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The Relationship between Nurses Assessment of Early Pressure Ulcer Damage and Sub Epidermal Moisture Measurement: A Prospective Explorative Study.

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Royal College of Surgeons in Ireland

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The Relationship between Nurses Assessment of Early Pressure Ulcer Damage and Sub Epidermal Moisture Measurement: A Prospective Explorative Study.

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Submitted in part fulfilment of the degree of Master in Science in Nursing (Advanced Practice)

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This thesis has not been submitted to any other institution and is entirely my own work.

Signed:  gillian o' brien

Gillian O’ Brien
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Abstract

Studies have demonstrated the feasibility of using sub epidermal moisture measurement which rises in the inflammatory process, as a predictor of early pressure ulcer damage. Once identified, and prevention strategies are implemented or heightened, more severe pressure ulcer damage may be averted. This study aimed to explore the relationship between nurses’ assessment of at risk patients’ skin and the assessment of skin using sub epidermal moisture measurement. A descriptive prospective observational design was employed. Following ethical approval and written informed consent, data were collected daily for 4 weeks, from patients assessed as being at risk of pressure ulcer damage within an acute health care facility in Ireland. Data included nurses (n=372) documented assessment of the patient’s skin condition and researcher led sub epidermal moisture measurement over the sacrum and both heels. A total of 47 patients were included, 38.3 % (n=18) were male and 61.5% (n=29) were female, with a median age of 74.7 years. Of the population studied, 34% (n=16) developed signs of early pressure damage. The mean number of days for nurses to detect this damage was 5.0 (SD 5.15; max 11, min 3), whereas the mean number of days that it took sub epidermal moisture measurement to detect damage was 1.1 (SD 0.75; max 2, min 1). Correlations were low for the left heel (r=.23), medium for the right heel (r=.43) and strong for the sacrum (r=.65) between nurses’ visual assessment and sub epidermal moisture measurement. All patients with sustained elevated sub epidermal moisture levels went on to develop visual signs of pressure ulceration. However, importantly, sub epidermal moisture measurement identified early damage, on average, 3.9 days earlier than nurses’ assessment. Given that pressure ulcers develop from within the deeper tissues, knowing that early pressure ulcer damage is present can facilitate heightening of prevention strategies to avoid extension. This is of particular importance in clinical practice as the earlier that pressure ulcers can be detected; the earlier interventions can be implemented to prevent further extension, avoiding their associated morbidity and mortality.
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Chapter 1 Introduction and significance of the study

1.0 Introduction

The exponential problem with financing health care services is a global phenomenon, necessitating numerous reform programs to prevent healthcare services collapsing under financial pressure (OECD 2010). Ireland is not exempt from this contentious issue, and with forecasts of nursing shortages of circa 600,000 nurses across Europe by 2020 (RN4CAST 2011), an ageing population and an increase in chronic disease prevalence (DOH&C, Future Health 2012), radical reform must occur or long term sustainability of health services will pose a significant problem (DOH&C, Tackling Chronic Disease 2008). Pressure ulcers have been examined in the literature for decades; however, an exact scientific consensus of the aetiology of pressure ulcers has yet to be reached (Guy et al. 2013, Coleman et al. 2013,). However, it is recognised, that formation of pressure ulcers is synonymous with ageing populations and populations with increasing co morbidities. Therefore, it is realistic to posit that an increase in pressure ulcer formation is likely to occur in the future, and hence, warrants intervention now in order to solve a potential healthcare calamity both from welfare and a budgetary perspective.

Prevention of hospital acquired pressure ulcers (HAPUs) can be cost effective for healthcare settings (Spetz et al. 2013), yet pressure ulcers frequently occur in this population (Clark 2007, Schurrman et al. 2009). Whilst, not all pressure ulcers are preventable, the majority are (McIntyre et al. 2012, Guy et al. 2013). Most are reported as grade 1 or 2 in severity of damage (Dealey et al. 2012, Moore & Cowman 2012,), and frequently occur on the sacrum, coccyx and heels (Groeneveld et al. 2004, Moore 2010). In Ireland, HAPUs are linked to the quality of care patients receive, and are recognized as an adverse clinical event (Health Information & Quality Authority) (HIQA 2012). Subsequently, prevention has become a priority. Furthermore, pressure ulcers prolong the length of hospital stay (Dealey et al. 2012, Balzer et al. 2013) and are expensive to manage. The amount spent, depends on
the severity of pressure ulcer treated, ranging from the least severe level of tissue damage, grade 1, to severe tissue damage, grade 4 (NPUAP/EPUAP/PPPIA 2014). If appropriate prevention strategies are applied from the onset, it is logical to suggest that grade 2, 3 and 4 pressure ulcers can be avoided (McIntyre et al. 2012). Despite this, eradication of HAPUs remains challenging (Balzer et al. 2013). Risk assessment is seen as the cornerstone of pressure ulcer prevention; however, risk assessment methods vary and can involve the use of formal risk assessment scales in isolation, or in conjunction with nurses' visual skin inspection (Moore & Cowman 2010, Johansen et al. 2014). This variance sparks frequent debate regarding validity of risk assessment tools, and subjectivity and accuracy of nurses' visual skin inspection (Joseph & Davies-Clifton 2013, Garcia-Fernandez et al. 2014, Johansen et al. 2014). Pressure ulcer research is undergoing significant change (Gefen et al. 2008a, 2008b, Gefen 2009a, 2009b), whereby, current practices relating to classification, risk assessment and management of pressure ulcer damage are under examination (Coleman et al. 2013). Further, scientific research pertaining to diagnostic measures for calculating risk and extent of pressure ulcer damage is an emerging science. Such research includes use of thermography (Nakagami et al. 2010), and measuring levels of sub epidermal moisture (Bates-Jensen et al. 2007, 2008, 2009).

Identifying risk of pressure ulcer damage sooner, suggests earlier intervention, which could have important health benefits and be more resource efficient than current methods used. Eliminating avoidable HAPUs is an important issue, perpetuating a paradigm shift in the way healthcare organisations manage patients at risk for pressure ulcer formation. Therefore, it is pertinent to conduct a study to further examine this important emerging science. The purpose of the ensuing research study is to investigate the accuracy of early pressure ulcer damage assessment using sub epidermal moisture measurement (SEM) compared to nurses' visual skin assessment. As such the literature pertaining to the significance of the study shall focus on, epidemiology, impact and cost to the patient and to the healthcare setting, aetiology of pressure ulcers, risk assessment, nurses’ visual
skin inspection and the research pertaining to SEM and its role in detecting early pressure ulcer damage.

1.1 Epidemiology of Pressure Ulcers in the Acute Care Setting

Epidemiological studies are becoming an important component in the decision making process pertaining to how budgets are devolved. However, an international group of experts (Baharestani et al. 2009); report difficulties with these studies and suggest that disparities in such studies can lead to error. Further, Baharestani et al. (2009) suggest that decision makers have little appreciation of what prevalence and incidence actually is. Further, different approaches to recording these epidemiological analyses, lends to variance in study design, hence, making comparisons difficult (Balzer et al. 2013).

1.1.1 Pressure Ulcer Prevalence in the Acute Care Setting

Pressure ulcer prevalence refers to the number of patients that have a pressure ulcer at a specific point in time (Defloor et al. 2005a). Documented prevalence rates range from 4% to 37 % in the Irish healthcare setting (Gethin et al. 2005, Gallagher et al. 2008, Moore & Cowman 2012). These figures are in keeping with international prevalence rates of circa 4% to 53.2% (Vanderwee et al. 2007, Moore & Cowman 2012, Pieper et al. 2012). Despite, proactive risk assessment and prevention strategies, and availability of international evidence based guidelines (NPUAP/EPUAP/PPPIA 2014), overall prevalence rates remain unchanged (Moore & van Etten 2011, Sibbald et al. 2011, Moore & Cowman 2012). Grade 1 and 2 pressure ulcers represent the majority of hospital acquired pressure ulcers (Pieper et al. 2012, Gunningberg et al. 2011, 2013). However, lack of universal, standardised methods to collect prevalence data limits its reliability, therefore, making international comparison less efficacious (Balzer et al. 2013, NPUAP/ EPUAP/ PPPIA 2014).
1.1.2 Incidence of Pressure Ulcers in the Acute Care Setting

Incidence refers to the number of patients who develop a pressure ulcer over a given period of time (Defloor et al. 2005a). Global incidence rates in the acute care settings report rates circa 2% to 49% in Europe (Vanderwee et al. 2007, Moore et al. 2013), Canada and the USA (Woodbury & Houghton 2004, Vangilder et al. 2008, 2009, 2010) and 5% to 15% in Australia (Phillips & Buttery 2009, Mulligan et al. 2011). Efficacy of incidence rates, similar to prevalence rates, is weakened by variations in methodologies such as study design and data collection methods (Balzer et al. 2013, NPUAP/ EPUAP/ PPPIA 2014)

1.2 Impact and Cost of Pressure Ulcers to the Patient and to the Acute Care Setting

Pressure ulcers present a significant financial burden to healthcare settings (Dealey et al. 2012). The National Patient Safety Agency (NSPA) (2010), estimates NHS expenditure of up to four billion pounds per annum to treat pressure ulcers and their related conditions such as sepsis and osteomyelitis. HAPUs extend lengths of stay, increase readmission rates, and in extreme cases can be fatal (Lyder et al. 2012, NHS 2010). Resources required depends on the severity and associated conditions of pressure ulcers being treated from the least severe level of tissue damage, grade 1, to severe tissue damage, grade 4 (NPUAP/EPUAP/PPPIA 2014). Moreover, the costs associated with management of avoidable hospital acquired pressure ulcers, would be better served financing other important healthcare needs (Posnett et al. 2009). Hospital acquired pressure ulcers also negatively impact health related quality of life (HRQoL), as pain and reduced quality of life is frequently reported by this population (Gorecki et al. 2009,2010, 2011, Moore & Cowman 2009, 2013).
1.3 Aetiology of Pressure Ulcers

It is important to understand the evolution of early pressure ulcer damage in order to implement appropriate prevention strategies. As such, the aetiology of pressure ulcer damage will be discussed in detail in the literature review in chapter 2. Broadly, the evolution of early pressure ulcer damage is influenced by etiological factors such as applied pressure, or pressure in combination with shear, including ischemia, reperfusion injury, impaired interstitial fluid flow and sustained cell deformity (Defloor et al. 2005b).

1.4 Risk Assessment

Use of risk assessment tools to inform appropriate pressure ulcer prevention strategies is synonymous with basic nursing care (Chou et al. 2013). Commonly used risk assessment tools include the Norton, Braden, and Waterlow scales (Chou et al. 2013), however few are fully effective, and have been criticised for being directed at populations rather than individual patient risk (Reynolds 2008). The Norton Score is the risk assessment tool used in the organisation where this research study is taking place. Norton et al. (1975) published the first risk assessment tool, the Norton Scale in 1962, directed at assisting nurses in identifying those patients at risk of pressure ulcer formation. The tool contains various subscales that are aligned with numerical values and addition of these values will yield an overall score indicative of the level of risk attached to the patient for pressure ulcer formation. Regardless of which tool is used, it has been generally accepted that such tools are the cornerstone of most pressure ulcer prevention strategies (NPUAP/EPUAP/PPPIA 2014, Guy et al. 2013).
1.5 Nurses Visual Skin Inspection

Stausberg et al. (2007), suggests that the ability to classify pressure ulcers accurately is directly related to the level of knowledge and experience of the nurse possess. Further, the authors posit that this knowledge and experience varies significantly depending on who undertakes the assessment, thus confounding the propensity for error. Notably, a study by Johansen et al. (2014), reported no significant difference in the planning, initiation and evaluation of pressure ulcer prevention strategies, regardless of whether risk assessment was undertaken using clinical judgement alone, or in combination with structured risk assessment. Moreover, visual skin inspection can only identify changes on the surface of the skin; however, the majority of pressure ulcers start to develop in the deeper layers of the tissues and emerge outwards (NPUAP/EPUAP/PPPIA 2014).

1.6 Sub Epidermal Moisture (SEM) and its Role in Detecting Early Pressure Ulcer Damage

Elevated sub epidermal moisture levels are associated with early pressure ulcer damage (Bates-Jensen et al. 2007). Bruin Biometrics have developed the SEM Scanner™, a point of care, diagnostic tool, that uses integrated pressure sensor technology to determine the levels of the sub epidermal moisture present, by emitting a low amplitude alternating current into the dermis (Bruin Biometrics 2013). Studies have demonstrated that SEM has the capacity to identify pressure induced tissue damage up to ten days, before the damage becomes visible on the skin’s surface (Bates-Jensen et al. 2007, 2008, 2009, Guihan et al. 2012). As such, SEM provides an objective, evidence based measurement that is non invasive and produces instant results. Results can be recorded rapidly, thereby, enabling earlier initiation of interventions for individuals displaying signs of pressure ulcer damage, therefore warrants further examination.
1.7. Research Question

The research question for this study is:

What is the relationship between nurses’ visual assessment of early pressure ulcer damage assessment of the pressure areas of the patients’ and SEM measures in ‘at risk’ patients?

1.7.1 Study Aim

The study aims to determine the relationship between nurses’ visual assessment of early pressure damage of patients’ and SEM measures in ‘at risk’ patients.

1.7.2 Study Objectives

- Establish the correlation between visual skin assessment and SEM findings.
- Establish if SEM is more accurate in detecting skin changes when compared to visual assessment alone.

1.7.3 Proposed Benefits of the Study

Hospital acquired pressure ulcers continue to be problematic, and in some cases, cause fatalities. Despite significant investment of resources in education and training; disparities in risk assessment exist. Studies relating to pressure ulcer risk assessment and prevention methods continue to be limited by weak methodological design, and nurses’ visual skin inspection is scientifically challenging due to its subjective nature. Pressure ulcer prevention strategies are labour intensive in view of frequent turning schedules, concurrently, a significant decline in the population of nursing is forecasted. No single risk assessment tool has been determined to be 100% valid for use in clinical practice, yet its continued use in advocated as a means to provide some semblance to structured risk
assessment. Early signs of pressure ulcer damage can be reversed, yet no objective means of measurement are available. SEM is an emerging science that has been shown to detect early pressure ulcer damage, before it is visible on the skin surface, warranting further examination. Furthermore, earlier identification will provide an opportunity for reversing the extent of tissue damage, thereby reducing the significant negative impact on the patient and enabling more appropriate use of scarce resources.
Chapter 2 Literature Review

2.0 Introduction

The aim of the ensuing literature review is to provide a critical appraisal and synthesis of the published literature pertaining to epidemiology, impact and cost, aetiology, risk assessment methods, nurses visual skin inspection and emerging concepts relating to SEM. The literature will focus on early pressure ulcer damage and its detection, as research suggests that this stage can be reversed, once appropriate strategies are implemented (Moore 2010, Guy et al. 2013). Consideration will be given to the epidemiological studies relating to prevalence and incidence rates. It is well documented that rates of HAPU’s, vary from setting to setting, however, prevalence rates across nations sit between the 2 and 10 percentile range (Moore & Cowman 2012, Pieper et al. 2012). Similarly, global incidence rates, range between 2 and 10 % (Vanderwee et al. 2007, Vangilder et al. 2008, 2009, 2010).

Further, HAPU’s subscribe to unnecessary suffering to patients and directly influence how hospital resources are spent. A HAPU is a pressure ulcer which has been identified post admission, and there is no documentation to support that it was present on admission (Zaratkiewicz et al. 2010). Prevention of HAPUs is not a new phenomenon, however the problem persists, and more recently, the Health Services Directorate, Quality and Patient Safety Division (2013) have focused their attention to these often preventable, adverse events (HSD Report 2013). Further, given the well documented suffering these wounds, inflict (Gorecki et al. 2009, 2010, 2011), the writer will examine the literature pertaining to the impact of such wounds on the patient. However, the patient does not suffer in isolation, use of finite resources, to treat avoidable HAPU’s can profoundly affect health care budgets, through direct costs associated with wound management, pressure relieving equipment and increased length of hospital stay (Dealey et al. 2012). Moreover, acquisition of
HAPU’s directly relates to quality of care perception by the public; and as such, is perceived as an adverse event (HSE National Service Plan 2015).

Current evidence pertaining to pressure ulcer risk assessment methods will be examined, including risk assessment tools and nurses visual skin inspection. It is important that healthcare organisations are guided by evidence based guidelines in clinical practice; however, such guidance is subject to criticism for being inherently flawed due to the poor design methods applied to studies, and will be further examined in the literature. Further, there appears to be a lack of connectedness between risk assessment and subsequent treatment which negatively impacts on patient care, otherwise grade 1 and 2 HAPU’s would not present as frequently as reported.

Finally, the review will explore emerging concepts in pressure ulcer research and will particularly focus on the role SEM provides, in achieving the objective measurement of sub epidermal moisture levels. Elevations in these levels detect inflammatory changes, synonymous with the formation of early pressure ulcer damage; therefore, highlighting the need to investigate further.

2.1 Literature Review

The literature review provides an objective, summary and critical analysis of the literature that pertains to a particular field or topic being examined (Creswell 2009, Polit & Beck 2010). A further purpose is to elicit gaps in existing research with a view to developing a hypothesis for further research (Polit & Beck 2010). A literature review does not lend itself to adding new considerations, its function is limited to the provision of a summary and synthesis of what is already known (Creswell 2009, Polit & Beck 2010).
2.2 Literature Search

The following electronic databases were searched for publications relating to the topic under review, Cumulative Index to Nursing and Allied Health Literature (CINAHL) using EBSCO host, plus with full text, Cochrane Library, Centre for Reviews and Dissemination, University of York, Index Medicus using citations from International Nursing Index (Medline), Science Direct, Sage, Google Scholar, and Pubmed. The search strategy included the following search terms ['pressure ulcer*'] OR ['epidemiology'] OR ['prevalence'] OR ['incidence']. In CINAHL and Medline, searches were combined with AND ['nurses visual skin inspection'] OR ['nurses pressure ulcer classification'] OR ['risk assessment '] OR ['sub epidermal moisture*']. Key words were used in isolation and combination with the use of Boolean connectors and smart text searching. Search limitations included; English text, peer reviewed journals, publication years 2000-2015. Publication years were extended in relation to seminal studies of the topic under construct. A hand search of the articles, bibliographies yielded more articles on the topic which the researcher deemed to be relevant.

A total 93 articles were reviewed and used in this literature review.

2.3 Epidemiology of Pressure Ulcers

Pressure ulcers are a growing concern, and frequently occurring health problem, therefore in order to contextualise its’ burden on the healthcare service, prevalence and incidence studies are often performed (Moore & Cowman 2012). Prevalence measures the number of patients with a pressure ulcer at a specific point in time and includes both hospital acquired pressure ulcers and those that were present on admission, divided by the number of people within the population (Moore & Cowman 2012). Research has shown that the prevalence figures are usually higher in the acute care
setting (Moore et al. 2013). It is well recognised that prevalence and incidence studies have the potential to provide important data for assessing quality of care and effectiveness of pressure prevention strategies (Baharestani et al. 2009). Further, these studies are being used to determine health care funding and in some countries reimbursement. Therefore, it is inherent that the use of a standardised approach should be taken when conducting these studies, as the absence of standardisation lends to invalid results, which could negatively affect the use of sparse health care resources (Baharestani et al. 2009).

Prevalence rates of 4% to 38% are reported in Irish hospitals (Moore & Pitman 2000, Gethin et al. 2005, Gallagher et al. 2008), and are not reducing in spite of the availability of international evidence based guidelines (Vanderwee et al. 2007, NPUAP/EPUAP/PPPIA 2014, Moore & van Etten 2011, Moore & Cowman 2012). Gallagher et al. (2008), carried out a point prevalence study over a two day period in three teaching hospitals in Ireland, and recorded the volume of pressure ulcers detected and the risk factors for their development. The total population assessed (n=672), resulted in a point prevalence score of 18.5%. Notably, 77% of the pressure ulcers were HAPUs, 49% grade 1 and 37% grade 2. This is in keeping with the international literature, suggesting that most HAPUs are grade 1 or 2 in severity (Dealey et al. 2012, Moore & Cowman 2012, McIntyre et al. 2012, and Guy et al. 2013). Interestingly, using multivariate regression analysis, the authors found that reduced mobility (p < 0.0001), and length of stay (p < 0.0001) to be predictive of the presence of pressure ulcers. Moore & Cowman (2012) attributes reduced mobility as a key risk factor for developing pressure ulcers.

Gallagher et al. (2008) acknowledge the difficulty in accurately comparing prevalence results due to variances in methodology. This theory is re-iterated in the literature (Baharestani et al. 2009, NPUAP/EPUAP/PPPIA 2014). The researchers used the EPUAP standardised methodology for data
collection, and exclusion criteria were clearly laid out. Pressure ulcer classification again was the EPUAP classification system; however risk assessment tools varied across the three sites, the Braden score, the Norton Score and the Waterlow score. Limitations to the study under consideration include validity and reliability of each tool (Defloor & Grypdonck 2004), including the comparability of these findings as each risk assessment tool has different parameters of scales and subscales to consider (NPUAP/EPUAP/PPPIA 2014). The authors acknowledge these limitations in their study.

Whilst prevalence studies indicate the total number of patients affected by pressure ulcers, incidence studies refers to the rate at which new pressure ulcers develop in a set population at a specific point in time (Defloor et al. 2005b). Whereas, prevalence studies can be used to demonstrate resource requirements, incidence studies should reflect adherence to pressure ulcer prevention policy and also the success of prevention strategies (Baharestani et al. 2009). There are many limitations to both types of study (Baharestani et al. 2009); however accurate data collection for both studies is essential to get meaningful results. Much of the validity of the data collected is dependent on the skill of the data collector, both in performing clinical assessment and recording accurate data. Both affect external validity of the studies (Anthony et al. 2010). Further, inter rater reliability may not reach 100% that is 2 nurses using the same tool may not achieve the same result (Baath et al. 2008). Retrospective prevalence and incidence studies may also reflect underestimates of pressure ulcer rates, as it is well eluded to that a significant proportion of pressure ulcers are not recorded (Moore & Pitman 2000, Whittington et al. 2004, Gunningberg et al. 2013). Conversely, inaccurate diagnosis of other skin conditions such as incontinence lesions may over estimate prevalence and incidence (Moore & Pitman 2000, Whittington et al. 2004, Gunningberg et al. 2013). As prevalence only provides a snapshot of the problem at a specific moment, the detail of how or why pressure ulcers occur is not obtained. Conducting epidemiological studies are costly, therefore methodological issues
should be fully explored beforehand as it is very important that limited resources are used efficiently (Baharestani et al. 2009).

2.4 Impact, Cost and Quality of Life

2.4.1 Cost

Economic analyses are often referred to as the science of scarcity (Morris et al. 2011), this seems fitting when referring to health care economics, as it is universally acknowledged that the volume of advanced healthcare technologies far exceeds the ability to pay (DOH&C Service Plan 2015). Furthermore, the association between cost and quality is a contentious issue in health policy, as investing money in healthcare does not necessarily result in better or more efficient care (Vowden et al. 2009, Milton et al. 2010, Hussey et al. 2013). The Department of Health’s Service Plan (2015) informs healthcare organisations, that budgetary decisions will be formulated upon analysis of the costs and benefits of treatments. This is particularly pertinent as new legislation, ‘First Change’, is due for ratification in January 2015. This act legislates that any budget overspend incurred will automatically be taken from the ensuing year’s budget. This mandate is fraught with challenges, as Healthy Ireland (DOH&C 2013) refers to Ireland’s increased ageing population with concomitant increase in incidence of chronic illness. Due to advances in modern medicine, persons with chronic and debilitating illnesses are living longer. Chronic disease accounts for 76% of deaths in Ireland (Healthy Ireland DOH&C 2013), and incurs major health care costs. Further, the report estimates an increase of up to 20% in chronic disease prevalence by 2020. Development of pressure ulcers is synonymous with this population, and is not an issue limited to the Irish context. The global economic downturn has resulted in substantial fiscal budgets, however, the OECD (2010), projects that through greater spending in public health spending, Ireland has the most potential of all OECD countries to reduce health care spending by nearly 5% through more efficient use of resources.
The health care burden of managing hospital acquired pressure ulcers is already being realised. Pressure ulcers are often related to poor prevention or care (HIQA 2012), they significantly diminish quality of life of persons affected, prolong the need for care and the duration of stay, incurring distress to the patient and additional costs to the organisation (Gorecki et al. 2009, 2010, 2011, Moore & Cowman 2009, Dealey et al. 2012). The Department of Health has made the improvement of quality and patient safety a priority focus for 2015 (HSE, Service Plan 2015). There are limited studies in Ireland relating to the cost of treating pressure ulcers. Gethin et al. (2005) estimated annual costs of €250,000,000 to manage pressure ulcers.

International studies also report varying costs for treating pressure ulcers. In the USA costs range from $2,770 to $5,630 to treat a grade 1-2 HAPU (Padula et al. 2011). Bennett et al. (2004) estimate that the NHS spends between 1.4 billion and 2.1 billion pounds annually to treat pressure ulcers, ranging from £1,064 to treat a grade 1 to £10,551 to treat a grade 4, depending on the severity of the damage and associated complications such as sepsis. A further UK economic analysis, by Dealey et al. (2012), attributed costs ranging between £1,214 to treat grade 1 to £14,108 to treat grade 4 pressure ulcers. A Dutch study (Severens et al. 2002), estimated costs ranging between $362 million and $2.8 billion per year. An economic evaluation study (Schuurman et al. 2009), attributed these cost variances to the fact that they were estimated based on expert opinion rather than actual data. Further, the authors based their cost evaluation using direct costs and ran the study concurrently with a prospective cohort study, the ‘Purse Value study’ on the incidence and risk factors for pressure ulcers. The study stratified care to a technical prevention ulcer strategy and to a human pressure ulcer prevention strategy; incidence did not vary significantly between either groups however the cost of the technical approach was 2 times lower than the cost of the human approach. However, the study did not evaluate the effectiveness of treatment and therefore, assumptions regarding treatment cost
efficiencies cannot be alluded to. Moreover, the authors recommended further examination of prevention and treatment costs.

Investment of finite health care resources on treatment for hospital acquired pressure ulcers alludes to lost opportunity costs (Morris et al. 2011). When resources are used to treat hospital acquired pressure ulcers, then logically they cannot be invested into developing other services; therefore, the benefits or opportunities that could have arisen are lost (Morris et al. 2011). This implies that prevention of pressure ulcers is extremely beneficial to both the patient and the organisation. Conversely, prevention strategies can be extremely costly, and measures such as repositioning regimes are labour intensive (Schuurman et al. 2009, Dealey et al. 2012). The authors posit, that nurses or healthcare assistant time accounts for 96% of the cost in ulcers of grade 1 or 2. Therefore, it is imperative that the appropriate risk identification methods, and subsequent pressure relieving measures are adopted into clinical practice (Reynolds 2008, Dealey et al. 2012).

2.4.2 Impact on Quality of Life

Pressure ulcers negatively affect person's quality of life and are associated with unwelcome symptoms such as pain, sleep disturbance, impaired appetite and social exclusion (Gorecki et al. 2009, 2010, 2011, Moore & Cowman 2009). Pain was the overarching theme reported in a qualitative study (Hopkins et al. 2006), a literature review (Moore & Cowman 2009) and a systematic review (Gorecki et al. 2009, 2010, 2011, Briggs et al. 2013). The considerable human cost associated with the formation of pressure ulcers is an important issue therefore the importance attached to their prevention cannot be overestimated. Further, most pressure ulcers are suggested as preventable if the appropriate pressure, prevention strategies are implemented to maintain tissue viability (Cowman et al. 2011, Moore and van Etten 2011).
2.5 Aetiology of Pressure Ulcers

In order to maximise the potential to eradicate hospital acquired pressure ulcers, it is important to understand what a pressure ulcer is, and how it develops (Moore 2008). As such, a pressure ulcer is defined as, a localised area of skin and underlying soft tissue damage caused by prolonged mechanical loading and shear (Beeckman et al. 2007, NPUAP/EPUAP/PPPIA 2014). Pressure ulcers may occur either in the superficial tissues or may begin in the deeper tissues (Stekelenburg et al. 2005, 2007, Gefen et al. 2008a, 2008b). Pressure ulcer research has been in existence for decades (Groth 1942, Husain 1953, Kosiak 1959, 1961, Reswick & Rogers 1976, Bouten et al. 2003, Gefen et al. 2009a, 2009b). However, current pressure ulcer research has highlighted some fundamental flaws in original research theories and suggests that further research pertaining to the mechanism of tissue injury is required. The overarching aim of the research is to better understand how pressure ulcers form in a bid to develop guidelines and technologies that prevent their occurrence (Berlowitz & Brienza 2007, Gefen et al. 2009a, 2009b). The authors allude to two pathways that may result in the formation of pressure ulcers; the first refers to friction of the skin against clothing, or bed sheets with ensuing shear damage, which can worsen in the presence of moisture, in the form of perspiration or incontinence. The resultant superficial tissue damage becomes visible on the skin, suggesting that once seen, prompt intervention can reverse the damage (Berlowitz & Brienza 2007). Conversely, the other path suggested leads to sustained deformation of deep tissues under bony prominences, due to presence of prolonged pressure of the bone on the tissue, resulting in damage that may not be relieved as quickly as necessary to prevent deep wounds, as this damage is not visible on the skin until it is too late to reverse (Berlowitz & Brienza 2007). Pressure ulcer damage ranges from non- blanching erythema of intact skin, to full scale tissue loss with, or without bone, muscle and tendon involvement (EPUAP/NPUAP/PPPIA 2014). Further, despite continuing research there exist a number of unknown factors pertaining to pressure ulcer formation (Nixon et al. 2005,
Guy et al. 2013, NPUAP/EPUAP/PPPIA 2014). However, it is suggested that there are four external mechanical forces that can have a deleterious effect on tissue viability. These mechanisms are local ischemia, reperfusion injury, impaired interstitial fluid flow and lymphatic drainage, and sustained deformity of cells (Stekelenburg et al. 2007). Traditionally, research pertaining to early detection of pressure ulcer damage focused on ischemia (Kosiak 1959), and evolved with new research regarding ischemia reperfusion injury (Bouten et al. 2003).

Bouton et al. (2003), examined sustained deformity of cells and its relationship to pressure ulcer damage, however, Ceelen et al. (2008) posit that despite all this research, these mechanisms still fail to clearly demonstrate the onset of pressure ulcer formation. The authors support the role of ischemia in pressure ulcer formation, but, suggest that other mechanisms of importance should be considered. Further, the inherent differences in the human body coupled with psychosocial factors render it difficult to compare human subjects with animal models (Ceelen et al. 2008). The role of ischemia and reperfusion in the formation of pressure ulcers was further explored by Pierce et al. (2000). The authors used a magnet to compress the shoulders of rats in a study and compared tissues exposed to ischemia with no period of perfusion to tissues with any blood flow restrictions. Findings reported that tissue exposed to ischemia/reperfusion cycles were more likely to develop tissue necrosis (n=13%), compared to tissues exposed to continuous ischemia (n=8%). These findings were further explored (Bonheur et al. 2004, Stekelenburg et al. 2007), and findings suggest that reperfusion may be a causative factor in pressure ulcer formation. Recently, sustained deformity of cells resulting in deep muscle damage that develops from the deeper tissues outwards, has been considered an important finding, as such damage is not visible on the skin in the early stages of damage, and leads to a lack of appreciation of the level of risk (Bouten et al. 2003, Stekelenburg et al. 2007, Ceelen et al. 2008). Unlike ischemia, whereby hypoxia is reversed when blood supply is restored, cell deformation causes the cell to rupture and therefore does not allow for reversal of cell damage.
Literature suggests that all of the aforementioned mechanisms have a role to play in pressure ulcer formation; however the extent of each role or the relative importance of one factor over the other has not been accounted for. Regardless of the mechanisms involved, applied pressure results in tissue injury, therefore, reducing the onset of injury is fundamental to preserving tissue viability.

2.6 Risk Assessment

Risk assessment is the process of determining the likelihood that a specific negative event will occur. Risk assessment tools used in pressure ulcer care are used to identify risk in the absence of applying pressure ulcer prevention strategies (Moore & Cowman 2014). International pressure ulcer guidelines recommend the use of validated risk assessment tools in clinical practice (NPUAP/EPUAP/PPPIA 2014), however, no single risk assessment tool can be considered 100% reliable (Moore & Cowman 2008). There are a number of risk assessment tools such as the Norton Scale, the Braden Scale and the Waterlow scale (Gallagher et al. 2008, Moore & Cowman 2014), none of which are 100% reliable for use across all population types (Moore & Cowman 2014). Indeed, the aforementioned tools differ in measures of specificity and sensitivity (Schoonhoven et al. 2002, Defloor & Grypdonck 2004, 2005c, Pancorbo Hidalgo et al. 2006). Further, the clinical implications regarding these different measures of specificity and sensitivity have not been examined (Moore 2008). In research, sensitivity refers to the ability of risk assessment tools to correctly calculate the percentage of patients who are at risk of developing pressure ulcers. Conversely, specificity refers to the correct calculation of the percentage of patients who are not at risk of developing pressure ulcers (Lalkhen & McCluskey 2008). Moore (2008) suggest that these differences leave risk assessment tools vulnerable to significant error.
The Norton risk assessment scale has a specificity of 61.8%, and a sensitivity of 46.8% (Garcia Fernandez et al. 2014). This implies a margin for error of 38.2% for specificity and 53.2% for sensitivity. Bolton (2007) examined the clinical effectiveness of the Norton and modified Norton scale, and found that despite its use, the incidence of pressure ulcers did not decrease. Conversely, the author reported an increase in the intensity and effectiveness of pressure ulcer care when risk assessment scales were used. Subsequently, inappropriate use of resources may occur as they are provided to patients who may not require those (Anthony et al. 2010, Moore 2010, Dealey et al. 2012, Guy et al. 2013).

Systematic review by Chou et al. (2013), failed to identify the effectiveness of formal pressure ulcer risk assessment as a superior method of risk assessment when compared to less standardised methods of risk assessment based on nurses’ clinical judgement. However, the author acknowledged limitations to the study, as only one trial was identified as suitable for inclusion. Applied research methods should serve as the basis for improving clinical care, however, it is well recognised that the quality of research relating to wound care is limited by poor research methods (Flanagan 2014). The author suggests that wound care research experts should be developed as clinical leaders in order to design better research studies within the limited resources that currently exist. From a budgetary perspective, prevention of pressure ulcers is more cost effective than treating them (Dealey et al. 2012), conversely risk assessment scales have been found to overestimate risk leading to unnecessary use of resources such as labour and preventative measures such as pressure relieving equipment (Defloor & Grypdonck 2005a, 2005b, Defloor et al. 2006, Webster et al. 2011, Dealey et al. 2012).

Whilst it is important to understand the evolution of pressure ulcer damage and associated risk factors, Moore et al. (2014), attribute activity and mobility as principle factors that expose
individuals to a higher risk of pressure ulcer formation. Directing risk assessment and prevention principles towards this population would therefore appear pertinent (Moore 2010).

2.7 Nurses Visual Skin Assessment

Ongoing visual skin inspection and assessment serve as a fundamental basis for implementing pressure ulcer prevention strategies, regardless of the risk assessment tools used (Balzer et al. 2013). In this German mixed methods study, the authors suggest that nurses’ clinical judgement alone serves as the primary basis for allocating preventative measures. Further, the authors posit that nurses’ clinical judgement considers multiple patient characteristics, including their capacity to engage in their own care. However, limitations were identified pertaining to deficits in nurses’ clinical judgement regarding conditions that affect tissue tolerance. Investigations pertaining to pressure ulcer prevention have seldom been examined (Moore 2010, Balzer et al. 2013). Balzer et al. (2013) piloted the study extensively and used two independent researchers to analyse the data which adds to the rigor of the study. The data collected by study assistants were tested for inter-rater reliability. Inter-rater reliability refers to which two raters, operating independently, assign the same values for an attribute being observed (Polit & Beck 2010). However, limitations to the study acknowledged by the authors included small sample size and time gaps of up to 24 hours between nurses’ risk assessments and study assistants’ observations. Also the study was of an exploratory nature and as such, does not test an actual hypothesis. An exploratory study investigates the full nature of the phenomenon, how it came about and its related factors, including factors that may have caused it. (Polit & Beck 2010). Exploratory studies have been criticised for leading to incorrect conclusions when two variables have been wrongly described as having a direct causal connection (Polit & Beck 2010).
Accurate pressure ulcer staging is considered an important clinical skill however; literature alludes to anomalies in staging abilities of clinical practitioners (Beekman et al. 2007, Mackintosh et al. 2014). Further, early recognition of grade 1 or 2 pressure ulcers is also clinically pertinent, as this can lead to reversal of damage once intervention strategies are implemented (NPUAP/EPUAP/PPPIA 2014, Mackintosh et al. 2014, Moore & Cowman 2014). Thorough documentation of skin assessment and staging is a pre-requisite to demonstrating the administration of evidence based care. There is sparse evidence to demonstrate that this occurs; retrospective chart reviews used in epidemiological studies allude to underestimation of prevalence and incidence rates due to lack of documentation (Baath et al. 2008, Kottner et al. 2009). Research exploring nurses knowledge and ability to stage pressure ulcers suggests that at least half or more of the staff assessed have significant knowledge deficits regarding pressure staging (Beekman et al. 2007, Armstrong et al. 2008, Chianca et al. 2010, Mackintosh et al. 2014, Samuriwo et al. 2014). This is not surprising, given the many titles attributed to pressure ulcer classification such as stage, category and grade (Kottner et al. 2009, EPUAP 2013).

Difficulty in the exact identification of non-blanching erythema (NBE) is frequently encountered (Defloor & Schoonhoven 2004). NBE is considered indicative of visible pressure damage secondary to friction and shear (Defloor & Grypdonck 2005a). It is imperative that recognition of this damage occurs as it will act as a precursor to preventing further deterioration. Current methods of identifying pressure ulcer damage are flawed. For example, Defloor et al. (2006), from a sample of 473 nurses, found that nurses confused NBE with blanchable erythema and moisture lesions. The authors found low inter-rater agreement between nurses (k=0.38). A British study provided pressure ulcer training to its tissue viability link nurses and carried out two audits post training. The first audit reported that nurses correctly categorised pressure ulcers 56% of the time. Subsequently, further intensive training was implemented and a repeat audit was performed. The findings demonstrated a small increase to 62%. Agreement was moderate for the first study (k=0.48), and (k=0.50) for the second audit. Due to
the small sample size, the study cannot be generalised to the other healthcare organisations. Studies report similar findings (Moore 2005, Vanderwee et al. 2007, Whiteing 2009, Kelly & Isted 2011). Therefore other methods of detecting early pressure damage need to be examined.

2.8 The Role of Sub Epidermal Moisture (SEM) in Detecting Early Pressure Ulcer Damage

Failure to identify stage 1 pressure ulcers means that more than 1 in 5 pressure ulcers deteriorate to higher stages within a week of admission to the acute care setting (Halfens et al. 2001). Current standards of care for prevention of pressure ulcers include visual skin inspection and may also include the use of risk assessment scales. Both methods are subjective, and dependent on the clinical skills of the assessor (Pancorbo-Hidalgo 2006, Schuurman et al. 2009, Kelly & Isted 2011, and Moore & Cowman 2014). Bruin Biometrics (BBI) developed the SEM Scanner™, a point of care, diagnostic tool that measures increased fluid content within the skin and underlying tissue known as sub epidermal moisture (SEM) (Bruin Biometrics 2013). Current research pertaining to early detecting of pressure damage examines the feasibility of obtaining biophysical measures of SEM to predict pressure ulcers (Bates-Jensen et al. 2007, 2008, 2009, Guihan et al. 2012, Harrow & Mayrovitz 2014). Inflammatory changes, with resultant tissue oedema, precede tissue degradation; this inflammation and oedema can occur 3 to 10 days before being visible on the skin surface (Herrman et al. 1999, Pack et al. 2002).

The SEM scanner picks up the signal that determines the levels of sub epidermal moisture via electrical capacitance (Bates-Jensen et al. 2007). Capacitance is the ability of a body to store an electrical charge. The stratum corneum has high electrical resistance which protects the protective barrier of the skin, which prevents penetration of chemicals and water (Tagami 1980), and its function has been quantified by dermatologist researchers through measurement of trans epidermal
water loss (Baker 1967, Grice & Bettley 1967). The impedance of the skin to electrical forces is used to calculate surface electrical capacitance which identifies the level of localised oedema in the epidermal and sub dermal tissues. The SEM Scanner™ measures this capacitance through a signal picked up when the machine is placed on the skin, through an integrated electrode. The stratum corneum of the epidermis is influenced by environmental moisture; the lower epidermal layers contain water generated from within the tissues and are not as affected by environmental moisture. The capacitance sensor measures skin and tissue water using electrical properties based on different water contents of the skin (Bates-Jensen et al. 2007).

SEM has been examined to determine wound healing in burn wounds, and to examine the relationship between SEM and chronic wound healing (Goretsky et al. 1995, Boyce 1996, Harrow & Mayrovitz 2006). Recent studies (Bates-Jensen et al. 2007, 2008, 2009, Guihan et al. 2012, Harrow & Mayrovitz 2014), have examined the relationship between a measure of SEM and visual skin assessment (VSA) of erythema and grade 1 pressure ulcers. An American descriptive cohort study (Bates-Jensen et al. 2007) examined whether SEM measures could be used to predict the presence or changes in erythema/Stage 1 pressure ulcers. The population for inclusion into the study was chosen from a population that was undergoing a randomized trial regarding nutrition in two long term care units. The study took place over a 52 week period. Prior to the study commencing, the nurses were provided with skin assessment training, thereafter visual skin assessment and readings were recorded concurrently. SEM was recorded using a dermal phase meter and the results were recorded in dermal phase units (DPUs). Higher readings than 999 suggested higher SEM levels. The observers were blinded to the rationale of the study. Three readings were taken at each site and represented a correlation coefficient (r= 0.90). Results indicated that a higher SEM level was associated with concurrent and incident (1 week later) skin damage. Although the research highlights important issues, its sample size is small (n=35) which renders the results vulnerable to sampling fluctuations,
therefore, a larger sample size may strengthen the supporting evidence (Polit & Beck 2010). There were also variances in the data collected ranging from 10 weeks to 44 weeks. Further, Coleman et al. (2013), posit that due to the researchers using only the risk assessment scale score in the multivariate analysis makes it impossible to identify the dominant risk factors.

Bates-Jensen et al. (2008) further examined the feasibility of SEM to further differentiate erythema and stage 1 pressure ulcers. Again, a descriptive cohort study design was the research method applied to a population using a small sample size of 31 patients. Also the study occurred in long term care setting, where patients could be assumed to be in better health compared to their counterparts in the acute care setting. Bates-Jensen et al. (2009) pooled the results of the previous studies and attempted to distinguish between light skin tone and dark skin tone patients. The authors concluded that sub epidermal moisture threshold values may assist in detecting early pressure ulcers particularly in dark skinned populations where visual skin assessment is more complex. Studies address the difficulty in assessing and staging pressure damage, particularly in darker skin toned populations (Whitening 2009, NPUAP/EPUAP/PPPIA 2014). A recent American prospective, single arm post-test observational design study (Guihan et al. 2012), assessed the feasibility of SEM to predict erythema and stage 1 pressure ulcers in patients with spinal cord injury. Results suggested that using SEM may be useful in this population, however, since the sample size was 32 a further large scale study was recommended. It should be noted that the parameters and measurements in the original studies were vast and varied, which made comprehension of the study methods difficult. The SEM Scanner has evolved since, and a single deviation of >0.5 SEM units indicates pressure induced tissue damage (Bruin Biometrics 2013). Further, Harrow & Mayrovitz (2014) used a convenience sample of sixteen spinal cord injury patients with existing stage three or stage four pressure ulcers to quantify sub epidermal moisture surrounding these pressure sores and concluded that SEM differentiates pressure ulcers from viable intact skin, SEM at pressure ulcer sites was greater by nine percent than at control
sites (P<0.05). Limitations to the study included that it did not report reliability or validity, from the context that it was a single observer study, however the study sought to examine characteristics of a means of quantifying SEM surrounding pressure ulcers as previously alluded to. Further, the study examined a cohort of spinal cord injury patients which excludes its generalisability to the wider population.

2.9 Conclusion

Despite investing resources into education and training, hospital acquired pressure ulcers continue to present as a significant health care burden. Patients who suffer from pressure ulcer damage report significant deterioration in health related quality of life, with pain being the most reported symptom. Small studies have demonstrated the feasibility of using SEM as a predictor of pressure ulcer damage. Sub epidermal levels are elevated in the early inflammatory process, therefore once identified, and prevention strategies are implemented or heightened, pressure ulcer damage can be averted. Early pressure ulcer detection is important to prevent further extension of damage. SEM has the capacity to detect this early inflammatory change, therefore warrants further examination. The purpose of this research study is to further examine the feasibility of adapting SEM as an adjunct to current risk assessment methods.
Chapter 3 Research Design

3.0 Introduction

The ensuing chapter will address the theoretical basis, design, process and methods used to carry out this study, including data collection and subsequent analysis of findings. A brief overview of the main types of research will be provided with reference to the various designs that equate to each research approach. Determining the best research approach elicits frequent debate, as all have their strengths and limitations (Carr 1994). Further, whilst there are many valid research paradigms, methodologies and strategies used in nursing research, none are universally recognised as superior to the other (Watson et al. 2008). Nursing research seeks, through application of systematic processes, new knowledge that will benefit the population as a whole, across a continuum of healthcare services addressing the needs of all age profiles (Drennan et al. 2007). Fundamentally, undertaking research entails choosing which paradigm and methodology that best answers the research question posed (Welford et al. 2011, Jones 2014). Quantitative research studies are formulated upon confirmatory and predictive nature, conversely qualitative research studies are formulated on the exploratory and interpretative nature (Ellis & Levy 2009).

3.1 Research Paradigms and Philosophical Background

Health related research is generally aligned to one of two main paradigms, or theoretical perspectives. Paradigms are often described as world views or ways of experiencing and thinking about the world (Kuhn 1970, Guba 1990, Weaver & Olsen 2006, Morgan 2011). Paradigms are characterised by ontological, epistemological axiological and methodological variances which influence the research approach, findings and subsequent contribution to knowledge (Welford et al. 2011). Ontology and Epistemology are the two fundamental philosophies that distinguish existing research paradigms (Wahyuni 2012). Further, the two basic beliefs that impact upon how reality is
investigated are axiology and methodology. Axiology reflects the researcher’s values and opinions of
the topic under investigation. Methodology denotes the model chosen to undertake the research
process (Polit & Beck 2012).

Nursing research endeavours to seek out solutions to answer a question or to understand a
phenomenon and is often influenced by the researcher’s ontological stance (Weaver & Olson 2006).
Morgan (2011) posits that paradigms are systems of beliefs and practices that directly influence how
researchers choose the questions they wish to study and the methods they apply to study them. The
paradigm provides the framework (Welford et al. 2011), or the research canvas (Jones 2014),
through which the research investigation originates. Anomalies exist with regard to the various
terms ascribed to paradigms such as ‘disciplinary matrix’ and ‘research tradition’ causing confusion
amongst neophyte researchers (Weaver & Olsen 2006). Broadly nursing research is conducted within
two main paradigms positivism and interpretivism (Welford et al. 2011). Positivism conforms to a
belief in the absolute truth where objective measurements explain casual relationships between
variables (Watson et al. 2008). Conversely interpretivists are of the opinion that in order to
understand specific populations, experiences meanings and language must be experienced and shared
(Watson et al. 2008). Patterson & Morin (2012) posit, initiation of a research study is predicated on
the world view the researcher brings to the study including the inception of the phenomenon under
consideration.

3.1.1 Positivist Paradigm
Quantitative research is frequently used in social science research and is concerned with determining
the relationship that exists among variables or using a hypothesis to predict the expected relationship
amongst variables (Creswell 2003). Quantitative research has its underpinnings in the philosophical
paradigm for human enquiry referred to as Positivism (Polit & Hungler 1999). Positivism is
concerned with verifying facts through a systematic and methodological process (Creswell 2003). Data are collected, quantified and subjected to statistical analysis to support or reject knowledge claims (Burns & Grove 1987, Creswell 2003). This is frequently described as accepting the experimental hypothesis and rejecting the null hypothesis (Salkind 2010). There are numerous ways to test the hypothesis and whilst there is no single correct way of doing so, it is up to the researcher to select the most appropriate method (Salkind 2010). Quantitative research designs include experimental, quasi-experimental, and non-experimental designs and are often referred to as descriptive, correlation and experimental research designs (Parahoo 1997). In quantitative research, the researcher provides an objective measure of reality, as opposed to qualitative research which views reality as a subjective experience for the group of subjects being studied (Polit & Beck 2012).

3.1.2 Interpretive Paradigm

Interpretivists are concerned with understanding social or human phenomenon within a natural context via text production and interpretation (Creswell 2002, Welford et al. 2011). Multiple perspectives are taken into account resulting in inductive emergence of theory (Welford et al. 2011). Qualitative research strategies include ethnography, grounded theory, case studies, phenomenological research, and narrative research. Regardless of the strategy chosen, all social aspects are taken into account providing in depth understanding of the phenomenon being studied (Parahoo 2006). The ontological stance of Interpretivists enables a greater understanding via detailed descriptions and understanding of life experiences and perspectives of the patient (Welford et al. 2011). Themes derived from observations and interviews form the basis of evidence of different perspectives in the researcher’s discussion of findings (Welford et al. 2011).
3.2 Research Methodology

Research methodology alludes to the theoretical and ideological foundations of a method, whereas research method refers to the set of steps taken to complete the actual research (Wahyuni 2012). A research design is the culmination of a research approach and a research methodology that will address the research question or hypotheses in order to examine social phenomena (Wahyuni 2012). Whilst it is appreciated that both quantitative and qualitative approaches provide important contributions to research, the chosen method should reflect the superior means of answering the research question (Wahyuni 2012). Both quantitative and qualitative research methods are valid means of positively contributing to nursing research, the ultimate aims is to provide the best patient experience with superior outcomes. Examining the relationship between visual assessment of intact skin and a measure of sub epidermal moisture (SEM) in ‘at risk’ patients fits well in the design of a quantitative descriptive study, which is defined by its ability to observe and describe patterns of disease occurrence (Daly & Bourke 2007). Consideration was given to other methodologies within the quantitative paradigm, however the role of SEM in pressure ulcer research is an emerging science and has mainly being explored in the US (Bates-Jensen 2007, 2008, 2009, & Guihan et al. 2012), and descriptive research studies are often used when researching new topics, events, diseases or conditions (Polit & Beck 2010). Further, descriptive research involves identification of attributes of a particular phenomenon based on observations made or can involve exploring the correlation between two or more phenomena (Williams 2007). Despite not having a control group, they can suggest hypotheses which can be tested allowing inferences to be made (Anderson et al. 2013). Descriptive observational methods were used in previous US studies (Bates-Jensen 2007, 2008, 2009 & Guihan et al. 2012).

Quantitative researchers advocate the use of a scientific approach through development of numeric measures to generate knowledge that is credible (Wahyuni 2012) through formation of a hypotheses
and use of statistical tests in the research process. Further, they believe that different researchers observing the same problem will obtain similar results by following the same research process (Creswell 2009). Previous cohort descriptive studies designed by Bates-Jensen et al. (2007, 2008 & 2009), were preceded by a large randomised control study from where the researchers obtained their sample for research for the 2007 and 2008 study, the (2009) Bates-Jensen study was an amalgamation of the two. Guihan et al. (2012) performed a prospective observational design to assess the feasibility of obtaining sub epidermal moisture (SEM) values of spinal cord injury patients as a means of preventing pressure ulcers. Therefore an ontological view employing positivist approach was chosen for the research process. Measurement of sub epidermal moisture (SEM), as a means to prevent early onset of pressure ulceration is an emerging science and fits well within the realm of positivism due to its research focus on the quantification of concepts and their relationship via measurement.

3.3 Philosophical Underpinnings

For the purpose of the study, the researcher examined their construct of reality and knowledge and the research question posed in order inform their choice of methodology. Grix (2004) suggests that the researcher’s ontological assumptions will inform their epistemological assumptions and subsequently inform choice of methodology, and thereafter the methods chosen to collect data. The researcher identifies most with positivist paradigm assumptions whose purpose in research is to prove or disprove a hypothesis. The objective of the research study is establish the correlation between visual skin assessment and SEM findings and to establish if SEM is more accurate in detecting skin changes when compared to visual assessment alone. For the purpose of the study, emphasis was placed on the scientific method of collecting data which can be quantified and statistically analysed. This is in keeping with the philosophical underpinnings of quantitative research whereby objects have meaning independent of thought and that truth can be obtained as
knowledge rests on truths that are indisputable and can be generated deductively from a theory or hypothesis (Grix 2004).

### 3.4 Population Sample and Sampling

Appropriate choice of study subjects serves the vital purpose of ensuring that findings in the study accurately represent what is happening within the population of interest (Creswell 2009). A poorly selected sample may yield biased results which affects external validity of the study, and as such, results cannot be applied to the wider population (Polit & Beck 2012). The population refers to all subjects of interest to the researcher and the sample refers to the proportion of the population selected to participate (Creswell 2009). Quantitative research generally yields large sample sizes, however, small samples are also found in descriptive quantitative studies (Polit & Beck 2012, Burns & Grove 2011). Further, sample size must be acceptable from a resource perspective both budgetary and time (Polit & Beck 2012, Burns & Grove 2011). Unlike qualitative sampling, where sampling is aimed at individuals who have experienced phenomena and can provide rich data, quantitative sampling aims to ensure confidence and generalisability of findings (Polit & Beck 2012). A key requirement for undertaking quantitative research is that the researcher remains as objective as possible. This requires a disciplined, structured approach to research in order to describe phenomena, test theories, or to predict or examine relationships regarding the topic being researched (Polit & Beck 2012). Ideally power analysis should be carried out during the design phase of the study. In general a list of inclusion and exclusion criteria is generated for potential study subjects (Polit & Beck 2012). A list of inclusion and exclusion criteria chosen for the research study will follow later. The two main forms of sampling, which are probability and non probability sampling (Polit & Beck 2012), will be discussed.
3.4.1 Probability Sampling
Probability sampling involves random selection of subjects allowing equal opportunity of being selected to participate in the study (Polit & Beck 2012). It remains the superior form of sampling providing the least risk of bias; however it is resource dependent both from a budgetary and time perspective (Panacek et al. 2007).

3.4.2 Non Probability Sampling
As the name suggests non probability sampling does not offer randomisation in its sample selection, and is often used for pilot studies, exploratory studies and qualitative studies and also studies where resources are limited or unavailable (Panacek et al. 2007).

3.4.3 Study Sample
Whilst the writer appreciates that random sampling methods are the superior form of sampling in order to ensure external validity of a study, a non random sampling method namely purposive sampling was chosen for the research study. Purposive sampling in quantitative research ensures that the researcher selects subjects who meet strict inclusion criteria and whilst purposive sampling is limited by bias from the process of sample selection itself, researchers may use such a sample when the sample size will be small and full cooperation is necessary (Panacek et al. 2007). For the purpose of the research study, it was necessary to sample patients who were admitted to hospital at risk of pressure ulcer development, but had intact skin. The researcher acknowledges that statistical analysis may be viewed as potentially flawed due to non-random selection and as such findings cannot be generalised to the wider population. All patients at risk of pressure ulcer formation were provided with information leaflets by the ward nurses pertaining to the study (appendix 1). The researcher then visited each patient considered eligible for the study, clarified any issues or queries and then obtained informed written consent (appendix 2).
3.4.4 Inclusion Criteria

- Patients considered at risk of pressure ulcer formation based on the Norton pressure ulcer risk assessment tool and nurses visual skin inspection.
- Patients without existing pressure ulcers.
- Patients who consented to participate.
- Patients who were assented by their next of kin.

3.4.5 Exclusion Criteria

- Patients, who are at risk, but have an existing pressure ulcer.
- Patients who did not consent to participate in the study.
- Patients with a normal Norton score.
- Patients without activity and mobility limitations.

3.4.6 Study Setting

The study was conducted in a medical and a surgical unit consisting of 62 beds in total of a general hospital in Ireland. The hospital has a 243 bed capacity and serves a catchment population of 243,000. As previously mentioned the research and ethics committee dictated the wards from which the sample was obtained. Over the four week period of recruitment and data collection, one of the wards experienced the winter vomiting bug which resulted in the closure of 12 beds over a two week period, reducing the availability of subjects to recruit.

3.5 Data Collection

This study focused on an emerging science in the field of pressure ulcer prevention namely SEM and its ability to assess for early signs of pressure damage equivalent to or better than nurses visual skin inspection. The data pertaining to each patient, was collected daily for the duration of the study over
a four week period and only ceased once the patient was discharged, transferred to another facility or another ward that was not chosen as the study site or when patients requested to desist from participating in the study. No patient left the study once enrolled. The data collected included demographic details obtained from the nursing and medical notes including

- Age
- Sex
- Mobility
- Activity levels
- Previous pressure ulcer damage
- Medical history
- Medications
- Documented nurses’ visual skin assessment.

Instruments used included the Norton Pressure Ulcer Risk Assessment Scale (appendix 3) and the SEM Scanner 200. The researcher concurrently recorded SEM readings of the sacrum, right and left heel of participants. The SEM scanner is placed directly in contact with the skin with appropriate pressure for at least 1 second, the unit processes the signal and results obtained are displayed on the monitor. Three readings are taken at each anatomical location and a difference of >0.05 between the lowest and highest values recorded denotes elevated sub epidermal moisture levels synonymous with early pressure ulcer development and is deemed abnormal. Similar data were included in seminal studies relating to SEM (Bates-Jensen 2007, 2008, 2009). A study by Clendenin et al. (2015), evaluated the inter rater and inter device agreement and reliability of the SEM Scanner. Agreement between operators was good with mean differences ranging between -0.01 to 0.11. Inter operator and inter device reliability surpassed 0.80 at all anatomical sites assessed. All of the data collected were quantifiable and measurable variables, which satisfy the necessary requirements for statistical analysis (Plichta & Garzon 2009). Data for the study was collected prospectively from the sample
group, which consisted of forty seven participants deemed at risk of pressure ulcer development. A total of 1,018 SEM values were collected and 323 days of nurses’ visual skin assessments were recorded.

3.6 Pilot Study

Pilot studies are designed to evaluate the feasibility, efficiency and cost of study methods, the accuracy and reproducibility of measurements, any discomfort procedures would cause such as when measuring SEM values which may involve repositioning participants which potentially may result in some discomfort (Hulley et al. 2007). Most importantly pilot studies provide a surmise of the potential number of participants which impacts outcome rates and effect size. The researcher choose a period of one week to pilot the study from which 11 potential participants were available for recruitment which indicated a potential overall sample of +/- 40 participants. MUST score measurements, which reflect nutritional status of the patients was removed from the data collection tool as the researcher found that they were absent in all but one of the pilot study participants charts as education pertaining to MUST score had not being completed on the two wards chosen for the study. The pilot study also informed the researcher of the significant time required to recruit and record all the data. Seminal studies related to SEM recruited sample sizes of 31-35 patients over the period of a year. The population for the aforementioned studies were recruited from long term care facilities and a spinal cord injury veteran’s facility. The pilot study served to identify and iron out problems for the researcher.

3.7 Data Analysis

Descriptive statistics are used to describe and summarize data to make them more meaningful (Plichta & Garzon 2009). They are often presented visually using frequency distributions and graphical displays such as graphs and histograms. (Plichta & Garzon 2009). Further, researchers may
also compare measurements on the same group that are taken over time and testing them with inferential statistics (Plichta & Garzon 2009). All data were categorised into variables, entered onto SPSS and analysed using descriptive and inferential statistics as appropriate. Prior to analysis data were checked for accuracy by an independent person. The writer became familiar with all of the variables, particularly the ones used to test relationships and questions. Frequency counts and estimations of means, medians and standard deviation were calculated and reported. The choice of inferential statistics is predicated on the assumptions and inferences that can be made from the data (Polit & Beck 2012). Parametric tests are used for variables which are normally distributed. Further a stringent set of assumptions are necessary in order to avoid violation of statistical assumptions (Polit & Beck 2012). In this study nurses visual skin assessments were correlated with SEM measures to determine the relationship between the two variables. Pearson’s correlation co-efficient was the test conducted to determine strength of the relationship between the two variables, which are reported as low, medium or strong correlations (Polit & Beck).

3.8 Issues of Validity & Reliability

Control, limitation of bias, reliability and validity are vital components of the quantitative process if the findings are to accurately reflect reality (Polit & Beck 2012). Control reflects the actions taken by the researcher in order to limit bias and maximise validity (Burns & Grove 2003). Objective measurement and recording of variables implies that some degree of control has been executed, which limits researcher bias and enhances validity and reliability (Polit & Beck 2012).

3.8.1 Validity

Validity refers to the degree to which an instrument used in a study, measures what it sets out to measure (Panacek et al. 2007). The data collected in the study consisted of objective measurements such as demographic data, mobility and activity levels, Norton risk assessment score, and SEM
measurements. These variables provide the foundation for the study, which measures the relationship if any, between nurses’ visual skin assessment, and SEM measurements in patients at risk of pressure ulcer formation. The data collection tool for the measurement of SEM values is an updated version of the unit used in seminal studies relating to measurement of sub epidermal moisture measurements (Bates-Jensen et al. 2007, 2008, 2009 & Guihan et al. 2012).

3.8.2 Reliability

Reliability refers to the ability of the data collection instrument to provide consistent reproducible results (Panacek et al. 2007). These include but are not limited to test/retest reliability, inter-observer reliability and internal reliability. Test/retest refers to the measure of consistency of results when the same data is collected from a subject on different occasions (Polit & Beck 2012). An inter rater, inter-observer study of SEM Scanner demonstrated inter-rater, inter-operator reliability of the device (Clendenin et al. 2015).

3.9 Ethical Considerations

Ethical considerations are a vital component of any research study, particularly when humans are involved. Ethical standards exist for the protection of vulnerable subjects being put at risk, and dictate the conduct of the researcher when carrying out all steps of the research process (An Bord Altranais 2007, Polit & Beck 2012, Nursing and Midwifery Board of Ireland 2013). NMBI (2014), publish set standards providing detailed guidance when conducting research. Ethical principles identified pertaining to undertaking research include respect for persons autonomy, beneficence, non-maleficence, justice/ fairness, veracity, fidelity and confidentiality (An Bord Altranais 2007, Polit & Beck 2012). For the purpose of this research study, the researcher submitted a research proposal to the local ethics committee and to the ethics committee of the educational institution, where the researcher attends. Pressure ulcers frequently occur in the elderly population, who often
present with complex conditions compounded by acute illness once hospitalisation is required (Duckett & Jackson 1999). Potential barriers include fatigue, normal age-related processes such as visual or hearing impairment, delirium or dementia (Hancock et al. 2003). The patients were given an information leaflet about the study and they were afforded time prior to consent to ask questions about the study. All potential participants that were approached consented to take part in the study. Where the patient was unable to consent assent was sought from their next of kin. Originally the research and ethics committee requested that these patients were excluded from the study, however the researcher with support of the HSE National Consent Guidelines (2013), argued that this very population were the most at risk of developing pressure ulcers and exclusion could be considered a disservice to this vulnerable population. Approval to include this population was granted thereafter (appendix 4).

Whilst the research study is primarily in part fulfilment of an MSc in advanced nursing practice, the researcher was keen to choose a study that might have a positive effect on patient outcomes, even if it demonstrated a need for more extensive research. Ethics committees, share the same goal as researchers, ultimately the goal is to produce high quality evidence that will inform clinical practice (Polit & Beck 2012).

4.0 Informed Consent

Informed consent ensures that individuals adequately understand all information pertaining to the research study, and thus consent forms must ensure that the option to withdraw from the study is clearly stated and made known to the participant (Polit & Beck 2012). Further, the participants must be informed that withdrawal from the study will not affect their care (Polit & Beck 2012). This study has addressed these issues in an information leaflet provided.
4.1 Anonymity & Confidentiality

Confidentiality reflects the responsibility of the researcher to respect the participants and protect all data obtained during the research study. Anonymity refers to the act of maintaining individuals’ privacy throughout the research process (Polit & Beck 2012). All data collected were stored in a locked filing cabinet, which can only be accessed by the researcher. Findings are reported, without divulging any information that may identify the patient.

4.2 Conclusion

This chapter describes the steps taken in the research process, from study design to analysis of findings. It provides an overview of the research paradigms, with particular emphasis on quantitative descriptive design, the method chosen for the research study. Data collection methods, sample selection issues, ethical considerations and data analysis are described. The research question, design, methodology and methods are fundamental components in choosing the most appropriate approach that will answer the research question (Polit & Beck 2012). Further, a sound understanding and adherence to each step of the research process is essential for the development of quality studies, so that valuable information regarding the research question is obtained (Polit & Beck 2012). A descriptive prospective observational study was chosen as the most appropriate design to examine the relationship between nurses’ visual skin assessment and SEM values.
Chapter 4 Presentation of Findings

4.0 Introduction

The ensuing chapter presents the key findings of the study. The study sought to determine the relationship between nurses’ visual assessment of early pressure ulcer damage of the pressure areas of ‘at risk’ patients and SEM values of those patients. The objectives were to establish the correlation between visual skin assessment and SEM findings and to establish whether SEM is more accurate in detecting early signs of pressure ulcer damage compared to visual assessment alone and further examine the feasibility of adapting SEM as an adjunct to current risk assessment methods. This was achieved through a descriptive research study of a cohort of patients on two ward units who were assessed as being at risk of pressure ulcer damage, but were pressure ulcer free on admission. Outcome measures for pressure ulcer development were calculated for the entire cohort. Descriptive and parametric statistics were used to analyse the data. Data will be presented in the form of written descriptions, bar charts and tables. Section 4.2 to 4.5 presents the descriptive analysis, describing demographic variables such as age, gender, Norton score, activity and mobility status and whether the patient had experienced previous pressure ulcer damage. Section 4.6 describes results from correlation analysis undertaken.

All data were analysed using Statistical Package for Social Sciences (SPSS) (version 21). Descriptive statistics were computed on variables to determine frequencies, means and medians. Inferential analysis through means of bivariate analysis determined the relationship between nurses’ visual assessment of early pressure ulcer damage and SEM findings of early pressure ulcer damage. Cross tabulation was performed to identify whether a time difference existed between nurses’ visual assessment of early pressure damage and SEM findings of early pressure damage. Level of statistical significance was set at \( p<0.05 \).
4.1 Demographics Details

4.1.1 Sample Profile

Forty seven patients assessed as being ‘at risk’ of pressure ulcer development with non-existing ulcers were recruited to participate to the study (Figure 1). Data collection took place over a four week period. A total of 372 days of data were recorded (Figure 2), 138 data entries were recorded from male patients and 234 data entries were recorded from female patients (Figure 3).

**Figure 1 Participant Flow**

```
Flow of Participants through the Study

Assessed for eligibility (n=167)

Excluded (n=120)
Not meeting criteria (n=120)
Refused to participate (n=0)

Included (n=47)

Lost to Follow Up (n=0)

Final Analysis (n=47)
```
Figure 2 Data days per patient

Figure 3 Data Days per gender
4.1.2 Gender

Of the total population, 38.3% (n=18) were male and 61.5% (n=29) were female (Table 1).

<table>
<thead>
<tr>
<th>Gender</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>18</td>
<td>38.3</td>
</tr>
<tr>
<td>Female</td>
<td>29</td>
<td>61.7</td>
</tr>
<tr>
<td>Total</td>
<td>47</td>
<td>100</td>
</tr>
</tbody>
</table>

4.1.3 Age

The minimum age was of participants was 34 years, the maximum age was 95 years and the median age was 74.7 years (Figure 4).

Figure 4 Patient Age
4.2 Risk Factors for Pressure Ulcer Development

4.2.1 Norton Score

As previously discussed, the Norton Score is a risk assessment scale with a series of five subscales which calculates a total risk score ranging from 5 to 20. A lower score indicates higher risk of pressure ulcer development.

- High risk = < 10
- Medium risk = 11-15

The mean Norton Score was 12 (medium risk), the minimum Norton Score was 8 (high risk) and the maximum Norton Score was 17 (low risk) (Figure 5).

![Figure 5 Norton Score](image)
4.2.2 Mobility Status

Of the total population 36.2% (n=17) were immobile, 25.5 % (n=12) had very limited with mobility and 38.35 (n=18) had slightly limited mobility (Table 2).

<table>
<thead>
<tr>
<th>Table 2 Patient Mobility</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Frequency</strong></td>
</tr>
<tr>
<td>------------------</td>
</tr>
<tr>
<td>Immobile</td>
</tr>
<tr>
<td>Very Limited</td>
</tr>
<tr>
<td>Slightly Limited</td>
</tr>
<tr>
<td><strong>Total</strong></td>
</tr>
</tbody>
</table>

4.2.3 Activity Status

Of the total population, 21.3% (n=10) were bedfast, 36.2% (n=17) were chair bound and 42.6% (20) required assistance to mobilise (Table 3).

<table>
<thead>
<tr>
<th>Table 3 Patient Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Frequency</strong></td>
</tr>
<tr>
<td>------------------</td>
</tr>
<tr>
<td>Bedfast</td>
</tr>
<tr>
<td>Chair</td>
</tr>
<tr>
<td>Walks with help</td>
</tr>
<tr>
<td><strong>Total</strong></td>
</tr>
</tbody>
</table>
4.2.4 Previous History of Pressure Ulcer

Of the total population 8.5% (n=4) had a history of pressure ulcer damage. Conversely, 91.5% (n=43) did not experience previous pressure ulcer damage (Table 4).

Table 4 Previous Pressure Ulcers

<table>
<thead>
<tr>
<th></th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>4</td>
<td>8.5</td>
</tr>
<tr>
<td>No</td>
<td>43</td>
<td>91.5</td>
</tr>
<tr>
<td>Total</td>
<td>47</td>
<td>47</td>
</tr>
</tbody>
</table>

4.3 Nurses Visual Skin Assessment

Nursing documentation was examined daily and nursing skin assessments specific for three anatomical locations, the sacrum and both the right and left heels were recorded and entered onto SPSS. Nurses assessed 34% (n =16) of the population as having abnormal skin. Twenty eight percent (n=13) were found to have grade 1 pressure ulcers and 6% (n=3) developed grade 2 pressure ulcers. The anatomical location of the documented skin damage and the number of days that it took for the nurse to identify the damage is displayed in table 5. The mean value of the SEM recordings leading up to the day that the nurses identified the pressure damage visually is also reported in table 5. The most common anatomical location displaying early signs of pressure damage was at the sacrum 77.8% (n=14), followed by the left heel 16.7% (n=3) and 5.5% (n=1) on the right heel. The mean number of days it took the nurses to detect early pressure ulcer damage 5 days (SD 5.15 days; max 11 days, min 3 days). The mean number of days that it took the SEM scanner to detect early signs of pressure ulcer damage was 1.1 (SD 0.075; max 2 days, min 1 day). The difference between the time
it took nurses to recognise pressure ulcer damage and SEM was found to be statistically significantly different \( (p \leq 0.0001) \).

Table 5: Days to detect early signs of pressure ulcers: Nurses Visual Assessment (NVA) versus SEM

<table>
<thead>
<tr>
<th>Patient #</th>
<th>Day identified using NVA</th>
<th>Day identified using SEM</th>
<th>NVA Result</th>
<th>Mean SEM Result</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>#002</td>
<td>3</td>
<td>1</td>
<td>Grade 1</td>
<td>2.06</td>
<td>Sacrum</td>
</tr>
<tr>
<td>#006</td>
<td>5</td>
<td>1</td>
<td>Grade 1</td>
<td>0.94</td>
<td>Sacrum</td>
</tr>
<tr>
<td>#009</td>
<td>5</td>
<td>1</td>
<td>Grade 1</td>
<td>0.94</td>
<td>Sacrum</td>
</tr>
<tr>
<td>#021</td>
<td>11</td>
<td>1</td>
<td>Grade 1</td>
<td>0.98</td>
<td>Sacrum</td>
</tr>
<tr>
<td>#022</td>
<td>3</td>
<td>1</td>
<td>Grade 1</td>
<td>1.80</td>
<td>Sacrum</td>
</tr>
<tr>
<td>#023</td>
<td>5</td>
<td>1</td>
<td>Grade 1</td>
<td>2.10</td>
<td>Left Heel</td>
</tr>
<tr>
<td>#024</td>
<td>6</td>
<td>1</td>
<td>Grade 1</td>
<td>1.00</td>
<td>Sacrum</td>
</tr>
<tr>
<td>#026</td>
<td>11</td>
<td>1</td>
<td>Grade 1</td>
<td>1.23</td>
<td>Sacrum</td>
</tr>
<tr>
<td>#005</td>
<td>5</td>
<td>1</td>
<td>Grade 1</td>
<td>0.76</td>
<td>Sacrum</td>
</tr>
<tr>
<td>#030</td>
<td>2</td>
<td>1</td>
<td>Grade 1</td>
<td>1.45</td>
<td>Sacrum</td>
</tr>
<tr>
<td>#044</td>
<td>5</td>
<td>2</td>
<td>Grade 1</td>
<td>0.90</td>
<td>Sacrum</td>
</tr>
<tr>
<td>#046</td>
<td>7</td>
<td>1</td>
<td>Grade 1</td>
<td>0.71</td>
<td>Sacrum</td>
</tr>
<tr>
<td>#031</td>
<td>4</td>
<td>1</td>
<td>Grade 1</td>
<td>1.17</td>
<td>Sacrum</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>1</td>
<td>Grade 1</td>
<td>1.35</td>
<td>Left Heel</td>
</tr>
<tr>
<td>#004</td>
<td>4</td>
<td>2</td>
<td>Grade 1</td>
<td>0.85</td>
<td>Sacrum</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>1</td>
<td>Grade 2</td>
<td>1.15</td>
<td>Left Heel</td>
</tr>
<tr>
<td>#012</td>
<td>3</td>
<td>2</td>
<td>Grade 2</td>
<td>1.20</td>
<td>Right Heel</td>
</tr>
<tr>
<td>#018</td>
<td>4</td>
<td>1</td>
<td>Grade 2</td>
<td>0.94</td>
<td>Sacrum</td>
</tr>
</tbody>
</table>

A further 4.2% (n=2) of the participants developed dermatological skin conditions which were noted by the nurses in the documentation resulting in erythema (see Table 6). The first condition was an acute flare of psoriasis and the second was an acute allergic drug reaction which also resulted in skin erythema. The two patients experienced elevated SEM readings concurrent to the skin disease which returned to normal with appropriate medical intervention, without subsequent pressure ulcer development.
Table 6 SEM recordings occurring with Dermatological Disease and as isolated elevations

<table>
<thead>
<tr>
<th>Patient Number (Complaint)</th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
<th>Day 6</th>
<th>Day 7</th>
<th>Day 8</th>
<th>Day 9</th>
<th>Day 10</th>
</tr>
</thead>
<tbody>
<tr>
<td>#020 (Psoriasis)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sacrum SEM score</td>
<td>0.7</td>
<td>0.6</td>
<td>1.5</td>
<td>1.5</td>
<td>2.0</td>
<td>3.0</td>
<td>2.8</td>
<td>2.5</td>
<td>1.0</td>
<td>0.6</td>
</tr>
<tr>
<td>Nurses VSA</td>
<td>NA D</td>
<td>NA D</td>
<td>Red</td>
<td>Red</td>
<td>Red</td>
<td>Red</td>
<td>Red</td>
<td>Red</td>
<td>Red</td>
<td>Red ↓</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>#040 (Acute drug allergy)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sacrum SEM score</td>
<td>0.5</td>
<td>0.4</td>
<td>0.3</td>
<td>0.2</td>
<td>0.3</td>
<td>1.0</td>
<td>0.8</td>
<td>0.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses VSA</td>
<td>NA D</td>
<td>NA D</td>
<td>NA D</td>
<td>NA D</td>
<td>NA D</td>
<td>NA D</td>
<td>Rash</td>
<td>Rash</td>
<td>Rash</td>
<td>Rash ↓</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>#041 (Isolated SEM elevation)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sacrum SEM Score</td>
<td>0.4</td>
<td>0.6</td>
<td>0.5</td>
<td>0.4</td>
<td>0.2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses VSA</td>
<td>NA D</td>
<td>NA D</td>
<td>NA D</td>
<td>NA D</td>
<td>NA D</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NAD = No abnormality detected

4.4 SEM Values of the Sacrum, the Right and the Left Heel.

SEM vales were recorded daily at the sacrum, the right and the left heel of each patient for the duration of their hospital stay and ceased once the patient was discharged home, transferred to another ward or died. Missing values reflected in the data occurred when patients were in compression bandages which are applied for a period of seven days. A further reason for missing data was when the patient had a history of lower limb amputation. Due to large volumes of data reflecting the daily scores for SEM readings from each anatomical location, mean scores per day for each anatomical location, including nurses’ visual skin assessment were calculated and these are reported with the associated standard deviations (SD) per day (Appendix 5). The results show that there were overall higher values at the sacral site and lesser, but similar patterns of values, from both right and left heels. Individual SEM values were recorded for each
anatomical location over the four week period and a snapshot of the same are displayed in table format (Appendix 6).

4.5 Relationship between nurses’ visual skin assessment of early signs of pressure ulcer damage & SEM findings.

The primary aim of the study was to examine the relationship between nurses’ visual skin assessment and SEM findings in order to determine if a relationship between these quantitative variables exists. Pearson product moment correlation co-efficient was calculated to determine this relationship. Values range from -1 to 1, where -1 represents a strong negative relationship, 0 denotes no relationship and 1 represents a strong positive relationship. Firstly, the correlation between assessments each day, for nurses’ visual assessment and SEM for each anatomical site were calculated (see table 7).

Table 7 Correlation between nurses’ visual skin assessment and SEM assessments,
Mean “r” values.

<table>
<thead>
<tr>
<th>Days</th>
<th>Sacrum</th>
<th>Right Heel</th>
<th>Left Heel</th>
<th>Mean Daily “r”</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>-0.005</td>
<td>1.000</td>
<td>1.000</td>
<td>0.83</td>
</tr>
<tr>
<td>2</td>
<td>-0.112</td>
<td>1.000</td>
<td>1.000</td>
<td>0.81</td>
</tr>
<tr>
<td>3</td>
<td>0.280</td>
<td>1.000</td>
<td>1.000</td>
<td>0.88</td>
</tr>
<tr>
<td>4</td>
<td>0.681</td>
<td>-0.109</td>
<td>-0.058</td>
<td>0.22</td>
</tr>
<tr>
<td>5</td>
<td>0.775</td>
<td>0.022</td>
<td>-0.028</td>
<td>0.28</td>
</tr>
<tr>
<td>6</td>
<td>0.660</td>
<td>0.132</td>
<td>-0.106</td>
<td>0.28</td>
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<tr>
<td>7</td>
<td>0.586</td>
<td>0.081</td>
<td>0.002</td>
<td>0.27</td>
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<tr>
<td>8</td>
<td>0.704</td>
<td>0.268</td>
<td>0.203</td>
<td>0.38</td>
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<tr>
<td>9</td>
<td>0.510</td>
<td>-0.172</td>
<td>-0.226</td>
<td>0.12</td>
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<tr>
<td>10</td>
<td>0.159</td>
<td>0.040</td>
<td>0.215</td>
<td>0.22</td>
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<tr>
<td>11</td>
<td>0.604</td>
<td>0.462</td>
<td>-0.250</td>
<td>0.44</td>
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<tr>
<td>12</td>
<td>0.555</td>
<td>0.363</td>
<td>-0.455</td>
<td>0.40</td>
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<tr>
<td>13</td>
<td>0.952</td>
<td>-0.167</td>
<td>-0.745</td>
<td>0.26</td>
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<tr>
<td>14</td>
<td>0.700</td>
<td>-0.577</td>
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<td>0.37</td>
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<td>15</td>
<td>1.000</td>
<td>0.971</td>
<td>0.500</td>
<td>0.87</td>
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<tr>
<td>16</td>
<td>1.000</td>
<td>1.000</td>
<td>0.500</td>
<td>0.88</td>
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<tr>
<td>17</td>
<td>1.300</td>
<td>0.866</td>
<td>0.698</td>
<td>0.97</td>
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<tr>
<td>18</td>
<td>1.000</td>
<td>0.500</td>
<td>0.866</td>
<td>0.84</td>
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<tr>
<td>19</td>
<td>0.866</td>
<td>0.500</td>
<td>0.500</td>
<td>0.79</td>
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<tr>
<td>20</td>
<td>0.866</td>
<td>0.500</td>
<td></td>
<td>0.79</td>
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</table>
As can be seen from the figures in Table 7, there is great variability in the correlation results, with some very strong correlations (0.97) and some very weak correlations (0.12). The mean correlation for each anatomical site was also calculated for the total study period (see Table 8).

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Range</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Mean</th>
<th>Std. Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sacrum Mean r value</td>
<td>20</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>.65</td>
<td>.357</td>
</tr>
<tr>
<td>Right Heel Mean r value</td>
<td>17</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>.43</td>
<td>.458</td>
</tr>
<tr>
<td>Left Heel Mean r value</td>
<td>20</td>
<td>2</td>
<td>-1</td>
<td>1</td>
<td>.23</td>
<td>.539</td>
</tr>
</tbody>
</table>

From the data presented in Table 8, it can be seen that the correlation for the sacrum was higher than for either heels. Results can be interpreted as follows: there is low correlation for the left heel ($r=.23$), a medium correlation for the right heel ($r=.43$) and a strong correlation for the sacrum ($r=.65$) between nurses’ visual assessment and SEM.

Further analysis was conducted to explore the overall correlation for nurses’ visual assessment and SEM readings for those who went on to develop pressure ulcers. Results yielded showed that $r=0.47$ ($p=0.001$); therefore demonstrating that there is a medium correlation between nurses visual assessment of the skin and SEM. Furthermore, a 22% (0.22) variance is shared between nurses’ visual assessment of early pressure ulcer damage and SEM findings. However, an expectation exists that eventually a correlation should exist between SEM and nurses’ visual assessment findings once pressure ulcer damage becomes visible on the skin.

4.6 Conclusion of Findings

Descriptive analysis and parametric tests were undertaken to describe the study variables and to determine the relationship between nurses’ visual skin assessment for early signs of pressure damage and SEM findings. The total number of patients included in the study were
47, the majority 61.5% (n= 29) were female, with a median age of 74.4 years. The mean Norton score was 12.2. Levels of mobility ranged from 36.2% (n=17) being immobile to 38.3% (n=18) being slightly limited in their ability to mobilise. The majority 42.6 % (n=20) required assistance with activities, whilst 21.3% (n=10) were bedbound. Of the total population 34 % (n=16) developed early pressure ulcer damage, both the nurses’ skin assessments and the SEM values detected this. Nurses’ visual skin assessment of early signs of pressure ulcer damage and SEM findings were moderately positively correlated with a shared variance of only 22%. The nurses detected early pressure ulcer damage between 3 and 11 days. The mean number of days that it took for the nurses to identify early signs of pressure ulcer damage was 5 days (SD 5.15). Conversely, the mean number of days that it took the SEM scanner to detect early signs of pressure ulcer damage was 1.1 days (SD 0.075). The study also found that inflammatory skin conditions can be reflected as abnormal elevations in SEM findings furthermore, isolated elevated SEM readings can occur without subsequent skin damage Overall, the study found that there is low correlation for the left heel (r =.23), a medium correlation for the right heel (r =.43) and a strong correlation for the sacrum (r =.65) between nurses’ visual assessment and SEM. Readings for those who went on to develop pressure ulcers showed that r=0.47 (p=0.001); therefore demonstrating that there is a medium correlation between nurses visual assessment of the skin and SEM. The ensuing chapter will focus on a discussion pertaining to the findings and these will be further examined with reference to aforementioned studies in the literature review.
Chapter 5 Discussion of Findings

5.0 Introduction

This study found that SEM detected early pressure ulcer damage on average; 3.9 days sooner than nurses’ visual skin assessment. The ensuing chapter provides a discourse of this important finding, including reporting the clinical significance of the research findings within the context of existing research studies. Existing studies clarify the tangible role that SEM plays in predicting early pressure ulcer damage (Bates-Jensen et al. 2007, 2008 & 2009, Guihan et al. 2012, Harrow & Mayrovitz 2014). It is therefore conceivable that SEM may be a more accurate means of identifying patients who are susceptible to pressure ulcer damage compared to current methods used. Research by the aforementioned authors formed an important context for this study. Similarities and differences between this study and existing research will be ascribed to. Further, risk of bias in this research study will be discussed and a discourse analysis of the relationship between nurses’ visual assessment of early pressure damage and concurrent SEM findings will ensue. This study was based on the premise that adapting SEM as a means to positively identify skin at risk of pressure ulcer formation would result in sooner and improved accuracy compared to current methods. The objective of the study was to explore the relationship between nurses’ assessment of early pressure ulcer damage and sub epidermal moisture measurement.

The key findings from the study ascribe to the findings from similar studies. Literature confirms that the exploration of pressure ulcer formation is long established in the acute care setting (Moore 2010, Clark 2007, Moore & Cowman 2011, Dealey et al. 2012, Guy et al. 2013, Coleman et al. 2013). Risk assessment through use of formal risk assessment tools and nurses’ visual skin assessment is the risk assessment methods employed by the majority of healthcare settings. Results of such assessments inform the appropriate pressure relieving
equipment and repositioning regimes that are required. These measures remain the key principles of effecting best practice in the prevention and treatment of pressure ulcers (Moore 2010, Johansen et al. 2014). However, hospital acquired pressure ulcers continue to pose a significant financial and personal burden to both patients and hospital settings (Clark 2007, McIntyre et al. 2012, Guy et al. 2013). Further, hospital acquired pressure ulcers can occur within 2 weeks of admission; as early as 2 days (Samuriwo & Dowding 2014). To understand this concept it is important to reflect again on the causal pathway whereby pressure ulcer damage occurs. A plethora of literature regarding pressure ulcers exist, yet a clear understanding of the aetiology of their formation is awaited (NPUAP/EPUAP/PPPIA, 2014). However, it is evident that pressure ulcers continue to present significant challenges both from a budgetary and a healthcare quality of life perspective (Coleman et al. 2013). Subsequently, appropriately identifying potential threats to tissue integrity and subsequent pressure ulcer formation sooner and better provides the impetus for this study.

The chapter begins with a discussion pertaining to demographic details and risk attributes of the study population. A brief summary of current concepts regarding the aetiology of pressure ulcers will be follow. Thereafter, the limitations pertaining to nurses’ visual skin assessment as a means of identifying potential pressure ulcer risk shall be discussed. The results of this study emphasise how much longer it took nurses to visibly identify early pressure ulcer damage compared to SEM. During this study, episodes of inflammatory dermatoses occurred, including an acute flare of psoriasis and an acute allergic drug reaction. The associated skin changes were visually identified by the nurses and a discourse regarding concurrent elevated SEM readings shall follow. An analysis of the SEM values from the sacrum and both the right and left heel will be provided, thereafter the extent of the relationship between nurses’ visual skin assessment of early signs of pressure damage and SEM findings will be discussed.
Results from bivariate analysis, namely Pearson’s correlation coefficient will be reported. Finally, recommendations are made for further research to build on these findings within the context of the identified limitations in this study. Fundamentally, a paradigm shift must occur to move away from existing subjective means of diagnosing pressure ulcers to a more quantifiable means of assessing for such damage.

5.1 Demographic Details

5.1.1 Research Participants

Forty seven patients assessed as being “at risk“ of pressure ulcer development with non-existing ulcers were recruited to participate in the study. Similar studies examining the use of SEM to predict pressure ulcer damage used cohorts of 35, 31, 66, 34 and 16 patients respectively (Bates-Jensen et al. 2007, 2008, 2009, Guihan et al. 2012, Harrow & Mayrovitz 2014). Recruitment selection for the studies varied, this writer’s study utilised purposeful sampling for selection of participants, Bates Jensen et al. (2007, 2008, 2009) and Guihan et al. (2012) obtained their sample from a subset sample of an RCT. Sampling from an RCT endorses the robustness and generalisability of study findings (Polit & Beck 2008). Purposive sampling has being associated with researcher bias; however once strict inclusion criteria are employed; such sampling choice can be defended (Polit & Beck 2010). The judgements this writer applied for participant selection was based on clear criteria for inclusion into the study, however, the writer acknowledges this method as a limitation to generalisation of the study findings.

A total of 372 days of SEM readings were recorded from the sacrum, right and left heel of each participant. Missing data accounts for either absence of lower limbs due to amputation or the presence of compression bandaging systems. Concurrent nurses’ documented skin
assessments were noted over the four week period of data collection. A total of 234 data entries were recorded for female patients and 138 data entries were recorded from male patients. Of the total population, 38.3% (n=18) were male and 61.5% (n=29) were female. The minimum age of the participants was 34 years, the maximum age was 95 years and the median age was 74.7 years. Data pooled from two nursing home participants in previous studies reported a mean age of 84 years and 83% were female (Bates-Jensen et al. 2009), similar to demographics reported in this study. Guihan et al. (2012) studied 34 male veterans with spinal cord injuries, with a mean age of 66 years (SD=11.5). Harrow & Mayrovitz (2014) studied 16 subjects with a mean age of 61 years (SD=14.6). Bates-Jensen et al. (2007, 2008 & 2009) report participant profiles similar to this study. The study location provided the main differentiation between the two. This study was undertaken in the acute hospital setting, as opposed to the authors’ study which occurred in nursing home settings.

5.2 Risk Factors for Pressure Ulcer Development

5.2.1 Norton Score

In this study, the risk for pressure ulcer development was determined using the Norton risk assessment scale. This scale is directed at assisting nurses in identifying those patients at risk. The mean Norton Score was 12 (medium risk), the minimum Norton Score was 8 (high risk) and the maximum Norton Score was 17 (low risk). The participants in the writer’s study were at risk of pressure ulcer formation but did not have pre-existing pressure ulcers upon enrolment to the study. Conversely, in Guihan et al. (2012) study, forty seven percent of the study participants had pre-existing pressure ulcers. All of the participants had pre-existing pressure ulcer damage in the Harrow & Mayrovitz (2014) study. Bates-Jensen et al. (2007, 2008, 2009) studies used the Braden risk assessment tool to assess participants’ risk for pressure ulcer formation. The authors report similar participant age and risk profiles as this
study. However, as aforementioned, one might assume that the majority of participants in the writer’s study differ from the nursing home patients as they warranted admission to the acute care setting suggesting that the participants had experienced an episode of acute illness. Further, this episode of acute illness may heighten their risk of pressure ulcer development. Interestingly, despite international consensus that acute illness may potentiate a heightened risk of pressure ulcer damage (Bry et al. 2012, EPUAP/NPUAP/PPPIA 2014); neither the Norton nor the Braden risk assessment scales account for co morbid conditions such as sepsis, diabetes or vascular disease.

The participants in Bates-Jensen et al. (2007) study had a mean Braden pressure ulcer risk score of 16.5 (SD 3.6). A score of < 18 indicates at risk of pressure ulcer damage on the Braden Scale. The mean score in the following study (Bates-Jensen et al. 2008) was 16.7 (SD 3.5). Finally, a cumulative study by the authors (2009) reported Braden scores of 16.3 (SD 3.6) in residents with light skin tones and Braden scores of 17.5 (SD 3.5) in residents with dark skin tones. Guihan et al. (2012) recruited 34 participants but did not refer to risk assessment scales. Seventeen (53.13%) of the participants were pressure ulcer free on admission to the study. In contrast to this study and studies by Bates-Jensen et al. (2007, 2008, 2009), 15 patients (46.89%) had pre-existing pressure ulcers on admission to the study.

5.2.2 Patient Activity

In this study, twenty one point three percent (n=10) of the population were bedfast, 36.2% (n=17) were chair bound and 42.6% (n=20) required assistance to mobilise. Bates-Jensen et al. (2007, 2008, 2009) reported bed mobility scores which range from 0-4, with 0=independent and 4= total dependence. The mean scores were 2.3 (2007 study), 2.38 (2008 study), 2.0 (2009 study, light skin toned patients) and 1.6 (2009 study, dark skin toned
patients). These mean scores are comparable to the writers study. All of the participants (n=34) in the Guihan study (2012) had spinal cord injuries and 31 were reported as requiring assistance, rendering comparison between the studies invalid due to inherent differences in patient characteristics.

5.2.3 Previous History of Pressure Ulcer Damage

Of the total population 8.5% (n=4), had a history of previous pressure ulcer damage. Interestingly studies by Bates-Jensen et al. (2007, 2008, 2009) did not report history of previous pressure ulcer damage. A history of previous pressure ulcer damage is considered important (Harrow & Mayrovitz 2014) since scar tissue is weaker than the skin it has replaced; therefore one might posit that it would be more prone to breakdown when compared to intact skin.

5.3 Pathophysiology of Pressure Ulcer Development

In the initial stages of pressure ulcer development, an inflammatory response is triggered as a result of damage to the tissue. An increase of both blood flow and capillary permeability ensues resulting in an influx of fluids into the area of damage resulting in oedema. Inflammation exists in the tissues before damage is visible on the skin surface (Bouten et al. 2003). If pressure is relieved in the early stages of pressure ulcer development, reactive hyperaemia occurs, which is a normal compensatory mechanism that reverses the damage. Conversely, if pressure is not sufficiently relieved the blood vessels collapse. This results in ischemia which in turn deprives tissue of oxygen causing anaerobic metabolism of cells, leading to tissue acidosis and finally cell death (Bouten et al. 2003). The authors further posit that the type of pressure ulcer developed is determined by their means of evolution, that is
whether they occurred in the skin layers as a result of shear, or the deep tissue injuries as a result of sustained compression.

Whilst, it is critically important that the concept of pressure ulcer development is fully understood, such understanding is still awaited (EPUAP/NPUAP/PPPIA 2014). According to emerging constructs, localised ischemia, reperfusion injury, impaired lymphatic drainage and sustained cell deformation form the theoretical underpinnings for development of pressure ulcers. In clinical practice the way that patients react to such threats to tissue integrity varies greatly. Further, these individualised reactions will determine whether patients will develop pressure ulcer damage. The need to understand pathways to pressure ulcer development are most important, in order to engage the appropriate prevention strategies and prevent hospital acquired pressure ulcer damage. The magnitude of this need has become quite prolific, especially since the mobilisation of watch dog groups such as HIQA (2012) has occurred. This disconnect with understanding aetiology negatively contributes to the ability to recognise early signs of threat to tissue integrity.

5.4 Nurses Visual Skin Assessment

The premise of the study was to examine the relationship between nurses’ visual skin assessment and concurrent SEM findings. As previously alluded to, recognition of skin damage and accurate pressure ulcer staging is considered an important clinical skill (Beekman et al. 2007, Mackintosh et al. 2014); yet significant anomalies in staging exist with particular emphasis on exact identification of non-blanching erythema (Defloor & Schoonhoven 2004, Defloor & Grypdonck 2005, Defloor et al. 2006). In this study nurses assessed 34% (n=16) of the study population as having abnormal skin findings that resulted
in pressure ulcer damage. The most common sites of pressure ulcer formation was at the sacrum (77.8%), followed by the heels (22.2%).

The EPUAP (2013) pressure ulcer classification system is the classification system used in the study site. Guihan et al. (2012) alludes to the limitations of visual skin assessment, and further posits that pressure ulcer damage may present as advanced damage as opposed to early pressure damage by the time it becomes visible on the skin surface. Bates-Jensen et al. (2009) further allude to the difficulties that exist pertaining to early identification of pressure ulcer damage with particular reference to darker skin toned individuals.

Prior to commencement of Bates-Jensen et al. (2007, 2008) studies, staff received education sessions regarding identification and classification of pressure ulcer damage. The authors also reported good interrater agreement between staff and classification; however SEM outperformed nurses’ visual skin assessment, confirming opinions associated with being unable to visualise what is happening beneath the skins surface until much later. This supports Bates-Jensen et al. (2008) research where they surmised that SEM recognised early signs of pressure damage with elevated abnormal readings which continued to be abnormal a week later when the resultant damage became visible on the surface of the skin. This further supports general consensus that nurses’ visual skin assessment is associated with significant discrepancies and is highly dependent on the skill of the caregiver (Beekman et al. 2007, Mackintosh et al. 2014).

Whilst, the findings from the aforementioned studies report an association between visual skin assessment and SEM, ultimately SEM identifies early signs of pressure ulcer damage 3 to 10 days prior to visible skin breakdown. Delay in identification of early pressure ulcer
damage, negatively impacts current practice in pressure ulcer prevention as preventative strategies are initiated on the basis of nurses visual skin assessment coupled with use of risk assessment scales. There is a growing appreciation of the magnitude of the problem evidenced by the HSE (2014) initiative advocating prevention of these nosocomial wounds as a measure of quality of healthcare delivery. This initiative was strengthened through inclusion of hospital acquired pressure ulcers higher then grade 2 as part of the quality and patient indicators in the National Service Plan (HSE 2015). Despite these promising advances, and a clear commitment on behalf of healthcare facilities, finding effective strategies for translating research evidence into practice remains fraught with difficulties. Clearly, as evident in the literature, severe limitations with visual skin assessment exist. Delay in time to identify early pressure damage and lack of capacitance to see under the skin to detect skin damage are cited as being extremely problematic (Beekman et al. 2007, Mackintosh et al. 2014). Importantly, devising a quantitative means of identifying early pressure ulcer damage can potentially shift away from the current subjective visual means of visual identification.

Within the context of the writer’s study, the difference between the time that it took nurses to recognise pressure ulcer damage and SEM was statistically significantly different (p 0.0001). The mean number of days that it took nurses to detect early pressure ulcer damage was 5 days (SD 5.15). Importantly, it took as long as 11 days for the nurses to visually identify pressure damage, preventing early intervention to potentially reverse the damage. This research study took place in an acute general hospital compared to nursing homes (Bates-Jensen et al. 2007, 2007, 2009) and a veteran spinal cord injury facility (Guihan et al. 2012). Despite differences in sample demographics and study settings, all patients included were assessed as being at risk of developing pressure ulcer damage regardless of whether they had pre-existing pressure
ulcers. Regardless of study setting and patient characteristics, all authors reported limitations associated with visual nurses’ skin assessment. In summary, early identification of pressure ulcer damage currently poses a significant problem and the potential availability of an objective means of assessing early pressure damage in the form of SEM is considered of significant clinical importance.

5.5 SEM Values of the Sacrum, the Right and the Left Heel.

SEM readings were recorded daily and results demonstrate higher SEM values at the sacrum, and lesser but similar patterns of readings from both heels. Original studies used an older version of the SEM scanner which reported results as dermal phase units (DPUs). DPU readings corresponded to values ranging from 0 to 999, with higher readings indicating more extensive skin damage and higher SEM values. Guihan et al. (2012) reported SEM values for normal skin as (41 DPU) (SD10).

Higher SEM values corresponded with ensuing stage 1 and 2 pressure ulcer damage across all anatomic sites. SEM values taken at heel sites were lower across all skin conditions. Guihan et al. (2012) reported SEM values for normal skin at the heels as 30 DPU, whereas stage 1 pressure ulcer damage at the same sites measured 33 DPU. Interestingly, Guihan et al. (2012) posit that hospital acquired pressure ulcers are an infrequent occurrence in spinal care injury units and more often prevail in the community setting where further research pertaining to SEM should occur. This may arise as a result of specialist spinal units having resources equipped to deal with these issues as opposed to when patients are living in the community setting where behavioural issues such as concordance with consistent application of visual inspection strategies and pressure relief may not compare with the acute hospital setting. Conversely, hospital acquired pressure ulcers, frequently occur in the acute care setting. Most
are reported in the literature as stage 1 and 2 hospital pressure ulcers (Clark 2007, Schurmann et al. 2009), the most common sites of occurrence being the sacrum and heels. As aforementioned, this provided the impetus for the writer to choose these anatomical sites for this research study.

5.6 Relationship between nurses’ visual skin assessment of early signs of pressure ulcer damage & SEM findings.

Correlations between nurses’ visual skin assessment and SEM findings were calculated per anatomical site, for the total study period. Correlations were reported as being strong for the sacrum (r=.65), medium for the right heel (r=.43) and low for the left heel (r=.23). Further analysis exploring the overall correlation for nurses’ visual assessment and SEM readings for patients who developed subsequent pressure ulcers was conducted, whereby r=0.47 (p=0.001), demonstrating a medium correlation between nurses’ visual skin assessment and SEM findings. This supports findings from previous studies, whereby SEM measures were responsive to changes in visual skin assessment (Bates-Jensen et al. 2007, 2008, 2009). Further, in the writer’s study SEM identified pressure ulcer damage between 3 and 11 days sooner than nurses’ visual assessment of pressure ulcer damage. This supports earlier reports that SEM identifies pressure ulcer damage 3 to 10 days sooner than nurses’ visual skin assessment (Bates-Jensen et al. 2007, 2008, 2009). This may prove a significant finding, as SEM may become an important clinical tool in providing an objective means of identifying early pressure ulcer damage. Moreover, a medium correlation between nurses visual was identified; however, one would expect to find an eventual correlation between SEM and nurses’ visual assessment of pressure ulcer damage, once pressure ulcer damage becomes visible on the surface of the skin. Therefore one might argue that the interpretation of such reported findings is important if the results are to be applied positively within the clinical
setting. To reiterate, it is evident that eventually the results of pressure damage particularly deep tissue injury will present on the skins surface and this is where the correlation exists. What is evident from the study is that in clinical practice this correlation may take up to 11 days to occur or 10 days as in the case of Bates-Jensen et al. (2007, 2008) study. It is this delay in visual detection that deters the initiation of early intervention to detect pressure ulcer damage. Conversely, Guihan et al. (2012) reported a possible relationship between SEM and nurses ’visual assessment of early pressure damage. The authors’ posit that study design and sample size limited their ability to examine the relationship definitively, but suggested that a further longitudinal study including a larger sample size and home visits to spinal cord injury patients would provide better data to enable informed analysis.

Harrow and Mayrovitz (2014) study simply quantified SEM measures surrounding stage 3 and 4 pressure ulcers and further examined the feasibility of using SEM as a means to differentiate pressure ulcers from intact skin. The authors concluded that SEM successfully differentiated between the two. Results from this writer’s study acknowledge the role that SEM plays in detection of early signs of skin damage through recognition of early inflammation.

A further significant finding from this study, not reported in previous studies highlights the importance of interpreting findings within the clinical context. Two participants as previously alluded to in chapter four, developed inflammatory dermatoses resulting in elevated abnormal SEM readings and concurrent documented abnormal skin findings by the nurses. These abnormal SEM findings and documented abnormal skin findings returned to normal once the appropriate medical treatment was initiated, without evidence of subsequent pressure ulcer development . Although not inflammatory dermatoses, Guihan et al. (2012) found that SEM
values differed over scar tissue when stage 1 pressure ulcers were present; again the authors acknowledged that they had insufficient data to evaluate this finding further and recognised that this may have important implications for clinical practice.

Throughout this study, there were occasions whereby SEM measures were elevated for one or two readings at a specific anatomical site which subsequently reverted back to normal readings over the ensuing days. The writer suggests that perhaps consistent abnormal SEM values may be more appropriate to determine actual pressure ulcer damage rather than isolated spikes of abnormal readings. Again this requires further analysis as none of the other studies reported similar findings.

In summary deep tissue injury and lesser extent of pressure ulcer damage resulting from friction and shear are physiologically evidenced through elevated levels of sub epidermal moisture levels. Currently, SEM allows for accurate detection of such levels which alert the healthcare professional to risk of impending damage. Visual skin inspection is not capable of such informed quantitative biophysical detection.

5.7 Conclusion

The clinical relevance of the study findings supports earlier studies, which posit that sub epidermal moisture has the capacity to detect early pressure damage sooner than nurses’ visual assessment. Of the study sample (n=47), 34% (n=16) patients subsequently developed pressure ulcer damage. Nurses’ visual skin assessment and concurrent abnormal SEM findings were observed for these patients. Findings from this study reported that SEM detected pressure ulcer damage on average 3.9 days sooner than nurses’ visual skin assessment. All patients with sustained elevated sub epidermal moisture levels subsequently
developed pressure ulcer damage. Therefore, knowing that early pressure ulcer damage is present can highlight awareness that increased prevention strategies are necessary to avoid further damage. This has multifactorial benefits including safer better patient care outcomes, and improved management of costs associated with acquisition of hospital acquired pressure ulcers. Conversely, SEM also detected abnormal findings in patients who experienced inflammatory skin disease suggesting that SEM findings should be appropriately interpreted within the correct clinical context. Further, isolated elevations in SEM readings do not appear to accurately reflect impending pressure ulcer damage, therefore as previously mentioned persistent abnormal SEM readings may be required to appropriately reflect pressure damage.

This study has highlighted the difficulties in identifying early pressure ulcer damage via visual assessment, and alludes to the associated human and financial costs associated with their occurrence. The problems associated with hospital acquired pressure ulcers will continue to persist in the absence of a better means of identifying impending pressure ulcer damage. The literature emphasises that hospital acquired pressure ulcers continues to pose a significant healthcare risk and further, results in significant investment of scarce healthcare resources that could be better invested elsewhere (NHS 2010, Dealey et al. 2012, Lyder et al. 2012).

The results of the study confirm the feasibility of using SEM as an adjunct to the current methods of assessing for early signs of pressure ulcer damage. This would suggest that the goal of enabling improved means of risk assessment to quantify each individual patients risk for the development of pressure ulcers can be attained. Further, the impetus into the future should perhaps focus on the implementation of SEM as a definitive means of risk assessment and build capacity and capability from the hierarchical management structures, financial
controllers and policy decision makers to allow SEM to make a positive clinical impact directly at the front line, to benefit the service user.
Chapter 6 Conclusion & Recommendations

6.0 Introduction

The purpose of the ensuing chapter is to reflect on the findings of this study and provide a discourse of the clinical implications and policy recommendations for further analysis. Major findings from the literature and data analysis will be discussed. Broadly, results from the data analysis demonstrates feasibility of adapting SEM as a means of identifying early pressure ulcer damage prior to it becoming evident on the surface of the skin. The underlying principle of nursing research is to examine methods that may positively impact clinical practice, further it is assumed that policy makers will give credence to robust evidence. The fundamental changes required to provide more objective means of assessing early pressure ulcer damage and prevent avoidable hospital acquired pressure ulcers (HAPUs) will be aimed at nursing management, nurse practice development and quality and risk management. Through reflection, the writer will acknowledge the strengths and limitations of the study and make recommendations for future research to ensure that the practice of pressure ulcer identification and prevention is both evidence based and cost effective (Dealey et al. 2012, Coleman et al. 2013).

6.1 Impact of Hospital Acquired Pressure Ulcers

Health care budgets are eroding and managers at all levels are expected to account for healthcare spending, particularly in relation to avoidable costs (OECD 2010). Prevention of hospital acquired pressure ulcers can be cost effective for all healthcare settings (Spetz et al. 2013), as once acquired they are expensive to manage (Dealey et al. 2012). Further, they prolong length of stay (Balzer et al. 2013), and in Ireland are recognised as an adverse clinical event (HIQA 2012). Prevalence rates of between 4% and 38% are reported in Irish settings (Gethin et al. 2005, Gallagher et al. 2008) and incidence is not reducing despite
availability of international evidence based guidelines (Moore & Cowman 2012). Therefore, it is necessary to adopt evidence based clinical practice to assist in preventing their occurrence. The results of this study provides significant evidence to advance exploration of the role that SEM plays in detecting early pressure ulcer damage, thereafter implementing earlier or more advanced prevention strategies.

6.2 Findings

The main findings from this study highlight the capacity for SEM to detect early pressure ulcer damage, on average 3.9 days sooner than nurses’ visual skin assessment. There was a medium correlation between nurses’ visual skin assessment of pressure damage and sub epidermal moisture measurement (SEM) \((r = 0.468; p = 0.001)\). However, it is recognised that correlation between the two would eventually exist once pressure damage becomes visible on the skin surface.

6.3 Nurses Visual Skin Assessment

Continuous visual skin inspection and assessment serves as a fundamental basis for implementing pressure ulcer prevention strategies (Balzer et al. 2013). However, limitations are identified in the literature pertaining to nurses’ ability to correctly identify early pressure ulcer damage (Defloor & Grypdonck 2005, Kelly & Isted 2011). The literature suggests that failure to identify stage 1 pressure ulcers results in 1 in 5 pressure ulcers deteriorating to greater stages within a week of admission (Halfens et al. 2001). Results from this study support these findings, as nurses’ identified pressure ulcer damage on average 3.9 days later than SEM detected pressure ulcer damage.
6.4 The role of Sub epidermal Moisture (SEM) in Detecting Early Pressure Ulcer Damage

Recent research has examined the feasibility of obtaining biophysical measures of SEM to detect pressure ulcer damage (Bates-Jensen et al. 2007, 2008, 2009, Guihan et al. 2012, Harrow & Mayrovitz (2014). Sub epidermal moisture levels are elevated in the early inflammatory process, resulting in localised oedema in the epidermal and sub dermal tissues. The SEM scanner detects this damage via electrical capacitance, producing values which represent normal or abnormal skin findings, therefore enabling identification of pressure ulcer damage. Results from this study, demonstrated that SEM detected pressure ulcer damage, on average, 3.9 days sooner than nurses’ visual skin assessment.

6.5 The Relationship between nurses’ visual skin assessment of early signs of pressure damage & SEM findings.

The overarching aim of the study was to examine the relationship between nurses’ visual skin assessment and SEM findings in order to determine if a relationship between these quantitative variables exist. Results from bivariate analysis exploring the overall correlation for nurses’ visual skin assessment and SEM readings for those who went on to develop pressure ulcers demonstrated a medium correlation between nurses’ visual skin assessment of the skin and SEM (r=0.47) (p=0.001). As previously discussed, an expectation exists that correlation will eventually exist between these two variables, when pressure ulcer damage becomes evident on the skin surface.

6.6 Implications of this study

Hospital acquired pressure ulcers continue to present a significant healthcare burden. In the absence of continuous clinical research pertaining to detection and prevention methods,
eradication of this burden will become problematic. Findings from this study, suggest that SEM detects pressure ulcer damage sooner than nurses’ skin assessment. This information will allow for construct with appropriate departments such as nursing management including nurse practice development and the quality and risk department with regard to potential adaptation of SEM into existing hospital policy regarding prevention, assessment and management of HAPUs.

6.6.1. Implications of this study for nursing management

The study will highlight to nursing management difficulties that exist pertaining to correct identification of pressure ulcer damage, increasing the risk of subsequent formation of hospital acquired pressure ulcers. Having such information will allow for managers to disseminate these findings to senior management responsible for making budgetary decisions pertaining to allocation of funding associated with pressure ulcer prevention strategies. Further, nurse practice development may become involved with education pertaining to visual skin assessment and if implemented, appropriate use and decontamination of the SEM Scanner, including the relevant alterations to existing hospital policy documentation.

6.6.2 Implications of this study for quality and risk departments.

The result of this study will inform the quality and risk department of the current risks and potential risks associated with hospital acquired pressure ulcers. This will enable the quality and risk department to make informed decisions prioritising quality and risk initiatives that promote safer better care.

6.7 Recommendations to management and service planners.

The writer will present the study findings to senior service managers with the recommendation that sufficient evidence exists demonstrating the feasibility of using SEM to
detect early pressure ulcer damage. Hence, this warrants further examination. Current pressure ulcer prevention strategies are failing due to disparities in visual assessment of pressure ulcer damage. The purchase of medical equipment is determined by senior management, and is subject to a sound business case and availability of funds. Commitment to purchase the SEM scanner is needed in order to affect change.

6.8 Strengths and limitations of this study.

The strengths of the study are that the methods applied were effective in collecting the necessary data that demonstrated findings similar to previous studies, albeit in different settings. Further, other important findings were realised that were not reported in previous studies. These findings included intermittent isolated elevations in SEM readings which returned to normal at the next reading. Also, SEM readings rose when conditions such as inflammatory dermatoses occurred. These findings have significant implications when interpreting SEM results in the clinical practice setting. Various limitations may exist in this study. Firstly purposive sampling formed the composition of the participants enrolled to the study. This form of sampling is frequently critiqued in the literature as it is limited by bias due to the process of sample selection. However, Panacek et al. (2007), acknowledge its usefulness when the sample size will be small. Further, strict inclusion criteria are set when using purposive sampling in quantitative research. All patients at risk of pressure ulcer development with intact skin were recruited to the study. The writer acknowledges that the findings of the study cannot be applied to the wider population. The next limitation is sample size. The study was conducted on two wards in an acute hospital setting. During the data collection period one of the wards had twelve beds closed as a result of the winter vomiting bug which resulted in the loss of potential participants. Time span for conducting the study was also a limitation, as a longer timeframe would enable recruitment of more participants.
6.9 Dissemination of Findings

It is incumbent on researchers to disseminate their findings, in order to maintain a culture of research based practice in nursing and provide robust evidence that will demonstrate the valuable contribution of nursing to the health of the wider population (DOH&C 2003). It is also important to add new knowledge to a previous researched area, particularly when such research is in its neophyte stage. Patients who suffer from pressure ulcers suffer from deterioration in health related quality of life with associated burden of pain (Gorecki et al. 2009). Failure to disseminate research findings regardless of the findings is a disservice to this afflicted population. The findings will be disseminated through the research and education forum, to nursing management and through poster presentation at national and international Woundcare conferences.

6.10 Future Research

Whilst there are limitations to the study as previously discussed, the writer is of the opinion that a larger longitudinal study would provide more robust support for the use of SEM, to detect early pressure ulcer damage. Further, more robust methods of sampling that better control issues relating to bias, reliability and validity are recommended.

6.11 Reflection

Johns (2009), posits that health professionals have the ability to become more self aware and positively contribute to professional development through reflective practice. The writer through this research process has become more aware and acknowledges the hard work and sustained drive to complete the research process. Further, the writer has developed a heightened professional respect for researchers. The writer concedes as a neophyte
researcher, that the research process frequently presents barriers to successful completion such as failure to recruit and indeed the everyday occurrences in the acute care setting that create further barriers such as infection control issues, staff shortages and general fast pace of the acute care setting. This course particularly with guidance from the writers mentor facilitated a greater appreciation of the research process through strengthening of the writer’s knowledge and a sound appreciation of the writer’s limitations with regard to the research process.

6.12 Conclusion

Whilst the findings of this study require further investigation with a larger sample size over a longer period of time, it is important to consider the fact that the research demonstrated that SEM detects pressure ulcer damage on average, 3.9 days sooner than nurses’ visual assessment. Further, despite application of international evidence based guidelines (EPUAP/NPUAP/PPPIA 2014), it has been established that hospital acquired pressure ulcers continue to present as a significant healthcare burden to both the healthcare facility and to the patient (Dealey et al. 2012, Balzer et al. 2013). Significant resources have been invested into prevention and treatment strategies for pressure ulceration, yet frequency of occurrence persists (Moore & Cowman 2011, Sibbald et al. 2011). SEM is an emerging science that has been shown to detect early pressure ulcer damage, before it becomes visible on the skin surface. Findings from this study support these findings from previous studies (Bates-Jensen et al. 2007, 2008, 2009). Further earlier identification may prohibit deterioration to higher grades. Therefore, it would appear prudent to further examine this concept in acute healthcare settings.
References:


National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel & Pan Pacific Pressure Injury Alliance (2014) *Prevention and Treatment of Pressure Ulcers:*


Appendix 1

(Version: 1 Date 23/10/2014)

Study title: An investigation of the accuracy of early pressure ulcer damage assessment using sub epidermal moisture measurement versus nurses’ visual assessment of the patients’ skin.

Principal investigator’s name: [Redacted]
Principal investigator’s title: Consultant Surgeon
Lead Investigator’s name: [Redacted]
Lead Investigator’s title: Tissue Viability Nurse Specialist
Telephone number of principal investigator: [Redacted]

You are being invited to take part in a research study carried out within Naas General Hospital to determine the accuracy of early pressure ulcer damage assessment using sub epidermal moisture measurement versus nurses’ visual assessment of your skin. The sub epidermal moisture is assessed using a scanner which is very similar to the thermometers we use to check your temperature and it does not cause any discomfort. It is hoped that the scanner will identify sooner if a patient is at risk of a pressure ulcer so the appropriate prevention strategies can be put in place.

Before you decide whether or not you wish to take part, you should read the information provided below carefully and, if you wish, discuss it with your family, friends or nurse/doctor. Take time to ask questions – do not feel rushed or under pressure to make a quick decision.

You should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. This process is known as ‘Informed Consent’. You do not have to take part in this study and a decision not to take part will not effect on your future medical care.
You can change your mind about taking part in the study any time you like. Even if the study has started, you can still opt out and you do not have to give us a reason. If you do opt out, it will not affect the quality of treatment you get in the future.

**Why is this study being done?**

Pressure ulcers are areas of damage to the skin and underlying tissues that usually occur in people who have difficulty moving themselves when they are seated in a chair, or when lying in bed. We usually assess the skin of patients at risk of pressure ulcers by looking at the skin to check for any areas of damage. The problem with this type of assessment is that we cannot see any damage that might be going on under the skin and sometime pressure ulcers develop from deep in the tissues slowly becoming evident on the skin over a number of days. If we had a way of understanding what was going on under the patient skin, we would be able to prevent more serious damage from occurring. The scanner we are using in this study is able to detect this type of damage, so we want to study whether the scanner is better than nurses’ assessment of the patient skin. In this way we will be able to understand the development of pressure ulcers in a better way, and then we will be able to take better action to prevent this from happening in the first place.

**Who is organising and funding this study?**

[Redacted] is undertaking this research study as part of her MSc in Nursing (Advanced Practice). No funding has been received to complete this research and it will be conducted during her clinical hours.

**Why am I being asked to take part?**

One ward in the hospital has been chosen for this study and you are currently a patient on this ward. You are being invited to take part in this study as you have being identified as being “at risk” of developing a pressure ulcer.

**How will the study be carried out?**

The nurses on the ward will continue to carry out your skin assessment as normal; [Redacted] will also come to the ward on a daily basis and check your skin on sites that are at risk of pressure ulcer damage such as the heels and the sacrum, using the SEM scanner. [Redacted] will then record the nurse’s assessment of your skin and the SEM scanner readings. This will continue every day for 4 weeks, or until you are discharged or move to another ward in the hospital.
What will happen to me if I agree to take part?

Should you agree to take part in the study, there will be no change to your care. Gillian O'Brien will check your nursing notes and will record the following:

1. Your age
2. Your sex
3. Your pressure ulcer risk score
4. Whether you have has a previous pressure ulcer damage
5. Your mobility and activity status

Gillian O'Brien will come to the ward on a daily basis and check your skin on sites that are at risk of pressure ulcer damage such as the heels and the sacrum, using the SEM scanner.

What other treatments are available to me?

You will be getting the same nursing and medical treatment whether you take part in the study or not. There is no obligation for you to take part in the study. If you choose not to take part this will not affect your care in any way.

What are the benefits?

There will be no personal benefits to you taking part; however information gained may help determine if the SEM scanner is a valuable tool in helping identify pressure ulcer damage at an earlier stage and therefore; help reduce or prevent pressure ulcer damage. The study may identify that the SEM scanner may be a useful tool to use hospital wide.

What are the risks?

There are no risks involved in this study. The SEM scanner does not cause any discomfort. As you have to be moved to check your skin, this may cause mild discomfort. Using the SEM scanner only takes a few seconds to record; therefore it should not take up too much of your time.

What if something goes wrong when I’m taking part in this study?

We do not anticipate that anything will go wrong as a result of this study.
**Will it cost me anything to take part?**

No payment of any kind will be made to participants in this study. It will not cost you anything to participate.

**Is the study confidential?**

All information gathered about you will be treated with strict confidence. Only [redacted] will know who the patients are. Results from all patients who participate will be combined and the combined results may be published in relevant journals and presented at conferences. Results will also be shared within the organisation. However, nobody will be able to identify that it is you have taken part in the study.

**Where can I get further information?**

If you have any further questions about the study or if you want to opt out of the study, you can rest assured it won't affect the quality of treatment you get in the future.

If you need any further information now or at any time in the future, please contact:

**[redacted]**

**[redacted]**

**[redacted]**

(between the hours of 8.30-5 Monday to Thursday).
Appendix 2

Participant consent

Research study: An investigation of the accuracy of early pressure ulcer damage assessment using sub epidermal moisture measurement versus nurses’ visual assessment of the patients’ skin.


Understanding of the research study

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<th>Understanding of the research study</th>
<th>Please tick if in agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>I have read and understand the information leaflet for the above study and have had the opportunity to ask questions/seek advice</td>
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</tr>
<tr>
<td>I know my participation is voluntary and I am free to withdraw at any time</td>
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<tr>
<td>I understand that the information collected will be used as part of the researchers educational programme</td>
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<tr>
<td>• The educational programme may be used in publications, presentations or conference papers</td>
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<td>• May be used in subsequent research</td>
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<td>I understand that the information collected about me will be anonymous if used for any of the above purposes</td>
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<tr>
<td>I freely consent to participate in this research study</td>
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</tr>
<tr>
<td>I understand that my medical records will be accessed in consenting to participate in this research study</td>
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</tbody>
</table>

Participant’s name ____________________________________________________________
(Block capitals please)

Participant’s contact details _________________________________________________

Participant’s signature______________________________________________________

Statement of researcher’s responsibility:

The researcher has outlined the nature and intention of the research study, the process to be followed and any risks that may be involved. The researcher has offered to answer any questions and wholly answered such questions. The researcher trusts that the participant understands and freely agreed informed consent.

Investigators signature ____________________________ Date____________________
Appendix 3

Norton Score

<table>
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<th>Norton Scale for Assessing Risk of Pressure Ulcers⁴</th>
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<td><strong>Name:</strong> ___________________  <strong>Date:</strong> ______</td>
</tr>
<tr>
<td><strong>Criterion</strong></td>
</tr>
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<td>----------------</td>
</tr>
</tbody>
</table>
| Physical condition | 4 = Good  
|                  | 3 = Fair  
|                  | 2 = Poor  
|                  | 1 = Very bad |
| Mental condition | 4 = Alert  
|                  | 3 = Apathetic  
|                  | 2 = Confused  
|                  | 1 = Stupor |
| Activity | 4 = Ambulant  
|          | 3 = Walk with help  
|          | 2 = Chair bound  
|          | 1 = Bed bound |
| Mobility | 4 = Full  
|          | 3 = Slightly impaired  
|          | 2 = Very limited  
|          | 1 = Immobile |
| Incontinent | 4 = Not  
|             | 3 = Occasionally  
|             | 2 = Usually/Urine  
|             | 1 = Doubly |

**TOTAL SCORE = _____**

⁴Calculated by the 4th of the scores in all 5 areas. A score < 14 indicates a high risk of pressure ulcer development.

Appendix 4

Ethics Approval Letter

24th November, 2014

Ms Xxxxxxxxxxxx
Tissue Viability Clinical Nurse Specialist
Xxxxxxxxxxx Hospital,
Xxxxxxxxx

Re: An investigation of early pressure ulcer damage assessment using sub epidermal moisture measurement versus nurse’s visual assessment of the patient’s skin.

Dear xxxx

I am happy to inform you that the above proposal has been approved by the hospital’s Ethics committee pending:

- Confirmation that 35 assessments per week.

Committee approved use of next of kin to consent on behalf of those who lack capacity such that we are not excluding a potentially vulnerable group from the study and its benefits.

Yours sincerely,

Xxxxx

A/General Manager
## Appendix 5 Mean and Standard Deviation of Nurses Skin Assessment & SEM

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