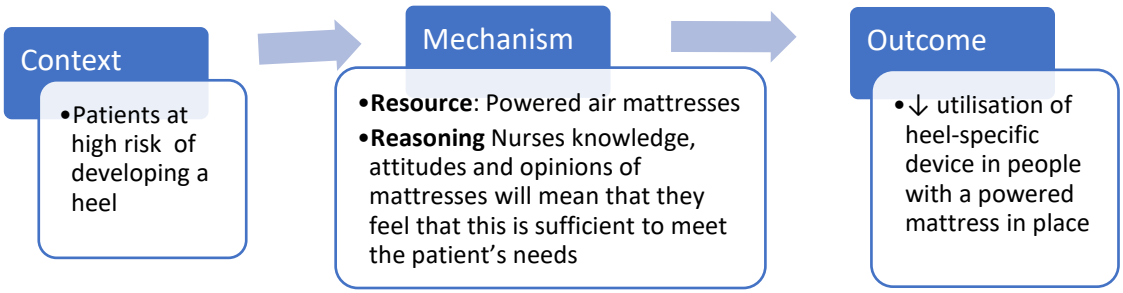
7.2.2 Summary

The TVNS felt that skin assessments were a mechanism that could highlight early signs of deterioration and therefore the need to offload the heel. This reactive use of offloading devices could be effective, through the recognition of early signs of pressure damage, highlighting that the current prevention plan is insufficient and therefore an additional element like an offloading device is required. When skin inspections are missed or deteriorating skin is not recognised, a heel pressure ulcer could develop and the opportunity to potentially prevent through offloading has been missed, so the offloading device is reactively implemented as a treatment of the heel pressure ulcer and to prevent further deterioration.

7.3 Candidate theories 8 and 9:

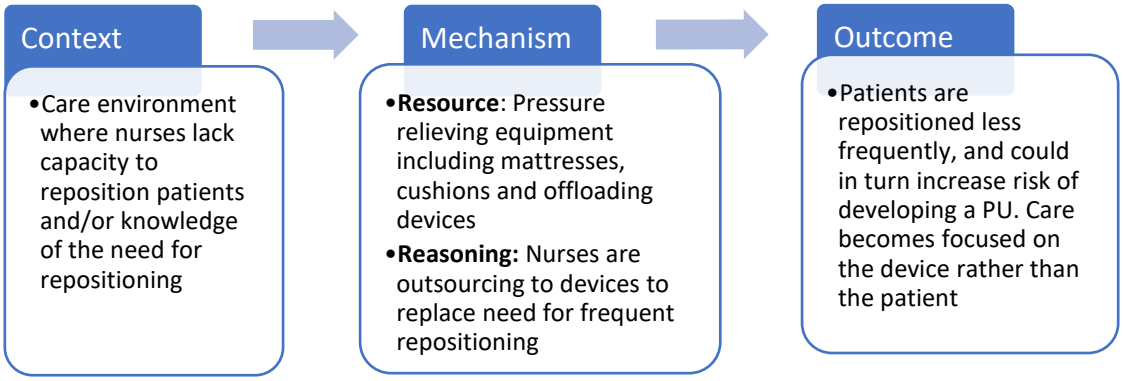
Candidate theory 8: If a powered air mattress is already in use, additional preventative methods are less likely to be implemented

Figure 7-2 Initial theory 8



Candidate theory 9: Repositioning is a key component of pressure ulcer prevention but is less likely to take place if devices are being utilised.

Figure 7-3 Initial theory 9



Very early on in the interviews it became clear that candidate theories 8 and 9 were connected, and therefore have been presented together.

The TVNSs felt that in most cases if a patient was on a dynamic mattress and regularly repositioned, then this would be sufficient to prevent heel pressure ulcers, and therefore an offloading device would not be required as illustrated by P1:

> *"if you have got a mattress in place that is providing support to relieve pressure areas, do you need more than one pressure relieving piece of equipment in place? Is it not down to other issues like, if their heels are deteriorating, are they actually deteriorating, not because they are not getting the pressure relief [from the mattress], but more because they are not being repositioned to relieve the pressure?" (P1, Band 6 CNS).*

It is not the mattress alone that is important – but the mattress used in conjunction with a repositioning plan; and it is the repositioning that appeared to be the main focus for the TVNS. It was often seen that repositioning was more important than any device, therefore linking this theory in with theory 9.

7.3.1 Care environments that lack capacity to reposition patients

Because the TVNSs felt that repositioning was the most important component of pressure ulcer prevention, it appeared that when repositioning could not be achieved, additional devices or interventions would be required. Barriers to repositioning within different care environments were explored during the interviews.

Repositioning is an integral part of pressure ulcer prevention, and as discussed in Chapter 2 there is a sound rationale for repositioning, however there is little RCT evidence to substantiate this (Gillespie et al., 2014). There was consensus from the TVNSs that repositioning is the most important aspect of pressure ulcer prevention and would be their main focus, with devices such as mattresses or offloading devices being additional requirements for high-risk patients where repositioning alone is insufficient, as explained by this TVNS:

> *"My first reaction is to increase repositioning…equipment cannot replace the need for repositioning" (P3, Band 6 CNS).*

Offloading devices were not viewed as a repositioning aid, but as an additional tool to be used when either repositioning could not be achieved or when there was evidence of vulnerable skin and used to prevent deterioration. Offloading would be the third line choice in pressure ulcer prevention after repositioning and a mattress if these were not sufficient to meet the patient's needs. This could be where a reactive response is appropriate; when there are signs of erythema or a heel pressure ulcer, this is a sign that an additional intervention is required.

TVNSs might promote the use of an offloading device proactively in high-risk clinical areas they have identified as requiring more than just a mattress and repositioning schedule to prevent heel pressure ulcers (as discussed in Chapter 6):

> *"Repositioning over anything is the most important aspect of pressure ulcer prevention, but if they're not repositioning for whatever reason or they're not repositioning effectively, if you've got heel devices in protecting the heels everyone's a winner are they not?" (P7, Band 7 CNS).*

But one issue raised here by P7 is whether patients are repositioned 'effectively' which could include the legs and feet being repositioned, so they are offloaded, or if it is just the torso that is moved, and the heels remain in the same position as P1 mentioned:

> *"the upper body moves, but the heels stay [in the same place]" (P1, Band 6 CNS).*

This could be due to patient factors, such as the medical condition of the patient, a procedure that means the patient cannot be repositioned or the patient not wanting to move. It is in these situations that an offloading device might be useful, as illustrated in this example:

> *"…when patients either are declining to be repositioned or maybe they can't be repositioned. For example, on the fractured neck of femur ward a lot of those patients when they first come back from surgery, they're either in pain initially … they find [repositioning] uncomfortable. A lot of them are very elderly, they've got a lot of other co-morbidities, so [offloading devices] are an additional aid to repositioning" (P6, Band 7 CNS).*

Where there are patient groups identified where both repositioning and a mattress are not sufficient to meet their needs, or they cannot tolerate, this is where the additional dimension of care is required, and an offloading device can be used proactively as this TVNS discussed:

> *"Where I tend to see it is our respiratory ward where you've got a patient who, maybe because of breathing difficulties, cannot go on their side and they desaturate when you put them on their side, and we've had it in [critical care] as well you know. I think then in that situation, if you are using a heel offloading device, that's more than justified in that situation" (P6, Band 7 CNS).*

This theory links in with theory 6 as 'effective repositioning' is dependent on the patient maintaining the position that they have been moved to and can therefore be better maintained in patients with reduced consciousness.

7.3.2 Lack of knowledge of the need for repositioning

As previously discussed, the TVNSs put greatest emphasis on the importance of repositioning, therefore repositioning would be central to the TVNSs care planning for a patient as well as for education packages delivered to staff. However, when patients are not repositioned it is not known if this is because of a lack of education, that ward

staff perceive that they can use devices to replace repositioning, or due to a lack of resources such as staffing levels.

Several TVNSs discussed how mattresses had historically been used as a replacement for repositioning, but due to ongoing education this misconception was becoming less common as discussed here:

> *"it was common for the misconception really that if a patient was on a dynamic mattress they wouldn't need to be turned, that the mattress was doing the job for them. I think that's probably less so now, you know, it's a big part of teaching, big part of discussions around that, so I think that is becoming less so" (P5, Lead Nurse).*

If the patient is wearing an offloading device then pressure is removed from the heel, but repositioning is still necessary as there is still pressure to other body sites. Although using a device (mattress or offloading) as a replacement for repositioning was reported as becoming less common, P1 discussed how this was still happening at times in their organisation:

> *"Based on my experiences of what I see out and about, I would say that if they have got a device in situ, that they perceive will provide offloading, repositioning support, they are less likely to implement the care because they feel that that's already doing it" (P1, Band 6 CNS).*

7.3.3 Summary

Theory 8 and 9 were combined because powered air mattresses are not used on their own, but in combination with a repositioning schedule as part of the pressure ulcer preventative plan of care. Repositioning is viewed by the TVNSs as being the most important component of pressure ulcer prevention, and if a patient is repositioned well and can maintain that position then the heels should be lifted from the bed. Mattresses are a second line choice followed by offloading devices. Offloading devices are considered when:

- Patients are assessed as high risk and another element to prevention is required additional to repositioning
- Patients cannot be repositioned, for example due to medical condition, procedure, or surgery
- Patients cannot maintain the position they have been moved to

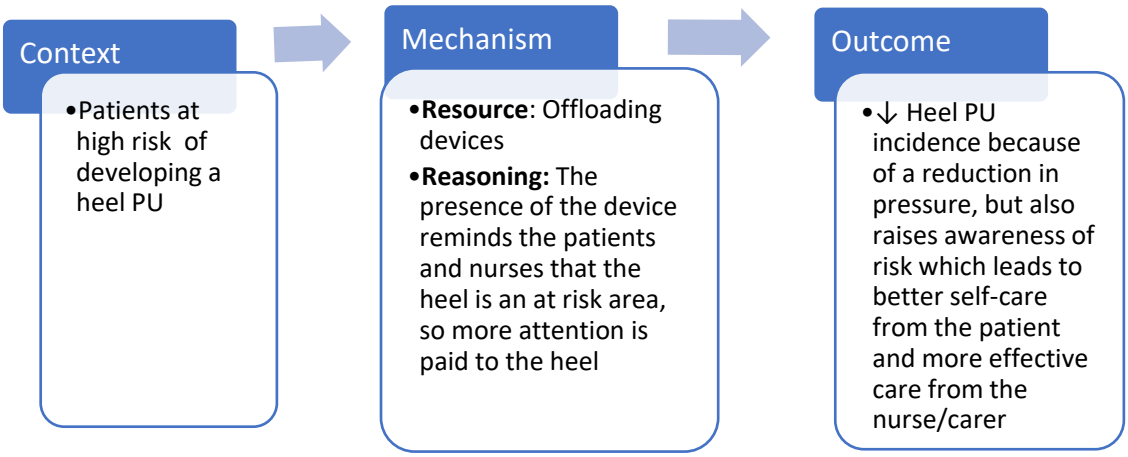
Theories 8 and 9 therefore inform the programme theory of how offloading devices are used reactively, because they appear to be a third line choice after repositioning and a powered mattress, and it is only when these are no longer sufficient to meet the patient's needs, which could be because their skin is visually deteriorating, that an offloading device is used in a reactive manner. In theory, the patient should be more

likely to be repositioned if they have a device in situ because the patient has been identified as being at high risk of developing a pressure ulcer and so require all pressure ulcer preventative interventions available.

7.4 Candidate theory 10

The offloading device is a physical reminder for nurses and the patients of their risk and therefore more attention is paid to this at-risk body site.

Figure 7-4 Initial theory 10



It has already been established that devices such as mattresses or offloading are used in patients who have been deemed at high risk of developing a pressure ulcer. It was theorised that if staff see that a patient has a device in place that this will act as a physical reminder of the risk. Some of the TVNSs utilised mattresses as a 'visual trigger' in their care planning with staff, as illustrated here:

> *"a dynamic mattress is a visual trigger to have the SSKIN bundle [a resource pack to aid in the assessment and care planning for people at risk of pressure ulcers] in place, so I think it goes that if a patient's on a mattress they are more vulnerable and therefore they're having intentional rounding [a structured approach to check patients at set times to assess and manage their fundamental care needs]" (P5, Lead Nurse).*

Dynamic mattresses are easy to identify due to the pump at the foot of the bed. However, for a patient who is in bed with an offloading device, this could be covered by blankets so would only be identified when the covers are pulled back. It could be that this would then be a reminder for staff to check the patient's heels. In contrast offloading devices could also be a barrier to checking the heels as staff might not want to remove the device if this is viewed as time consuming, if staff are not sure what the offloading device is for or how to reapply them. Little was mentioned about the devices raising awareness of heel pressure ulcer risk.

7.5 Candidate theories 7-10 summary

The TVNSs focused on the importance of risk assessments to help identify which patients are at risk of developing a heel pressure ulcer, but it was perceived that ward nurses do not consider individual body sites during this process, rather the patient as a whole. This could lead to risk of heel pressure ulcer development not being identified and an offloading device not being implemented until a heel pressure ulcer has occurred.

Skin assessments at the heel could sometimes get missed, for example if repositioning is difficult or if there are physical barriers such as bandages, casts, splints or devices, including the offloading device itself, which could lead to nurses not recognising early signs of pressure damage. Early signs of pressure damage can be a visual indicator that the current management plan is insufficient and an additional preventative intervention, such as a dynamic mattress or offloading device is required.

The TVNS perceived repositioning to be the most important component of pressure ulcer prevention, followed by implementing a dynamic mattress. When repositioning cannot be successfully achieved or the mattress and repositioning is insufficient, offloading might then be considered. This can lead to a reactive use of offloading devices as they are used only when the other interventions are found not to be working and either erythema or a pressure ulcer develops. From the interview data Figure 7-5 was developed as a proposed model that TVNSs' use, to illustrate when they would consider using an offloading device. This adds more to the algorithm created by NICE (2014a) which recommends offloading for patients at high risk of developing a pressure ulcer, who are also at risk of developing a heel pressure ulcer.

Utilising offloading devices in a reactive manner is not necessarily a negative outcome. Where repositioning and dynamic mattresses are already in use, in many cases this is sufficient to meet the pressure ulcer prevention requirements of the patient, especially if the heel is moved and/or lifted off the bed during repositioning. Early signs of a heel pressure ulcer can be a visual prompt that the current plan of care does not meet the patients' need, and it would be these patients that might benefit from an offloading device.

7.6 Programme theory 2

Programme theory 2 explored factors that could lead to a reactive use of offloading devices; where they are used once erythema or pressure damage has already been identified and an offloading device is used to either prevent deterioration and/or as a treatment.

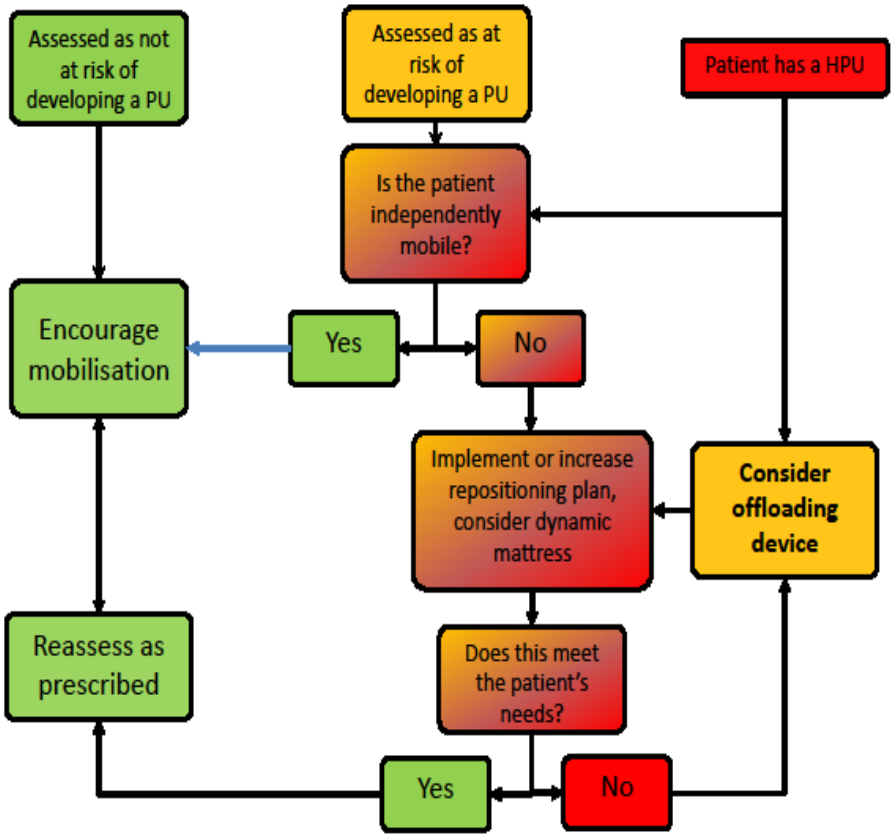
In the micro context of individual patients found to be unable to tolerate or be concordant with the repositioning plan or mattress use, an offloading device is supplied in response. Another micro context is that if a patient is found to be at high risk of developing a heel pressure ulcer, it could be only once the pressure areas start to deteriorate that staff recognise the risk and react to the signs of pressure damage by initiating a device. The mechanism through which these patients are identified could therefore be viewed as a reactive response.

7.7 Summary

This chapter has presented how candidate theories 7-10 have been refined into programme theory 2 regarding how offloading devices are used reactively for the prevention of heel pressure ulcers when there are early signs of skin changes such as erythema, or once a heel pressure ulcer has occurred as a treatment of the heel pressure ulcer and to reduce the risk of deterioration.

Chapter 8 will go on to refine candidate theories 11-13 into a third programme theory.

Figure 7-5 Proposed model for use of offloading devices



Chapter 8 Programme theory 3: Patient factors that influence how offloading devices are used

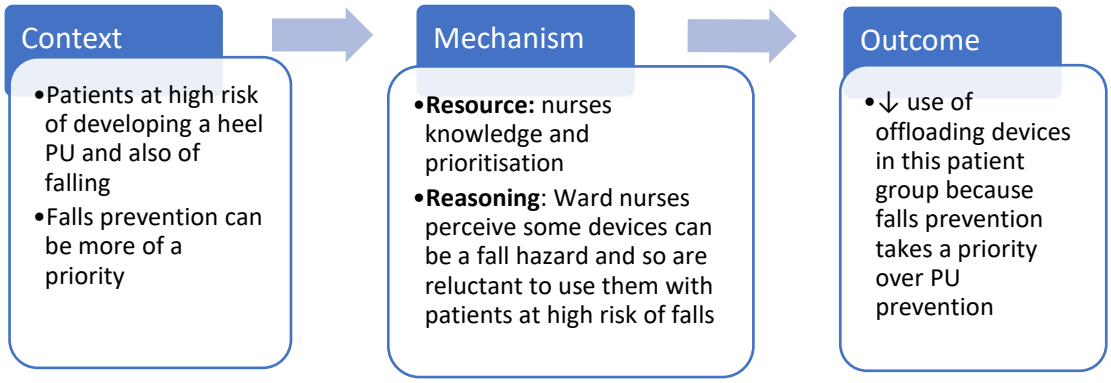
8.1 Introduction

Chapters 6 and 7 have presented the first two programme theories, which are focused on the prevention and treatment of heel pressure ulcers, as this is a desired outcome from the perspective of the TVNSs and clinicians in most situations. However, this might not be the desired outcome for patients, where comfort and mobility are of importance, or there could be contexts where offloading is not possible or safe. This was explored in candidate theories 11-13 and refined into programme theory 3.

8.2 Candidate theory 11

Offloading devices are not suitable for use in patients who are at high risk of falls as they could become a fall hazard.

Figure 8-1 Initial theory 11



This theory started from personal clinical experience of caring for patients who are both at risk of developing a pressure ulcer and at risk of falling, and how the pressure ulcer preventative care is prioritised and delivered. Due to the job role and priorities of a TVNS there is an interest and motivation towards preventing pressure ulcers, but also insight into the consequences of the care decisions, thereby allowing an informed decision to be made with regards to what is perceived to be in the best interest of the patient. The interviews therefore explored how decisions are made with regards to the use of offloading devices in patients who are also at risk of falling.

8.2.1 Patients at high risk of developing a heel pressure ulcer and falling

The grey literature review identified two papers that were looking at devices for patients whilst sitting out, Bale et al. (2001) recommended an offloading device whilst sitting out and Bateman (2014) used egg-crate foam pads under the feet whilst sitting out. Overall, the TVNSs did not feel offloading devices should be used when patients are sitting out in a chair, and they should primarily be used on patients nursed in bed, especially if the patient has been assessed as at risk of falling as the offloading device can become a trip hazard. This could be due to a cognitive impairment that might mean the patient does not realise they should not mobilise with an offloading device on, or they do not have the ability to mobilise safely as described here:

> *"When the patient is sat in a chair with [offloading device brand] and they attempt to walk because either they're confused or they're not able to walk that well, then they're at risk of falls" (P2, Lead Nurse).*

These patients might not have the capacity to understand the risks and the interventions implemented by the nurses, therefore the nurses must assess what is in the best interest for the patients. This could involve balancing the most immediate or severest risk for that patient, developing a heel pressure ulcer or falling. There is also a possibility that the patient's capacity can fluctuate so an intervention might not be suitable from one day to the next and therefore requires an ongoing assessment.

These patients might still need to be offloaded when in bed, and some of the TVNSs felt that staff were aware of this risk factor when using the devices as this example illustrates.

> *"I tend to find that if somebody is up and mobile then the wards would not be keen to use any heel devices in the day. They may use them when the patient's in bed but only in bed, they'll not use them in the chair. That's my experience" (P5, Lead Nurse).*

There is a difficulty in managing patients who are starting to mobilise but could still be at risk of developing a heel pressure ulcer. As most patients at risk of developing a heel pressure ulcer tend to be bed bound, the devices are designed accordingly, and if they are used in patients out of bed, they could cause the patient to fall. P4 had identified this as an issue and was trying to find a device that was suitable for ambulatory patients but identified that there was a gap in the market for this.

> *"We're going out to tender in the next few weeks and we've actually written in our tender spec. that we're looking for something suitable for ambulatory patients. But you and I both know that there probably is not anything out there, but you know, we're asking the question" (P4, Lead Nurse).*

Theoretically when a patient is sat in a chair the heel should not be at risk as the pressure should be going through the plantar aspect of the heel, where the foot pad is designed to take the load. If the patient has poor posture whilst sat out or slides down in the chair, or sits with their heels on a footstool, this could lead to the pressure going through the posterior heel. This can be rectified with correct positioning or a chair that stops the patient from sliding down, so theoretically there should not be many circumstances when an offloading device is required in a chair.

Offloading devices whilst in bed can still be a fall hazard if a patient attempts to get out of bed without realising, they are wearing them.

8.2.2 Falls prevention can be more of a priority

For the nurses, there are risk assessments to assist in identifying if patients are at risk of developing a pressure ulcer, and if they are at risk of falling, but if a patient is at risk of both they can be given conflicting advice and so the nurse must assess which is the most immediate risk. P3 gave the following example:

> *"On a high/low bed an air mattress is not allowed[5], so even the patient with Category 4 pressure ulcers to the back or bottom, because they need a high/low bed as a priority for risk of climbing out of bed, they have to have a high specification foam mattress which is not ideal for the pressure ulcer" (P3, Band 6 CNS).*

Some of the TVNSs perceived there to be competing priorities from management which could influence how wards prioritised falls prevention and pressure ulcer prevention, as this TVNS discusses:

> *"I think falls are high on the agenda which I do not think they should be, but they investigate it in the same way as pressure ulcers, as a serious untoward incident and they're being put higher on the agenda than the pressure ulcer" (P3, Band 6 CNS).*

This could be personal biases of the TVNSs because pressure ulcer prevention is a large component of their job role, or differences between leadership priorities between organisations. Overall, there is an interest in finding the safest and best option for the patient and identifying what will cause the least harm as illustrated in this example:

> *" ...if they cannot safely offload the heel, so for example if they are using pillows or a wedge and they cannot keep the heels free from pressure because the patient is agitated or you know, is pretty mobile in the bed, then it's safer to just nurse the heels on the mattress" (P2, Lead Nurse).*

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[5] A high-low bed can be positioned lower than conventional beds, so the patient is closer to the floor. There could be issues with entrapment with bedrails, or due to the depth of the cells raising up the height of the patient and decreasing the effectiveness of the bedrails

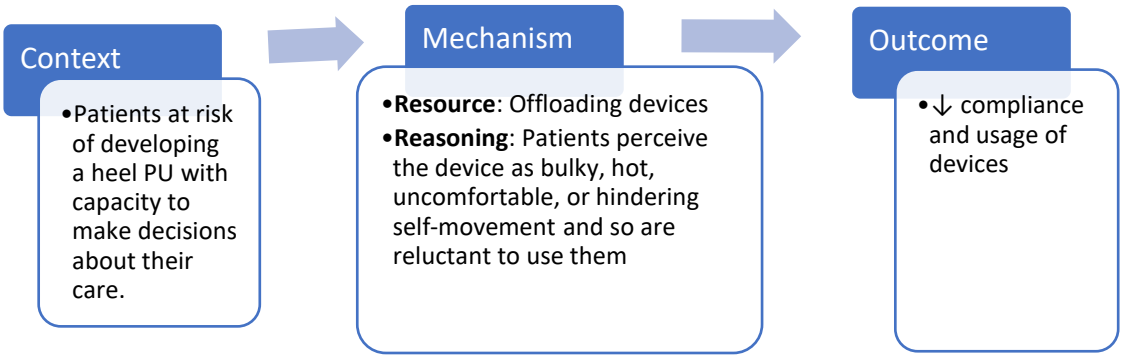
8.2.3 Summary

In vulnerable patients who might be at risk of both falling and developing a pressure ulcer the nurse must assess and care plan according to which is the most immediate or severest risk. The TVNSs felt that offloading devices are best used when the patient is in bed as they can become a trip hazard when sat out.

8.3 Candidate theory 12

Patients are not always concordant with the use of the devices due to comfort factors

Figure 8-2 Initial theory 12



This theory was initially developed based on the findings of some of the RCTs included in the systematic review. Gilcreast et al. (2005) reported that some patients found the devices 'hot & bothersome' and did not allow free movement in the bed, whilst Donnelly et al. (2011) reported that some participants found the boots hot, bulky and restricted movement, which they felt ultimately affected compliance in their trial. Different devices were used in these trials, so it is not an issue unique to a particular device, but what is not known is whether this is the case for all offloading devices; they all tend to be padded and bulky as this is what is required in order that the heel is effectively offloaded whilst distributing the pressure to the rest of the leg. Some of the TVNSs also shared experiences regarding none of the devices being 'liked', as illustrated here:

> *"We've used Repose®, Prevalon®, Heel-Lift®, and there does not seem to be one that [patients] particularly like" (P2, Lead Nurse).*

Comfort of the device is likely to be a high priority for patients; however, it does not seem to be a priority to the same extent for the healthcare workers. When selecting an offloading device to use in their RCT, Campbell et al. (2010) used a nominal group process to prioritise selection criteria, and patient comfort was only ranked fifth out of seven in terms of importance, with the device being reusable, cleanable and approved by infection prevention as being most important, followed by ease of use and price. It

could be that healthcare workers are so focused on doing what is perceived to be best for the patient in terms of pressure ulcer prevention, patient comfort is less of a priority when selecting an offloading device as this example by P1 shows:

> *"I've never thought about it from the device being comfortable actually…I'd thought about it more that if the patient is less responsive, quite weak or sedated or some other medical condition going on, then they are less likely to fidget or kick it off" (P1, Band 6 CNS).*

If a patient is unable to communicate discomfort, they might attempt to remove the device through fidgeting and trying to kick it off which could be viewed as the patient being 'awkward' or 'agitated'. This links in with theory 6 as comfort is less of an issue, and therefore less of a priority in patients with reduced consciousness, making them more 'compliant' with offloading as they cannot physically remove the device. The context would be that if the patient is unable to make decisions about pressure ulcer prevention, the nurse becomes the advocate for the patient, acting in their best interests and will deliver pressure ulcer preventative care, possibly including an offloading device.

Patient comfort might also be less of a priority for the TVNS and ward staff as they perceive that there is no device available that will be liked by and suitable for all patients. Nursing staff instead try and work with the patients to find solutions and improve concordance, but this is not always successful and as a result reduces the effectiveness of the device, as this TVNS's example illustrates:

> *"The most that we've used are the Repose® boot, and I do get a lot of feedback that patients do not find them comfy, they find them hot and sweaty. The nurses then attempted to put a pillowcase over them so they're hammocking[6], so they have no benefit at all. Or they wrap them with inco[ntinence] sheets, to make them not so hot and sweaty, which again negates the sort of benefit of them. So, I think there's an education issue there, but I think the nurses are trying to get the patients to use them, so they see the need for them, but not really in the right way when they step in to try and improve compliance" (P5, Lead Nurse).*

An individualised assessment that involves the patient might identify patients who would not be able to tolerate a device. Some patients 'on paper' might seem like they would benefit from an offloading device, such as patients with peripheral arterial disease who are at high risk of developing a heel pressure ulcer due to decreased blood flow to the lower limb, but due to claudication pain (pain and/or cramping in the lower leg due to inadequate blood flow to the muscles. By lowering the leg gravity

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[6] Where the pillowcase creates a sling over the offloading device, so the heel is in contact with the sheet rather than being offloaded

improves the circulation to the foot, relieving the pain) they might not keep a device on as this TVNS discussed:

> *"on the vascular ward [the nurses] have the offloading device in place, but [the patients] like to dangle the legs off the side of the bed, and of course then the device does not work, it slides off in that particular way so when they put their legs back up, the device is not there, its somewhere on the floor or at the bottom of the bed" (P1, Band 6 CNS).*

This could be viewed as patients being 'non-compliant' but through working with the patient could lead to a better solution for that patient. Some of the TVNSs and research articles discussed 'patient compliance' which implies that there should be an element of 'obedience' from patients and that they are passive recipients of their healthcare, as this example shows:

> *"I mean sometimes it could be the device is not right for that patient, but it could be the patient will not be compliant with any device" (P3, Band 6 CNS).*

It is unclear whether the use of the term 'compliance' was intentional or if it was a lack of understanding of the term, although it was found to be used more by junior TVNSs whilst more senior TVNSs used 'concordance', these terms were sometimes used interchangeably. Concordance is synonymous with patient centred care where there is an agreement between the patient and healthcare professional that respects the beliefs and wishes of the patient (Aronson, 2007). In contrast compliance refers to the degree in which the patient follows the advice of the healthcare professional (Aronson, 2007). There was discussion around how some of the TVNSs worked in partnership with patients and relatives as a method of improving device use alongside other pressure ulcer preventative interventions as this TVNS reflected upon.

> *"…this is not a compliance issue, this is concordance, that we work with the patient. And also, patient centred care, that it needs to be individualised; so, we've had a real drive on that generally within the Trust as well. So, it is about working with the patients" (P8, Nurse Consultant).*

P4 also talks about concordance as a method for improving pressure ulcer prevention and device use, however there is still a hierarchical element in the description where the ultimate aim is for the patient to 'accept the treatment' provided by the nurses as this quote illustrates:

> *"So, we've just developed a non-concordance checklist and it's to help the nurses to understand why the patient's being non concordant. That's not compliance it's concordance. And it has things in there like, have you spoken to the relatives or the carer; have you given them all the information involved and why you're doing these things. And basically, part of it is because we want the nurses to not just say, 'oh the patient is quite challenging', but to say, 'actually this is what we've gone through to see if we can get them to accept the treatment or the options that we're giving them'" (P4, Lead Nurse).*

It could therefore be that, due to the design of these devices, they will never be suitable for all patients. However, when the context is patients with capacity to make decisions about their care, working in partnership with the patient and explaining the reasoning for their use and giving different options leads to a better understanding of their use, and the patient would be more likely to adhere with the treatment plan as this TVNS gives an example of:

> *"in Wales it's co-production; it's working together in unity with the patient, trying to give ownership back to the patient … they have some involvement in their management as well and have a responsibility. And I think it links to that and it links to if they have some understanding" (P5, Lead Nurse).*

As discussed previously, offloading appears to be most effective in the immobile limb, so as the patient recovers and becomes more mobile offloading might no longer be necessary. Campbell et al. (2010) reported that as patients recovered and became more mobile, offloading devices would be less likely to stay in place. Gilcreast et al. (2005) also reported similar findings; they analysed the Braden subscale for sensory perception and saw that as participants became more alert, compliance with offloading decreased. What was not reported was whether as these patients became more mobile, whether they still required offloading and whether reassessment of risk for heel pressure ulcer is undertaken. Theoretically an increase in mobility would mean a decrease in risk. This was reflected in the opinions of the TVNSs as this example shows:

> *"So, for example if you've come in with a fractured neck of femur you do not want to move, and you might actually be very comfortable with your [offloading] boot in situ. But once you have had your surgery and you're starting to get a bit more mobile, pain is under control, then you find that the boot is actually getting in your way of actually trying to be independent…so I think there's something about use in terms of where in the patient's journey" (P2, Lead Nurse).*

This illustrates that offloading devices are not suitable for all patients at all points in time but is a more fluid requirement as the patients' condition changes. In realist terms we should therefore be asking "what works for each patient at which part of their journey?"

This theory started out about patient comfort factors affecting device use, but it has developed more about factors that can affect concordance with offloading. The context here is the capacity of the patient to make decisions about their care. Where patients are unable to make decisions, the nurse becomes the advocate for the patient and prescribes their care, including offloading device use, in the best interests of the patients.

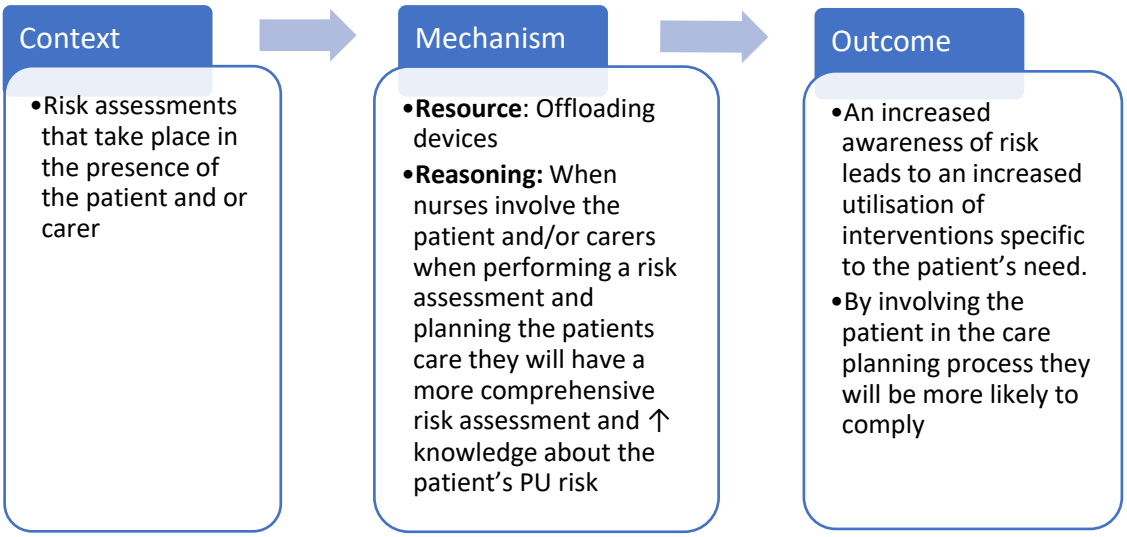
Due to the nature of the devices, it is unlikely that there will ever be a device that will be liked by all patients, but where the patient has capacity to make decisions about their care, working in partnership with the patient to help them make decisions about their care in turn could improve device use.

Both the patient's capacity to make decisions about their care and their heel pressure ulcer risk can change throughout their admission, therefore the patient's offloading requirements need to also be reassessed.

8.4 Candidate theory 13

Risk assessments that involve the patient and/or carer are more likely to highlight specific risk factors/ high risk areas leading to plan of care that is more patient specific and the patient will comply with

Figure 8-3 Initial theory 13



This links with theory 12 as it is focusing on the outcome of increasing compliance with device use through concordant working with the patient. From discussions with the TVNSs, although the risk assessment did play a part, it was working in concordance with patients in the care planning, along with providing them with a sound rationale for their treatment that was important. There are situations where this might not be appropriate such as the unconscious patient, or when the patient is acutely unwell, as this TVNS's example illustrates:

> *"if I think about a patient who is acutely unwell with sepsis and someone is saying "I need to give you these antibiotics and then we need to put this line in for these fluids and then we need to offload your heels, and then we need to make sure you are eating and drinking well, and then we need to be turning you" I think that information is too much at that acute stage, but I think what we are not good at doing is once the acute stage has gone, is then relooking at the plan that we put in place" (P1, Band 6 CNS).*

This ties in with “what works for each patient at which part of their journey”. In this example the nurse would act as an advocate for the patient and offload the heels, but as the patients’ condition improves then the care planning should involve working in partnership with the patient.

8.5 Candidate theories 11-13 summary

Individual patient preferences and risk factors need to be considered when implementing an offloading device. Certain patient groups have been identified during the interviews where offloading is less likely to be used or as effective. Here it is the responsibility of nurses to make a clinical judgement by weighing up which is the most immediate, or severest risk for the patient.

Mobilising is an important part of a patient’s recovery and offloading devices could become a hindrance or can even become a trip hazard. Offloading is primarily used in bedbound patients when they are acutely unwell but should be stepped down as patients recover.

Where there are comfort issues for the patient, nurses try to be resourceful and collaborate with the patients to improve comfort and in turn concordance, but this can lead to the devices being used incorrectly with reduced effectiveness.

8.5.1 Programme theory 3

Within the micro context of individual patients, offloading is not suitable for every patient, or at every point during the patient’s recovery. Offloading should be viewed as a fluid requirement, considering “What works for each patient at which part of their journey?”. Individual patient preferences and risk factors need to be considered when implementing an offloading device and working with the patient can improve concordance (Figure 8-4).

8.6 Summary

Chapters 6-8 have presented the findings from interviews with eight TVNSs using the teacher-learner interviewing method (Pawson, 1996). All of the theories started out as different aspects of care that might influence how offloading devices are used in practice but have been refined into three programme theories; factors that lead to a proactive or reactive use of offloading devices and patient factors that influence how offloading devices are used.

Offloading devices are not suitable for every patient at every point in their journey, but through identifying potentially at-risk patient groups where most patients would benefit

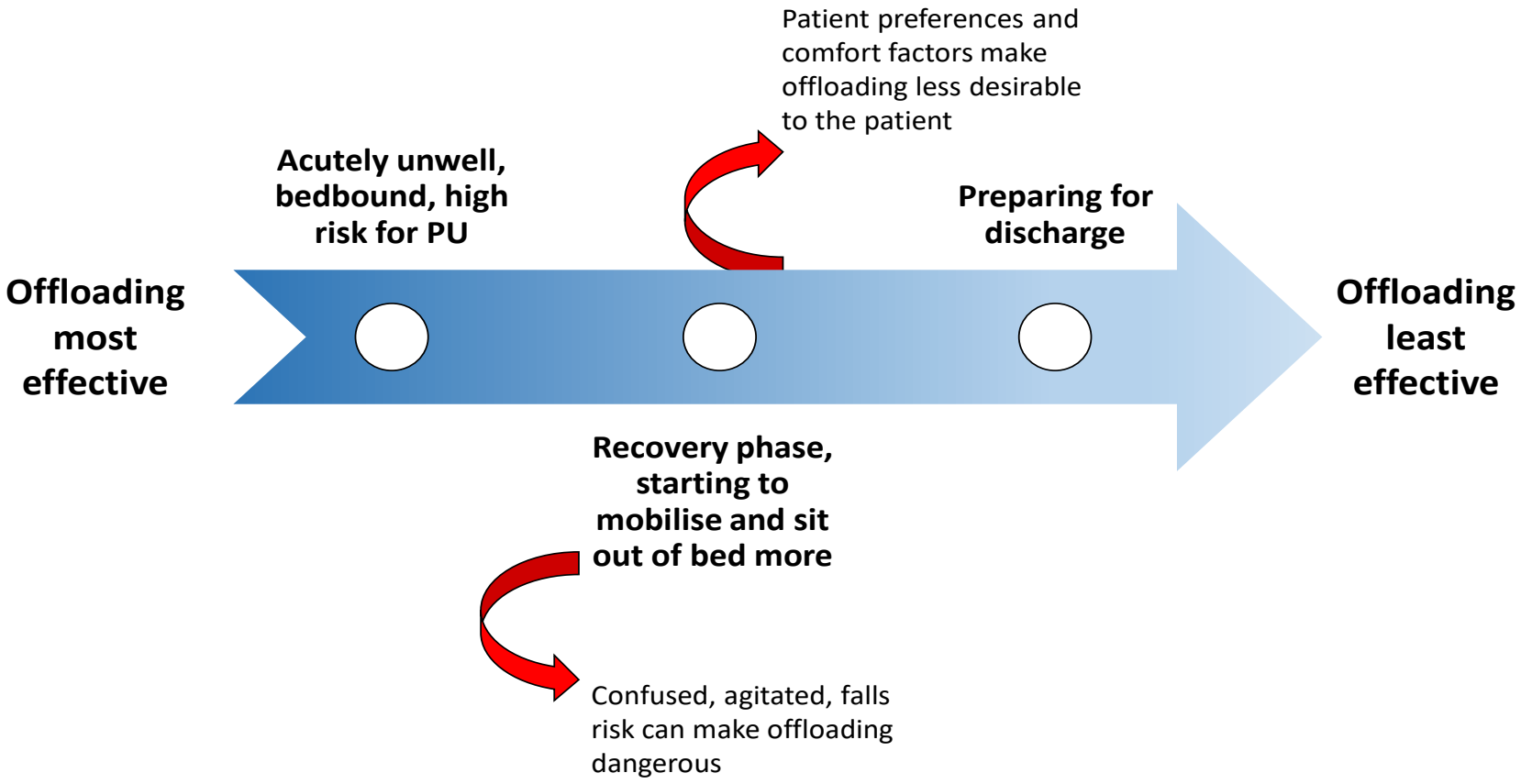
from offloading can lead to a proactive use of the devices. A reactive use of offloading devices is not necessarily a negative response but can be an effective use of devices where repositioning and a dynamic mattress are not meeting the requirements of the patient, or early signs of deteriorating pressure areas are identified and acted upon in a timely manner. It was also theorised that care planning in concordance with the patient can lead to improved use of devices.

TVNSs were interviewed during this phase as they would be experienced in prescribing offloading devices primarily in the field of pressure ulcer prevention and/or treatment. It is important to acknowledge that these devices are brought into an organisation and used by other specialities as well as or alongside the TVNS (e.g., all members of the nursing team, podiatry, physiotherapy, occupational therapy, orthotics).

The TVNSs perceive education to be a large part of their role, which has been found in previous research into the role of the TVNS (Flanagan, 1996, Ousey et al., 2015) and important in the successful implementation and use of offloading devices in practice. Education is also numerically measurable, with TVNS being able to provide evidence to senior managers of how many members of staff they have educated. However, the effectiveness of the education is difficult to evaluate.

In the absence of robust evidence, the recommendations and care provided by the TVNSs were often based on personal preferences which appear to be informed by perceptions informed from personal experiences, along with experiences of colleagues from within and outside of their organisation. The findings from these interviews were based on the opinions and views of the TVNSs and what they perceive is happening in practice in their organisation. It is also based upon their recommendations, however the reality of what happens on the wards could be very different. This is where an ethnographic study will add another layer of evidence, going beyond the evidence of contexts and outcomes identified during the interviews and making explicit the mechanisms that lead to expected or unexpected outcomes. Chapter 9 will describe how one of the programme theories was selected for testing in the form of an ethnographic study.

Figure 8-4 Patient factors that impact upon the need for, and effect of, offloading



Chapter 9 Realist Evaluation Phase 2: Ethnography

9.1 Introduction

Chapters 6-8 presented how 13 candidate theories were refined into three overarching programme theories about how offloading devices are used in clinical practice.

Chapter 5 described the rationale for choosing ethnography for the testing and refinement of a programme theory as part of a realist evaluation. This chapter will describe how the methods were developed and the study was conducted to attempt to test programme theory 1 (Figure 6-7). Gaining an insight into the interactions, processes, and behaviours of nursing staff in clinical practice will aid in the understanding of the mechanisms and contexts that lead to the proactive use of devices for the prevention of heel pressure ulcers.

9.2 Methods

9.2.1 Selection of programme theory for testing

Three programme theories were developed following the TVNS interviews:

- Programme theory 1 – How offloading devices are used proactively in the prevention of heel pressure ulcers
- Programme theory 2 – How offloading devices are used reactively for the prevention of heel pressure ulcers and as a treatment of heel pressure ulcers
- Programme theory 3 – Patient factors that can affect compliance with the use of offloading devices

There was not capacity within the confines of the PhD to test all three programme theories, therefore programme theory 1 was selected, as it was felt that this would best answer the research questions set out in Chapter 4.

9.2.2 Role of the researcher

The role of the researcher is paramount to the conduct of the study with regards to both the collection and interpretation of the data. In observations the researcher can adopt an overt approach; where the participants know they are being observed or a covert approach; where participants are unaware they are being observed. Gold (1958) first described the role of the researcher and the degree in which they participate in observations as being on a spectrum. These approaches are discussed in Table 9-1.

Table 9-1 Approaches to participant observations and rationale for choice of observer as participant method, adapted from (Jones and Smith, 2017, Nicholls et al., 2014)

Method	Approach	Example	Rationale for use/not use
Complete observer	Covert approach, researcher is separate and invisible to the participants.	Observing via a two-way mirror or observing a crowd in a public place. Assumption that the role of the researcher will make little difference to what is being observed.	Would be ethically difficult to conduct in a ward setting as removes the participants right to consent to participation.
Observer as participant	Overt approach, observation is primary role of the researcher, some interaction with participants but is limited and researcher remains neutral.	Observing a meeting or classroom, engaging in the setting for short periods, as unobtrusively as possible. Researcher is open about their purpose and may be visibly recording in the setting.	Greater depth in the field notes as research is sole purpose. Participants are aware that they will be observed by a nurse, therefore could change practice.
Participant as observer	Overt approach, researcher integrates self into the group/setting, whilst observing.	Working clinically on a ward alongside the team and patients, but open about their purpose as a researcher. Assumption that the role of the researcher within the context of the study has been acknowledged.	Would see more from the perspective of the team being observed, although participants are aware that they are being observed which could change practice. Would not be able to record as much detail in the field notes in real time.
Complete participant	Covert approach, researcher fully immersed and integrated into the research setting whilst concealing role as observer.	Working clinically on a ward alongside the team and patients, doing so without disclosing purpose as a researcher.	Would be ethically difficult to conduct in healthcare as removes the participants right to consent to participation. Would see more from the perspective of the team being observed but would not be able to record as much detail in the field notes in real time.

A covert approach would be desirable as the researcher becomes an ‘insider’ with as little contamination as possible to the environment, because participants might change their practice if they are aware that they are being observed. However, it could be argued that this is ‘ethically untenable’ as it removes the participants’ right to informed consent (Angrosino and Rosenberg, 2011). It was decided to take the observer as participant approach, with the researcher present in the clinical environment but

detached from clinical care, as it would allow for a greater depth of field notes as the researcher's focus is primarily on the observation.

9.2.3 Unit of analysis

To establish the most effective way to perform the observations, the unit of analysis needed to be decided upon. There were several different options that were explored in Table 9-2 to help to decide on the unit of analysis for this study. In order to facilitate a more in-depth study, the focus of the research should be on a smaller group of people (Hammersley and Atkinson, 2007), and as the research is looking at how healthcare staff utilise devices, it was decided that the unit of analysis would be on a team of qualified nurses (QNs), student nurses and healthcare assistants (HCA) caring for a single bay of patients. Within the hospital, wards usually consist of between 26-30 patients, and a team will look after between a quarter to half of the ward, depending upon acuity of the patients and staffing levels. A bay of patients usually accommodates between four and six patients cared for by a single team.

9.2.4 Sampling

The site of the study was chosen to exemplify what were theoretically most rich in terms of the range of contextual conditions for offloading devices to be used in a proactive way in order to trigger the conjectured mechanisms in the theory (Pawson and Tilley, 1997b). Ethnographic observations were therefore conducted within orthopaedic wards at a large NHS hospital in the North of England, this was in part due to this being a patient population with a high proportion of patients who are at risk of developing heel pressure ulcers and therefore more likely to require pressure ulcer preventative interventions, and because some, but not all these wards keep heel offloading devices as a stock item. There is no standard guidance within the hospital regarding the use of offloading devices; whether they should be kept as stock, the quantities of stock, which devices should be kept or where they are stored. To try and explore the influence of this contextual factor, the selected wards were in the same speciality and therefore had access to the same equipment, but how they were selected, stocked, and used could differ. As the speciality, patient group and sex of the patient were not identified as contextual factors in the theory being tested, variation was not sought when selecting wards. Therefore, three orthopaedic wards including both male and female patients were selected using purposive sampling, completing four observations per ward: twelve observations in total. The contextual influences of this Trust and the ward could be studied as the wards would have the same senior management from matron level and above, but different ward managers; so,

consistencies across wards could suggest influence from the wider organisation level whereas differences might suggest influential factors at the ward level.

9.2.5 Recruitment Process

9.2.5.1 Wards

The researcher contacted the ward manager of potentially suitable wards and provided them with information about the study (Appendix E Ward Manager Participant Information Sheet) and asked to provide written consent for their ward to participate in the study. At this point shift patterns, handover times, ward round times, safety huddle times and who is involved, what stock is kept on the ward and where were established. A minimum of four observations per ward was agreed with the ward manager, ensuring a range of shift patterns, covering different times of the day along with weekdays and weekends. The frequency of the observations and times of the day of the visits to the field need to be able to provide a representative sample of the events and range of activities that occur there. Nights were not included as it was anticipated that once the patients had been settled for bed during the evening, it would be unlikely that any pressure ulcer preventative interventions relevant to this theory would take place, other than repositioning. It is not possible to record everything that goes on in the field, but the aim is to get an overview of the care practices and to be able to distinguish between irregular, routine and frequent activities that take place (Brewer, 2000).

9.2.5.2 Patients

On the first day of observations on each ward the researcher attended handover and a bay of patients was selected to be observed using purposive sampling. The bay would be selected either based on the information provided during handover or identified by the nurse in charge as having a minimum of one high risk patient with mobility levels being either chair or bedfast, either with capacity to consent themselves or having a potential consultee present. By definition, someone who is bedfast or chair fast cannot leave their bed or chair due to illness or incapacity, however on an orthopaedic surgical ward early mobilisation is a key part of the recovery pathway and therefore mobility levels can change on a daily basis. Patients would be recruited on the assumption that they met these criteria based on information given by the nursing team. Between one and six patient participants would be recruited per observation, with a minimum target of twelve patients in total: one per observation. A bay would be excluded if it were closed due to infection control reasons or it had been previously observed (defined as more than 50% of the patients observed previously).

Table 9-2: Unit of analysis options for observation work, highlighting the chosen option

	Ward	**Team**	**Bay of patients**	**Individual staff member**	**Patient**
What will be observed?	Usually between 26-30 patients, all QNs, student nurses and HCAs on shift along with other members of the multi-disciplinary team (MDT).	Ward could be split between 2 and 3 teams so 9-15 patients, 1-2 QNs and 1-3 HCAs.	Consists of between 4-6 patients managed by a single team (1-2 QNs and 1-3 HCAs).	Single member of staff who would be shadowed for the whole observation period	Could select a patient at risk or with an offloading device in situ
Level of detail	Potentially more interactions and people to observe. Can see ward dynamics, interactions with other members of the MDT. Could miss some pressure area care as cannot watch all members of staff at the same time. As there are more people to observe, overall, the observations will be lacking in detail	Team interactions and other members of MDT can be observed. Could be more selective of who to observe at a time depending upon their current tasks. Overall, there will be less detail as more people to observe	Team interactions and other members of MDT can be observed in more detail. Could be more selective of who to observe at a time depending upon their current tasks.	Fewer observations of pressure ulcer preventative care as the individual will have lots of other duties to perform, what is observed could be seen in more detail	There might be fewer interactions – could go long periods without any interventions or might only see one pressure ulcer preventative intervention for the whole observation period but would be very detailed – would be more like a case study. Would be issues around representativeness & generalisability that would need addressing
Consent process	Posters on the ward and information leaflets, opt out process, consent for staff interviews	Posters on the ward and information leaflets, opt out process, consent for staff interviews	Posters on the ward and information leaflets, opt out process, consent for staff interviews	Posters on the ward and information leaflets, opt out process, consent from individual being observed for both observations and interviews	Posters on the ward and information leaflets, opt out process, consent from individual being observed – could be consent issues if the patient lacks capacity. Would need to consent staff for interviews

Gaining personal consultee assent (9.3.1) could only be done in the presence of relatives/visitors, and hence was restricted to visiting time (2-8pm). This meant that observations of people requiring consultee assent were either done for an afternoon observation shift by approaching consultee on the day, or for morning observation shifts, by seeking out the consultee the previous afternoon. When this was not possible due to the researcher's clinical commitments, a bay would be selected where participants could consent themselves. The nature of the research was explained to the patients and/or relatives prior to the start of the observations, a participant information sheet (Appendix F Patients Participant Information Sheet) was provided and written consent gained, for both the observations and for a review of their medical and nursing notes, although no patient identifiable information was collected. For patients who had capacity to give consent but were unable to complete the consent form, witnessed verbal consent was completed. Any person in the observed bay who was not eligible for inclusion or chose not to participate had no data collected about them, including interactions that they might have with those involved in the research project.

9.2.5.3 Staff

Following the observation period, a purposive sample of up to four members of staff per observation, who had interacted with the observed bay of patients, were invited to participate in a short audio recorded interview as close to the period of observation as possible. This number was decided based on the anticipated number of staff who would be observed working in a single bay (Table 9-2), with a target of at least twelve interviews in total, but recruitment stopped once data saturation had been achieved. A participant information sheet (Appendix G Ward Staff Participant Information Sheet) was provided and the opportunity to ask any questions about the study given. Full written consent was gained.

9.2.6 Data collection

In ethnographic research there is no consensus with regards to a suitable sample size or number of periods of observations required to provide an adequate overview of current practice and to answer the research question (Hammersley and Atkinson, 2007). It is therefore dependent on the objectives of the study, characteristics of the group being observed and the resources available to the researcher (Angrosino, 2007). It was therefore decided, due to the limitation of the time and resources of the researcher, that four observation periods per ward would take place. Each observation lasted approximately four hours, on the basis that patients at risk of developing a

pressure ulcer should be on a minimum of four hourly repositioning (NICE, 2014b), therefore they should receive at least one reposition and/or skin assessment / pressure ulcer intervention during that period. The observation process is illustrated in Figure **9-1**.

Figure 9-1 Observation and data collection process

9.2.6.1 Non-participant observations

Data were collected in the form of field notes and photographs of non-patient areas. At the beginning of each observation period, contextual data were collected in the form of photographs and structured field notes. Photographs of the ward stockrooms provided evidence of what devices were kept as stock and their accessibility. Structured field notes included a general description of the ward, a map of the ward and bay being

observed, including patient location within the bay and their pressure relieving equipment.

Unstructured field notes (with labels to codify entries) were made, distinguishing between what actually happened and feelings about what happened using detailed description [DD] of what happened, observers' comments [OC] for ideas, views or theories about what happened, subjective reflections [SR] for personal feelings. Times were recorded throughout to give an accurate timeline of events. Field notes were transcribed in full by the researcher as soon as possible following the period of observation.

9.2.6.2 Documentation review

A documentation review took place at the end of each observation for patients who had provided written consent to the study. A structured data collection form was used to record whether there were any medical risk factors that could put the patient at risk of developing a heel pressure ulcer (e.g., diabetes, peripheral vascular disease, neuropathy) along with pressure ulcer risk assessment, presence of any pressure ulcers through the skin assessment, and what equipment was prescribed in the pressure ulcer prevention care plans and when (i.e., before or after any pressure damage might have occurred). No patient identifiable information was collected.

9.2.6.3 Post observation interviews

Short audio-recorded interviews took place on the ward as close to the end of the observation as possible so that it was still memorable for the staff. The purpose of the interviews was to clarify what was observed and to explore the knowledge that underpinned the observed behaviours. The interviews were therefore iterative, and the questions led by what had been observed. The interviews were also used as an opportunity for reflection upon whether the presence of the researcher influenced practice in any way.

It was found during these interviews, respondents reported that the role of the ward manager was important, so it was decided to go back and do more in-depth interviews with the three ward managers after the observations had finished.

9.3 Research governance issues

The University of Leeds was sponsor and responsibilities were delegated as appropriate to the Researcher, Supervisors, the School of Healthcare and the hospital

through a Research Sponsorship Agreement. All necessary approvals including NHS Permissions and ethical approvals took place prior to the start of recruitment.

9.3.1 Ethical Considerations

The main ethical consideration was around the observation of the delivery of patient care and interactions between patients and staff. Information about the study was displayed around the ward in the form of posters, and the research was explained to all staff participants and the opportunity to withdraw given at any time up until three days post observation at which point all data would have been transcribed and anonymised. Staff were reassured that the intention of the observations was not to assess quality of practice, just to observe patient care delivery. The specific focus of the research was withheld so as not to influence the care being delivered.

Although the researcher was present for the observations in a purely research capacity, as a registered nurse, as per the guidance from the Nursing and Midwifery Council (2019), there was a responsibility to be prepared to intervene if dangerous or unsafe care was seen, or if there was a risk of immediate serious harm to an individual. If there was no evidence base surrounding the practice being delivered, but it was just viewed as poor practice, then there was no need to intervene.

Minimal ethical issues regarding interviewing NHS staff were foreseen as, due to the nature of the interview topic guide, it was unlikely to involve disclosure of sensitive information.

Full written consent was obtained for participants who were observed and to have their medical and nursing notes reviewed, although no patient identifiable information was collected. For patients who had capacity but were unable to complete the consent form, witnessed verbal consent was completed.

A large proportion of patients who suffer from pressure ulcers or are at risk of developing pressure ulcers have receptive, comprehension or language difficulties. They may also have general cognitive impairment affecting their understanding and/or dementia (Jaul et al., 2017, Jaul and Meiron, 2017). Cognition impacts upon compliance with pressure ulcer preventative care along with the ability to self-care. It was important that the research included a cross-section of the normal patient population for the included wards; therefore, recruitment procedures facilitated consultee or nearest relative/guardian agreement.

The assessment of capacity related specifically to decisions pertaining to this research project. Each patient was assumed to have capacity unless it was established that they

lacked capacity by assessing the patient's ability to understand what decisions they needed to make and why; the consequences of the decision to participate; their ability to understand, use and retain the information related to the decision to participate and ability to communicate their decisions effectively (Department of Health, 2005). If there were any concerns about capacity the researcher consulted further with other members of the attending clinical team and/or relative/carer/friend (as appropriate) and a decision made with the relative/carer/friend as to whether the patient was able to provide consent. Where the patient was thought not to have capacity to consent, a relative, carer or friend who was interested in the patient's welfare would act as a personal consultee.

The relative/carer/friend was involved in the information and decision-making process with the patient and asked to advise the researcher on their presumed wishes and feelings and personal consultee assent would be obtained on behalf of the patient. If despite taking all reasonable steps a personal consultee could not be identified and contacted, then a nominated consultee would be approached. This person would have no connection with the research project and would not be observed. They would be nominated by the researcher and would be a member of the medical team directly involved in the patients' care.

The personal consultee or nominated consultee would be provided with the information leaflet describing the research study and the role of the personal/nominated consultee would be emphasised; that they were being asked to act on behalf of the participant, rather than on any personal views or feelings.

9.3.2 Data Protection and Confidentiality

All data collected throughout the study were anonymised and kept strictly confidential. The only personal information collected were the names on the consent forms, and email addresses or postal addresses should the participant wish to receive copies of the research results. These were stored on a spreadsheet on a password protected secure drive at the University of Leeds and would be deleted along with the email trail once the results had been sent out.

Hard copies of any data collected (field notes, consent forms and research journal) were stored in a secure lockable place within the School of Healthcare, only accessible to the researcher and supervisors. Once transcribed, the data were stored on a password protected secure drive at the University of Leeds.

Audio recordings were transcribed by a 3rd party external to the research team through a University of Leeds trusted transcription service. A confidentiality agreement was signed by the transcription service and a secure data exchange programme used. No confidential, sensitive, or personally identifiable information was sent to the transcriber.

9.3.3 Archiving

Data were securely archived in line with the University of Leeds procedures for a minimum of 5 years, following which data will be destroyed in a secure and safe manner.

9.3.4 Ethical approval

Ethical approval was gained from the Health Research Authority (HRA) on 18th September 2018 (Appendix H HRA Ethical Approval (September 2018)). Capability and capacity confirmation were required from the hospital to indicate that the speciality had capacity for the research to take place. As this research project was taking place in one speciality; orthopaedics, only one capability and capacity form required signing off, and permissions from the hospital came through on 22nd October 2018 (Appendix I [redacted]).

9.4 Data analysis

In qualitative research there are numerous different possible approaches to data analysis, dependent upon the desired output. This could be from providing a detailed description of the phenomenon being studied, to developing explanations of the patterns seen in the data to constructing more general theories from the data (Spencer et al., 2014b). Realist evaluation aims at providing more than just detailed descriptions, but to generate theories and conjectures about what works for who in which situations. Its fundamental guiding principles require data to be examined in configurations of ‘mechanisms’ with their triggering ‘contexts’ and ‘resultant outcomes’. Therefore, a more deductive approach to data analysis was required in order to test the theory generated in the previous chapter in order to develop concepts, categories, themes and explanations of the results (Spencer et al., 2014b).

An iterative approach to data collection and analysis took place to allow for testing, explanation, and refinement of the theory, which was then taken into subsequent observations for further testing and revisiting the data. Qualitative analysis has two key stages; the first involves data management (often referred to as coding) and the second involves making sense of the data (Spencer et al., 2014a). Once transcribed,

all interviews, field notes and photographs were inputted into NVIVO 12 (QSR International Pty Ltd, 2018) for indexing against the existing theory. They were coded against the three contexts identified in the theory (nodes); the ward, TVNS and the organisation/NHS, and additional nodes could be added to allow for open coding as new or unexpected findings emerged. Within a node, child nodes were used for each mechanism identified in the theory. Once the data had been grouped into these categories a thematic analysis was used to analyse the data, combining elements to yield categories that capture conceptual differences in the data and to offer both explicit and implicit explanations (Spencer et al., 2014a). Cross-participant (QNs, HCAs and student nurses) and cross-site (wards) comparisons added depth and richness to the analysis as they identified commonalities or similarities that appeared independent (non-causal) or connected (causal) (Maxwell, 2012).

Because of the limitation of resources available and the time restraints of a PhD, the researcher did the data collection and analysis alone, but findings were discussed and scrutinised during supervision meetings. Where possible, the thirteen steps described by Miles et al. (2014a) for testing and confirming findings were followed to increase the rigour of the data collection and analysis process and findings. How they apply to this research is presented in Table 9-3.

Table 9-3 Tactics for testing and confirming findings in this study using Miles et al. (2014a)

Assessing the Quality of the data	**Checking for representativeness**	When developing findings, how typical and representative are they in this context? The use of purposive sampling can lead to participants being recruited who were not representative of the population due to the accessibility of both staff and patients. The researcher only observed for a limited time therefore it is important not to assume what is observed is happening when absent.
	Checking for researcher effects	The researcher attempted to minimise biases stemming from the researcher's presence by not disclosing to the staff observed the clinical background of the researcher or the focus of the research. Staff were invited during the interviews to reflect on how the researcher's presence affected practice. Avoiding biases stemming from the effects of the site on the researcher by attempting to observe and interview a wide variety of patients and staff. A reflective diary was also kept as part of the field notes.

	Triangulation	Data were collected during the observations from a range of sources: field notes, interviews, medical and nursing notes review and photographs of non-clinical areas. Corroboration from different data sources can give deeper insight and enhance the trustworthiness of the findings (Evers and Staa, 2010). Inconsistent and conflicting findings were scrutinised.
	Weighting the evidence	The above points will help in assessing the quality of the evidence and which data sources are stronger – Conclusions made were based on the strength of the evidence
Looking at "unpatterns"	**Checking the meaning of outliers**	Any exceptions found were explored to test the generalisability of findings, reduce biases, and build explanations
	Using extreme cases	Extreme cases might be from persons with a strong bias and exploring these could lead to a more in-depth understanding of their reasoning and reactions to the available resources
	Following up surprises	Surprises are when something occurred outside of the range of expectations. Following up and reflecting upon surprise findings can give insight on personal expectations and assumptions, but also build upon existing theories.
	Looking for negative evidence	Actively searching for data that opposes the researcher's conclusions; if found then an alternative conclusion was sought to allow for this evidence
Testing explanations	**Making if-then tests**	Creating if-then statements can help unpick the contexts and mechanisms to help build on the theories
	Ruling out spurious relations	When two variables look correlated or causally associated, consider whether there could be a third variable that caused, influences, or underlies one or both.
	Replicating a finding	Consider how replicable or transferrable the findings would be in a different context Could this study be replicated?
	Checking out rival explanations	During final analysis 'next best' explanations were explored as an alternative to the original theories
	Getting feedback from participants	As new tentative findings emerged, due to the iterative nature of the data collection, new participants were used to explore these.

9.5 Summary

This chapter has presented the methods used to conduct an ethnographic study to test Programme theory 1. The method was designed to be ethically sound and reproducible, along with being able to explore the contexts and mechanisms described in the theory. Chapter 10 will present the findings from this study.

Chapter 10 Testing of programme theory 1 – Proactive use of offloading devices

10.1 Introduction

Chapter 9 described how programme theory 1 was selected for testing, and the methods used to conduct an ethnographic study. This chapter presents descriptive results to set the scene of the study, including a description of standard care, the patient population observed as well as the ward staff observed and interviewed. The findings will then be presented in order to test programme theory 1 which identifies factors that influence the proactive use of offloading devices from the micro context of the ward, the meso context of the TVNSs and the macro context of the wider organisation and NHS. Programme theory 1 was initially made up of six candidate theories:

1. Healthcare professionals with advanced knowledge of pressure ulcer prevention are more likely to appropriately implement an offloading device as a preventative measure.
2. Nurses working in clinical areas that frequently care for patients at high risk of developing pressure ulcers are more likely to implement an offloading device as a preventative measure because pressure ulcer prevention becomes more of a clinical priority and staff are more experienced at managing at risk patients and aware of the resources available to them.
3. Nurses are more likely to implement an offloading device if it is easily accessed within the care environment.
4. If patients are moved frequently between different care environments, then offloading devices are less likely to be utilised because of cost factors.
5. Single patient use offloading devices versus reusable devices will be more desirable dependent on the care environment and priorities of the ward manager.
6. Offloading devices are more effective in patients with reduced consciousness.

The contexts and mechanisms identified in Chapter 6 (Figure 6-7) were presented in turn, along with any new configurations and theories identified from the research data. This chapter includes some discussion of the findings and how they link in with existing theory as this will help to test and further refine the theory, but further detail along with a critical analysis of the findings are presented in Chapter 11.

10.2 Description of standard care

Standard care across the organisation where the study took place, with regards to pressure ulcer prevention and management, included a risk assessment (PURPOSE T) completed within 6 hours of admission, which is a national requirement (NICE, 2014b). All patients had a high specification foam (HSF) mattress, electric profiling bed and an armchair as standard, and if the risk assessment had identified the patient as at risk of developing a pressure ulcer, a minimum of four hourly repositioning and SSKIN bundle commenced (an intentional-rounding chart). AP and CLP air mattresses and chair cushions could be ordered and delivered within four hours, based on clinical judgement of patients' needs. Offloading was recommended in the hospital's guidelines for 'patients at risk of developing a heel pressure ulcer', based upon international guidelines (EPUAP et al., 2019), but no heel-specific devices were specified to be used across the organisation as part of standard care. Any device available through the NHS supply chain could be ordered through supplies. Prophylactic dressings were not recommended in the hospital's guidelines as part of standard care. Standard care can differ between organisations, and the definition of standard care is often overlooked in research papers other than mattress use. Table 10-1 shows what the standard care that was delivered to the patient participants during the observations.

Table 10-1 Standard care received by participants

	Risk assessment completed	Care plan in nursing notes	Repositioning plan in place?	Min. 4 hourly repositioning observed	Mattress used	Mattresses use documented
Ward 1	100% (n = 9/9)	100% (n = 9/9)	33% (n = 3/9)	89% (n = 8/9)	AP n = 1 HSF n = 8	56% (n = 5/9)
Ward 2	100% (n = 11/11)	91% (n = 10/11)	100% (n = 11/11)	100% (n = 11/11)	AP n = 2 CLP n = 1 HSF n = 8	82% (n = 9/11)
Ward 3	100% (n = 12/12)	92% (n = 11-12)	92% (n = 11/12)	100% (n = 12/12)	AP n = 1 HSF n = 11	83% (n = 10/12)
Totals	**100% (n = 32/32)**	**94% (n = 30/32)**	**78% (n = 25/32)**	**97% (n = 31/32)**	**AP 13% (n = 4/32) CLP 3% (n = 1/32) HSF 84% (n = 27/32)**	**75% (n = 24/32)**

During the observations, five patients in total across all three wards (n = 5/32, 15.6%) were observed with heel-specific devices in use, however there was no documentary evidence in the nursing or medical notes about their use (Table 10-2). Of these five patients, three also had an AP mattress in place. The documentation review did not

reflect the care that was received, as throughout the observations 31/32 patients received a minimum of four hourly repositioning. The patient not repositioned was on Ward 1, and although they were not turned, they did have their heels checked and repositioned, and had an offloading device and a dynamic mattress in place.

Within the study site at the time of the observations the standard practice for quality improvement and monitoring of pressure ulcer rates involved completing a datix (incident report form) for all patients with a pressure ulcer to measure incidence, and monthly safety thermometer prevalence audits. Each department would be given an annual target specific to their area to reduce acquired pressure ulcer rates, most would involve a 5-10% reduction year on year. A root cause analysis investigation would take place for all patients who develop a Category 3, 4 or Unstageable pressure ulcer as an inpatient. Following a root cause analysis investigation, an action plan would be completed with the aim to gain learning from the incident and minimise the risk of another patient developing a pressure ulcer if a similar situation were to arise.

10.3 Observations and documentary review

Twelve observations took place on the three wards: four on each ward. A total of 49 hours and 35 minutes of patient care was observed. This section will describe the findings from the observations and documentation review before using this data, along with the staff interviews, to test and refine programme theory 1 in section 10.4.

10.3.1 Wards

The wards were in the same wing of the hospital but had different numbers of beds and layout differed including the locations of the nurses' station and stock rooms. All the wards cared for patients admitted acutely requiring orthopaedic surgery.

10.3.1.1 Ward 1

Ward 1 was a 27 bedded ward caring for male patients. It had three bays each with six beds, one bay with five beds, and four side rooms. They stocked the Repose® reusable offloading boots which were easy to locate in the storeroom that were in a clear place that was easy to find. The store room was organised, tidy and the tubes were at eye level and, if you know what you are looking for, are easily identified (Figure 10-1) and all staff interviewed knew where they were kept.

Figure 10-1 Ward 1 stock room, highlighting offloading devices

10.3.1.2 Ward 2

Ward 2 was a 27 bedded ward caring for female patients. It had four bays each with six beds and three side rooms. The Junior Ward Manager stated during their interview that they kept the egg-crate heel pads and boots (heel-specific CLP devices) as stock items, along with the Repose® offloading boots and wedges. Only 2/6 of other staff interviewed were able to identify what items they kept as stock and where, however only two Repose® tubes were found on the ward in patient areas, and no other devices were found in the stock rooms (Figure 10-2) or observed in use. It is possible that the researcher could not locate the devices as the storerooms were cluttered and not well organised, or that the ward was out of stock during the observation period. A TVNS was observed reviewing patient 5.4 on Ward 2 and they did request offloading as part of their plan of care for the patient. The Qualified Nurse did not know how to source the offloading device, and it was initiated by the TVNS rather than the ward, which further suggests that their use was not routine on Ward 2.

Figure 10-2 Ward 2 stock room

10.3.1.3 Ward 3

Ward 3 was a 23 bedded ward caring for female patients. It had five bays each with four beds and three side rooms. They stocked Repose® offloading boots and wedges as well as egg-crate heel pads and boots as stock items which were easy to locate in the store room (Figure 10-3), and all staff interviewed knew where they were kept.

Figure 10-3 Ward 3 stock room showing stock of Repose® offloading devices (left) and heel-specific CLP devices – the egg-crate heel pads (right)

10.3.2 Devices

Due to the large range of heel-specific devices available for the prevention of heel pressure ulcers, the research objectives in 4.3 limited the research to any device that works by offloading/floating the heel. However, it was not just offloading devices that were observed being used, with wards 2 and 3 reporting that they used egg-crate heel cups and pads which are heel-specific CLP devices, as well as the Repose® heel protectors which are offloading devices. This will be discussed further in 10.4.1.4.

10.3.3 Patient participants

10.3.3.1 Screening and consent/assent

Across the three wards, a total of 65 patients were screened (Figure 10-4) and of those 32 (49%) consented to be observed and have their medical and nursing notes reviewed. Only 5 patients (7.7%) were screened as not eligible to participate due to not being at risk of developing a pressure ulcer.

Twenty-six of the screened patients (40%) lacked capacity which demonstrates the importance of being able to recruit this potentially vulnerable patient group. Eight (31%) of the patients without capacity were assented by a personal consultee. There was the option to assent using a nominated consultee, this had to be a member of the patient's medical team and on each occasion, there was no members of the medical team available to be approached for assent. This was a limitation of the research as 17 patients screened (26%) could not be assented due to the accessibility of personal and nominated consultee. The researcher visited the observation wards at different times of the day and visited during visiting hours to attempt to access this population and ensure that those recruited to the study were representative of the patient population across these wards.

10.3.3.2 Patient characteristics

Patient characteristics were collected from the nursing and medical notes review. Thirty-two patients were recruited with a mean age of 73.9 years, nine were males and twenty-three were females. This split is due to observing two female wards and one male ward. The patients were given a unique study number denoting the observation number followed by the order in which they were consented, for example participant 7.1 was the first patient recruited during the seventh observation. Table 10-2 gives details of the patients' characteristics.

Although the recruitment criteria stated that participants were at risk of developing a pressure ulcer due to being bed-bound or chair-bound,13/32 (41%) of patients were observed mobilising with assistance (Table 10-2) but all patients observed had reduced mobility and were therefore still at risk of developing a pressure ulcer (Coleman et al., 2013). All participants had a completed risk assessment in their nursing notes and were all assessed as at risk of developing a pressure ulcer, apart from participant 4.2 who had been assessed as not at risk. The researcher had assessed this patient as being at risk because although he was normally fully mobile, during the observations he was non weight bearing and bedfast whilst waiting for theatre.

No patients were seen or documented to have a dressing for prevention. These are similar findings to the 14.0% of patients with an adjuvant device or dressing as reported in PRESSURE 2, a multi-centre study involving 2029 patients (Nixon et al., 2019). In a prevalence study Gunningberg et al. (2011) reported that 11% of patients had a 'heel cushion', although it is not disclosed what this is. Two offloading devices were observed for prevention, two offloading devices for treatment of an existing heel pressure ulcer and one CLP device for prevention.

Six patients (n = 6/32, 18.8%) included in this study had a Category 2 or above pressure ulcer, three of which (n = 3/6, 50.0%) were to the heel. One of the limitations of the study is that it was not possible to tell whether a patient had their heels offloaded with a pillow as their legs would be covered with a blanket. This information would not be included separately in the documentation as it would be counted as part of repositioning, but this would not guarantee that it would happen every time for every patient.

The most frequent reason for admission (n = 16/32, 50.0%) was following a fractured neck of femur (mean age 78.8 years). Of the 16 patients with a fractured neck of femur in this study, five (31.3%) had a pressure ulcer, three of which were to the heel (Table 10-2). Three of the fractured neck of femur patients (n = 3/16, 18.8%) had a heel device, two for treatment of a heel pressure ulcer (offloaded) and one for prevention (CLP device), this is broken down according to wards in Table 10-3. This patient group has been identified as being at high risk of developing pressure ulcers due to pain, increased age and the general health status of this population (Houwing et al., 2004, Lindholm et al., 2008, Galivanche et al., 2019). Between 2013-2018 the National Hip Fracture Database have reported an annual incidence in England, Wales and Northern Ireland for Category 2 or above pressure ulcers of 2.8-6% for patients undergoing surgery for hip fractures (Royal College of Physicians, 2019). This is similar to an

incidence of 3.8% reported by Haleem et al. (2008) over a seventeen year period for hip fracture patients, with 44% of all pressure ulcers at the heel.

Figure 10-4 Screening and consent flow diagram

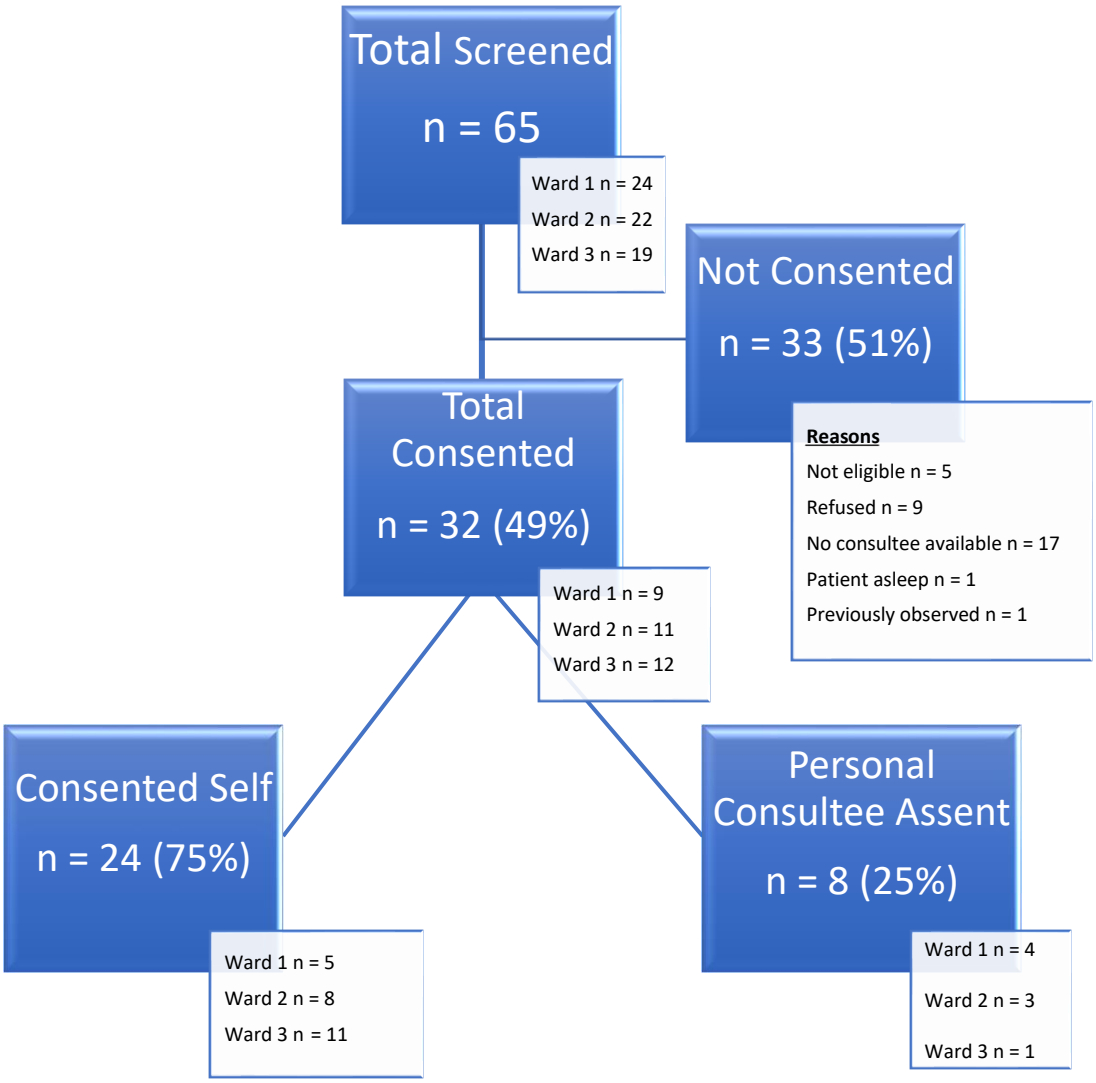


Table 10-2 Patient characteristics[7]

Ward	Patient Number	Sex	Age	BMI	Reason for admission	Mobility	Perfusion problems	Pressure ulcer history	Heel device used	Device type
1	1.1	M	90	22.6	Fractured left acetabulum	Can mobilise but spends majority of time in bed	PVD, diabetes	No	No	
1	1.2	M	90	Not measured	Fractured pubic rami, left ankle, tibia, and fibula	Bedfast, required repositioning	No	No	Yes prevention	offload
1	2.1	M	81	23.6	Fractured left neck of femur	Bedfast, required repositioning	No	No	No	
1	2.2	M	56	Not measured	Right 4th and 5th toe amputation	Can mobilise but spends majority of time in bed	PVD, diabetes	No	No	
1	3.1	M	80	26.4	Fractured left neck of femur	Chair-fast, can reposition self	No	No	No	
1	3.2	M	88	Not measured	Fractured right neck of femur	Chair-fast, can reposition self	No	No	No	
1	3.3	M	40	Not measured	Fractured left ankle, tibia, and fibula	Chair-fast, can reposition self	No	No	No	
1	4.1	M	80	22	Fractured right femoral shaft	Bedfast, required repositioning	No	No	Yes prevention	offload
1	4.2	M	50	25.1	Fractured right ankle	Chair-fast, can reposition self	No	No	No	
2	5.1	F	86	Not measured	Fractured left neck of femur	Can mobilise but spends majority of time in chair	No	No	No	

[7] Data from a combination of medical and nursing notes review and observations. Patients highlighted in blue denote fractured neck of femur

Ward	Patient Number	Sex	Age	BMI	Reason for admission	Mobility	Perfusion problems	Pressure ulcer history	Heel device used	Device type
2	5.2	F	69	Not measured	Fractured left neck of femur	Can mobilise but spends majority of time in bed	No	No	No	
2	5.3	F	43	23.4	Pubic fusion and bilateral screw insertion	Bedfast, can reposition self	No	No	No	
2	5.4	F	80	22.3	Fractured right neck of femur	Bedfast, required repositioning	No	Category U left heel, Category 2 right heel	No	
2	6.1	F	94	Not measured	Necrotic right 2nd toe	Can mobilise but spends majority of time in bed	PAD	No	No	
2	6.2	F	83	25	Fractured right neck of femur	Chair-fast, required repositioning	No	Category 2 both heels	Yes treatment	offload
2	7.1	F	89	17.8	Fractured right neck of femur	Bedfast, required repositioning	No	Category 2 sacrum	No	
2	7.2	F	90	24.7	Fractured right neck of femur	Bedfast, required repositioning	No	No	No	
2	8.1	F	83	Not measured	Fractured right neck of femur	Bedfast, required repositioning	Diabetes	Category 2 both heels	Yes treatment	offload
2	8.2	F	70	Not measured	Left leg Ischaemic ulcers and vomiting	Can mobilise but spends majority of time in bed	PAD	No	No	
2	8.3	F	58	Not measured	Fractured right femoral shaft and pelvis	Bedfast, required repositioning	No	No	No	
3	9.1	F	55	41	Fractured left tibia, fibula, and patella	Bedfast, paraplegia, required repositioning	No	Healed Category 4 to ischium	No	

Ward	Patient Number	Sex	Age	BMI	Reason for admission	Mobility	Perfusion problems	Pressure ulcer history	Heel device used	Device type
3	9.2	F	60	35.7	Fractured right neck of femur	Bedfast, required repositioning	No	No	No	
3	9.3	F	89	20	Fractured right neck of femur	Can mobilise but spends majority of time in chair	No	No	No	
3	10.1	F	86	22.7	Septic arthritis right wrist	Can mobilise but spends majority of time in chair	No	No	No	
3	10.2	F	90	23.2	Fractured pubic rami	Can mobilise but spends majority of time in chair	IHD, pre-diabetic	No	No	
3	10.3	F	56	25.5	Fractured right neck of femur	Bedfast, required repositioning	Diabetes	No	No	
3	10.4	F	81	30.9	Fractured right neck of femur	Can mobilise but spends majority of time in chair	No	Category U to buttock	No	
3	11.1	F	62	27.4	Fractured left neck of femur	Chair-fast, required repositioning	No	No	Yes prevention	CLP
3	11.2	F	61	19.3	Fractured tibia, Illisarov frame, infected pin sites	Can mobilise but spends majority of time in chair	Diabetes	No	No	
3	11.3	F	84	18.3	Fractured left neck of femur	Can mobilise but spends majority of time in chair	Diabetes	No	No	
3	12.1	F	93	20.6	Fractured C2 and pubic rami	Bedfast, required repositioning	No	Category 2 to buttocks	No	
3	12.2	F	48	38.6	Fractured right ankle, left wrist, C5/6	Can mobilise but spends majority of time in chair	No	No	No	

Table 10-3 Summary of patients with pressure ulcers and how heel-specific devices were used

	Patients with a fractured neck of femur	Patients with a device for prevention	Patients with a pressure ulcer	Proportion of pressure ulcer patients with a heel pressure ulcer	Patients with a device for treatment
Ward 1	33.3% (n = 3/9)	22.2% (n = 2/9)	0% (n = 0/9)	0% (n = 0/0)	0% (n = 0/0)
Ward 2	63.6% (n = 7/11)	0% (n = 0/11),	36.4% (n = 4/11)	75% (n = 3/4)	66.7% (n = 2/3)
Ward 3	50% (n = 6/12)	8.3% (n = 1/12)	16.7% (n = 2/12)	0% (n = 0/2)	0% (n = 0/0)
Totals	50% (n = 16/32)	9.4% (n = 3/32)	18.8% (n = 6/32)	50% (n = 3/6)	66.7% (n = 2/3)

10.3.4 Ward staff

The nursing team was made up of several different job roles, bands, and level of qualification. When starting the observations, it was sometimes difficult to identify the different job roles whilst getting familiar with the different uniforms, as not only were there numerous different uniforms specific to the hospital, but there were also different uniforms for agency staff. To try and understand the roles of the nursing team with regards to pressure ulcer prevention, they were separated into Qualified Nurses (QNs), Healthcare Assistants (HCAs) and nursing students (Table 10-4). The Nursing Associate role is new, with the first cohort qualifying and registering with the Nursing and Midwifery Council during the observation period. The Nursing Associate role contributes to most aspects of nursing care, including delivery and monitoring, but the Registered Nurse leads on assessment, planning and evaluation, as well as managing and coordinating care (Nursing and Midwifery Council, 2018). Although the job roles differ at ward management level, the day-to-day care observed in the bay was similar, so a post observation decision was made to group Registered Nurses and Nursing Associates together as QNs.

10.3.4.1 Handover

One handover was observed on each ward to get an overview of what was communicated about pressure ulcer prevention. Ward 1 and 3 did not discuss pressure ulcer risk or repositioning plans, whilst Ward 2 did. All the wards included whether the patients had a pressure ulcer on the handover sheet. Devices were not discussed at handover or included on the handover sheet.

Table 10-4 Job roles that make up the nursing team

Qualified Nursing Staff (QNs)	Healthcare Assistants (HCAs)	Nursing Students
Senior Sister/Charge Nurse (Ward Manager)	Assistant Practitioners[8]	Nursing student
Junior Sister/Charge Nurse	Healthcare Assistant (including agency)	Apprentice Nursing Associate
Staff Nurse (including agency)	Apprentice Healthcare Assistant	
Nursing Associate		

10.3.4.2 Staff and patient interactions

Times that staff entered and left the bay, along with all interactions between the patient participants and all staff on the ward (i.e., Doctors, Physiotherapists, Occupational Therapists etc.) were recorded in the field notes, including verbal interactions and direct patient care. Most of the interactions between the patients and ward staff were with members of the nursing team (Table 10-5). During 49 hours and 35 minutes of observations, a total of 305 interactions were observed lasting 16 hours and 49 minutes. During each observation period the participants had a mean of 2.9 QN interactions and 0.7 student nurse interactions compared with 4.8 interactions with HCAs (Table 10-5). The interactions with the HCAs also tended to be longer, averaging at 15 minutes per participant compared with an average of 8.7 minutes spent with the QNs and 2.5 minutes with student nurses. The majority of QN time spent in the bay was doing medication rounds and documentation. Only documentation that was completed at the bedside during an interaction with the patient was recorded in the fieldnotes, but in most cases documentation was completed away from the bedside with the care plans being taken out of the bay or completed without a conversation or interaction with the patient. The HCAs were doing most of the direct patient care such as performing observations, assisting patients with hygiene needs, skin assessments, mobilising, and repositioning patients. This is similar to the findings by Sving et al. (2012) who reported that QNs delegated most of the pressure ulcer preventative care to HCAs. The Nursing students observed functioned at a level between the QN and HCA role, assisting on medication rounds and dressings, but also performing direct patient care.

[8] Although there were Assistant Practitioners working in the observed hospital, none were observed

Along with more patient interactions, the HCAs were present in the observed bays more than QNs. This is in part due to a protocol in some of the bays that were designated “falls bays” where patients at high risk of falls are all placed in the same bay and a member of staff would need to be always in the bay to try and prevent patients mobilising or climbing out of bed unaided; a duty that was primarily undertaken by the HCA.

Ward 3 saw more QN interactions and time spent with the participants, but this was mainly from medication rounds. There is a potential reporting bias here though, as due to the iterative nature of the research project, Ward 3 was observed after Wards 1 and 2 had been analysed, so what was being observed and reported was more focused and the interactions between the patients and staff were more comprehensively documented in the field notes.

The HCAs performing most of the pressure ulcer preventative care is an important finding, as the majority of the initial theories did focus on QNs, but the focus of the theory needs to be changed to include all staff in a QN led team when providing direct care. Two physiotherapists were also observed completing skin assessments so there is evidence of an MDT approach to pressure ulcer prevention starting to take place within this organisation. Theory development therefore needs to consider the whole MDT.

10.3.4.3 Staff interactions

Overall, of the observations, only 20 interactions between QNs and HCAs were observed in the bay, mainly to discuss the results of vital signs observations. A total of four short interactions, lasting less than 1 minute each, between QNs and HCAs about pressure ulcer prevention were observed and three occasions where HCA staff were observed discussing amongst themselves repositioning plans or pressure ulcer prevention care needs of patients. When the Nursing Students worked alongside the QNs the work was aligned to the activities of the QN for example medication rounds and completing a referral to occupational therapy. When the Nursing Students were working alongside the HCAs, they would align to the HCA role. There were no interactions involving Student Nurses that included pressure ulcer preventative care or education.

Table 10-5 Staff and participant interactions per observation period

Participant number	Shift time	QN time (mins)	Number of QN interactions	HCA time (mins)	Number of HCA interactions	Nursing student time (mins)	Number of Nursing student interactions	Other staff time (mins)	Number of other staff interactions
1.1	07.15-11.30	12	4	22	4	0	0	0	0
1.2	07.15-11.30	11	4	7	6	0	0	9	1 Physiotherapist (physio)
2.1	14.50-18.15	6	4	9	3	0	0	1	1 Speech and language therapist (SALT)
2.2	14.50-18.15	1	1	5	4	15	1	10	1 Doctor
3.1	14.10-18.30	2	2	31	12	0	0	0	0
3.1	18.00-22.10	4	2	5	5	0	0	0	0
3.2	14.10-18.30	1	1	9	5	0	0	0	0
3.3	14.10-18.30	4	1	16	3	0	0	0	0
4.1	18.00-22.10	6	2	17	4	0	0	0	0
4.2	18.00-22.10	0	0	1	1	0	0	4	1 Trauma co-ordinator
Totals		47	21	122	47	15	1	24	4
Means (Ward 1):		**4.7**	**2.1**	**12.2**	**4.7**	**1.5**	**0.1**	**2.4**	**0.4**

Participant number	Shift time	QN time (mins)	Number of QN interactions	HCA time (mins)	Number of HCA interactions	Nursing Student time (mins)	Number of Nursing student interactions	Other staff time (mins)	Number of other staff interactions
5.1	07.15-12.00	5	2	33	7	0	0	0	0
5.2	07.15-12.00	5	2	20	3	0	0	17	1 Occupational therapist (OT), 1 Physio,
5.3	07.15-12.00	9	5	60	5	0	0	3	1 OT, 1 Physio, 1 Doctor
5.4	07.15-12.00	32	7	14	3	9	1	25	1 Physio, 1 Medical Illustration, 1 TVNS
6.1	10.00-14.00	0	0	10	9	6	3	0	0
6.2	10.00-14.00	3	2	26	14	7	6	9	1 Physio, 1 Physiotherapy assistant (PA)
7.1	14.15-18.20	6	3	4	3	0	0	0	0
7.2	14.15-18.20	7	3	22	4	0	0	0	0
8.1	18.00-22.05	5	4	12	6	0	0	28	1 Student Doctor
8.2	18.00-22.05	17	8	2	2	0	0	0	0
8.3	18.00-22.05	7	4	21	3	0	0	0	0
Totals		96	40	224	59	24	10	82	11
Means (Ward 2):		**8.7**	**3.6**	**20.4**	**5.4**	**2.0**	**0.9**	**7.5**	**1.0**

Participant number	Shift time	QN time (mins)	Number of QN interactions	HCA time (mins)	Number of HCA interactions	Nursing student time (mins)	Number of Nursing student interactions	Other staff time (mins)	Number of other staff interactions
9.1	07.15-11.30	13	4	11	3	22	3	9	3 Doctors
9.2	07.15-11.30	10	4	23	4	11	3	9	1 doctor, 1 PA
9.3	07.15-11.30	2	2	2	2	1	1	19	1 Physio, 1 PA, 1 doctor
10.1	10.15-14.20	8	5	1	1	0	0	4	1 Doctor
10.2	10.15-14.20	12	3	17	7	0	0	0	0
10.3	10.15-14.20	38	4	14	5	0	0	5	2 Doctors
10.4	10.15-14.20	6	3	24	7	0	0	0	0
11.1	14.20-18.40	7	2	16	2	7	2	0	0
11.2	14.20-18.40	10	3	12	5	2	1	0	0
11.3	14.20-18.40	12	3	12	6	0	0	3	1 British Red Cross
12.1	18.15-22.05	12	3	14	7	0	0	0	0
12.2	18.15-22.05	5	1	4	3	1	1	0	0
Totals		**132**	**37**	**150**	**52**	**44**	**11**	**49**	**12**
Means (Ward 3):		**11.3**	**3.1**	**12.5**	**4.3**	**3.7**	**9.2**	**4.1**	**1.0**
Totals for all observations		**275**	**98**	**496**	**158**	**83**	**22**	**155**	**27**
Means for all observations		**8.7**	**2.9**	**15.0**	**4.8**	**2.5**	**0.7**	**4.7**	**0.8**

One limitation of this study was that the observations all took place in a bay, therefore there could have been more interactions and conversations between staff at the nurses' station or elsewhere on the ward. Previous studies have demonstrated that crucial informal communication often occurs in hallways, break rooms and around nursing stations (Ellingson, 2003). The nurses' station does seem to be a central location where interactions and discussions about patients would happen; during two observations, on different wards, the nurses' station could be seen from the bay and QNs, HCAs and Nursing Students would be seen to congregate during quieter periods. Without being able to hear the conversations, some of the discussions appeared to be about the patients, but some were also social conversations. Having a central space where the nursing team can communicate with one another along with other members of the MDT is important for not only work-related conversations, but also provides an opportunity for important relational, mentoring, teaching, and learning interactions (Real et al., 2017). It has however also been found that a centralised nursing station leads to higher walking distances for the nursing team (Real et al., 2019), which has been associated with reduced patient care activities and communication with the family (Ulrich et al., 2008).

At this hospital the medical and nursing notes were partially electronic and partially paper. The nurses would tend to sit at the nurses' station to complete all care plans and documentation, rather than at the bedside, even though there were mobile computer workstations that could be moved into the bay. This is likely to be one of the reasons why the QNs were observed in the bays for less time and were observed being involved in fewer patient interactions compared with the HCAs, as discussed in 10.3.4.2.

10.3.4.4 Staff Interviews

A total of 19 ward staff (Table 10-6) were approached immediately after the observations and recruited to participate in a short interview; each lasting between 5-10 minutes. All staff who were approached agreed to be interviewed, although not all staff observed could be approached as they might have finished their shift or were no longer on the ward. This is a limitation to this research as the number of staff not available was not recorded, and their accessibility could be connected to differences in their workload which could affect the representativeness of those recruited. On reflection, although it was not intentional, it is possible that staff who were easiest to access could have been more likely to be recruited leading to a selection bias.

Each interviewee was assigned a unique participant number, the number relates to the observation number and the letter is the order that they were consented, for example

participant 3b was the second staff member recruited during the third observation. Eleven of the interviewed staff were HCAs (n = 11/19, 57.9%), reflecting the staff observed delivering most of the direct patient care (Table 10-6).

Table 10-6 Job roles of interviewees

Ward 1		Ward 2		Ward 3	
Participant Number	Job Role	Participant Number	Job Role	Participant Number	Job Role
1a	HCA	5a	HCA	9a	QN
1b	HCA	5b	QN	9b	HCA
1c	QN	6a	Agency HCA	9c	HCA
2a	QN	6b	Agency HCA	10a	Junior Sister
2b	HCA	6c	Apprentice HCA	10b	Nursing Associate
3a	HCA	6d	Trainee Nursing Associate	11a	Junior Sister
3b	HCA	WM2	Junior Sister	WM3	Ward Manager
WM1	Ward Manager				

During the interviews it became apparent that the role of the Ward Manager could be significant, and therefore due to the iterative nature of the research, it was decided to do three additional in-depth interviews with the Ward Managers (WM) for the three observed wards, each lasting approximately 30 minutes. The Ward Manager for Ward 2 was not available for interviewing, therefore one of the Junior Sisters was interviewed instead, taking the total number of staff interviews to 22.

It needs to be acknowledged that although the nursing team were mostly unaware of my job role as a TVNS during the observations, they were made aware before the interviews which could have influenced their responses.

The interviews tended to confirm my interpretation of the observations, and no major disparities in the answers was noted between the different job roles, although due to the depth of the ward manager interviews, these did provide greater depth.

10.4 Testing of programme theory 1

Based on the programme schema developed following the TVNS interviews for programme theory 1, this section will present the findings from the ethnography study

under the contexts of the ward, TVNS and organisation/NHS with the mechanisms as sub headings, as per Figure 6-7.

10.4.1 Ward context

During the TVNS interviews, there were four mechanisms identified within the context of the ward that influenced the use of offloading devices for the prevention of heel pressure ulcers: Staff awareness and knowledge, stock and supply of devices, identification of a suitable patient group and leadership/management. The TVNS all felt that knowledge & awareness was key for the proactive use of offloading devices, so they ensured that imparting knowledge and raising awareness was a key part of what they did.

10.4.1.1 Staff awareness and knowledge

10.4.1.1.1 Training and education

No direct training or education with regards to pressure ulcer prevention was witnessed between any staff members during the observations. There was one opportunity, with a TVNS being observed reviewing a patient's heel pressure ulcer. A nursing student was present during the assessment, so it was possible that observational learning occurred, and it is also possible that teaching about the patient assessment was delivered once they had left the bay instead of doing it in front of the patient.

During the staff interviews a wide range of sources of training and education were described, from formal teaching at induction to informal teaching on the ward by the clinical educators, other members of staff, link practitioners and the Ward Manager, along with shadowing the TVNS.

Within the organisation all members of the nursing team were required to undertake pressure ulcer prevention training every 2 years as a minimum, but none of the interviewed members of staff could recall this training. Three of the interviewed members of staff were new to the hospital (within the previous four months) so had undergone pressure ulcer prevention training during this time as part of their induction; where all new staff receive as much of their mandatory and priority training required for their role within the first four weeks of employment. None of the new members of staff could recall any of the training being about offloading or heel pressure ulcer prevention, but it is unknown if this was omitted from the training or if staff were unable to recall this information.

Only one member of staff identified that they had received training that was specifically about the prevention of heel pressure ulcers or the use of offloading devices, delivered by the Ward Manager on Ward 1:

> *"[I've had] more [education] about the pressure on the heels on here with [the Ward Manager], she loves the boots"* (Participant 1C, QN, Ward 1)

Learning theories describe a process that leads to a change in an individual's understanding, which ultimately changes the way in which they perform a task or skill (Wills and McEwen, 2011). For example, most staff interviewed knew that offloading devices could reduce the risk of their patients developing a heel pressure ulcer, but it could be argued that only once this has become incorporated into routine practice that learning has occurred.

10.4.1.1.2 Staff knowledge

From the observations no evidence of formal training and education on the use of offloading devices was witnessed. On Wards 1 and 3 there was evidence of knowledge about what devices were available and when to use them, with staff using collective terms like "we" to illustrate something they all do as a team; potentially learning and working as a community of practice, as this example illustrates:

> *"if we find that their heels are quite red on admission, we'd straight away put them on repose® boots"* (Participant 2a, QN, Ward 1)

From the interviews with staff, it does appear that staff have gained their knowledge through tenacity, authority and *a priori* (Kerlinger and Lee, 1986). The Ward Manager for Ward 1 gives an example of how knowing through authority is supplemented by evidence and *a priori:*

> *"I'm sure if someone said 'if you run round the ward with an orange bag on your head it would prevent this, that and the other' [knowledge through evidence], we'd probably go along with that if it made sense! So, if it makes sense and it's understandable [knowledge through a priori] then your staff are more likely to follow your lead [knowledge through authority].* (Ward Manager, Ward 1)

Knowledge through authority will be discussed further in 10.4.1.2 as this was seen to be an important element of leadership. As well as knowledge through authority, staff on Ward 1 were also able to demonstrate knowledge through a priori by demonstrating reasoning behind why they were offloading fractured neck of patients, as this HCA can evidence:

> *"we deal with a lot of hip problems, like broken hips, so with them being less mobile we tend to concentrate on the heels, it's one of the things that the Ward Manager is very keen on doing" (*Participant 2b, HCA, Ward 1)

There is also an element of experience required to gain knowledge through tenacity and *a priori.* Something that is illustrated by this HCA who has identified that they have little experience in pressure ulcer prevention:

> *"I wouldn't say I was massively confident anyway with like pressure ulcer prevention care, I haven't seen that much to be fair, I just kind of follow what other people are doing, but if I've seen breakdown of skin, I'd let the nurse know and then just do whatever they told me to do".* (Participant 6b, agency HCA, Ward 2)

This does also give further evidence to the importance of communication between staff, but also how inexperienced staff can look to colleagues to gain knowledge through communities of practice(Andrew et al., 2008, Wenger, 2010).

10.4.1.1.3 Visual awareness

Another mechanism whereby offloading devices increase awareness for staff is by being a visual reminder that the patient's heel is at risk and therefore they will put in extra measures to offload the heel even though they already have a device in place, which was part of candidate theory 10 discussed in Chapter 7, as this quote gives an example of:

> *"when we actually ran out of [heel devices] we had slightly more [Category 1 pressure ulcers] because people, if you put the eggshell thing in [CLP device], people will actually [profile the bed at the feet] to offload but if you don't have it, they'll forget"* (Ward Manager, Ward 3)

This is a perception of the Ward Manager and junior sister on Ward 3 and was not something that was evident during the observations. Only one patient on Ward 3 was observed with a heel-specific CLP device, and the foot of the bed was not profiled, and they were not repositioned any more frequently than any of the other patients. This does link in with the stock and supply of devices (10.4.1.4) as if access to devices is not maintained, it could contribute to a heel pressure ulcer not just because they do not have a device, but they do not have the additional interventions that the Ward Manager and Junior Sister on Ward 3 believed happened. No research evidence could be found about whether visual cues such as mattresses or offloading devices prompt more interventions.

10.4.1.2 Leadership and management

During the interviews, leadership with regards to the Ward Managers' influence on pressure ulcer prevention and the use of offloading devices was explored. This links in with the theory by Kerlinger and Lee (1986) about gaining knowledge through authority, as this quote indicates.

> *"every fractured neck of femur patient on here should really have Repose® boots given to them, that's what the manager likes to have on here, as like a protocol"* (Participant 1a, HCA, Ward 1)

Staff on Ward 3 were also able to give examples of leadership having an impact on offloading device use, as something that has been embedded into ward practice as this quote illustrates.

> *"we've got quite a focus on pressure ulcers on here, and our sisters are quite hot on it, and it's just been instilled in us to always offload someone's heels"* (Participant 9a, QN, Ward 3)

In contrast, none of the staff on Ward 2 discussed the preferences or opinions of the current Ward Manager and there appeared to be a lack of focus on heel pressure ulcer prevention, which does seem to influence practice by omission.

A staff member on Ward 2 suggested that a former Ward Manager had influenced pressure ulcer prevention practice, but this was then over-ruled by Senior Managers due to financial costs. Although this staff member talks about the use of mattresses it gives a generic example of how ward leadership can impact upon practice.

> *"it was a manager that I [previously] worked for and they basically wanted all patients with neck of femur fractures to be put on Nimbus® mattresses [AP mattress], at least for the first few days until they started sitting out, but [Matron and Head of Nursing] stopped us doing it because we were doing that, we were ordering mattresses and cushions for everybody but then they were kept on the mattresses far too long"* (Participant 5b, QN, Ward 2)

Leadership appears to be influential on device use, as staff on both Ward 1 and 3 discussed the preferences of the Ward Manager and how this impacted upon their use of devices Gunningberg et al. (2010) concluded that it is the nursing managements' responsibility to stimulate collaboration amongst the nursing team as well as the wider MDT to embed pressure ulcer prevention in daily practice. Leadership seems to be an important mechanism for the proactive use of offloading devices within the ward context. However, what was discussed by staff was not witnessed during the observations, with only one patient with a fractured neck of femur on Ward 3, had a heel-specific device proactively for prevention.

10.4.1.2.1 Protocol

On Wards 1 and 3 there was evidence of an informal protocol for when offloading devices should be used, which was developed and/or initiated and maintained by the ward leadership teams. The preferences and opinions of the Ward Manager on Ward 1 appear to be influential on the ward team and the success of the protocol as this quote illustrates:

> *"The protocol normally is that if someone's been admitted with a fractured [neck of femur] we tend to put the Repose® boots on as soon as"* (Participant 2a, QN, Ward 1)

From the evidence provided during the interviews, staff on Ward 1 perceived themselves to be proactive in the use of offloading devices for the prevention of heel pressure ulcers, although no patients were observed pre- or immediately post-operatively with a device to support this.

Ward 2 had no protocol in place for the use of offloading devices, which the Junior Sister did reflect upon and did seem keen on developing and initiating. Here the Junior Sister has provided some insight into why they think the protocol helps in that it gives ward staff a rationale behind their practice.

> *"I think you do need a protocol; I think if you give a protocol then [the nursing team] have got something to concentrate on, they've actually got a rationale of why we're doing it. I don't think a lot of staff understanding the reasoning why they actually are doing a task, because it's literally just a tick box sometimes, … if they understand the rationale why you're doing it, and I think you'd have a better response from it, so having a protocol in place and saying this is the research behind it, now it's in place you've got to do it, you'll have better success" (*Junior Sister, Ward 2*)*

The staff on Ward 3 said their protocol was initiated as part of the fractured neck of femur pathway; a national quality improvement project designed to improve the care of vulnerable patients admitted to hospital in the UK with hip fractures (Royal College of Physicians, 2019). Pressure ulcer rates in orthopaedic units are monitored on the National Hip Fracture Database (Royal College of Physicians, 2019), but no written evidence or guidance could be found locally or nationally about the use of offloading devices. Through informal conversations with a Clinical Educator and the Fracture and Fragility Nurse Specialist, it was discovered that the heel-specific CLP devices were brought in a couple of years previously by the Fracture and Fragility Nurse Specialist along with one of the Matrons within orthopaedics for use in this patient group, but only Ward 3 appeared to continue to use them.

Although it was apparent that staff on Ward 1 and Ward 3 knew more about the heel-specific devices available to them and when they should be used, this was not evident from the observations. No clear difference was seen between the patients or the wards in terms of when a device would be used proactively, and it appeared that device use was on an ad-hoc basis, although these observations provide only a snapshot of clinical practice.

10.4.1.3 Identification of a suitable patient group

There appeared to be consensus across all the observed wards with regards to the vulnerability of fractured neck of femur patients, with Wards 1 and 3 having an informal protocol to provide these patients a heel-specific device on admission. A total of sixteen patients (50%) were observed who had been admitted with fractured neck of femurs (highlighted in Table 10-2), of which three (n= 3/16, 18.8%) had a heel-specific device, two to treat a pre-existing heel pressure ulcer (n = 2/16, 12.5%), and one (n = 1/16, 6.3%) as prevention.

One of the benefits of ethnography is its ability to allow you to view a snapshot of what is really going on in the real world, compared to interviews that give an individual's accounts and beliefs about what is happening. For example, in the interviews staff were able to demonstrate their knowledge with regards to the protocols and processes in place for the use of heel-specific devices, whereas the observations demonstrate the application (or not) of this knowledge. The mechanism demonstrated through the interviews is that knowledge and awareness of the vulnerability of patients with a fractured neck of femur should trigger the implementation of a device, but the observations can help to unpick the contextual factors that means it only happened for one patient.

10.4.1.4 Stock and Supply of Devices

During the TVNS interviews it was theorised that in the context of a ward that frequently cares for patients at high risk of developing heel pressure ulcers, and where staff are knowledgeable about the risk factors for their patients, nurses are more likely to use offloading devices especially if they are readily available to them. From the observations, Wards 1 and 3 had a stock of offloading devices (10.3.1), but this did not appear to lead to more patients being offloaded during the period of observation.

There was not a consistent approach to the type of device used within the context of the orthopaedics department, and the reasoning behind this seemed to be down to personal preferences of individual wards. There was also little differentiation made by staff between heel cushioning devices and offloading devices which is important to acknowledge because the initial theories focused on offloading devices. From the systematic review, it is unknown whether the offloading or the cushioning devices are more effective, but in the absence of this evidence, the outcome is that ward staff are attempting to reduce risk through the implementation of a heel-specific device, therefore the theory will be amended to include all 'heel-specific devices.

With regards to knowledge about the devices themselves, Ward 1 only had access to a single type of offloading device, so their knowledge and responses were limited to just this device, but there was evidence that they knew when the device should be used and for which patients. There was no clarity from the staff interviewed on Ward 2 over which devices they stocked or used and when, and there appeared to be no set process for stocking and using the devices. Two patients had an offloading device for treatment, but none of the staff knew if they had been ordered in or were ward stock. Staff on Ward 3 had access to both an offloading device (Repose® offloading boot) and a heel-specific CLP device (egg-crate heel pads and boots). Some staff described using the heel-specific CLP devices for prevention and offloading for treatment as this example illustrates.

> *"I think we tend to do use the [offloading device] when a pressure [ulcer] has occurred, not more as a preventer, I think the [heel-specific CLP devices] are more of a preventer, whereas the [offloading device] are just, I think they are more for once the pressure damage is already there"* (Participant 9b, HCA, Ward 3)

This was discussed with the Ward Manager for Ward 3 to try and establish why they were used in this manner, however the Ward Manager viewed the offloading devices as being for high-risk patients, but the CLP devices being for patients at medium risk, as this quote demonstrates:

> *"If we've got a patient that is medium risk [of developing a pressure ulcer] it's [heel-specific CLP device] fine, but if we've got a patient with higher risk that hasn't got a pressure ulcer people are less likely to switch and upgrade [to Repose®] because they still haven't got [a pressure ulcer] …. I would say [Repose®] would take a higher risk but we would only go to the complete offload boots that you get from Orthotics if somebody actually did have [a pressure ulcer]" (*Ward Manager, Ward 3)

There is a differentiation between two different offloading device types, the Repose® re-usable device and the 'complete offload boots that you get from orthotics' which are single patient use padded offloading devices that are fixed to the limb. This does imply that the Ward Manager made a distinction, based on clinical judgement, between being at risk and having a pressure ulcer and viewing the single patient use offloading devices as being required for patients who have a heel pressure ulcer. Therefore, not only are the heel-specific CLP devices and offloading devices not viewed as having equal benefits, but not all offloading devices are viewed equally.

The Junior Ward Manager for Ward 2, where no devices were observed in the stock room, thought that a more consistent approach with regards to stock of a heel-specific device across the speciality could influence their use, but this idea was not shared with the other wards. It could be because Ward 2 needed to implement and embed the use

of heel-specific devices into practice, that shared practice from similar wards could aid with this, as this quote demonstrates:

> *"There's that many different types [of heel-specific device] you'd lose focus of which one's best, which one's not. If it was [standardised] to [your department] it should be easier, and actually it's only one thing for staff to go to for your patients"* (Junior Ward Manager, Ward 2)

Another finding was that staff have a belief about the effectiveness of the devices and have associated patients developing a heel pressure ulcer due to the device not being available. Both a Junior Sister and the Ward Manager on Ward 3 discussed patients developing a heel pressure ulcer when they ran out of heel-specific devices; demonstrating tenacity in the belief of the effectiveness of the devices from senior members of the nursing team, which could have an impact on the wider nursing team, as this quote illustrates:

> *"… we did see a patient develop a pressure ulcer to the heel, and that was because we did run out of the [heel-specific CLP devices]"* (Participant 10a, junior sister, Ward 3)

10.4.1.5 Summary

Leadership of the ward emerged as an important mechanism to raise staff awareness regarding the proactive use of heel-specific devices. There was evidence of the ward leaders influencing practice through developing and maintaining an informal protocol to give clarity to staff about when the devices should be used that was specific to their patient population. There was also evidence of staff gaining more knowledge about the devices through authority, tenacity, and a community of practice within the ward rather than through formal teachings. This is in keeping with other research that has reported perceptions that clinical areas with strong leadership and role modelling does have an impact on the delivery of good pressure ulcer preventative care (Spilsbury et al., 2008).

Heel-specific devices were only observed being used sporadically, not as part of standard care for the prevention of heel pressure ulcers, either for the general orthopaedic population or for the fractured neck of femur patients. Leadership and protocols appear to be influential over raising the awareness for nursing staff regarding proactive use of devices. Having a stock of the devices was important to the nursing staff, however the specific mechanism with regards to how this knowledge and awareness leads to the device being used, remains unclear. It is possible that devices were being used pre and immediately post-operatively, but as it was not documented or observed it could not be evidenced. It is also possible that there could have been specific patient factors that were not explored, that meant these devices were not suitable for every patient.

10.4.2 TVNS context

Chapters 6-8 established that the TVNSs felt that they were influential in the sourcing and implementation of heel-specific devices, developing education packages, guidelines, and campaigns across their organisation for pressure ulcer prevention and the use of offloading devices as well as prescribing the devices through direct patient care, which was attempted to be tested through the ethnographic study.

10.4.2.1 Training and education

During the TVNS interviews, training and education was discussed by all as being a large and important component of their job role; influential on a macro contextual level of their organisation by developing educational packages, protocols, guidelines, and campaigns, as well as at a micro contextual level of the ward through direct delivery of the training and education. The pressure ulcer prevention guidelines for this organisation specifies that patients at risk of developing a heel pressure ulcer should be offloaded but does not recommend device type. There was no evidence of the TVNS team for this organisation being directly involved in the development, implementation, or ongoing monitoring of the informal protocols in place on Wards 1 and 3.

As previously discussed in 10.4.1.1.1 in the organisation where the study took place, pressure ulcer prevention training is a priority training requirement across the organisation for all members of the nursing team to complete every two years. The TVNS team identifies what needs to be included in the training and education packages and develop the resources for the whole organisation. From the context of the TVNSs they would appear to have an indirect influence on the pressure ulcer prevention practices of ward staff by developing the training and education, but due to the size of the organisation to deliver the competencies they require the assistance from designated members of staff. It was not possible in this study to identify the success of these education packages on changing practice or influencing the proactive use of heel-specific devices, although none of the interviewed members of staff could recall having any formal teaching about heel pressure ulcer prevention.

10.4.2.2 Knowledge and personal preferences

The knowledge of the TVNS team were viewed as a resource for the wards to access. The TVNS is seen as an expert on pressure ulcer prevention due to their experience, knowledge of research evidence and different devices and products; but this knowledge should be used in conjunction with the knowledge of the ward staff, as they are the experts in their specific patient groups as this quote illustrates:

> *"The tissue viability team are very important as they see a lot of reps don't they, and they see a lot of equipment coming through, see a lot of research bits what are happening, so actually [the TVNS] probably can tell us which [device is] better, but actually from our client group, our patient group that's when the ward staff need to have a little bit of an influence."* (Junior Ward Manager, Ward 2)

It was suggested that the knowledge of the TVNS should be used in collaboration with the knowledge of the ward staff. The ward staff need to have ownership of pressure ulcer prevention practice in their clinical area, as this nurse discusses:

> *"but I think the ward staff do need to own [pressure ulcer prevention practice] because we are asking [TVNS] for advice … we don't expect [TVNS] to take over with it, so I still think we need the courage of our own"* (Ward Manager, Ward 3)

One of the members of staff discussed working directly with the TVNS team by shadowing them, another example of how ward staff can access the resource of the TVNS knowledge. Although this had a direct influence on their interests, it is not possible to demonstrate if or how this acquired knowledge changed their practice.

> *"When I first started this course, I worked with the TVNS for a week…I did learn a lot with the TVNS and it made me interested to do my dissertation on [pressure ulcer prevention]"* (Participant 6d, Trainee Nurse Associate, Ward 2)

This does however link in with the theory by Kerlinger and Lee (1986) showing how the nursing team acquire pressure ulcer prevention knowledge through authority from both the Ward Manager and the TVNS, but this is not necessarily through training and education, and what remains unknown is the mechanism through which this knowledge is used leading to a change in practice.

10.4.2.3 Campaigns and protocols

Within the study organisation there were no campaigns or protocols evident for the use of heel-specific devices that were developed or implemented by the TVNS team.

10.4.2.4 Direct patient care

One TVNS was observed on Ward 2 visiting a patient with a heel pressure ulcer present on admission. It was evident during the interviews that ward staff wanted more input from the TVNSs on the management of their patients, as they were seen as a valued resource by the ward staff, however the TVNS team at the study site did not seem able to meet the demand from the wards. The direct patient care delivered by the TVNS was viewed by some of the ward staff as being more reactive to damage that has already happened rather than being proactive and being a mechanism for initiating interventions, as this example illustrates.

> *"If we develop a pressure area and it's [reported] they come, they look, they either say "yes it is, no it isn't, do [an investigation], get medical photography, whatever and they just dictate but they don't…there isn't enough of them to be able to sit and do other interventions, teachings and things"* (Ward Manager, Ward 1)

10.4.2.5 Summary

Within this theory the TVNSs were initially seen as a context, however it is emerging that within the context of the ward the TVNSs are also a mechanism, with their knowledge about pressure ulcer prevention and best practice being a resource accessed and valued by the ward staff as well as a resource to advise about the care of individual patients. From the context of the TVNS, it was theorised that the knowledge of the TVNS team about pressure ulcer prevention and the different products available is a mechanism to bring devices into the organisation and identify clinical areas that they might be relevant for, although this was not evident during these observations. The ward-based nursing team are the experts on their patient population therefore using this in conjunction with the TVNSs knowledge of devices and pressure ulcer prevention could lead to the development of a successful protocol.

10.4.3 Organisation context

The context of how the wider organisation influences an individual ward was difficult to establish through the observations. The Ward Manager interviews were therefore used to further explore this context.

10.4.3.1 Leadership and management

All three wards were managed by the same Senior Managers (Matron and Head of Nursing). The Ward Managers felt that there was little influence from their managers and the wider organisation with regards to pressure ulcer prevention and the use of heel-specific devices. It could be because for Wards 1 and 3 they already had heel-specific devices available that they perceived themselves to be using and therefore there was no need for the Matron or Head of Nursing to become involved, or there was no perceived need to intervene.

The Ward Managers did feel that the practice of senior management was more reactive, and it was only when an incident occurred like a patient developing a severe pressure ulcer, that they became involved through the root cause analysis process (10.4.3.4). Ward Manager 1 felt that their managers focused on 'mistakes' rather than 'incidents', which seem to be attributable to people rather than processes on the ward, as this quote illustrates:

> *"They're [Senior Managers] not around, they're not visible, so they don't really influence an awful lot unless somebody's made a mistake somewhere then they're likely to be more visible and share that experience with everybody and get people to learn from a mistake that somewhere else has made"* (Ward Manager, Ward 1)

The role of Senior Managers is more focused on finances, serious incidents, wider organisational issues such as monitoring incident rates, patient throughput as well as staff management. This does position them further away from clinical practice, but the Junior Sister for Ward 2 felt that because the Senior Managers are further away from direct patient care, they have less insight on what works directly on the ward for that patient group, as this quote shows:

> *"I'm going to say this but actually it sounds really, really bad, but [Senior Managers] they're not aware of the challenges that we have on the ward, because I suppose the higher up you get in chain of command, the less clinical you are. You don't actually see how much of a struggle we have on the ward every day, so whether or not it might be patient acuity, or might just be your generally deteriorating patients or you might have difficulties with Doctors who don't see [every patient] – all they do is come back and say, "your pressure ulcer numbers have increased, you've had a fall this day, this has increased" (Junior Sister, Ward 2).*

This could be why, from the perspective of the nursing team, that the organisational context appears to have little influence on pressure ulcer prevention practices and the use of devices. During the observations, one Senior Manager was seen once on Ward 3, and that was at the nurses' station for a total of 4 minutes talking to the nurse in charge. At no point did they enter the bay or were seen interacting with patients, although the observations are only a snapshot of the day-to-day running of the wards.

10.4.3.2 Finance

The cost of the devices does not appear to be a mechanism that has a direct influence over ward staff and how they use heel-specific devices. No members of ward staff discussed the financial cost of heel-specific devices, but does seem to be a more important factor from a senior management and organisational context as this example shows:

> *"I suppose for your Matron from that level, I suppose a lot of budgeting and costs [of devices] is a massive influence"* Junior Ward Manager Ward 2

One of the QNs felt that when senior management influenced the way in which they used mattresses due to financial implications and that this did have a direct impact upon their heel pressure ulcer rates as this quote illustrates.

> *"in our unit we were using [the highest numbers of alternating air] mattresses and spending the most money on mattresses so they [senior management] decided, the [high specification foam] as they're a high-risk mattress as well, and so if [patients] had no pressure damage they were*

> *saying leave them on an [the high specification foam] unless they started portraying signs of pressure damage. But we found since we stopped [using alternating air mattresses] that heel damage has increased" (*Participant 5b, QN, Ward 2)

Although there is no actual evidence that there was an increase in heel pressure ulcers or if this was directly related to the change in mattresses, this does give some insight into how the QNs might perceive the importance of mattresses and other devices in pressure ulcer prevention. It is also possible that if a patient develops a pressure ulcer because the mattresses were taken away, then the nursing staff can attribute responsibility on someone/ something else.

10.4.3.3 Priorities and targets

Prevention of avoidable harms such as pressure ulcers, infections and falls is a nationwide priority as well as within the study site (Harm Free Care, 2019). It had been theorised that targets set by the organisation such as a reduction in pressure ulcer rates could be a mechanism by which devices are initiated, aimed at reducing heel pressure ulcer rates.

The only evidence during the observations of organisational priorities and targets was a patient safety board seen on Ward 1 showing that the ward had been 253 days without a hospital acquired pressure ulcer, although this number was not updated throughout the observations. It is likely that Ward 2 and 3 had this information on display but it was not noted during the observations, this could be because they were not in as noticeable place, or because Ward 1's poster gained my attention due to the high number. These numerical targets can lead to a sense of pride for wards that are doing well, but equally could lower morale for struggling wards, as this Ward Manager gives an example of:

> *"it's about getting your staff to be engaged and being proud, you know, 414 days, over a year without any [pressure ulcers] being developed. Pretty damn good and we were very pleased. But that wasn't, oh that's a target for the [hospital], that was because we were doing it for <u>our</u> patients on <u>our</u> ward because they belong to us, it kind of comes to belonging to us and owning that responsibility"* (Ward Manager, Ward 1)

Numerical targets set by the organisation do not appear to have a direct influence over the nursing team, but awareness of patient safety and reduction in harms is important to staff as this quote demonstrates.

> *"… [nursing staff] are trying to prevent harm to patients, it's probably of more importance than saying that we have to reduce by 10% I would say… because 10%, 10% of what? It's quite difficult, numbers are numbers, and you can bend statistics, can't you?"* (Ward Manager, Ward 3)

Although the wider organisation does not seem to have a direct influence on the implementation of heel-specific devices, the use of targets such as pressure ulcer free days is a management priority and target which seems to have influenced awareness.

10.4.3.4 Identifying practice that needs improving through RCA investigations

From personal experience, documentation is often a focus during root cause analysis investigations because, whilst good record keeping is a professional and legal requirement of nurses, it is believed that poor record keeping is linked to poor practice (Andrews and St Aubyn, 2015). Documentation is also something that can be a measurable outcome that can be audited to demonstrate an improvement in practice.

On discussion with the Ward Managers, it was established that Ward 1 had the lowest acquired pressure ulcer rate, going above 414 days, but had less documentary evidence in the care plans about the pressure ulcer preventative care received compared to the other wards. There was therefore no link seen here between the quality of the documentation and pressure ulcer development. One theory behind this could be because Ward 1 had not had an acquired pressure ulcer, and therefore a root cause analysis investigation, for over one year, so there was less of a focus on their documentation.

Within the context of the organisation, root cause analysis investigations were viewed as a reactive response to incidents that had occurred. The Ward Managers disclosed that Senior Managers shared learning from root cause analysis investigations across all wards within the speciality, but not all the Ward Managers saw this as a good thing especially if they felt it was not relevant to the practice on their ward, as this quote demonstrates.

> *"so, we've now got a competency so that's now being taught to avoid the pressure areas that we've had from the traction. So again, it's a kneejerk, it's not a proactive, it's a kneejerk, this has happened, we must do something about it, which we are doing" (*Ward Manager, Ward 1)

The root cause analysis process was a potential mechanism by which the devices were first initiated on Ward 3, which was associated with a positive outcome on the perceived reduction in the number of patients subsequently developing heel pressure ulcers, as discussed:

> *"So, the decisions have come off the back of [root cause analysis] meetings… I presume it came through the Education Team for the [egg-crate heel pads] but I can't remember. I think it was a trial we started off the back of heel pressure ulcers that were [not caused by a cast or a device], so we've had a massive reduction [in heel pressure ulcers] using those"* (Ward Manager, Ward 3.)

10.4.3.5 Summary

The ward nurses perceived that the wider context of the organisation was less influential on the nursing team's day-to-day pressure ulcer prevention practices and the use of devices, compared to the influence of the Ward Manager. However, through lessons learnt from root cause analysis investigations, devices might be implemented reactively. During the TVNS interviews, it was felt that the TVNS team might introduce a heel-specific device to meet organisational targets for reducing heel pressure ulcer rates, but this was not evident during the ethnographic study.

10.5 Other findings

Programme theory three discussed how heel-specific devices are not suitable for all patients, at all points in their recovery journey, and there was agreement from the TVNSs that they were not suitable for patients whilst sitting out as they could become a fall hazard. Patient 6.2 initially had the offloading boots in place when she was sat out, but the staff were observed discussing concerns about patient 6.2 being a fall risk with the physiotherapists as she was sliding down in her chair, and when the physiotherapists repositioned her into a better sitting posture, they removed the offloading boots and placed them on the bedside table. Patient 11.1 had an egg-crate heel pad in bed, but when she was transferred to the chair this was also moved to the bedside table by the HCA. As this theory was not the focus of the ethnography this was not explored further during the interviews.

Patients 6.1 and 8.2 were also examples of where heel devices were not suitable for all patients; as even though they both had PAD and were therefore very high risk for developing a heel pressure ulcer, patient 6.1 was agitated and confused and kept trying to climb out of her bed, so would have either kicked the device off or it could have become a fall hazard. Patient 8.2 had ischaemic leg ulcers but was independently mobile and was observed repositioning her legs frequently.

10.6 Chapter summary

This chapter has presented the findings from data collected from the ethnographic study conducted on three orthopaedic wards through observations, case notes review and interviews. The programme theory developed from the interviews with TVNS in Chapter 6 about the proactive use of offloading devices was tested using the data collected.

Due to the large range of heel devices available, to increase the depth of the research the initial candidate theories (Chapter 4) were limited to any device that works by

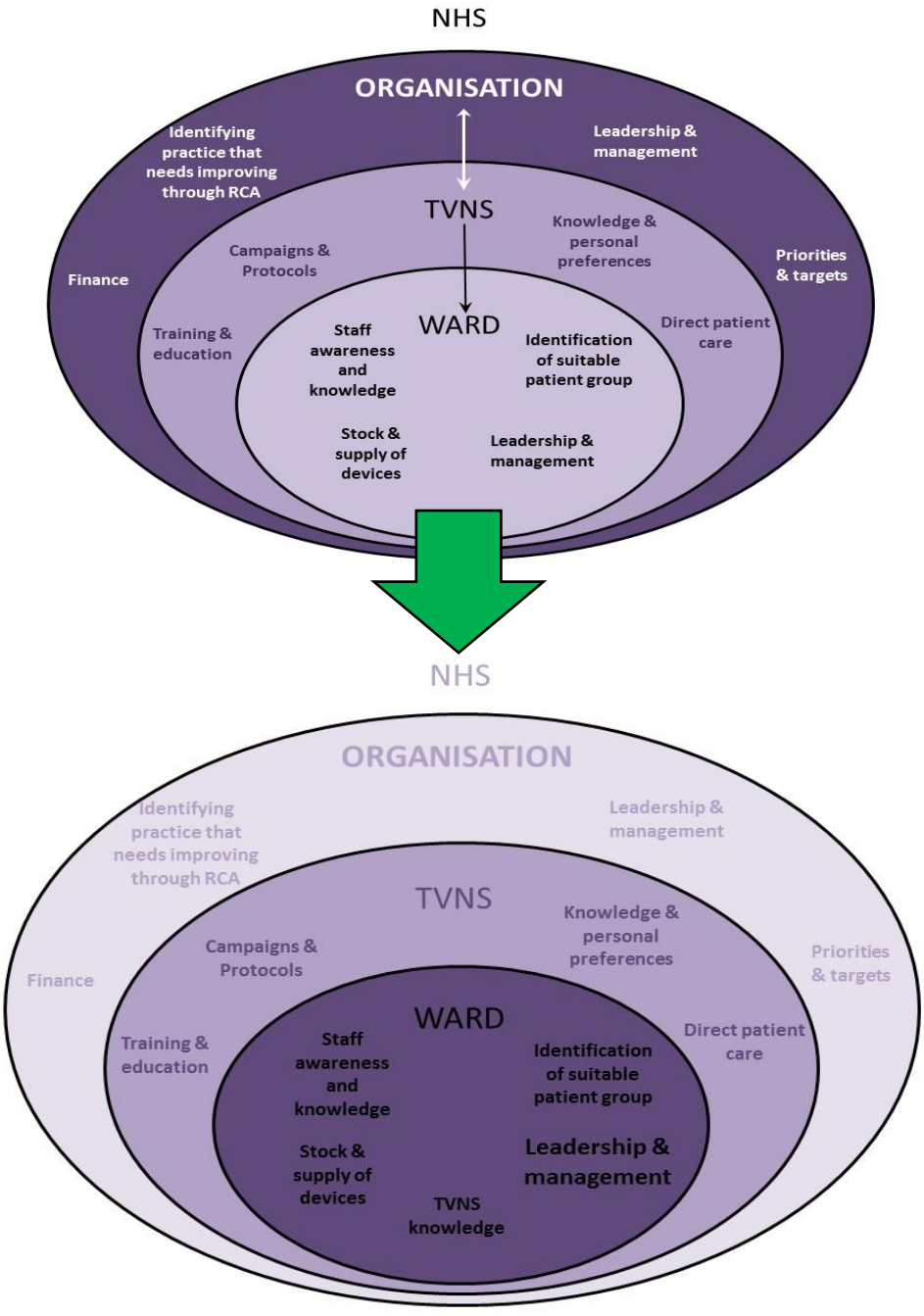
offloading/floating the heel. However, during the observations several different 'heel-specific' devices were observed in use, and although they work differently staff referred to them all as 'offloading devices'. There is no evidence that one is better than the other, therefore if they are being implemented it is felt that they are having a positive impact in preventing heel pressure ulcers, then all devices should be considered. The theory has been further developed from 'offloading devices' to 'heel-specific devices' to include any device that either offloads or reduces pressure to the heel.

For the context of the ward, nursing staff perceived leadership from the Ward Manager to be a key mechanism for the proactive use of heel-specific devices. This was done through the development of a protocol specific for their ward and patient population, as well as influencing the practice of their staff through authority, as well as being conducive to a community of practice. Alongside the staffs' knowledge, the stock and supply of devices and awareness of what was available to them was perceived to have a positive impact on device use. Ward 1 and Ward 3 had both identified fractured neck of femur patients as being a high-risk patient group that should be proactively offloaded, however this was not observed on any of the wards. The context of the ward was felt to have the most significant impact on the proactive use of devices, so the diagrammatic representation of this programme theory originally presented in Figure 6-7 was adjusted accordingly to emphasise the ward context by making it a darker colour and therefore the focal point of the diagram (Figure 10-5).

Within the context of the TVNS, the mechanism of training and education was difficult to test, and none of the staff interviewed could recall any training and education from the TVNS team that consciously influenced their practice with regards to heel pressure ulcer prevention. There was no evidence of any heel related protocols or campaigns initiated by the TVNSs. Direct patient care from one TVNS was observed on one occasion, but this was reactive, reviewing a patient who was admitted with a heel pressure ulcer, but they did recommend an offloading device, something that the ward had not initiated. As well as the TVNS being a context, they were also identified as a mechanism within the context of the ward, with the nursing team seeing their specialist knowledge as a valuable resource that they would access. The context of the TVNS was also a link between the ward and the wider organisation, and therefore the second most significant context that influences the proactive use of offloading devices, therefore it is placed in the diagrammatic representation between the ward and organisational context, with a lighter colour than the ward, but a darker colour than the organisational context (Figure 10-5).

The macro context of the NHS and the organisation is more influential over the practice of the TVNS team and Senior Managers through National and organisational targets to reduce avoidable harms to patients, which has led to the root cause analysis process identifying practice that requires improvement, such as initiating a heel-specific device to reduce the risk of heel pressure ulcers.

Figure 10-5 Diagrammatic representation of how theory has developed for the proactive use of heel-specific devices, highlighting the most influential context being the ward using the darker colours to emphasise greater influence



Chapter 11 Discussion

11.1 Introduction

The results of the systematic review, along with its strengths and limitations, are presented at the end of Chapter 3, as this influenced the development of the research question and choice of realist evaluation for the remainder of the research. This Chapter will discuss the results of the realist evaluation in relation to the study aims set out in Chapter 4. It will provide a critical appraisal of the study methods and results along with the strengths and weaknesses of the realist evaluation. It will finally present personal reflections of being a practitioner researcher.

11.2 What factors influence the implementation of a heel-specific device in clinical practice?

During the TVNS interviews it was identified that priorities set by the macro context of the wider organisation, along with investigations into serious pressure ulcers, would lead the TVNS to identify clinical areas that require heel-specific devices. The TVNS were a meso context being influenced by the wider organisation, but also influential on device use through identifying the need for offloading, identifying which devices should be used, promoting their use through training and education, and prescribing them for individual patients. Several mechanisms were identified that appeared to be influential over the implementation of heel-specific devices at the micro context of individual wards, which were explored further in the ethnographic study.

11.2.1 Influence of the TVNS

The TVNSs perceived themselves to be key in the implementation of devices, in part due to the dedicated time they have to focus on pressure ulcer prevention, through their influential role within their organisation or direct patient care. The TVNSs felt they are perceived by both ward staff and the wider organisation as being a valuable resource for driving forward and influencing the initiation and use of heel-specific devices through training and education along with the development of guidelines and protocols.

11.2.2 Staff awareness and knowledge

None of the ward staff interviewed during the ethnographic study discussed research evidence informing practice. A reliable body of empirical evidence should guide practice and could influence implementation, but in a constantly changing healthcare context the body of knowledge and evidence is constantly growing, updating and

adapting (Van Achterberg et al., 2008). There is an expectation that healthcare workers need to adapt accordingly, which can be difficult based on the volume and quality of the evidence. For heel pressure ulcer prevention, evidence is informing and guiding, rather than being the basis for practice.

In the context of the wards observed, staff gained their knowledge of the devices, awareness of what was expected of them and when to implement them, through an informal protocol and guidance from ward leaders.

11.2.3 Leadership and management

The TVNSs identified strong leadership to be influential in pressure ulcer prevention, which was also seen during the ethnography. Previous research has identified leadership as being influential in pressure ulcer prevention through providing guidance and clear expectations for their staff, as well as through personal preferences influencing practice. Spilsbury et al. (2008) interviewed research nurses about their experiences of working on a clinical trial related to pressure ulcer prevention and reported that leadership and role-modelling were important in influencing good pressure ulcer preventative care. In a review of the literature, Wurster (2007) concluded that nurse leaders must shape the environment of care through providing guidance and clear expectations.

11.2.4 Stock and supply of devices

The TVNSs suggested that if a device is kept as a stock item and therefore easily accessible to ward staff, it is more likely to be initiated in a timely manner. This could be because delays in the supply process or poor communication can lead to a delay in the device being initiated or be a barrier to it being used altogether.

Despite being in the same department, the three observed wards all kept different devices and levels of stock, with one ward having no evidence of any devices in their stock rooms. There appeared to be a connection between stocking the devices, and staff being aware of what they had access to and when they should be used, although there was no evidence that this increased usage.

11.2.5 Identification of patients most at risk

Recognition of a patient group at high risk of developing a heel pressure ulcer, where the majority would benefit from a heel-specific device could potentially influence implementation. Fractured neck of femur patients were highlighted in both the TVNS interviews and during the ethnographic study as being a vulnerable patient group for

heel pressure ulcer development, and therefore all should have a device implemented on admission.

There was no explicit awareness in any of the ward staff interviewed of conditions like diabetes or PAD/PVD being a risk factor for heel pressure ulcers (Coleman et al., 2013), and there was no evidence of proactive use of devices for these patients. It could be that fractured neck of femur is the primary condition and reason for admission, and therefore is discussed more and regularly highlighted during handovers, ward rounds and care planning. Therefore, more opportunities for this risk factor to be identified and if missed by the admitting nursing team, identified by someone else and a device initiated. In contrast diabetes and PAD/PVD are secondary morbidities, and therefore less likely to be picked up on as a requirement for a device without knowledge about these being a risk factor for heel pressure ulcer development.

Despite staff being aware of the need for fractured neck of femur patients to have a heel-specific device, this was not routinely observed in practice. There are two possible reasons for this discrepancy:

1. Most of the fractured neck of femur patients observed were later in their post-operative recovery journey: it may be that a device had been used when the patients were first admitted, but was no longer required at the time of observation, hence heel-specific devices had been used and subsequently discontinued. This could not be explored further as patient length of stay was not recorded as part of the documentation review. Furthermore, the use of heel-specific devices was not documented in the medical or nursing notes for any of the patients on any of the wards, despite there being a section in the pressure ulcer prevention care plan.
2. Despite there being an informal protocol in place, knowledge about when to use them and a stock and supply of the devices, there is a missing mechanism that meant devices were not implemented every time.

There is a vast amount of literature looking at implementation in health care including theories surrounding implementation science such as adoption and diffusion (Institute of Health Economics, 2015), normalisation process theory (Murray et al., 2010) and diffusion of innovations theory (Rogers, 2003). There is also a Cochrane group that focuses on interventions designed to improve professional practice and the organisation of health care service (Cochrane Effective Practice and Organisation of Care (EPOC), 2017). It is therefore not possible to explore all the existing literature, but an overview of some of the relevant literature that could help to identify this missing mechanism will be presented here.

The Institute of Health Economics (2015) looked at factors affecting the adoption and diffusion of medical devices. There was evidence that some of the wards had adopted and diffused heel-specific devices as the decision had been made to accept the need for the intervention and communicated amongst ward staff. However, adoption and diffusion does not necessarily ensure its utilisation; the process of putting the decision to adopt the device into practice is implementation (Rye and Kimberly, 2007).

A number of theories surrounding implementation science in nursing focus on the evidence base (Van Achterberg et al., 2008). The actual level of evidence behind an intervention could hinder implementation if there are doubts about its need and benefits (Grol and Grimshaw, 2003, Van Achterberg et al., 2008). This is not the case here, as despite there being insufficient good quality research evidence to inform the use of heel-specific devices for the prevention (Chapter 3) or treatment (McGinnis and Stubbs, 2014) of heel pressure ulcers, it was known to the researcher that these devices were widely used in clinical practice, and the ethnographic study demonstrated that the devices are being used sporadically. This is in keeping with other wound care and prevention devices that are routinely used in clinical practice despite a poor evidence base. For example alternating pressure mattresses are used on approximately 10-20% of hospital beds without the evidence to support their use (McInnes et al., 2015, Nixon et al., 2019) and negative pressure wound therapy is widely used for the treatment of complex wounds, also without any robust evidence (Arundel et al., 2016, Dumville et al., 2015).

Van Achterberg et al. (2008) identified a contextual factor where the integration of a protocol into wider structures and processes within an organisation, can improve implementation. In the context of the orthopaedics department observed, this could involve embedding the devices into the admission pathway for fractured neck of femur patients. For this to be effective this would require all members of the MDT involved in this pathway to be on board.

11.3 How are heel-specific devices used/not used in clinical practice?

During the TVNS interviews, it was identified that heel-specific devices are used in clinical practice proactively or reactively. The previous section (11.2) covers the proactive use of devices. The reactive use of devices is to prevent deterioration of early signs of pressure ulceration, or as a treatment once a heel pressure ulcer has occurred.

The TVNSs viewed offloading devices as being a third line approach to pressure ulcer prevention, following repositioning and dynamic mattress use. Only if these were not meeting the needs of the patient, or they were unable to tolerate or be concordant with the repositioning plan or mattress use would they consider the addition of a heel-specific device, in a reactive manner.

Chapter 8 surmised that offloading devices are not suitable for all patients, at every point in their inpatient journey; mainly being useful during the acute phase when patients are unwell and bedbound, and becoming less effective during the rehabilitation phase as patients start to mobilise. Fractured neck of femur patients are an example of this, with ward staff describing how they would use a device when the patient is admitted and immediately post operatively.

Heel-specific devices were also identified during the TVNS interviews as not being suitable for patients who were sitting out and a falls risk, something that was observed, with two patients with heel devices having them removed when sitting out.

There is evidence of the devices being perceived by patients as hot, uncomfortable, and restricting movement (Gilcreast et al., 2005, Donnelly et al., 2011, Bååth et al., 2016), and this was acknowledged by the TVNSs. Examples were given of nurses attempting to improve comfort and therefore compliance, through using items like pillowcases to line the devices, so the skin was not in direct contact with the device. This reduces the effectiveness of the devices, but we do not know by how much.

During the ethnographic interviews it was found that staff referred to all heel-specific devices as ‘offloading’, although they were not all viewed equally. Despite there being no evidence of effect for offloading versus CLP devices, there appeared to be a preference for offloading boots for ‘higher risk’ patients, or those already with a pressure ulcer over CLP for ‘medium risk’ patients.

11.4 Strengths of the research

The strengths and limitations of the systematic review are presented at the end of Chapter 3. Additionally it should be acknowledged that a thorough knowledge of existing research, especially that gained through systematic reviews, should be used to design future studies (Liberati et al., 2009), which was the basis for this thesis.

Realist evaluation is a relatively new methodology which originated in social policy in the 1990s, but more recently is being used more to evaluate healthcare systems. This methodology was selected as it was acknowledged that my own knowledge and clinical experience was relevant and needed to be included. Research needs to reflect the reality of clinical practice which was incorporated throughout this thesis.

Not many examples have been found regarding the use of realist methodology to evaluate pressure ulcer preventative strategies; Teo et al. (2019) used a realist case study approach to explore nursing staff's pressure ulcer preventative strategies but little was mentioned about the use of devices and nothing was discussed regarding heel pressure ulcer prevention. Harris et al. (2019) looked at intentional-rounding strategies as a method to improve engagement between nurses and patients, which included but did not focus on pressure ulcer prevention strategies. This is the first realist evaluation to focus on the use of devices in pressure ulcer prevention or that focused on the prevention of heel pressure ulcers.

The first part of the realist evaluation involved interviews with TVNSs who were recruited purposefully through personal and national Tissue Viability Networks. This allowed for timely recruitment of TVNSs from across the UK and the recruitment target was easily met. It was felt that interviewing over the telephone did not diminish the quality of the interviews and was more time and cost efficient than travelling to conduct face to face interviews. The TVNS interviews provided a rationale behind their use of offloading devices, as professional knowledge is often implicit and intuitive, especially in the absence of robust research evidence.

During the ethnographic study consent was obtained though written, witnessed verbal consent or consultee agreement. This allowed inclusion of all patients at risk of developing a heel pressure ulcer including those with receptive, comprehension, language difficulties, general cognitive impairment affecting their understanding and/or dementia (Jaul et al., 2017, Jaul and Meiron, 2017), in a way that is both meaningful and ethically sound.

The unit of observation was debated in Table 9-2 and it was decided to observe the bay. This gave more insight into the patient experience along with allowing for a wide range of job roles to be observed. If an individual member of staff had been the unit of analysis more information might have been gained about staff interactions and communication, but the importance of the HCA role in pressure ulcer prevention might not have been identified, along with the emergence of an MDT approach to pressure ulcer prevention; with physiotherapists being observed performing and documenting skin assessments.

Other than evaluations into the effectiveness of the devices for the prevention of heel pressure ulcers, there is little research about how heel-specific devices are used (and not used) in clinical practice, and little evidence has been found regarding their use as part of standard pressure ulcer preventative care. Only two observational studies were identified that described standard pressure ulcer preventative care practices which

included heel pressure ulcer prevention (Hoviattalab et al., 2015, Özdemir and Karadag, 2008) and are summarised in Table 11-1.

Table 11-1 Summary of standard care in observation studies

	Location	% on a high-risk mattress	High risk foam	Powered air mattress	Heel device used
This thesis	Orthopaedics in England	100%	84.4%	15.6%	15.6%
Hoviattalab et al. (2015)	Medical and surgical wards in Germany	43.8%	Unknown	Unknown	40% 'heels lifted'
Özdemir and Karadag (2008)	Intensive care in Turkey	86.7%	Unknown	Unknown	53.3% 'lifting heels'

Neither study stated how the heels were lifted, demonstrating that this something that is seldom reported on and is therefore new knowledge. This thesis also gives a detailed description of what standard care looks like.

Leadership of the ward emerged as an important mechanism to raise staff awareness regarding the proactive use of heel-specific devices. There was evidence of the ward leaders influencing practice through developing and maintaining an informal protocol to give clarity to staff about when the devices should be used that was specific to their patient population. There was also evidence of staff gaining more knowledge about the devices through authority, tenacity, and a community of practice within the ward rather than through formal teaching. This is not new knowledge but is in keeping with other research and supplements a small body of evidence that clinical areas with strong leadership, a positive attitude towards pressure ulcer prevention and role modelling is essential for staff to work effectively and delivery of good pressure ulcer preventative care (Hommel et al., 2017, Spilsbury et al., 2008).

11.5 Limitations of the research

This was the researcher's first time conducting and analysing qualitative research interviews. There would be times during the analysis where it would be noted that one of the TVNSs had said something relevant, which should have been followed up on, but was missed. This is likely due to inexperience and concentrating on the next questions, rather than actively listening to the responses of the participants; something that was learnt from and applied in the ethnographic interviews.

As described in Chapter 5, due to the iterative nature of realist evaluation a preliminary analysis of each interview was performed before the next would take place. Due to the timescale of the interviews, only a basic analysis was performed, and a full analysis at the end. A more thorough analysis between each interview might have also given greater depth in the latter interviews.

In the TVNS interviews, the use of a heel-specific campaign was highlighted as a method of improving device use. However, the wards in the observed hospital had no heel-specific pressure ulcer prevention campaign led by the TVNSs, just what the Ward Managers had devised or led upon. If a different hospital was observed that did have a heel-specific campaign it might have been possible to compare and contrast whether there was any link to device use, staff knowledge and the influence of the TVNS on device use.

The observations took place on three orthopaedic wards in one hospital, and the generalisability of the findings need to be taken into consideration. The identification of a specific patient group that could benefit from a heel-specific device, as the fractured neck of femur patients were identified in orthopaedics, could be transferable to different specialities. The research was also limited to acute care as this was where most of the research evidence, along with the experience of the researcher sits. Heel-specific devices are also used in community care settings, but they are likely to be used differently, primarily using single patient use devices as they will likely be used more long-term for treatment of existing pressure ulcers or for permanently immobile and/or individuals at constant high risk of developing a heel pressure ulcer.

Another limitation of the research is that more patients might have had a device at the beginning of their admission and had since been discontinued, but no patients were observed pre-operative and the number of days post-operative was not recorded. Although there was space in the care plans, no participants had heel-specific devices documented to be able to find out if they had been used previously. Data on the length of stay and acuity of the patients would have given a better picture of the acuity of the wards, where the patients were on the recovery journey along with whether they would have benefitted from a heel-specific device. Sixteen patients with a fractured neck of femur were observed, if they were all immediately post op then this would have evidenced that devices were not being used proactively and therefore the informal protocol was ineffective. However, if the patients were further along the recovery, they might not have needed the devices anymore. On reflection, non-leading questions during the staff interviews could have indicated whether the devices had been used

previously, providing more data on “what devices work for this patient group at which stage of their journey”.

It was decided not to interview patients for this study, as it was felt that there was already data in the literature about patients’ experiences of using offloading devices, but there was an omission of literature surrounding how nurses use, and their thoughts on, the devices. The inclusion of patients was limited to observations and record review, and although useful insights of the interactions between patients and staff were gained, if the patients had been interviewed, they might have been able to recall whether they had heel-specific devices previously, or if this had been discussed. Also, as the observations were just in the bay, and care that took place behind the curtains were not observed made it difficult to tell if the heels had been repositioned. It was not possible to tell if the patients had a device in place, or if the heels were offloaded with a pillow when the legs were covered with a blanket, so the assumption was made that unless a device was seen in use, then they were not in place. Involving the patients in the observations could also have given insight into whether the patients perceived the nurses to care for the heels differently when the device was in place, for example if they felt the ward staff repositioned them more due to the device, or opinions and perceptions ward staff might have disclosed to the patients or other members of staff about the devices.

There could be a possible selection bias due to the observed bays being selected based on which patients could be consented. As many different bays as possible were observed across the observation period, however if patients did not have relatives or carers visiting, they were more difficult to recruit. Although there was an option to assent via nominated consultee, it was difficult to find members of the medical team as they were not easily identified on the wards, or if they were seen they were busy with ward rounds or patient care. It was considered whether the ward nurses could have been a nominated consultee, but this was identified as being a potential conflict of interests as they were being observed, along with other members of the MDT.

11.6 Personal reflections

11.6.1 Reflections on being a practitioner researcher

During the PhD I have maintained my clinical practice as a TVNS and developed my role as a clinical academic, trying to blend the separate communities of academia and clinical practice. This is a vital role that can act as a bridge and influence how we develop research that is relevant to clinical practice and can also be influential on the running and recruitment of a trial (Andrew et al., 2008).

As a TVNS the topic for this thesis came about through clinical practice. Whilst going to conferences and meeting with representatives from manufacturers it became clear that there were numerous different devices available promoted for the prevention of heel pressure ulcers, but with little good quality clinical evidence to help inform practitioners. Whilst my experience in clinical practice informed the research question and design, a balance was required between using this knowledge to develop the research and not letting my own opinions cloud my judgement. The choice of realist methodology acknowledged my knowledge and experience as a valid part of the research.

For the key stakeholder interviews, I was able to recruit TVNSs from across the UK due to my knowledge of various networks. The interviews were focused and relevant to those being interviewed, and by being a fellow practitioner I was able to develop a rapport as being one of them, it also meant they were able to describe their practice using language familiar to me, such as trade names for equipment, models of practice and standardised assessments. This enabled a flow of conversation during interviews as I rarely needed to interrupt to ask the TVNS to explain a term or phrase.

When analysing the TVNS interviews, because at times they would be reflecting my own practice and experiences, it would sometimes feel like I would be writing about something that feels obvious to me, but to the non-clinician this is not always known and therefore could be relevant, giving a picture of standard care practices.

I feel that being a practitioner researcher, along with experience of sitting on the School research ethics committee as a student representative, made the ethics process easier. My clinical knowledge of organisational structures and how wards work was beneficial, allowing me to plan for the data collection to be done in an ethically sound way that would minimise impact on staff and their treatment of patients.

During the ethnography I was concerned about the Hawthorne effect and the possibility of my presence influencing practice. This has been evident in previous healthcare observation studies such as in a study of hand-washing among medical staff, where compliance in hand-washing was 55% greater when staff knew they were being watched, compared to when they were not (Eckmanns et al., 2006). I tried not to disclose my role until after the observations had finished, dressing in non-uniform clothing, and introduced myself as a ‘nurse researcher’. When staff were observed on multiple occasions, and therefore had become aware of my job role and research focus, no differences were seen in their practice between observations. During the staff interviews my presence and whether it had consciously altered practice was explored, and overall staff felt that it had not, although some of the more junior members of the nursing team reported feeling nervous about my presence and being watched.

I was also conscious of observer bias during the ethnography. If there is subjective judgement as part of the observation, different observers could get variable results which could lead to bias (Catalogue of Bias Collaboration, 2017). I tried to minimise this through recording in the field notes as factually as possible, but also writing reflections to try and acknowledge some of my personal thoughts and feelings. I did at times find myself having a bias towards Ward 1 as they seemed to be using offloading in a way that is desirable to support my programme theory, and there was evidence that this did work as they appeared to have fewer pressure ulcers than the other two wards, although this was only speculative. However, the aim was to seek to understand the perspectives of others, rather than to judge their behaviours to be correct or incorrect, something that could potentially have been easier to achieve as a non-practitioner researcher.

During one of the observations, I witnessed a trainee nursing associate do an unobserved medication round. As I had recently returned from maternity leave and was not familiar with this role due to it being relatively new, it was only when I investigated afterwards that I discovered that this was a professional misconduct issue on the part of the nurse who had not supervised the trainee nursing associate, requiring me to report it to senior management. If I had not been a practitioner researcher, it would have been less likely that this might not have been identified.

Being a practitioner researcher has not only shaped the construction of the research question and the design of the study, but my knowledge and understanding of acute care and pressure ulcer prevention did influence how the results were interpreted. I would not have been able to immediately step into the interviews and observations without the understanding of the job roles and the routines of the wards I already had. Throughout the thesis I have been explicit about how my dual role as a practitioner researcher has influenced the study design and conduct, along with identifying and addressing any potential biases.

11.6.2 Experiences of the publication process

The systematic review was written according the Cochrane collaboration format and publication standards (Higgins, J.P. and Green, S., 2011) by Cochrane. A protocol was written, accepted and published on 14th March 2014 (Greenwood et al., 2014). The review was conducted according to the protocol and submitted for editorial review on 12th August 2015. Following a thorough and lengthy editorial and peer review process over a period of 20 months, including an updated search in April 2016, the systematic review was not accepted for publication. Feedback included concerns about the reporting of trial quality using GRADE and inclusion of outcome data from a sub-group

of the whole trial population in some cases, where heel pressure ulcer data were extracted from trials of whole-body devices. It was felt that this approach threatened the validity of randomisation as well as reducing power. The planned analysis was included in the protocol, accepted and published by Cochrane, and these issues were not identified during the publication of the protocol (Greenwood et al., 2014), but the developing standards for publication have resulted in this being now tailored for an alternative publication.

It is important to establish if whole body devices such as mattresses and overlays prevented pressure ulcers from developing at the heel. Clinical staff often see mattresses as a first line choice for pressure ulcer prevention, and it would be more efficient and cost effective to use a single device if it prevents pressure ulcers equally to all body sites. Therefore, by establishing whether whole body devices prevent heel pressure ulcers can inform whether, if, and when additional interventions such as heel-specific devices are required. However, no mattress trials were identified that looked specifically at just heel pressure ulcers, therefore 18 trials that reported heel pressure ulcer incidence were included. This is an outcome-based subgroup which there are concerns that their use can lead to misleading results if a particular treatment effect influences classification to the subgroup. This can mask whether the outcome is a true effect of treatment or the result of inherent patient characteristics that led to a particular response (Hirji and Fagerland, 2009).

One of the issues with performing this outcome-based subgroup analysis is that the power to detect clinically meaningful effects is reduced considerably as only heel pressure ulcers were included. This is problematic especially when several of the included studies had a moderate or small sample size to start with. All that were randomised were included in the analysis as per ITT, although assumptions were made that baseline confounding would account for participants with amputations and repositioning or offloading of the heels would be equal in both groups. To be able to perform a meaningful subgroup analysis for this outcome, the guidelines on subgroup analysis by Wang et al. (2007) should have been applied (Hirji and Fagerland, 2009), although this would likely require the support of a statistician.

This was a very frustrating and upsetting experience as a great deal of work and time was invested into the preparation for the review to be published by the Cochrane Library. Professional rejection is a frequent experience in academia with the most prestigious journals and grant applications having low acceptance rates (DeCastro et al., 2013). Fostering resilience and persistence is something that many academics must learn. It was therefore decided to continue with an updated publication of the

systematic review for heel-specific devices in an alternative journal, with an updated protocol published on PROSPERO (Greenwood et al., 2019). The review of whole-body devices will be revisited in the future following consultation with a statistician.

11.6.3 Unexpected /additional findings

The word ‘trial’ was used with interchangeable meanings during the interviews. Three of the TVNSs along with two members of nursing staff during the ethnographic study used ‘trial’ to describe an approach to understanding the effectiveness of a product through a product evaluation, whilst the researcher used ‘trial’ to discuss empirical research. An interpretation of this could be that nurses are not as exposed to the research process, or where there is no research evidence, nurses are attempting to develop their own evidence in a process they believe to be fair and impartial, hence calling it a ‘trial’.

Another unexpected finding was that in the absence of clinical evidence a mechanism through which TVNSs gain knowledge is through networking and seeking the opinions and advice of their peers from outside of their organisation. This could be because the TVNSs are the experts in pressure ulcer prevention for their organisation, therefore turn to others outside of their organisation for peer support and collaborative working.

Chapter 12 Summary and recommendations

12.1 Introduction

This chapter will summarise the key findings for this research, the systematic review followed by the two phases of the realist evaluation: theory elicitation and testing. It will then go on to provide recommendations of further research along with the implications for clinical practice.

12.2 Summary of findings

12.2.1 Systematic review

The aim of this thesis, set out at the end of Chapter 2, was to explore the use of devices in the prevention of heel pressure ulcers, both in terms of their clinical effectiveness but also how they are actually used and perceived in clinical practice. The clinical effectiveness of the devices was explored by conducting a systematic review to meticulously search and summarise the current evidence base.

The primary outcomes of the systematic review are summarised in Table 12-1. Twenty-nine RCTs were identified that provided separate heel pressure ulcer data. Due to the wide range of device types investigated, fifteen different comparisons and a total of eight meta-analyses were performed. A maximum of three RCTs were included in each meta-analysis, and they often had low numbers of participants and were underpowered, which along with the poor quality of most of the included trials, reduced the certainty of the results. Comparisons between heel-specific offloading devices and standard care found a significant difference in favour of offloading for all Categories of heel pressure ulcer, although the quality of evidence was low according to GRADE for ≥Category 1 pressure ulcers, and moderate for ≥Category 2 pressure ulcers.

Secondary outcomes of interest included time-to-heel pressure ulcer development, acceptability of the intervention and cost. These were infrequently reported, and for those trials which did report these outcomes there was insufficient data to be able to combine data. Adverse events were seldom reported. This could be because the outcome of interest is an adverse event itself, however other adverse events that could be attributed to the devices in question need to be reported.

Evidence of effectiveness is not a requirement prior to product marketing for medical devices (Department of Health and Social Care, 2002) therefore a full RCT rarely happens. For the heel-specific device trials included in the systematic review, there were several issues with compliance, withdrawals, and protocol violations. Along with

the mechanical properties of heel-specific devices, variables that can influence how and why they are utilised in practice do not appear to be considered in the included trials.

12.2.2 Realist evaluation phase 1 – Theory elicitation

Realist evaluation was selected as it is a methodology that allows for an exploration of the effectiveness of an intervention, through gaining an understanding of how the causal mechanisms are influenced by both human decisions and actions; asking what works for whom in which situations (Pawson and Tilley, 1997f).

Due to the wide range of devices used in numerous different clinical settings, and the limitations of the thesis, the research was limited to offloading devices in an acute care setting because this was the area where there seemed to be some evidence of effectiveness, but problems with compliance.

The first phase of the realist evaluation consisted of developing candidate theories about the use of offloading devices in acute care. Thirteen theories were developed informed by the systematic review, in combination with personal experiences of clinical practice. These focused-on factors that influence the implementation and use of offloading devices in practice to address the first two research questions. These theories were then refined and added to using interviews with key stakeholders: TVNSs from across the UK. The thirteen candidate theories were refined into three over-arching programme theories.

12.2.2.1 Programme theory one

This theory focused on the proactive use of offloading devices for the prevention of heel pressure ulcers. The TVNSs viewed their role as being central to pressure ulcer prevention and the implementation of offloading devices, providing a link between the contextual levels of the NHS and wider organisation and individual wards. The analysis suggested that the macro context of the organisation and NHS influences the TVNSs through the monitoring of pressure ulcer rates and investigations into severe pressure ulcers, acting as a mechanism for the TVNSs to identify clinical areas or patient populations that would benefit from the proactive use of offloading devices. Subsequently, the TVNSs would source the devices, considering costs and usability, and promote device use in the meso context of the ward through training and education, along with recommending devices for individual patients they would review. The TVNSs focused on training and education as being a large part of their job role, however it remains uncertain whether education can prevent pressure ulcers, or affects the knowledge of healthcare staff about pressure ulcer prevention (Porter-Armstrong et

al., 2018). Other factors that were felt to be influential included accessibility of the devices for ward staff, and leadership.

12.2.2.2 Programme theory two

Programme theory two explored how offloading devices are used reactively, either as a response to signs of early pressure damage to reduce the chance of deterioration, or to treat a pre-existing heel pressure ulcer. Initially it appeared that using offloading reactively was a negative response, in that it was only once a heel pressure ulcer had developed that a device would be implemented, which could be viewed as being 'too late' to prevent the pressure ulcer. However, if the skin to the heel is monitored and early signs of pressure damage are recognised, such as blanching or non-blanching erythema, then initiating a device at this point to prevent deterioration could be an effective way of using the device. This is supported in the study by Vanderwee et al. (2007a) where they saw no difference in pressure ulcer rates when preventative interventions were initiated as a response to non-blanching erythema in comparison to interventions being initiated based on the results of a risk assessment. More research is needed into this as the results seen by Vanderwee et al. (2007a) could be the result of a type II error, and there is also a reliance on correct and timely skin assessments, and ability of staff to recognise the early signs of pressure damage.

Studies into the ability of nursing staff to be able to recognise Category 1 pressure ulcers has been variable, with Sterner et al. (2011) finding visualisation of the skin and using the finger to press the skin to identify blanching erythema was unreliable, whereas Vanderwee et al. (2006) found that interrater reliability to recognise non-blanching erythema was high, with agreement rates for the finger method of 92.1% and 91.7% when using a transparent disk pressed to the skin. There are numerous variables that could lead to the differences seen here such as trial settings, patient types, sample size or the education received by the nursing staff prior to trial. It also reflects the difficulties in assessment and diagnostic uncertainty of pressure ulcers. Vanderwee et al. (2006) did however find skin assessments to be less reliable at the heel compared to the sacrum, which they theorise could be because patients would primarily be in the supine position when assessed, making visualisation of the skin at the heels more difficult. It is also possible that the thicker epidermis of the heel can mask the capillary blood flow and reperfusion in the dermis. Neither of these studies included participants with darker skin tones, in which blanching and non-blanching erythema can be more difficult to detect due to the higher concentration of melanin in the skin (Sprigle et al., 2003).

Table 12-1 Summary of systematic review findings

Comparison	Intervention	Control	Primary outcome	Number of participants (studies)	Relative effect (95% CI)	Quality of evidence (GRADE)	Comments
1	AP mattress	Standard hospital mattress	Category 1 or above heel PU	413 (3 RCTs)	RR 0.77, (0.27 to 2.16)	Very low-quality evidence	Downgraded once for design & execution due to attrition bias although there was also poor reporting within these studies; downgraded once for imprecision due to small sample size and wide 95% CI that crossed no effect.
			Category 2 or above heel PU	306 (2 RCTs)	RR 0.68, (0.14 to 3.35)	Very low-quality evidence	Downgraded once for design & execution due to attrition bias and lack of blinding, downgraded once for imprecision due to small sample size and wide 95% CI that crossed no effect
2	AP mattress	CLP mattress	Category 1 or above heel PU	219 (2 RCTs)	Not possible to pool		One trial reported total number of heel pressure ulcers rather than participants with a heel pressure ulcer
			Category 2 or above heel PU	587 (2 RCTs)	Not possible to pool		Interventions were clinically heterogenous therefore not pooled
3	AP mattress with multi-stage alternating cycles	AP mattress with single stage alternating cycles	Category 2 or above heel PU	610 (1 RCT)	0.64, (0.18 to 2.23)		No clear difference
4	AP replacement mattress	AP overlay mattress	Category 2 or above heel PU	1972 (1 RCT)	1.05, (0.55 to 1.98)		No clear difference
5	High spec. foam mattress	Standard hospital mattress	Category 1 or above heel PU	1729 (1 RCTs)	RR 1.09, (0.18 to 6.49)		No clear difference

Comparison	Intervention	Control	Primary outcome	Number of participants (studies)	Relative effect (95% CI)	Quality of evidence (GRADE)	Comments
			Category 2 or above heel PU	145 (2 RCTs)	Not possible to pool		One trial reported total number of heel pressure ulcers rather than participants with a heel pressure ulcer
6	New high spec. foam mattress	Old high spec. foam mattress	Category 2 or above heel PU	100 (1 RCT)	RR 0.33, (0.01 to 7.99)		No clear difference
7	High spec. foam mattress	High spec. foam mattress	Category 1 or above heel PU	105 (1 RCT)	Unknown		Reported total number of heel pressure ulcers rather than participants with a heel pressure ulcer
8	Sheepskin overlay	Standard hospital mattress	Category 1 or above heel PU	297 (1 RCT)	Unknown		Reported total number of heel pressure ulcers rather than participants with a heel pressure ulcer
9	Static air overlay	High spec. foam mattress	Category 2 or above heel PU	124 (2 RCTs)	RR 0.34, (0.07 to 1.60)	Low quality evidence	Downgraded once for design & execution due to lack blinding, downgraded once for imprecision due to small sample size and wide 95% CI that crossed no effect.
10	CLP air mattress	Standard hospital mattress	Category 1 or above heel PU	40 (1 RCT)	RR 0.18 (0.01 to 3.56)		No clear difference
11	Specialist mattress overlay	Visco-elastic overlay	Category 1 or above heel PU	50 (1 RCT)	0 in both groups		No difference
12	Heel-specific offloading device	Standard care	Category 1 or above heel PU	492 (3 RCTs)	RR 0.20, (0.05 to 0.80)	Low quality evidence	Downgraded once for design & execution due to lack blinding, downgraded once for imprecision due to small sample size.

Comparison	Intervention	Control	Primary outcome	Number of participants (studies)	Relative effect (95% CI)	Quality of evidence (GRADE)	Comments
			Category 2 or above heel PU	422 (2 RCTs)	RR 0.08, (0.01 to 0.67)	Moderate quality evidence	Downgraded once for design & execution due to lack blinding.
13	Heel-specific offloading device	Heel-specific offloading device	Category 1 or above heel PU	124 (2 RCTs)	Not possible to pool		Controls were clinically heterogenous and number of participants in each intervention group was not disclosed for one trial
14	Heel-specific offloading device	Heel-specific CLP device	Category 1 or above heel PU	338 (1 RCT)	RR 1.42, (0.40 to 5.07)		No clear difference
15	Heel-specific CLP device (dressings)	Standard care	Category 1 or above heel PU	833 (3 RCTs)	RR 0.30, (0.05 to 1.63)	Very low-quality evidence	Downgraded once for design & execution due to lack blinding, downgraded once for inconsistency due to high I^2 and $P<0.05$, downgraded once for imprecision due to small sample size and wide 95% CI that crossed no effect
			Category 2 or above heel PU	446 (1 RCT)	RR 4.83 (0.57 to 41.0)		No clear difference

Higher prevalence rates have been reported in people with darker skin tones (VanGilder et al., 2010, VanGilder et al., 2008), which could be due to a failure to identify early signs of pressure damage, leading to a delay in the implementation of preventative care. Therefore, as well as being able to recognise non-blanching erythema, healthcare staff need to be aware of the indicators of early pressure damage in individuals with darker skin, which includes localised heat, oedema and a change in the consistency of tissues in relation to surrounding area (EPUAP et al., 2019). This is important for the successful use of offloading devices reactively in clinical practice, with the discriminant ability of staff to be able to recognise early signs of skin damage in all patients in a timely manner essential.

12.2.2.3 Programme theory three

This theory explored patient factors that could influence how offloading devices are used or not used. It was established that offloading is not suitable for every patient who is at risk of developing a heel pressure ulcer, nor is it suitable at all time points during a patient's journey, so the question is "What works for each patient at which part of their journey". Individual patient preferences, and risk factors need to be taken into account when implementing an offloading device and working with the patient can improve concordance.

Patients at risk of falling were discussed as a patient group potentially unsuitable for offloading. Only six trials included in the systematic review reported adverse events (3.2.3.3), and only Donnelly et al. (2011) reported falls; both groups experienced falls and none were attributed to a device. Despite the lack of evidence, it is recognised that they could become a trip hazard in ambulatory patients, however it was agreed that offloading should be primarily used when patients are in bed and removed as patients recover and become more mobile.

Comfort issues were reported by the TVNSs as a major factor affecting patient concordance, likewise Donnelly et al. (2011) reported 88 protocol violations related to patients not wearing the device for comfort reasons. Bååth et al. (2016) reported comfort issues such as the device being "sweaty", not being comfortable when side lying, and saw more patient withdrawals in the intervention group than the control but did not give a reason. The TVNSs reported that ward staff would try to be resourceful and collaborate with the patients to improve comfort of the device, and in turn concordance. This would involve things like lining the device with a pillowcase, but this might decrease the effectiveness of the device due to causing a hammocking effect.

12.2.3 Realist evaluation phase 2 – Theory testing

Programme theory 1 was selected to be tested, as it would best answer the research questions set out in Chapter 4. Although patient factors are important when looking at withdrawals and protocol violations, there had already been an attempt to identify these issues, and general feedback was that patients found the devices bulky, hot and restricted movement (Bååth et al., 2016, Campbell et al., 2010, Donnelly et al., 2011). Without changing the design of the devices, the perceptions of the patients cannot be altered, but the contexts and mechanisms through which the devices are implemented, used, and how the nursing staff work with the patients to deal with concordance could help inform practice and future clinical trials.

The ethnographic study took place across three orthopaedic wards within a single hospital in the North of England. Orthopaedics was selected due to having a large proportion of patients at risk of developing a heel pressure ulcer and being a known user of offloading devices.

During the TVNS interviews, training and education was highlighted as being a large part of their job role, and they felt that this was an important mechanism in the proactive use of heel-specific devices. However, within the context of the observed wards and the staff interviews, no formal training and education from the TVNSs was evidenced with regards to heel pressure ulcer prevention or the use of heel-specific devices, and no heel-specific campaign was used within the observed hospital. None of the interviewed members of staff could recall receiving any education about heel pressure ulcer prevention.

Personal preferences of the Ward Manager, along with strong leadership appear to be influential on heel-specific device availability and use. This manifested as an informal verbal protocol to identify which patients required a heel-specific device and when. On two of the wards, patients were identified according to reason for admission, rather than based on individual risk assessments, with fractured neck of femur patients identified as requiring offloading on admission. This informal protocol driven by the Ward Manager and senior members of the nursing team, along with a stock of heel-specific devices, led to staff perceiving themselves to be using the devices proactively. In contrast one participating ward had no devices identified as stock, leadership was not identified through the interviews as influential on device use and there was no protocol in place. Despite this, little difference was observed across the three wards in the use of devices for the prevention of heel pressure ulcers. This is an important finding in this study; the discrepancy between what should have happened, what staff said was happening during the interviews and what was actually observed. This

discrepancy between what members of the nursing team are saying they are doing and what actually happens has been observed in other areas of nursing practice, with Dihle et al. (2006) seeing this during post-operative pain management and (Bolster and Manias, 2010)reported nurses perceived themselves to be conducting medication activities using a person centred approach which was not always observed. One of the possible reasons for the discrepancy suggested by Dihle et al. (2006) was due to an inadequate transfer of knowledge into practice, due to superficial or inadequate knowledge by staff; although it was not possible to establish the level and depth of knowledge with regards to heel pressure ulcer prevention amongst the observed staff.

Although the focus of the realist evaluation was on the use of offloading devices, it was found that both offloading, and heel-specific CLP devices were being used in this hospital. The mechanisms through which the devices prevent a heel pressure ulcer differs; offloading devices aim to completely remove the pressure to the heel whereas CLP devices reduce the magnitude of the pressure by increasing surface area for contact between the heel and the support surface. Despite this, some members of staff referred to all heel-specific devices as 'offloading devices', therefore not differentiating between the mechanistic properties of the devices and would use them in the same manner. However, some members of staff viewed the offloading devices as being 'better' and therefore should be used for higher risk patients and those already with a heel pressure ulcer. The theory changed accordingly to include 'heel-specific' devices, although this does not include dressings or low friction devices as they were not observed in use.

12.3 Recommendations for further research

12.3.1 Future intervention comparisons

The systematic review and meta-analyses summarised a series of mostly poor-quality studies in which patient compliance, methodological quality and low event rates were prevalent. It appeared to conclude that offloading devices, when compared to standard care, were more effective at preventing Category 1 or above (RR 0.20, CI(0.05 to 0.80)) and Category 2 or above heel pressure ulcers (RR 0.08, CI(0.01 to 0.67)), however precision and risk of bias means that this result is likely to need revision in the face of the quality of the research evidence. #. It also remains uncertain whether any of the following prevent heel pressure ulcers:

- Offloading devices when compared to heel-specific CLP devices
- Heel-specific CLP devices, including dressings, compared to standard care
- AP mattresses when compared to CLP mattresses

- AP mattresses or CLP mattresses when compared to standard care

A key priority for future mattress trials should be a requirement to report pressure ulcer incidence by body site. If a mattress is found to reduce the risk of developing a heel pressure ulcer, additional devices might not be required.

The next logical step in developing evidence for heel specific devices, is therefore to strengthen the existing evidence base through high quality, appropriately powered RCT comparing offloading devices and standard care. It could be argued that an RCT with sufficient power that is designed following the CONSORT statement (Begg et al., 1996) would be time consuming, resource heavy and costly. However, the alternative of continuing to use devices in clinical practice without evidence could also be costly if they are ineffective or could be potentially causing harm, such as increasing the risk of pressure ulcers developing to other body sites.

For the generalisability of any future clinical trial, it is important to establish what standard care looks like across all sites: what support surfaces are used, frequency of repositioning including how the feet are repositioned, and the use of pillows to offload the heels,. None of the heel-specific trials included in the systematic review included data regarding mattress type or repositioning frequency in their publications. This research found that devices could act as a visual reminder of the patient's pressure ulcer risk and trigger other interventions. This was something that one TVNS encouraged, using mattresses as a visual trigger that the patient required an intervention care plan bundle. One of the Ward Managers felt that if patients had a heel-specific device in place, staff were more likely to profile the foot of the bed, further relieving pressure to the heels. However, this was not observed in practice, although when patients were in bed with a blanket it was not always possible to tell if there was a device in situ or if the heels were offloaded with a pillow. As it would not be possible to blind the participants or staff to the intervention, if the devices do act as a visual reminder of the patient's risk and therefore increase other pressure ulcer preventative interventions this needs to be considered as a potential confounding variable. A pragmatic trial design would consider this in the sum of total effects of the intervention but would not disentangle them or identify the relevance of these factors.

Standard care in some clinical areas included using pillows to reposition or offload the heels. However, as heel-specific devices are used as a replacement, it is unlikely that pillows would be used in both arms, so they could be an intervention if used routinely in the control arm. It is not known if pillows prevent heel pressure ulcers, therefore if a protocol specified not to use pillows as part of the control, this could have ethical

implications, as well as staff not wanting to recruit if they believe this could increase the risk of the control group developing a heel pressure ulcer.

12.3.2 Implications for research design

Although the focus of this research was on heel-specific devices for the prevention of heel pressure ulcers, this thesis has demonstrated the benefits of performing a realist evaluation prior to performing a clinical trial, a method that could be transferrable to other device trials. Increasing our understanding of the mechanisms that influence device use in different contexts will inform trial design, which in turn could improve trial compliance. Other researchers have successfully used realist evaluation as part of a feasibility study to inform trial design (Fletcher et al., 2016, Randell et al., 2020). How this thesis will influence the design of future heel-specific device trials will be discussed further.

This research identified that heel-specific devices are viewed as a third line intervention, following repositioning and mattress use. The context of different care environments, patient factors and dynamics of the nursing teams could also be influential on the utilisation and effectiveness of the intervention. A realist RCT would aim to determine if it were the intervention itself, or a combination of factors that implemented the change, whilst a pragmatic trial design would be beneficial to mimic usual practice, with the mattress and repositioning needing to be considered alongside a heel-specific device, which could be done in the form of a pragmatic realist RCT.

The second phase of the PhD used realist evaluation prior to a potential clinical trial to try and inform the trial question, trial development, intervention compliance and feasibility. Although the focus was on offloading devices, it was identified that nurses used heel-specific CLP devices, CLP foam pads and offloading devices interchangeably. This research suggests that heel-specific CLP devices might be more frequently used in practice due to their lower costs, usability by patients and nursing staff along with both patient and nursing preferences. A pragmatic two arm intervention trial comparing offloading to heel-specific CLP devices could therefore be more beneficial to reflect clinical practice and address patient and healthcare professional usability as well as cost effectiveness.

12.3.2.1 Clinical equipoise

Grebel & Wilfer 2010 looked at technology adoption and reported that clinicians behave according to preferences that are formed through experience and the influence of champions. Clinical equipoise demands that there should be no rational basis whatsoever for choosing one intervention over the other, and to maintain this during a

clinical trial virtually no information should be available on an intervention under investigation (Olsen, 2000). However, if a trial is conducted for an intervention that is already used in practice, clinicians will have already developed their own opinions and preferences with regards to the effectiveness of the device, and if it is viewed that this device is necessary for their patient they will not want to randomise to a control or a device that they view as inferior. Ward leadership opinion rather than evidence of effectiveness was a key feature in the perceived utilisation of these devices in practice. This suggests that undertaking a trial to compare an offloading or CLP device against standard care may be problematic as nursing teams are not in equipoise. The TVNSs interviewed already had strong opinions on the devices used in their organisations. Clinical equipoise in heel-specific device trials could be difficult to achieve when they are already in routine use. One solution would be conducting a trial in an area where there could be clinical equipoise due to not being familiar with the devices, although as these devices are already widely in use this would be difficult. The solution could be to compare two interventions, rather than an intervention and control, along with engaging with the TVNSs and ward leaders during trial design and set up to address any biases towards an intervention.

12.3.2.2 Gatekeepers

TVNSs view themselves as central for training and education, implementation of devices and a resource for ward nurses. Although the TVNSs were not seen to have much of an impact upon day-to-day ward practice during the observations, they are a resource for wards and often evaluate and introduce new devices. Ward level leadership is also an important consideration for trial design and set up, as it has been previously acknowledged that engaging clinical leaders and senior staff facilitates in the cooperation of all staff during a clinical trial (Spilsbury et al., 2008).

However, what the TVNSs and ward staff think they do, and what they were observed doing were not the same. There is a perception from most of the interviewed TVNSs and ward staff on two of the observed wards that heel-specific devices are in common use, but, they were not. This needs to be considered during trial set up as a potential gatekeeper issue, as there could be compliance issues with device use, as well as contamination issues in a standard care arm.

12.3.2.3 Patient population

To ensure high external validity within a trial, there needs to be a representative sample of the patient population with a broad inclusion criterion, and minimal exclusion criteria. Forty percent of patients screened for inclusion were found to lack capacity,

therefore assent using a personal consultee was demonstrated as a viable option. Including nurses as well as medical staff as a nominated consultee would widen recruitment further, as demonstrated by Nixon et al. (2019). Two of the RCTs included in the systematic review discussed using next of kin or 'surrogates' to consent patients, (Gilcreast et al., 2005, Tymec et al., 1997) but none of the trials discussed capacity. Consideration is needed into whether a patient without capacity would be likely to keep the device on, and whether the device could be a trip or fall hazard.

Immobile patients or those with reduced consciousness would be a suitable patient group to study as they are at high risk of pressure ulcers and would lead to fewer withdrawals and attritions as they would not be able to remove the device, therefore comfort would not be an issue, although there are more ethical implications.

12.3.2.4 Patient and public involvement

Some of the trials included in the systematic review provided anecdotal data about patients' perceptions of offloading devices. Involving patients and public who have experience of heel pressure ulcers, wearing, or using heel-specific devices, as part of a priority setting methodology, might help to identify the key priority questions patients have with regards to heel pressure ulcer prevention, and to aid in the selection of which devices should be tested.

12.3.2.5 Protocol compliance

Heel-specific devices are more likely to stay in place when a patient is bed bound or immobile, therefore a trial should aim to recruit earlier during this 'acute phase' of illness, when the patient is more likely to be immobile. For example, during the ethnography it was theorised that for fractured neck of femur patients, heel-specific devices are more beneficial either pre, or immediately post operatively.

Ease of access to the devices was found to be an important factor limiting their use and having devices available at recruitment could lead to fewer protocol deviations due to incorrect intervention. None of the trials included in the systematic review reported problems with implementation of the heel-specific device (Bååth et al., 2016, Cadue et al., 2008, Campbell et al., 2010, Donnelly et al., 2011, Gilcreast et al., 2005, Tymec et al., 1997). It is assumed that the device was supplied at the point of randomisation in these trials as offloading devices are small enough to be carried and supplied by the researcher, although only Bååth et al. (2016) confirmed this in the methods. This contrasts with mattress trials where the research nurse cannot supply the mattresses due to size, so it is the responsibility of ward staff to ensure that the patient is placed on the allocated mattress. Because of this, two large mattress trials have reported that

10%-17.7% of randomised participants did not receive the allocated intervention (Nixon et al., 2019, Nixon et al., 2006b) which has an impact on intervention fidelity.

This research also showed that most of the direct patient care relating to pressure ulcer prevention was done by HCAs, and therefore including them in the research during trial set up could help to improve compliance with any trial by both the ward and the patient.

12.3.2.6 Safety

There are potential safety implications with the use of heel-specific devices, such as the increased risk of trips and falls so it is important to be aware of these and to monitor.

12.4 Recommendations for clinical practice

No recommendations for practice can be given following the systematic review for heel-specific devices due to the quality of the evidence. Heel offloading devices probably decrease the incidence of Category 2 or above heel pressure ulcers when compared to standard care alone, however this is based on evidence of moderate quality.

This thesis, along with an updated version of the systematic review for publication (Greenwood et al., 2020) found no significant difference in the effectiveness of prophylactic dressings for heel pressure ulcer prevention. The systematic review by Moore and Webster (2018) found that there was a low level of certainty in the use of silicone dressing for the prevention of all pressure ulcers. However, findings from individual studies are being pushed by manufacturers recommending prophylactic dressing for the prevention of heel pressure ulcers (Smith and Nephew, 2020, Mölnlycke, 2020) and recommendations in the EPUAP et al. (2019) guidelines and by Ramundo et al. (2018) are that dressings should be used as an adjunct to heel offloading and other heel pressure ulcer prevention strategies, something not supported by the evidence in this thesis.

No recommendations can be made with regards to the use of support surfaces for the prevention of heel pressure ulcers due to the sparsity and poor quality of the evidence.

A risk assessment should be undertaken to assess the risk of using heel-specific devices when a patient is not in bed, as they could become a fall or trip hazard.

Heel-specific devices can be used proactively in high-risk patient groups, such as the fractured neck of femur patient, or in patients who do not tolerate a dynamic mattress or repositioning plan. They can also be used reactively in patients with early signs of pressure damage, such as blanching erythema to prevent further skin damage, but there is a danger in using this method as pressure ulcers can develop quickly in

patients with multiple co-morbidities, or early signs of skin damage could be missed in patients with darker skin.

Proactive device use can be influenced by having the devices easily accessible, staff being knowledgeable about which patients they are suitable for through an informal protocol initiated and supported by senior members of the ward team. Therefore, when introducing a device to a clinical area, engagement from ward leaders is important and staff knowing when to use the devices could improve device use. It is also important to acknowledge that the majority of pressure ulcer preventative care observed was delivered by the HCAs, therefore even though care planning is the responsibility of the QN, any pressure ulcer prevention improvement interventions should focus on the whole ward.

This thesis has demonstrated that leadership has been found to be a significant influential factor in the use of devices, or other pressure ulcer prevention intervention. Strong leadership gives staff clear expectations of what they should be doing and when. Leadership was also influential in how staff gain their knowledge, through learning through authority and developing a community of practice.

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Appendix A Search Strategy

The following search strategy was used for Ovid Medline and was then adapted accordingly to the other databases searched.

1.exp Beds/

2.(bed or beds or frame*)

3.(mattress* or cushion* or pillow*)

4.(foam*1 or cutfoam or overlay*)

5.(pad or pads or padding)

6.gel*

7.pressure relie*

8.pressure device*

9.pressure redistribution*

10.low pressure support*

11.((constant or alternat*) adj pressure*)

12.((air or water) adj suspension*)

13.(sheepskin* or sheep skin*)

14.foot waffle

15.air bag*

16.(elevat* adj2 device*)

17.static air

18.exp Shoes/

19.(shoe*1 or boot*1 or booties or cup*1)

20.(footwear or foot wear)

21.exp Orthotic Devices/

22.(orthotic adj (device* or therapy))

23.(orthos* or insole*)

24.((contact or walk*) adj cast*1)

25.(aircast or scotchcast)

26.((foot or feet) adj2 pressure)

27.((foot or feet) adj2 protect*)

28.((foot or feet) adj2 device*)

29.(heel* adj2 pressure*)

30.(heel* adj2 protect*)

31.((foot or feet) adj2 device*)

32.(heel* adj2 (lift* or float* or splint* or glove* or suspension or elevat*))

33.(trough* adj2 (leg* or foot or feet or heel*))

34.or/1-33

35.exppressure ulcer/

36.(pressure adj (ulcer* or sore* or injur*))

37.(decubitus adj (ulcer* or sore* or injur*))

38.(bedsore* or bed sore*)

39.or/35-38

40.34 and 39

41.randomized controlled trial.pt.

42.controlled clinical trial.pt.

43.randomi?ed.ab.

44.placebo.ab.

45.clinical trials as topic.sh.

46.randomly.ab.

47.trial.ti.

48.or/41-47

49.exp animals/ not humans.sh.

50.48 not 49

51.40 and 50

Appendix B Risk of bias tables

Bååth et al. (2016)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Computer generated block randomisation that divided interventions and controls amongst the participating patients and ambulance stations"
Allocation concealment (selection bias)	Low risk	Sealed envelopes removed by the Research Nurse from a box kept in the ambulance
Blinding of participants and personnel (performance bias)	Unclear risk	Does not discuss blinding of participants or personnel
Blinding of outcome assessment (detection bias)	High risk	Data collected by 5 research nurses who had training in pressure ulcer grading, but does not appear that they were blinded to the intervention or that there was any inter-rater reliability testing
Incomplete outcome data (attrition bias)	Unclear risk	405 participants were randomised in the ambulance prior to consent, but only 183 participants were included in the analysis as a large proportion of participants were not admitted to hospital or one of the wards involved in the trial. This is unlikely to lead to bias as the intended effect of the intervention is dependent on the participant being admitted to hospital, which cannot be influenced by the randomised allocation
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported
Other bias - were groups similar at baseline regarding the most important prognostic indicators?	Low risk	No significant differences between the 2 groups in terms of age, sex and level of risk. There was a difference in the average length of stay between the 2 groups - 7.9 days in the intervention group and 10.4 days in the control

Berthe et al. (2007)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Unknown method of randomisation; "when a patient was admitted to any of these departments, a mattress was randomly assigned". Randomisation ratio was changed during the trial; "an interim analysis after 3 months showed that participants with the worst Ek scores were more often assigned to a Kliniplot mattress. Therefore, the bed randomisation was modified in favour of

Bias	Authors' judgement	Support for judgement
		the standard mattress by using a 1:2 allocation ratio to circumvent a potential selection bias"
Allocation concealment (selection bias)	Unclear risk	Allocation not discussed
Blinding of participants and personnel (performance bias)	Unclear risk	"The patient and the nurse were not explicitly informed of the type of mattress used" It is unclear if the mattresses could be differentiated
Blinding of outcome assessment (detection bias)	Unclear risk	No information given regarding the outcome assessors
Incomplete outcome data (attrition bias)	Low risk	No withdrawals or participants lost to follow up reported
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported
Other bias - were groups similar at baseline regarding the most important prognostic indicators?	High risk	Allocation ratio was changed to ensure there was a match at baseline of modified Ek's scale (they were only interested in the mobility variable). No other baseline comparisons were reported

Cadue et al. (2008)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Two groups drawn at random using a randomisation table"
Allocation concealment (selection bias)	Low risk	"The distribution being determined following a patient's inclusion by a pre-sealed sequentially numbered envelope included in the observation documents"
Blinding of participants and personnel (performance bias)	High risk	Participants would have been unaware of the intervention as they were sedated, it was not possible to blind personnel
Blinding of outcome assessment (detection bias)	Unclear risk	"Every day, a physiotherapist and a nurse evaluated the extent of lesions on the heels, the sacrum and the calves in accordance with a scale ranging from lesion absence (stage 0) to bone visibility (stage 5)". There is no discussion of whether the physiotherapist and nurse were blinded to the intervention. No inter-rater reliability testing discussed. Appearance of interventions easy to distinguish

Bias	Authors' judgement	Support for judgement
Incomplete outcome data (attrition bias)	Low risk	No withdrawals or participants lost to follow up reported
Selective reporting (reporting bias)	Low risk	All the study's pre-specified outcomes have been reported
Other bias - were groups similar at baseline regarding the most important prognostic indicators?	Low risk	No clear difference between the 2 groups in age, gender, Waterlow scores, weight, BMI, smoking status, DM, arteritis of the lower limbs, sedatives, ventilation, curarization, haemo-filtration and catecholamines. The only significant difference between the 2 groups was in the simplified severity scale II, which was higher in the experimental group

Campbell et al. (2010)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	which of the three devices that the patient received was determined randomly using a table of random numbers"
Allocation concealment (selection bias)	Unclear risk	Not discussed
Blinding of participants and personnel (performance bias)	High risk	Not possible to blind the intervention to the participants and personnel
Blinding of outcome assessment (detection bias)	High risk	A single "Heel pressure ulcer champion" carried out the study, no interrater reliability testing (although no new pressure ulcers were reported)
Incomplete outcome data (attrition bias)	Low risk	72 subjects randomised and pressure ulcer incidence of all 72 participants reported
Selective reporting (reporting bias)	Low risk	All outcomes appear to be reported
Other bias - were groups similar at baseline regarding the most important prognostic indicators?	Unclear risk	Baseline data not given

Cavicchioli and Carella (2007)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Control group not randomised therefore excluded from analysis - treatment arms were randomised but does not state how
Allocation concealment (selection bias)	Low risk	Sealed envelope
Blinding of participants and personnel (performance bias)	Unclear risk	Not discussed
Blinding of outcome assessment (detection bias)	Low risk	"As there is no visible difference between these 2 modes, the external observer was blinded as to which one was in use"
Incomplete outcome data (attrition bias)	High risk	Reasons for attrition and exclusion reported, no ITT analysis
Selective reporting (reporting bias)	Low risk	All relevant pre-specified outcomes reported
Other bias - were groups similar at baseline regarding the most important prognostic indicators?	Low risk	Similar in terms of male to female ratio, age and Braden score at the beginning and end of the trial

Conine et al. (1990)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Only information given: "a modified sequential clinical trial as described by Pocock (1981) was used to assign subjects randomly to one of the two mattresses in groups of 20" does not state how
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias)	High risk	"Although disguising the equipment was impossible, care was taken to control bias by separating the responsibilities for subject selection and assignment and for taking the measures. These duties were carried out by external professional personnel

Bias	Authors' judgement	Support for judgement
Blinding of outcome assessment (detection bias)	Unclear risk	"The research assistant, a professional nurse with tissue trauma experience, was responsible for the assessment of all outcome measures. She was not associated with the institution and was not informed about the study" Does not discuss if participants were blinded
Incomplete outcome data (attrition bias)	High risk	Reasons for attrition and exclusion reported, no ITT analysis
Selective reporting (reporting bias)	Low risk	All relevant pre-specified outcomes reported
Other bias - were groups similar at baseline regarding the most important prognostic indicators?	Low risk	No clear difference between the 2 groups in age, gender, Norton scores, weight, diagnoses, years diagnosed, years of wheelchair use, previous bedsores, sensory loss, spasticity/shearing, incontinence and anaemia

Daechsel and Conine (1985)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of randomisation not reported: "All qualified subjects were entered into the trial for a period of three months and all were randomly assigned to one of the two types of mattress"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias)	Unclear risk	Not reported
Blinding of outcome assessment (detection bias)	Unclear risk	Not reported
Incomplete outcome data (attrition bias)	Low risk	"All were admitted to the trial, and all completed it"
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported
Other bias - were groups similar at baseline regarding the most important prognostic indicators?	Low risk	"Statistical tests of significance indicated that the groups were comparable on the factors that are considered to be associated with the development of decubitus ulcers". However, states "additional preventive aids, such as heel and ankle protectors were used as typically directed by the occupational therapist" for both groups, but we do not know how many heel and ankle protectors were used and how they were separated per group

(Demarre et al., 2012)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random allocation sequence was based on a computer-generated list of random numbers
Allocation concealment (selection bias)	Low risk	When the participant was eligible, and a study mattress was available, they were assigned to one of the mattresses by contacting the researcher (24-hour telephone accessibility). The ward nurse received several the type of allocated mattress
Blinding of participants and personnel (performance bias)	High risk	both mattresses were covered with an identical mattress cover...The study could not be blinded because of the visible differences of the external control unit of the study mattresses". "No information was provided to the ward nurses about the differences between the experimental and control study device, both were presented as alternating pressure air mattresses". No discussion about blinding of the participants
Blinding of outcome assessment (detection bias)	High risk	Daily skin assessment and the risk assessments were performed by the ward nurses. No inter-rater reliability testing. Blinding issues as above
Incomplete outcome data (attrition bias)	Low risk	Reasons for attrition and exclusion reported and ITT analysis done
Selective reporting (reporting bias)	Low risk	All the study's pre-specified outcomes of interest in the review have been reported in the pre-specified way
Other bias - were groups similar at baseline regarding the most important prognostic indicators?	Low risk	Experimental and control group were comparable for all baseline characteristics which included age, weight, height, BMI, Braden score and maximum time sitting and/or transport

Donnelly et al. (2011)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated block randomisation
Allocation concealment (selection bias)	Low risk	Randomisation schedule was held and managed by a senior research nurse manager not directly involved in the study

Bias	Authors' judgement	Support for judgement
Blinding of participants and personnel (performance bias)	High risk	"It was not possible to blind the participants as the intervention was very distinctive. Ward nurses were not blinded and "for pragmatic reasons, mattress type was determined by ward nurses according to perceived need"
Blinding of outcome assessment (detection bias)	High risk	"It was not possible to blind the investigator as the intervention was very distinctive, however there was a blinded inter-rater reliability test; "an experienced tissue viability nurse who was blinded to the subject's history, the investigators assessment of the skin and the group to which the subject had been assigned, viewed photographs of suspected pressure damage, as well as intact pressure points"
Incomplete outcome data (attrition bias)	Low risk	Reasons for attrition and exclusion reported ITT analysis done
Selective reporting (reporting bias)	Low risk	All the study's pre-specified outcomes of interest have been reported in the pre-specified way
Other bias - were groups similar at baseline regarding the most important prognostic indicators?	Low risk	Both groups were comparable at baseline in terms of co-morbidities and the length of time spent lying on a hard surface prior to study enrolment. Subjects in the intervention group had a shorter wait from injury time to theatre, but spent longer in theatre than the control group

Ferrer Sola et al. (2013)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random list generated by computer application
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias)	High risk	Blinding of participants is not stated due to differences in the interventions
Blinding of outcome assessment (detection bias)	Unclear risk	Not reported
Incomplete outcome data (attrition bias)	Unclear risk	Not reported
Selective reporting (reporting bias)	Unclear risk	Not enough information

Other bias - were groups similar at baseline regarding the most important prognostic indicators?	Low risk	Both groups were comparable at baseline in terms of demographic and clinical characteristics, including age, sex, Braden score, dementia, diabetes, infection, and other ulcers

Gilcreast et al. (2005)

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"A set of 21 cards were prepared in advance, 7 with each intervention on them. These were placed in identical envelopes and shuffled 3 times. The first card was taken from the box once a participant had been enrolled"
Allocation concealment (selection bias)	High risk	Assignment envelopes were not sequentially numbered. Does not state who kept the cards or who would do the allocation
Blinding of participants and personnel (performance bias)	High risk	Due to the nature of the intervention, it is likely that it would not be possible to blind the participants or personnel
Blinding of outcome assessment (detection bias)	High risk	"The 1 nurse was performing all research tasks and was not blinded to the device to which the participant was assigned". "Interrater reliability for assessment and staging of pressure ulcers was obtained by the concurrent assessment of 10 patients' by the 2 RNs"
Incomplete outcome data (attrition bias)	High risk	"53 subjects were eliminated from the analysis because they did not wear the devices for at least 48 hours. 24 of these subjects were eliminated because of early discharge from the hospital and only 24 hours in the study. The others were dropped because either they did not want to wear the devices, or the devices were not replaced by family members or staff after patient-care activities as requested". 338 subjects randomised, 240 had complete data and included in the analysis, it is unclear how many participants were initially randomised to each group and therefore which arms the dropouts came from. No ITT analysis done
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported
Other bias - were groups similar at baseline regarding the most important prognostic indicators?	Unclear risk	The distribution of gender was not equal between groups. No other baseline demographics reported

Gray and Smith (2000)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of randomisation unknown: "Individuals who met the entry criteria were randomised to a control or trial mattress using an opaque envelope"
Allocation concealment (selection bias)	High risk	Randomised using an opaque envelope; but unclear who performed the randomisation, where the envelopes were stored and if they were sequentially numbered and sealed
Blinding of participants and personnel (performance bias)	Unclear risk	Does not discuss whether the participants and personnel were blinded to the intervention
Blinding of outcome assessment (detection bias)	Low risk	The two mattresses had similar covers and "tissue damage was assessed by staff who were unaware of which mattress the subject was using"
Incomplete outcome data (attrition bias)	Low risk	Two subjects from the control group were withdrawn from the trial due to the mattress covers being torn. ITT analysis performed
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported
Other bias - were groups similar at baseline regarding the most important prognostic indicators?	Low risk	States that the groups were comparable in terms of age, sex, risk (Waterlow score) and length of time spent in bed

Gunningberg et al. (2000)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"on arrival in A&E patients with a suspected hip fracture were randomised to an experimental or control group with allocation concealment"
Allocation concealment (selection bias)	Unclear risk	As above, states allocation concealment but not how
Blinding of participants and personnel (performance bias)	High risk	It is assumed that due to the nature of the intervention the participants were not blinded but this is not discussed. "Although the nurses knew which study group the patient belonged to, there is no reason to suspect that there were any differences in the documentation procedure between them"
Blinding of outcome assessment (detection bias)	Unclear risk	Main outcome not blinded, but 25pressure ulcers in 13 participants were photographed and inter-rater reliability tested by a blinded expert nurse

Incomplete outcome data (attrition bias)	Unclear risk	18 participants were excluded from the study, but it is unclear which arm they were randomised to or at what point they were excluded; "The study included 119 patients.... 18 were excluded because they died (2), did not have a skin assessment documented on arrival (3) were admitted with a pressure ulcer (13). Of the remaining 101 patients, 48 and 53 were allocated to the experimental and control groups, respectively"
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported
Other bias - were groups similar at baseline regarding the most important prognostic indicators?	Low risk	“No significant differences were found between the groups in terms of gender, age, modified Norton scores, waiting time for surgery, time in the operating theatre and other inclusion characteristics"

Hofman et al. (1994)

Bias	**Authors’ judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Each group of 6 consecutively admitted participants were randomly divided into 3 participants nursed on control and 3 on intervention. Does not state how they were "randomly divided"
Allocation concealment (selection bias)	Unclear risk	Allocation concealment not discussed
Blinding of participants and personnel (performance bias)	High risk	It was not possible to blind in respect to the observer or the nurse...because “making the Decube mattress unrecognisable would influence its effectiveness”. It is not discussed if the participants were blinded
Blinding of outcome assessment (detection bias)	Low risk	Outcome assessment not blind to treatment group. Participants were examined 1 and 2 weeks after surgery by 2 physicians independently; disagreement resolved by a 3rd observer
Incomplete outcome data (attrition bias)	High risk	Of the 46 participants randomised, 2 were excluded due to the randomisation not being performed correctly (no further details) both in the intervention group. By week 1, 1 participant had left each group (1 death, 1 discharge). By week 2, a further 3 participants in each group had been discharged or died. It appears that only those remaining were included in the 2-week analysis (n = 17 in cubed foam mattress group and n = 19 in the standard hospital mattress group), no ITT analysis

Selective reporting (reporting bias)	Low risk	Main outcome of interest was occurrence of pressure ulcers and this was recorded
Other bias - were groups similar at baseline regarding the most important prognostic indicators?	Unclear risk	Age and length of hospital stay were similarly matched. Sex and fracture type were not similar at baseline

Matsui et al. (2001)

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"All subjects were randomly divided into 3 groups": method of randomisation not given
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias)	Unclear risk	Not reported
Blinding of outcome assessment (detection bias)	Unclear risk	Three people were trained relating to all data measurements and 2 people would check, does not mention if they were blinded to the intervention
Incomplete outcome data (attrition bias)	High risk	107 participants randomised, 1 participant dropped out of the single layer group due to discomfort and 1 person in the 2-layer group who developed a pressure ulcer (does not specify severity of pressure ulcer) due to the mattress not being plugged in. It does not appear that these participants were included in any analysis
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes appear to have been reported
Other bias - were groups similar at baseline regarding the most important prognostic indicators?	Low risk	All groups were comparable in terms of average age, sex, and diagnosis. There was a significant difference between the groups in CRP results, but it is uncertain how significant this would be

McGowan et al. (2000)

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Stated, "patients were randomly allocated (using sealed envelopes) by research nurses to receive one of two interventions"

Allocation concealment (selection bias)	Low risk	Sequence generation based on sealed envelopes
Blinding of participants and personnel (performance bias)	High risk	It was not possible to blind either the participant or the investigator as the intervention was very distinctive and participants could not be moved from their beds for skin assessments
Blinding of outcome assessment (detection bias)	High risk	Two registered nurses were employed as research nurses who undertook all the assessments. One of the investigators undertook regular inter-rater reliability comparisons
Incomplete outcome data (attrition bias)	Low risk	“Data collection for patients up until the time of withdrawal has been included in the analysis with the exception of 5 controls and 2 from experimental group for whom study participation time was not available", ITT analysis performed
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported
Other bias - were groups similar at baseline regarding the most important prognostic indicators?	High risk	More males and more knee replacement surgeries in the experimental group. Other baseline comparisons were similar between the two groups

Nixon et al. (1998)

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Randomisation was stratified by centre (Leeds or Hartlepool) and by age (55 - 69 and ≥ 70). "A telephone randomisation schedule was developed within random permuted blocks of 6, with a run in of 8, and managed by the Northern and Yorkshire Clinical Trials and Research Unit"
Allocation concealment (selection bias)	Low risk	Randomisation schedule held by centre external to the data collectors. "The record pertaining to the intra-operative randomised mattress allocation remained separate from the main data collection pro-forma to maintain the blind"
Blinding of participants and personnel (performance bias)	Low risk	"All pre- and intra-operative data were recorded by the research nurse, and post-operative data recorded by recovery and ward staff who were blind to the intra-operative mattress allocation". Does not discuss if the participants were blinded to which intervention they received, but they would have been under anaesthetic whilst the intervention took place

Bias	Authors' judgement	Support for judgement
Blinding of outcome assessment (detection bias)	Low risk	"All pre- and intra-operative data were recorded by the research nurse, and post-operative data recorded by recovery and ward staff who were blind to the intra-operative mattress allocation"
Incomplete outcome data (attrition bias)	Low risk	The main endpoint was determined for 416 participants, with incomplete data for 30 participants. A sensitivity analysis was carried out assuming that the participants with missing endpoints were in fact failures and reported that the effects of the 2 mattresses were "in the same direction as that in the main analysis". ITT analysis performed
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported
Other bias - were groups similar at baseline regarding the most important prognostic indicators?	Low risk	Standard mattress group: longer length of operation, longer preoperative stay, more time in hypotensive state than dry polymer pad group. Adjusted analysis was performed to consider these differences

Nixon et al. (2006b)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Randomisation was through an independent, secure, 24-hour randomisation automated telephone system, ensuring allocation concealment...we used minimisation, so groups were comparable"
Allocation concealment (selection bias)	Low risk	Randomisation was through an independent, secure, 24-hour randomisation automated telephone system, ensuring allocation concealment
Blinding of participants and personnel (performance bias)	High risk	"It was not possible to mask the randomised intervention to the patients participating in the trial, ward nursing staff or clinical research nurses conducting the skin assessments...To minimise the potential for bias it was planned that qualified ward-based nursing staff would record daily skin assessments and clinical research nurses would undertake assessments twice weekly to validate ward staff records, ward staff remaining blind to the CRN record"

Bias	Authors' judgement	Support for judgement
Blinding of outcome assessment (detection bias)	Low risk	"the main limitation of our trial was the lack of blinded outcome assessment". Inter-rater reliability assessments and data quality monitoring identified problems associated with the accuracy and completeness of the ward-based nurses records....it was therefore recommended that the clinical research nurse assessments were used for the trial analysis but neither the clinical research nurses not the ward nurses were informed of this decision
Incomplete outcome data (attrition bias)	Low risk	ITT analysis conducted
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported
Other bias - were groups similar at baseline regarding the most important prognostic indicators?	Low risk	Groups were comparable at baseline, no concerns

Ozyurek and Yavuz (2015)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation was performed through an independent, secure, 24-hour randomisation automated telephone system. "We used minimization so that groups were parallel"
Allocation concealment (selection bias)	Low risk	Secure and independent automated telephone system ensuring allocation concealment
Blinding of participants and personnel (performance bias)	High risk	Nurses were not blind to participant assignments. Does not discuss blinding of participants
Blinding of outcome assessment (detection bias)	High risk	"The main limitation of this trial was the lack of blinded outcome assessments; it was difficult to mask viscoelastic support surfaces and it would be unethical to frequently move critically ill participants from bed to bed"
Incomplete outcome data (attrition bias)	High risk	Randomised n = 357, however only 105 were included in the analysis. Reasons for loss include hospitalised for less than 7 days (n = 245), lost to follow up (n = 29), without risk/no limitation of movement minimum 3 days after surgery (n = 6) and discontinued intervention (n = 1). Does not appear to have an ITT analysis

Bias	Authors' judgement	Support for judgement
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported
Other bias - were groups similar at baseline regarding the most important prognostic indicators?	High risk	Viscoelastic foam 2 had significantly lower GCS scores, and viscoelastic foam 1 had significantly more participants with a higher Braden score (15 - 18)

Ricci et al. (2013)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomised according to a computer generated pre-defined assignment list in sealed envelopes
Allocation concealment (selection bias)	Unclear risk	Unknown if the envelopes were opaque, sequentially numbered or who held them
Blinding of participants and personnel (performance bias)	Unclear risk	Does not discuss
Blinding of outcome assessment (detection bias)	Unclear risk	Does not discuss
Incomplete outcome data (attrition bias)	Low risk	Does not appear to be any dropouts or incomplete outcome data
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes addressed
Other bias - were groups similar at baseline regarding the most important prognostic indicators?	Low risk	Participants were comparable in terms of age, gender, and other demographic and clinical characteristics with no significant differences between the two groups

Russell et al. (2000)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	States double blinded, but does not state how
Allocation concealment (selection bias)	Low risk	"Randomisation was done blindly using a sealed opaque envelope that contained the randomisation information"

Bias	Authors' judgement	Support for judgement
Blinding of participants and personnel (performance bias)	Unclear risk	Does not discuss
Blinding of outcome assessment (detection bias)	Unclear risk	Does not discuss
Incomplete outcome data (attrition bias)	High risk	Stated that they did ITT, but is inaccurate: "ITT sample included all patients who signed consent forms and who were placed on either (mattress) and had at least one day of observations post-surgery"
Selective reporting (reporting bias)	Low risk	The pre-specified outcomes of interest have been reported
Other bias - were groups similar at baseline regarding the most important prognostic indicators?	Low risk	Baseline characteristics were comparable in terms of major physiological and demographic characteristics

Sanada et al. (2003)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Random allocation" Does not state how
Allocation concealment (selection bias)	Low risk	Random allocation by sequentially labelled sealed envelopes
Blinding of participants and personnel (performance bias)	High risk	The subjects were blinded to which surface they were receiving; the participating nurses could not be blinded because they needed to change and inspect the bedding. The nurses were unaware of the efficiency of the support surfaces used
Blinding of outcome assessment (detection bias)	Unclear risk	Does not discuss if the outcome assessors are blinded to the intervention or if anything was done to attempt to minimise this bias
Incomplete outcome data (attrition bias)	High risk	"A total of 123 patients were recruited to this study, of which 41 patients withdrew before completion. Reasons for withdrawal included some patients not requiring head elevation, some patients refusing to accept head elevation as part of their treatment, and others asking to be withdrawn." 15 were excluded before randomisation and 26 after. No ITT analysis

Bias	Authors' judgement	Support for judgement
Selective reporting (reporting bias)	Low risk	The pre-specified outcomes of interest have been reported
Other bias - were groups similar at baseline regarding the most important prognostic indicators?	Low risk	No clear difference on prognostic indicators at baseline between groups

Santamaria et al. (2013)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Retrieving the next envelope in a pre-prepared series of envelopes that had been randomised using a computer-generated set of random numbers to determine group allocation"
Allocation concealment (selection bias)	Low risk	"The randomisation of participants was undertaken by an ED research nurse when the patient was admitted to the ED and following screening to determine if they met the inclusion criteria, they would then determine group allocation by retrieving randomisation envelope". These envelopes were sequentially numbered and kept in a locked drugs cabinet
Blinding of participants and personnel (performance bias)	High risk	Participants were likely to be unaware of the intervention, however the data collectors and staff caring for the participants could not be blinded to the nature of the treatment interventions.
Blinding of outcome assessment (detection bias)	High risk	The only data collectors who assessed the participants daily were members of the study team and each had undergone inter-rater testing for staging pressure ulcers prior to the commencement of the study, but does not state if they were blinded
Incomplete outcome data (attrition bias)	Unclear risk	States that "the analysis was based on ITT where all patients randomised to the intervention were analysed regardless of protocol violations". However, there were several patients who were randomised but didn't go to ICU, and patients who went to ICU but were discharged prior to first pressure ulcer assessment, who were not included in the analysis
Selective reporting (reporting bias)	Low risk	The pre-specified outcomes of interest have been reported

Bias	Authors' judgement	Support for judgement
Other bias - were groups similar at baseline regarding the most important prognostic indicators?	Low risk	Baseline characteristics were comparable in terms of major physiological and demographic characteristic

Takala et al. (1996)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Only 2 patients could be studied simultaneously, consecutive eligible patients were randomised to one of the two study mattresses..." The participants were randomised in blocks of four. When two participants were on the special mattress, the randomisation was paused until further availability
Allocation concealment (selection bias)	Low risk	Opaque sealed envelopes were used, and the randomisation was done by a person not involved with the trial
Blinding of participants and personnel (performance bias)	High risk	"Type of mattress could not be blinded"
Blinding of outcome assessment (detection bias)	High risk	"This study was not blinded since the severity of the illness of the patients precluded their transfer for evaluation of the skin condition by a blinded reviewer. There is some evidence that there was an attempt to blind some of the outcome assessments as it states "All sore areas were measured and photographed for independent verification of severity"
Incomplete outcome data (attrition bias)	Low risk	All 40 participants recruited were included in the ITT analysis, however numerous withdrawals were reported: "10 patients were randomised but not treated due to either early discharge or death, and so were included in the ITT analysis. 6 patients randomised on the pressure relieving mattress were included only in the ITT analysis, since the start of treatment was delayed due to mattress non-availability due to delayed discharge of patients already in the study. Accordingly, 40 patients were included in the ITT analysis and 24 patients were included and treated according to the protocol"
Selective reporting (reporting bias)	Low risk	The pre-specified outcomes of interest have been reported

Bias	Authors' judgement	Support for judgement
Other bias - were groups similar at baseline regarding the most important prognostic indicators?	Low risk	Treatment groups similar at baseline, however, not compared for degree of pressure ulcer risk

Torra i Bou et al. (2002)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Participants were allocated using a list of random numbers. It is not clear how the random number list was generated
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias)	Unclear risk	Not reported
Blinding of outcome assessment (detection bias)	Unclear risk	Does not mention who the outcome assessors were and if any measures were taken to minimise bias
Incomplete outcome data (attrition bias)	High risk	130 participants included in the study (65 in each arm) but only 111 completed. 1 person not accounted for "6 people from the bandage group died and 8 left the study ... which left 50 still in the group at the end of the study". Four deaths were reported in the dressings group leaving 61 participants at the end of the study. No ITT analysis
Selective reporting (reporting bias)	Low risk	The pre-specified outcomes of interest have been reported
Other bias - were groups similar at baseline regarding the most important prognostic indicators?	Unclear risk	The two groups were comparable at baseline "once the inclusion of patients with diabetes was rejected"

Tymec et al. (1997)

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Assignment to either pillow or Foot Waffle was undertaken "...using a block randomised list" and the participant's position order "...was determined by a coin toss"
Allocation concealment (selection bias)	High risk	Coin toss is not possible to blind allocation
Blinding of participants and personnel (performance bias)	Unclear risk	Not reported
Blinding of outcome assessment (detection bias)	Unclear risk	Does not mention who the outcome assessors were and if any measures were taken to minimise this bias
Incomplete outcome data (attrition bias)	Unclear risk	52 participants (23 women and 29 men) in the study, but nowhere was the number in each group reported. 8/52 participants developed a pressure ulcer, which was a completion criterion of the study, so it appears that all participants were followed up
Selective reporting (reporting bias)	Low risk	Pressure ulcer occurrence mean survival time (i.e., time until one occurred), and mean interface pressures were reported. These are all meaningful outcomes
Other bias - were groups similar at baseline regarding the most important prognostic indicators?	Unclear risk	No participant characteristics provided

Van Leen et al. (2011)

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Randomisation was performed using numbered envelopes, unclear if sealed or opaque
Blinding of participants and personnel (performance bias)	Unclear risk	Not reported

Bias	Authors' judgement	Support for judgement
Blinding of outcome assessment (detection bias)	Unclear risk	"A weekly inspection of the skin ... was done by an independent nurse" but it does not state if this person was blinded to the intervention
Incomplete outcome data (attrition bias)	Low risk	9 participants died during the trial; all were included in the statistical analysis
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes appear to have been reported
Other bias - were groups similar at baseline regarding the most important prognostic indicators?	Low risk	"More patients in the static air group had a very low Norton score…further relevant differences were encountered between both groups"

Van Leen et al. (2013)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Randomisation was performed using numbered envelopes, does not state if opaque or sealed
Blinding of participants and personnel (performance bias)	Unclear risk	Not reported
Blinding of outcome assessment (detection bias)	Unclear risk	Not reported
Incomplete outcome data (attrition bias)	Low risk	In total 5 participants died during the study period, 3 in the first 6-month period. Participants who died during the first 6-month period were included in the analysis
Selective reporting (reporting bias)	Low risk	The pre-specified outcomes of interest have been reported
Other bias - were groups similar at baseline regarding the most important prognostic indicators?	Low risk	Due to the crossover nature of the trial each participant serves as his or her own control, but there could have been a "carry-over" effect between both interventions which may have confounded the estimates of the intervention effects, this has been taken into account by only including the data for this trial up until the point of crossover

Vanderwee et al. (2005)

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"...randomisation tables generated with the SPSS 10 software package..."
Allocation concealment (selection bias)	Low risk	"Serially numbered, closed envelopes were made for each participating area. The envelope with the lowest number was opened upon admission of a new patient"
Blinding of participants and personnel (performance bias)	High risk	There was not really an easy option to blind or camouflage the type of mattress, therefore the ward nurse, data nurse and researcher were not blinded to the intervention. Does not discuss if the participants were blinded to the intervention
Blinding of outcome assessment (detection bias)	Low risk	Skin inspections would be done daily by the ward nurses. "A random sample of patients was observed at unexpected moments by both the researcher and the data nurse". The inter-rater reliability for the classification of pressure ulcers between researcher, nursing staff, and data nurse ranged from κ=0.88 (95% CI 0.78–0.97) to κ=0.94 (95% CI 0.91–0.97)
Incomplete outcome data (attrition bias)	Low risk	No dropouts/withdrawals reported. Flow chart showed 447 participants enrolled in total, 297 assessed by Braden and 150 by non-blanchable erythema. Numbers in the results match these
Selective reporting (reporting bias)	Low risk	Published reports include all pre-specified and expected outcomes
Other bias - were groups similar at baseline regarding the most important prognostic indicators?	Low risk	Participants well balanced at baseline.... "Since the groups were similar in all characteristics except medical specialty, this variable was adjusted for in the analysis"

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Appendix C Participant information sheet

An exploration of the use of offloading devices for the prevention of heel pressure ulcers

You are being invited to take part in a research project looking at how offloading devices are used in secondary care for the prevention of heel pressure ulcers. Before you decide whether or not to take part it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully and discuss it with others if you wish. Ask me if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of this study?

The aim of this research project is to explore how offloading devices are used in clinical practice in the prevention of heel pressure ulcers, both in terms of their clinical effectiveness but also how they are actually used and perceived in clinical practice when individual patient preferences, nursing knowledge, resources and care environment are taken into account. This research will aim to inform practice with regards to the use of heel offloading devices when individual patient factors and nursing preferences are taken into account.

Who is doing the study?

The interviews will be conducted by Clare Greenwood, a Clinical Nurse Specialist in Tissue Viability at Leeds Teaching Hospitals. This study will become part of her PhD thesis being conducted at the University of Leeds. This study is being overseen by her PhD supervisors: Prof Andrea Nelson, Prof Jane Nixon, Dr Elizabeth McGinnis and Dr Rebecca Randell.

Who is being asked to participate?

I am looking to recruit Tissue Viability Nurses who primarily work in a secondary care environment as they will have experience of caring for a wide variety of patients at risk of developing pressure ulcers. You have been invited to participate as you will have experience of assessing and implementing a plan of care for patients at risk of developing a heel pressure ulcer, which might or might not include the utilisation of an offloading device.

What will be involved if I take part in this study?

You will be invited to participate in a single telephone interview that will be anticipated to last no more than 60 minutes. These will be arranged at a date and time convenient to you. The interviews will be audio recorded.

We do not anticipate that there will be any risk to you in participating

What are the advantages and disadvantages of taking part?

The main disadvantage to participating will be the time commitment that will be required of you. Whilst no immediate benefits or advantages can be anticipated for those people participating in the project, it is hoped that this work will lead to an improved understanding of how and why offloading devices are used (and not used) in clinical practice for the prevention of heel pressure ulcers and will lead to a series of evidence based practical recommendations.

Can I withdraw from the study at any time?

You are free to withdraw from the study before, during or up to the point of transcription which will take place shortly after the interview (within 48 hours), at which point all data will be anonymised. You do not have to give a reason for withdrawing. If you chose to withdraw during this period, any data collected will be destroyed.

Will the information obtained in the study be confidential?

All participants will be assigned a study ID number and will be referred to by this number throughout the study and in future publications in order to protect the identity of the individual participants. Any identifiable details (e.g., place of work) will not be included in any publication.

All data collected will only be accessible by the researcher and supervisors named on this information sheet. All data collected as part of this research will be stored in a password protected drive of the University computer system and will be kept for at least 3 years after completion of the PhD or publication, whichever is longer. All data handling procedures are in accordance with the Data Protection Act 1998.

What will happen to the results of the study?

The main output of this research will be part of a PhD thesis.

Study participants will each be provided with a summary of the findings at the end of this stage of the research. The overall results of the PhD will be disseminated through journal publications and conference presentations.

Who has reviewed this study?

Ethical approval has been granted by the School of Healthcare Research Ethics Committee *(HREC15-014, October 2015).*

If you agree to take part, would like more information or have any questions or concerns about the study please contact Clare Greenwood via email within the next 3 days on c.e.greenwood12@leeds.ac.uk

Thank you for taking the time to read this information sheet.

Appendix D School of Healthcare ethics approval (November 2015)

Faculty of Medicine and Health

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UNIVERSITY OF LEEDS

20th November 2015

Clare Greenwood
PhD Student
School of Healthcare
Faculty of Medicine and Health
School of Healthcare
Baines Wing
University of Leeds
LEEDS LS2 9JT

Dear Clare

Ref no: HREC15-014

Title: An exploration of the use of devices for the prevention of heel pressure ulcers – a realist evaluation

Thank you for submitting your documentation for the above project. Following review by the School of Healthcare Research Ethics Committee (SHREC), I can confirm a favourable ethical opinion based on the documentation received at date of this letter and granted subject to the following condition(s):

- **Given the response to QA7 on the ethics application form, please confirm whether NHS Trust R&D permission is required prior to commencement of the research**

Document	*Version*	*Date Submitted*
Ethical_Review_Form_October 15 V2	2	17/11/2015
2a _SHRECInformationSheet_October 15 V2	2	17/11/2015
2b _SHREC OralConsentForm October 15 V2	2	17/11/2015
Recruitment email October 15 V2	2	17/11/2015
Interview topic guide version 1	1	13/11/2015

Please notify the committee if you intend to make any amendments to the original research as submitted at date of this approval. This includes recruitment methodology and all changes must be ethically approved prior to implementation. Please contact the Faculty Research Ethics Administrator for further information FMHUniEthics@leeds.ac.uk

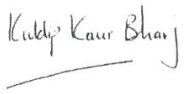
Ethical approval does not infer you have the right of access to any member of staff or student or documents and the premises of the University of Leeds. Nor does it imply any right of access to the premises of any other organisation, including clinical areas. The SHREC takes no responsibility for you gaining access to staff, students and/or premises prior to, during or following your research activities.

Please note: You are expected to keep a record of all your approved documentation, as well as documents such as sample consent forms, and other documents relating to the study. This should be kept in your study file, and may be subject to an audit inspection. If your project is to be audited, you will be given at least 2 weeks notice.

It is our policy to remind everyone that it is your responsibility to comply with Health and Safety, Data Protection and any other legal and/or professional guidelines there may be.

The committee wishes you every success with your project.

Yours sincerely



Dr Kuldip Bharj, OBE
Chair, School of Healthcare Research Ethics Committee

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Appendix E Ward Manager Participant Information Sheet

An exploration of the use of offloading devices for the prevention of heel pressure ulcers – an observation study

You are being invited to take part in a research project looking at how offloading devices are used (and not used) in secondary care for the prevention of heel pressure ulcers. Before you decide whether or not to participate it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully and discuss it with others if you wish. Ask me if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of this study?

There are numerous different devices available on the market designed for the prevention of heel pressure ulcers; however, the evidence base for these devices is sparse. The aim of this research project is to explore the use of devices in the prevention of heel pressure ulcers, specifically with regards to how they are actually used and perceived in clinical practice when individual patient preferences, nursing knowledge, resources and care environment are taken into account.

Who is doing the study?

The research will be conducted by Clare Greenwood, a Clinical Nurse Specialist in Tissue Viability at Leeds Teaching Hospitals. This study will become part of her PhD thesis being conducted at the University of Leeds. This study is being overseen by her PhD supervisors; Prof Andrea Nelson, Prof Jane Nixon, Dr Elizabeth McGinnis and Dr Rebecca Randell.

Who is being asked to participate?

I am looking to recruit wards within Trauma & Orthopaedics and Acute Medicine CSUs who keep a stock of offloading devices and therefore have these devices easily accessible to your staff. You have been invited to participate as your ward routinely cares for patients at risk of developing a heel pressure ulcer, which might or might not include the utilisation of a device.

What will be involved if I take part in this study?

You will be consenting to an observation study of pressure ulcer preventative care practices to take place on your ward, and therefore consenting to any staff member working on your ward to being observed including patients, nurses, CSWs and wider members of the MDT.

There will be a minimum of 4 separate observation periods that will take place over different shift times including evenings and weekends, which will be arranged at a date and time convenient to you and your team. The observations will primarily take place within a bay of patients which has at least one patient at high risk of developing a pressure ulcer, which will be determined by the patient being either bed-fast or chair-fast, but the observations will also include ward handovers/safety huddles/board rounds. The layout of the ward will also be observed including photography of the storerooms. At each separate observation period a different bay of patients will be observed each time, or the same bay if a minimum of 50% of the patients have changed between observations. All patients in the observed bay will be verbally consented to be observed and those at risk of developing a pressure ulcer will be consented, either personally or through consultee agreement as applicable, to have a review of their medical and nursing notes following the period of observation.

All patients in the observed bay will be verbally consented to be observed and those at risk of developing a pressure ulcer will be consented, either personally or through consultee agreement as applicable, to have a review of their medical and nursing notes following the period of observation.

All patients and members of staff involved in the observations will be provided with information about the study and given the opportunity to opt out at any point. Staff and patients will be informed that this is an observational study of care, but the specific focus of the research will not be disclosed so as not to influence practice. You will therefore be asked not to disclose to staff the specific focus of the study for this reason.

1-3 members of ward staff who have been working in the observed bay will be invited to participate in a short audio-recorded interview, anticipated to last 15-30 minutes. The interviews will take place as close to the end of the period of observations as possible. The interviews will seek to gather the thought processes behind the implementation of the plan of care and choice of equipment in use and when it was implemented.

The only personal information that will be collected during the study will be email addresses if participants decide that they would like to receive copies of the results once the study has been completed. This information will be stored on the University of Leeds M: drive which is password protected and only accessible to the principal investigator.

The only anticipated risk that can be foreseen if you choose to take part could be if poor or dangerous practice is observed or disclosed during the interviews. If there is any immediate danger to patients or staff, then I will intervene during the observations. Anything I perceive to be bad practice will be fed back to yourself at the end of the observation period. The intention is not to assess the practice that is being delivered, just to observe what is actually happening.

<u>What are the advantages and disadvantages of taking part?</u>

The main disadvantage associated with taking part will be the time required of your staff. However, we have chosen data collection methods, such as observation, that seek to minimise this burden. The researcher will aim to not get in the way during the observations and will minimise any disruption by scheduling interviews at times convenient to both the member of staff and the ward, and observation periods can be rescheduled if requested.

Whilst no immediate benefits or advantages can be anticipated for those people participating in the project, it is hoped that this work will lead to an improved understanding of how and why offloading devices are used (and not used) in clinical practice for the prevention of heel pressure ulcers. A summary of the research findings will be made available to all participants if requested.

Can I withdraw from the study at any time?

You are free to withdraw your ward from the study before, during or up to the point of transcription of the field notes which will take place shortly after the observation (within 3 days), at which point all data will be anonymised. You do not have to give a reason for withdrawing. If you chose to withdraw during this period, any data collected will be destroyed. Individual members of staff will also have the option to withdraw at any point up until the point of transcription.

Will the information obtained in the study be confidential?

All participating wards will be assigned a study ID number and will be referred to by this number throughout the study and in future publications in order to protect the identity of the individual participants. Any identifiable details will not be included in any publication.

Data of any sort (field notes, interview tapes, consent forms and research journal) will be stored in a secure lockable place within the School of Healthcare and will only be accessible to the researcher and supervisors. Once they have been transcribed, the data will be stored on a password protected secure drive at the University of Leeds for 5 years after completion of the PhD or publication, whichever is longer. All data handling procedures are in accordance with the Data Protection Act 2018.

The University of Leeds is the sponsor for this study based in the United Kingdom. We will be using information from your patients in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Leeds will keep identifiable information about you for 5 years after the study has finished.

Your rights to access change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.

You can find out more about how we use your information at

http://www.leeds.ac.uk/secretariat/data_protection.html.

What will happen to the results of the study?

The main output of this research will be part of a PhD thesis. Study participants will each be offered a summary of the findings at the end of this stage of the research. An email address will be collected in order to disseminate the results. These will be stored on a spreadsheet in a password protected drive of the University of Leeds computer system and will not be shared with anyone. Once the results have been sent out this spreadsheet will be destroyed, and the email will be deleted from the sent items folder.

The overall results of the PhD will be disseminated through journal publications and conference presentations.

What if I have a complaint about the research?

If you have a concern about any aspect of this study, you should ask to speak to the researchers and they will do their best to answer your questions, their contact details are at the end of this leaflet. [redacted]

Who has reviewed this study?

This study is sponsored by the University of Leeds and Ethical approval has been granted by the NHS Research Ethics Committee *(8/YH/0272 18/09/2018).*

If you agree to take part, would like more information or have any questions or concerns about the study please contact Clare Greenwood via email on c.e.greenwood12@leeds.ac.uk or Rebecca Randell (PhD supervisor) on R.Randell@leeds.ac.uk

Thank you for taking the time to read this information sheet

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Appendix F Patients Participant Information Sheet

An exploration of the use of offloading devices for the prevention of heel pressure ulcers – an observation study

A large-print version of this sheet is available on request

You are being invited to take part in a research project looking at how different products are used in hospital to prevent heel pressure ulcers. Before you decide whether or not to participate it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully and discuss it with others if you wish. Ask me if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of this study?

Pressure ulcers (also known as pressure sores or bedsores) are injuries to the skin and tissues beneath, mainly caused by long periods of lying or sitting. They can happen to anyone, but usually affect people who are unwell and spend a long time in bed or sit in a chair or wheelchair for long periods of time.

There are lots of different products available to nurses that are designed to prevent pressure ulcers to the heel; however, there isn't much information available about which are the best and how and when they should be used. The aim of this research project is to explore how nurses prevent pressure ulcers to the heel, and how patients react to the care given.

Who is doing the study?

The research will be conducted by Clare Greenwood, a Clinical Nurse Specialist in Tissue Viability at Leeds Teaching Hospitals. This study will become part of her PhD thesis being conducted at the University of Leeds. This study is being overseen by her PhD supervisors; Prof Andrea Nelson, Prof Jane Nixon, Dr Elizabeth McGinnis and Dr Rebecca Randell.

Who is being asked to participate?

You are being invited to participate because you may be at risk of developing a pressure ulcer due to your stay in hospital and longer times spent in the bed and/or chair. It does not mean that you will develop one and staff will be trying to reduce your risk, and this is what is being studied.

What will be involved if I take part in this study?

You are being asked to consent to having your medical and nursing records reviewed by the researcher. All data collected will be anonymous and therefore won't be identifiable to you. The researcher will be looking at how the nurses and doctors have planned and cared for you with regards to preventing you from developing a pressure ulcer, or how they have treated your pressure ulcer if you have one.

What are the advantages and disadvantages of taking part?

Whilst there are no immediate benefits or advantages to taking part, it is hoped that this work will lead to an improved understanding of how and why products are used (and not used) for the prevention of heel pressure ulcers and could lead to better practice in the future.

No disadvantages to taking part can be foreseen.

Can I withdraw from the study at any time?

You do not have to take part in this study. If you choose to consent to having your medical and nursing notes reviewed, you are free to change your mind and pull out of the study up to 3 days after. Your care will not be affected should you chose to withdraw.

What will happen to the results of the study?

The main output of this research will be part of a PhD thesis.

If you are interested a copy of the study findings can be sent to you as a lay summary. An email address or your home address will be collected in order to send this information to you. The overall results of the PhD will be shared through journal publications and conference presentations.

Will the information obtained in the study be confidential?

You will be assigned a study ID number by the researcher and will be referred to by this number throughout the study and in future publications in order to protect your identity. The only personal details that will be collected is your name on the consent form and email address and/or personal address should you wish to receive a copy of the results. The email address and/or personal address will be stored on a spreadsheet in a password protected drive of the University of Leeds computer system and will not be shared with anyone. Once the results have been sent out this spreadsheet will be destroyed, and the email will be deleted from the sent items folder.

The University of Leeds is the sponsor for this study based in the United Kingdom. We will be using information from your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Leeds will keep identifiable information about you for 5 years after the study has finished.

The researcher may use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from the University of Leeds and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The researcher will pass these details to The University of Leeds along with the information collected from your medical records. The

only people at the University of Leeds who will have access to information that identifies you will be people who need to audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

All data collected as part of this research will be stored in a password protected drive of the University computer system and will be kept for 5 years after completion of the PhD or publication, whichever is longer. All data handling procedures are in accordance with the Data Protection Act 2018.

Your rights to access change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.

You can find out more about how we use your information at

http://www.leeds.ac.uk/secretariat/data_protection.html.

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to the researchers, and they will do their best to answer your questions. Clare Greenwood is leading the research and her contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting Dr Rebecca Randell on R.Randell@leeds.ac.uk. [redacted]

Who has reviewed this study?

This study is sponsored by the University of Leeds and Ethical approval has been granted by the NHS Research Ethics Committee *(8/YH/0272 18/09/2018).*

If you agree to take part, would like more information or have any questions or concerns about the study please contact Clare Greenwood via email on c.e.greenwood12@leeds.ac.uk or I can be contacted on the ward during the observation period.

Thank you for taking the time to read this information sheet

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Appendix G Ward Staff Participant Information Sheet

An exploration of the use of offloading devices for the prevention of heel pressure ulcers – an observation study

You are being invited to take part in a research project looking at how offloading devices are used in secondary care for the prevention of heel pressure ulcers. Before you decide whether or not to participate it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully and discuss it with others if you wish. Ask me if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of this study?

There are numerous different devices available on the market designed for the prevention of heel pressure ulcers; however, the evidence base for these devices is sparse. The aim of this research project is to explore the use of devices in the prevention of heel pressure ulcers, specifically with regards to how they are actually used and perceived in clinical practice when individual patient preferences, nursing knowledge, resources and care environment are taken into account.

Who is doing the study?

The research will be conducted by Clare Greenwood, a Clinical Nurse Specialist in Tissue Viability at Leeds Teaching Hospitals. This study will become part of her PhD thesis being conducted at the University of Leeds. This study is being overseen by her PhD supervisors, Prof Andrea Nelson, Prof Jane Nixon, Dr Elizabeth McGinnis and Dr Rebecca Randell.

Who is being asked to participate?

All members of ward staff working in the observed bays on the days that the observations take place will be invited to participate.

What will be involved if I take part in this study?

You are being invited to participate in a short audio-recorded interview, anticipated to last 15-30 minutes. The interviews will take place as close to the end of the period of observations as possible. The interviews will seek to gather the thought processes behind the implementation of the plan of care and choice of equipment in use and when it was implemented.

The only anticipated risk that can be foreseen if you choose to take part could be if poor or dangerous practice is disclosed during the interviews. Anything perceived by the researcher to be bad or dangerous practice will be fed back to the ward manager.

What are the advantages and disadvantages of taking part?

The main disadvantage to participating in the interviews will be the time commitment that will be required of you. Whilst no immediate benefits or advantages can be anticipated by participating in the project, it is hoped that this work will lead to an improved understanding of how and why offloading devices are used in clinical practice for the prevention of heel pressure ulcers and might lead to better care in the future.

Can I withdraw from the study at any time?

If you choose to participate in the interviews, you are free to withdraw from the study before, during or up to the point of transcription of the interviews which will take place shortly after (within 3 days), at which point all data will be transcribed and anonymised.

What will happen to the results of the study?

The main output of this research will be part of a PhD thesis.

Study participants will be offered a summary of the findings at the end of this stage of the research via email. The overall results of the PhD will be disseminated through journal publications and conference presentations.

Will the information obtained in the study be confidential?

All participants will be assigned a study ID number and will be referred to by this number throughout the study and in future publications in order to protect your identity. Any identifiable details will not be included in any publication. The only personal details that will be collected is your name on the consent form and email address should you wish to receive a copy of the results. The email address will be stored on a spreadsheet in a password protected drive of the University of Leeds computer system and will not be shared with anyone. Once the results have been sent out this spreadsheet will be destroyed, and the email will be deleted from the sent items folder.

Audio recordings may be transcribed by a 3rd party external to the research team. This will be through a University of Leeds trusted transcription service. A confidentiality agreement will be signed by the transcription service and a secure data exchange programme will be used. No confidential, sensitive or personally identifiable information will be sent to the transcriber.

The University of Leeds is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Leeds will keep identifiable information about you for 5 years after the study has finished.

The researcher may use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from the University of Leeds and regulatory organisations may look at your interview transcripts to check the accuracy of the research study. The researcher will pass these details to the University of Leeds. The only people at the University of Leeds who will have access to information that identifies you will be people who need to contact you to audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

All data collected as part of this research will be stored in a password protected drive of the University computer system and will be kept for 5 years after completion of the PhD or publication, whichever is longer. All data handling procedures are in accordance with the Data Protection Act 2018.

Your rights to access change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.

You can find out more about how we use your information at

http://www.leeds.ac.uk/secretariat/data_protection.html.

What if I have a complaint about the research?

If you have a concern about any aspect of this study, you should ask to speak to the researchers and they will do their best to answer your questions, their contact details are at the end of this leaflet. [redacted]

Who has reviewed this study?

This study is sponsored by the University of Leeds and Ethical approval has been granted by the NHS Research Ethics Committee *(8/YH/0272 18/09/2018).*

If you agree to take part, would like more information or have any questions or concerns about the study please contact Clare Greenwood via email on c.e.greenwood12@leeds.ac.uk or Rebecca Randell (PhD supervisor) on R.Randell@leeds.ac.uk

Thank you for taking the time to read this information sheet.

Appendix H HRA Ethical Approval (September 2018)

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Mrs Clare Greenwood
[redacted]

Email: hra.approval@nhs.net
Research-permissions@wales.nhs.uk

18 September 2018

Dear Mrs Greenwood

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**An exploration of the use of devices for the prevention of heel pressure ulcers**
IRAS project ID:	**232057**
Protocol number:	**N/A**
REC reference:	**18/YH/0272**
Sponsor	**University of Leeds**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

How should I continue to work with participating NHS organisations in England and Wales?
You should now provide a copy of this letter to all participating NHS organisations in England and Wales, as well as any documentation that has been updated as a result of the assessment.

Participating NHS organisations in England and Wales **will not** be required to formally confirm capacity and capability before you may commence research activity at site. As such, you may commence the research at each organisation 35 days following sponsor provision to the site of the local information pack, so long as:

- You have contacted participating NHS organisations (see below for details)
- The NHS organisation has not provided a reason as to why they cannot participate
- The NHS organisation has not requested additional time to confirm.

You may start the research prior to the above deadline if the site positively confirms that the research may proceed.

If not already done so, you should now provide the local information pack for your study to your participating NHS organisations. A current list of R&D contacts is accessible at the NHS RD Forum

website and these contacts MUST be used for this purpose. After entering your IRAS ID you will be able to access a password protected document [redacted] The password is updated on a monthly basis so please obtain the relevant contact information as soon as possible; please do not hesitate to contact me should you encounter any issues.

Commencing research activities at any NHS organisation before providing them with the full local information pack and allowing them the agreed duration to opt-out, or to request additional time (unless you have received from their R&D department notification that you may commence), is a breach of the terms of HRA and HCRW Approval. Further information is provided in the "*summary of assessment*" section towards the end of this document.

It is important that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details of the research management function for each organisation can be accessed here.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within the devolved administrations of Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) has been sent to the coordinating centre of each participating nation. You should work with the relevant national coordinating functions to ensure any nation specific checks are complete, and with each site so that they are able to give management permission for the study to begin.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?
The document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

I am a participating NHS organisation in England or Wales. What should I do once I receive this letter?
You should work with the applicant and sponsor to complete any outstanding arrangements so you are able to confirm capacity and capability in line with the information provided in this letter.

The sponsor contact for this application is as follows:

Faculty NHS Research Ethics Officer
E-mail governance-ethics@leeds.ac.uk
Telephone 0113 343 7587

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **232057**. Please quote this on all correspondence.

Yours sincerely

Catherine Adams
Senior Assessor
Email: hra.approval@nhs.net

Copy to: *Faculty NHS Research Ethics Officer*
[redacted]

Appendix I Trust Approval (October 2018)

[redacted]

Dear Clare ,

Re. (An exploration of the use of devices for the prevention of heel pressure ulcers), R&I No: (IM18/112976)

This email confirms that [redacted] has no objection to the above research study, further to the HRA's approval letter confirming that participating NHS organisations in England are not expected to formally confirm their capacity and capability to host this research.

Please find attached:

- Agrees Statement of Activities
- Agreed Schedule of Events
- HRA Approval Letter

[redacted]

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